NOBCON 2024

1st International Conference on Research & Innovation in Multidisciplinary Domains (ICRIMD)

Date: 27 – 28 December, 2024

Venue: Noble University Campus, Bhesan Road, Gujarat, Junagadh

Conference Proceedings

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Volume - 1

Edited by:
Dr. Riddhi Sanghvi

Organized by
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Junagadh

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About The Conference

Because of the overwhelming response and encouragement by the researchers, academicians and industrialists, Noble University is happy & encouraged to hold the 1st International Conference on Research and Innovation in Multidisciplinary Domains, ICRIMD -2024. Join us for a premier platform where students, academicians, and industrialists converge to share innovative ideas and showcase talents.

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Conference Themes

- Engineering
- Management
- Commerce
- Science
- Ayurveda
- Homeopathy
- Library Science
- Pharmacy
- Education
- Animal Husbandry
- Nursing
- Humanities
- Computer Applications
- Vocational Studies
- Arts

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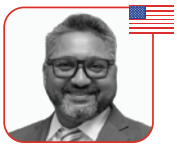

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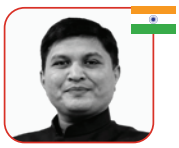

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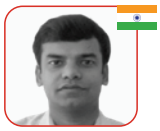

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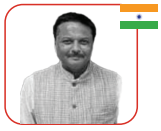

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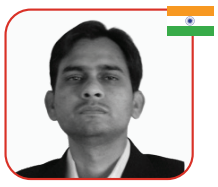

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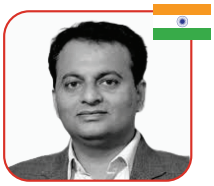

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Publication Opportunities

NOBCON 2024 Conference Proceedings - ISBN Number: 978-81-969738-1-0

A Peer Reviewed Journal

Journal Name: STM journals
Link: https://journals.stmjournals.com/

Journal Name: International journal for innovative research in multidisciplinary field
Link: https://www.ijirmf.com

Scopus / UGC CARE Indexed Journal

Subject to acceptance by the journal and payment of publication charges by authors.

Journal Name: Frontiers in Health Informatics
Link: https://healthinformaticsjournal.com/index.php/IJMI

Journal Name: Vedant Publications
Link: www.MyVedant.com

vedant
Knowledge Systems Pvt. Ltd.

Journal Name: South Eastern European Journal of Public Health
Link: https://www.seejph.com/index.php/seejph/index

BEST PAPER AWARD

STM JOURNALS | Scopus | UGC Care List

Submission Guidelines

All papers must be original and not simultaneously submitted to another journal or conference. The following paper categories are welcome:

1. **Full papers** presenting original, completed research, typically including thorough analyses and experiments.
2. **Systematic Review** papers that provide a comprehensive overview of a specific research area by summarising and synthesising existing literature.
3. **Case Study** Papers that present practical experiences, often in industry settings, which provide insights or lessons for the research community.
4. **Posters** that are visual presentations of ongoing or completed research, summarising key findings, methods and implications.

Registration Fees

Particulars	**Registration Fees along with Proceedings in e-copy**	**Paper Publication in Peer Reviewed of Journal** (REGISTRATION CHARGES INCLUDED)	**Paper Publication in Scopus & UGC CARE** (REGISTRATION CHARGES INCLUDED) (*APC SUBJECT TO CHARGE BY RESPECTIVE JOURNAL)	**Attendees** (Any Track)
Students – Noble University (UG and PG)	750	2250	1750 + APC	NIL
Students- other University (UG and PG)	1000	2500	2000 + APC	100
Research Scholars and Academicians – Noble University	1500	3000	2500 + APC	100
Research Scholars/ Academicians / Scientists / Industry Persons – Other University	2000	3500	3000 + APC	100
Students with Foreign National	$ 55	$ 110	$ 55 + APC	-

The above fees are valid for 3 authors, for additional author from foreign $10 & Indian author Rs.500/- will be charged extra.

Key Dates

Last Date For Abstract Submission : November 25, 2024

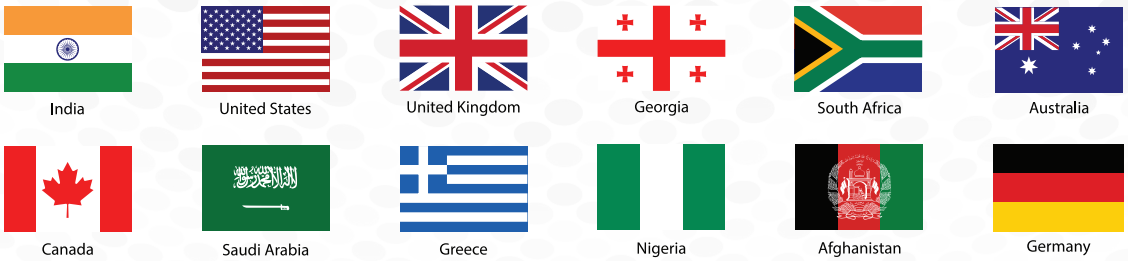
Last Date For Full Paper Submission : December 2, 2024

Submission of Presentation : December 20, 2024

Registration Link:

https://easychair.org/conferences/?conf=nobcon2024

Participants From



Notes

- Accommodation facilities are available upon request at an additional cost.
- Registration fees cover the kit and food for one author. Additional authors can avail these benefits at an extra cost.

Contact Us

nobcon24@gmail.com

www.nobleuniversity.ac.in

Venue: Noble University Campus,
Bhesan Road, Bamangam, Junagadh, Gujarat - India

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Message from the Chief Petron

Dear Scholars, Researchers, and Participants,

It is a proud moment for Noble University to host the 1st International Conference on Research and Innovation in Multidisciplinary Domains. This initiative reflects our university's commitment to fostering collaboration and innovation in research across diverse fields.

With participation from 829 authors representing 7 countries, this conference brings together a vibrant mix of ideas, perspectives, and expertise. The meticulous review process resulted in the selection of 248 high-quality papers out of 424 submissions, ensuring a rich and engaging program. Furthermore, our association with 8 reputed journals, including Scopus and Web of Science indexed platforms, highlights the high academic standards of this event.

I would like to take this opportunity to acknowledge the exceptional efforts of Dr. Riddhi Sanghvi and Dr. Darshan Jani, the conference co-chairs, whose dedication and hard work have been instrumental in organizing this grand event.

I congratulate the participants and encourage you to make the most of this platform to share your research, build networks, and explore new opportunities for collaboration. I also applaud the organizing team, led by Dr. Jay Talati, for their dedication in making this event a success. Wishing everyone a productive and inspiring conference!

Warm regards,

Dr. H. N. Kher Kher

Chief Patron

Provost, Noble University

Message from the Conference Chair

Dear Participants, Academicians, and Researchers,

It is my privilege to welcome you all to the 1st International Conference on Research and Innovation in Multidisciplinary Domains, a major step by Noble University toward promoting research excellence. This conference stands out not only for its hybrid format, allowing participation online and offline, but also for the diverse participation of researchers from 7 countries, showcasing a truly global academic platform.

This event provides an exceptional opportunity for researchers to present their ideas and gain recognition through collaborations with distinguished journals, including Scopus and Web of Science indexed publications. I am particularly proud of the interdisciplinary focus, which opens avenues for impactful discussions and innovative solutions to real-world challenges.

I extend my heartfelt gratitude to the management of Noble University for their unwavering support, guidance, and encouragement, which have been critical in making this event possible. I also express my appreciation to our Chief Patron, Dr. H. N. Kher, for his visionary leadership and to the organizing team for their tireless efforts in shaping this conference.

I wish all participants an enlightening and fulfilling experience as they contribute to shaping the future of multidisciplinary research.

Best regards,

Dr. Jay Talati

Conference Chair
Registrar,
Noble University

1st International Conference on Research & Innovation in Multidisciplinary Domains (ICRIMD)

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About the University:

Shri Vivek Bharti Trust, led by four visionary philanthropists, proudly established Noble Group of Institutions (NGI) in Junagadh, Gujarat, to provide quality education in Engineering, Science, Management, Pharmacy, Education, and Nursing. Since 2007, NGI has been a hub for technological and scientific growth, offering modern labs, a world-class library, spacious classrooms, green playgrounds, a gym, and strong industry connections.

In 2022, NGI became Noble University (NU), expanding across 30 scenic acres near Girnar Hill, fostering innovation and creativity in a serene environment. NU is dedicated to empowering students with ethical, high-quality education to serve society and advance humanity.

With partnerships across academia and industry, NU nurtures skilled, compassionate individuals ready to lead globally. Focused on interdisciplinary learning, NU harmonizes intellect, emotion, and action to shape a brighter, sustainable future for India and the world.

Faculty of Ayurveda

The main aim of Noble University is to impart to the students high-quality technical & scientific knowledge with ethics, so as to serve society and mankind through Ayurveda with full devotion, dedication, and commitment. It is the dream of the management to take this institute to a greater height in order to achieve a “Centre for Excellence” in teaching-learning, research, and innovative activities within and outside the campus.

Faculty of Homeopathy

NU ensures student welfare with comfortable accommodations, nutritious meals, recreational facilities, and a ragging-free environment. We nurture healers by fostering self-awareness, self-expression, and mastery of homeopathic knowledge. As a retreat for personal growth, NU provides diverse tools and methods, empowering students to craft their unique healing journey.

Faculty of Pharmacy

- Work within the digital sectors
- Give the best guidance and placement in a positive manner
- Excellent Pay Potential
- Creative student’s potential across the industry
- Think differently do different and get different

Faculty of Engineering

At NU, we prioritize a student-centric education system designed to meet industrial standards through a carefully crafted syllabus. Our campus offers state-of-the-art laboratories, modern infrastructure, and a comprehensive library to support hands-on training and skill development.

We nurture entrepreneurial ambitions with start-up and incubation facilities, alongside placement and internship opportunities in multinational organizations. Our highly qualified and dedicated faculty focus on recognizing and cultivating each student's true potential, ensuring their 360-degree development. With strong corporate tie-ups, we bridge the gap between education and industry, while encouraging holistic growth through extracurricular activities.

Faculty of Nursing

Noble Nursing College aims to deliver high-quality theoretical and practical knowledge through a "learning by doing" approach. Our dedicated faculty go beyond teaching, offering personalized support and expert instruction. Nursing education here emphasizes clinical skills, critical thinking, communication, leadership, and ethical decision-making. We prepare students to excel in diverse healthcare settings, working collaboratively to provide exceptional patient care. With a focus on evolving healthcare technology and policies, our programs ensure students are equipped for the future of nursing.

Faculty of Science

The Faculty of Science is a complete, student-oriented science faculty where research and education are closely related. The faculty aims to be an academic community with an international character, where staff members from different backgrounds can combine their talents with the common goal of being a leading faculty of science in India.

Our study programmes prepare students for positions in scientific research and professional careers related to societal themes such as energy, food, water, health, or innovation, as well as careers in entrepreneurship or teaching.

Faculty of Management and Commerce

NU is a buzzword for its cutting-edge education in the management domain. Every single tenet of management at NU is holistic and erudite in every prism of management. At NU, we encompass every single detail of management education in a nitty-gritty way making our students head and shoulder in the vista.

Faculty of Computer Applications

Our programs focus on industry-relevant subjects, offering specializations in Web Development, Data Science, and Full Stack Development. With innovative assessment methods and an emphasis on practical learning aligned with market trends, students gain hands-on experience in highly equipped labs under the guidance of experienced faculty. We foster holistic development through academic and cultural events, various seminars, workshops, and diverse student development clubs, creating a vibrant and enriching learning environment.

Faculty of Humanities/ Arts/ Education

Our University is proud to have a team of qualified, accredited, and doctorate-degreed staff who provide personalized guidance to students, ensuring each individual receives the attention they deserve. We emphasize experimental work in high-quality schools to offer practical learning experiences, and we integrate advanced technology into education to enhance the learning process. Face-to-face visits to specific nominated school institutions are conducted to provide students with real-world exposure. We also place great importance on co-curricular activities, encouraging students to engage in them alongside their studies. Furthermore, we offer free pre-preparation for the TET and TAT exams to help students succeed in their future careers.

Faculty of Library Science

The Faculty of Library Science is a complete, student-oriented science faculty where research and education are closely related. The faculty aims to be an academic community with an international character, where staff members from different backgrounds can combine their talents with the common goal of being a leading faculty of science in India.

Our study programmes prepare students for positions in scientific research and professional careers related to societal themes such as energy, food, water, health, or innovation, as well as careers in entrepreneurship or teaching.

Objectives:

- Facilitate knowledge exchange and the presentation of innovative research across various disciplines such as engineering, sciences, humanities, management, healthcare, and vocational studies.
- Encourage the development and dissemination of multidisciplinary research that addresses global challenges.
- Provide a platform for showcasing talent and fostering discussions that lead to actionable solutions and advancements.
- Offer opportunities for participants to publish their research in peer-reviewed and indexed journals.
- Promote interaction between academia and industry to bridge gaps and drive technological and academic advancements.

About the Event :

ICRIMD-2024 is a good platform for fostering collaboration and innovation by bringing together students, researchers, academicians, and industry professionals from diverse fields. It provides an excellent opportunity to present original research, exchange ideas, and explore advancements across multidisciplinary domains such as engineering, sciences, management, healthcare, humanities, and more. The event not only facilitates the dissemination of

knowledge through paper presentations and discussions but also encourages networking and collaboration among participants. With opportunities for publication in reputed peer-reviewed and indexed journals, IC-2024 serves as a catalyst for academic and professional growth, enabling participants to contribute to addressing global challenges through innovative and multidisciplinary solutions.

About the Proceedings:

The proceedings of ICRIMD-2024 will include a compilation of high-quality research papers presented during the conference, reflecting the innovation and multidisciplinary focus of the event. These proceedings will be published with an ISBN number (978-81-969738-1-0) to ensure authenticity and recognition.

Participants have the opportunity to publish their work in peer-reviewed journals, including Scopus and UGC CARE-indexed journals, subject to acceptance and any associated publication fees. The publication options range across various reputed platforms such as STM Journals, the International Journal for Innovative Research in Multidisciplinary Fields, Frontiers in Health Informatics, and the South Eastern European Journal of Public Health.

The proceedings will serve as a valuable resource for academic and industry professionals, offering insights into the latest research trends and innovations across diverse domains.

Example Tracks / Topics:

- **Track 1 – Engineering**
- **Track 2 – Management**
- **Track 3 – Commerce**
- **Track 4 – Science**
- **Track 5 – Ayurveda**
- **Track 6 – Homeopathy**
- **Track 7 – Library Science**
- **Track 8 – Pharmacy**
- **Track 9 – Education**
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Dual drug analysis: Stability-indicating RP-HPLC method for dapagliflozin and linagliptin in combined pharmaceutical dosage form

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Abstract: *Type II diabetes is managed with linagliptin and dapagliflozin. Dapagliflozin works by specifically blocking the sodium-glucose co-transporter-2 (SGLT-2) protein, while linagliptin belongs to the dipeptidyl peptidase-4 (DPP-4) inhibitor class, a relatively new and developing class of medications.*

The aim of this study was to develop and validate a straightforward, accurate, and stable reversed-phase liquid chromatographic (RP-HPLC) method for determining the combination pharmaceutical dosage form of dapagliflozin and linagliptin, along with a stability-indicating assay. Forced degradation studies involving acid and base hydrolysis, oxidation, heat, and photodegradation were conducted on linagliptin and dapagliflozin. Separation and forced degradation were achieved using a rp - Nova (C18, 250 mm x 4.6 mm, 5 µm) column and isocratic elution. The eluent consisted of methanol and phosphate buffer (65:35 % v/v), with the pH maintained to 4.0 using ortho phosphoric acid, and a flow rate of 1 mL/min. Detection was performed at 226 nm with a photodiode array detector.

The method effectively analyzed linagliptin, dapagliflozin, and their degradant products. It demonstrated suitable accuracy, linearity, and precision for concentration ranges of 4–40 µg/mL for linagliptin and 8–80 µg/mL for dapagliflozin.

The proposed method is innovative, straightforward, accurate, specific, sensitive, quick, and economically feasible, as it does not require any prior separation operations. It can be used for the simultaneous determination of dapagliflozin and linagliptin in tablet formulations.

Key Words: *Dapagliflozin, Linagliptin, Chromatography, Force degradation, Diabetes.*

1. INTRODUCTION:

In light of their independent metabolic routes and complementing processes, which improve therapeutic results and lessen side effects, dapagliflozin and linagliptin are used to manage type 2 diabetic mellitus (T2DM). The blend of a dipeptidyl peptidase-4 (DPP-4) blocker, linagliptin and a sodium-glucose co-transporter 2 (SGLT2) blocker, dapagliflozin, out come in improved glycemic management, weight loss, and suppresed systolic blood pressure.[1-3]

Dapagliflozin helps control blood sugar levels by selectively and permanently blocking SGLT2 in the kidneys, which decreases glucose reabsorption and increases glucose excretion through urine. (1S)-one,five-anhydro-one-C-[four-chloro-three-[(4-ethoxyphenyl) methyl] is its chemical name. According

to the Biopharmaceutical Classification System (BCS), -D-glucitol (Figure 1.1) is a class III molecule, meaning it has poor permeability but high solubility.[4]

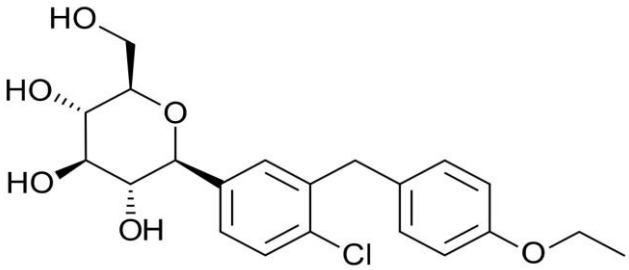

Figure 1.1 - Structure of Dapagliflozin

On the other hand, linagliptin is an orally hypoglycemic medication that related to the DPP-4 inhibitor class.[5] Its chemical name is eight-[(3R)-three-aminopiperidin-1-yl]-seven-but-2-ynyl-3-methyl-1-[(4-methylquinazolin-two-yl) methyl]-4,5-dihydropurine-2,6-dione shows Figure 1.2. To help T2DM patients better regulate their blood sugar, linagliptin can be taken either by itself with lifestyle modifications or in conjunction with other drugs like metformin or thiazolidinedione.[6-10]

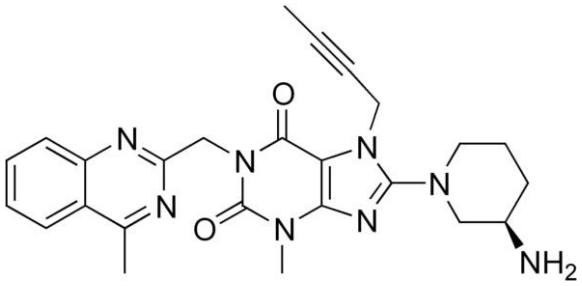

Figure 1.2 - Structure of Linagliptin

Linagliptin acts by preventing the dipeptidyl peptidase-4 (DPP-4) enzyme, which increases the amounts of active incretins such glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1).11-12

2. LITERATURE REVIEW:

Numerous analytical techniques have been developed to assess dapagliflozin (DAPA) and linagliptin (LINA), both separately and in combination with other drugs, according to a thorough study of the literature. Reverse-phase high-performance liquid chromatography (RP-HPLC) techniques for the simultaneous measurement of DAPA and LINA are, nevertheless, comparatively scarce. [13-16]

3. OBJECTIVES:

To create and establish simple, accurate, and precise techniques for the simultaneous measurement of linagliptin and dapagliflozin utilizing stability-indicating RP-HPLC.

4. METHODOLOGY[17]:

Standard stock solution preparation :

Dapagliflozin and linagliptin 100 mg each were added to a 100mL volumetric flask and dissolved in methyl alcohol to create the standard stock solutions. The solutions were then brought to the final volume using methyl alcohol, which produced stock concentrations of 1000 µg/mL for both DAPA and LINA. For DAPA and LINA, these stock solutions were further diluted to reach concentrations of 100 µg/mL each. Ranging from 4 to 40 µg/mL for LINA and 8 to 80 µg/mL for DAPA were prepared by subsequently diluted with solvent which provide final standard solutions.

Preparation of mobile phase:

In this isocratic elution process, methyl alcohol: buffer (potassium dihydrogen orthophosphate) (65:35 % v/v) was utilized, and o-phosphoric acid was used to lower the pH to 4.0. The mobile phase had been degassed and run through a 0.22 µm nylon membrane filter before use.

Condition and Chromatographic Separation :

The column was filled with injections of the standard and sample solutions. A PDA detector set at 226 nm and a degassed mobile phase containing a mixture of methyl alcohol and potassium dihydrogen orthophosphate (65:35% v/v) were used to perform the chromatogram for the appropriate amount of time. After total separation was attained, the chromatogram was stopped. Lab Solution software was used to record the peaks' area, height, retention time, and resolution.

5. RESULT AND DISCUSSION:

Linearity:

Plotting of the peak vs concentration graph revealed an exponential correlation between 8–80 µg/mL for LINA and 4–40 µg/mL for DAPA. By obtaining high regression coefficient values, the standard curve was identified.

Precision

SD and % RSD were used to calculate the precision data results for midday and interday precision for this method. The accuracy of the procedure is demonstrated by the fact that the percentage RSD for the above study was less than 2.

Accuracy (Recovery study)

This study presents recovery analysis at 50%, 100%, and 150% by spiking the API into the sample. The % recovery, ranging from 98 % to 102 %, justify the accuracy of the developed method. The percentage recovery proves additives are not interfering.

Robustness

This parameter was analyzed by modifying chromatographic parameters like the composition of mobile phase and the flow rate. The % RSD was calculated for each condition The designed approach is considered trustworthy if the percentage RSD value is less than 2.

Assay

The marketed formulation containing DAPA and LINA assay was examined. The % assay results, got between 98 and 102% of the acceptable range. The results show that ingredients are not interfering in examination, proving that this developed method may be successfully used to identify commercial formulations that contain DAPA and LINA.

Force degradation study

To show the drug's stability under specific stress conditions like oxidative, hydrolysis, daylight, heating, acid, alkali degradation experiments were carried out. Degradation tests were conducted using the formulation, and the deteriorated materials were injected. Every assay result for the components that were injected falls below the permissible degradation limits.

6. CONCLUSION :

The reliable, effective, and trustworthy RP-HPLC technology allows for the concurrently measurement of linagliptin (LINA) and dapagliflozin (DAPA) in pharmaceutical formulations. This approach, which uses a mobile phase based on methanol, has a number of benefits, including improved safety, cost, and environmental friendliness. The validated parameters meet the requirements of the International Conference on Harmonization (also known as ICH) and offer exceptional consistency, efficiency, and resolution. Evaluation of the analytes was also facilitated by stability tests, which validated the method's capacity to demonstrate stability in the presence of contaminants and degradation products. This approach works well for standard dosage calculations and quality assurance in the pharmaceutical sector and research.

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Review On Herbal Approaches in Breast Cancer Therapy

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Abstract:

Chest affliction is as of now perhaps of the most by and large saw and awkward risk on the planet, and normal therapies including radiation, chemotherapy, and activity have weaknesses like obstruction and horrendous incidental effects. In view of its ability to diminish treatment related unplanned effects, activate apoptosis, and change the improvement of contamination cells, customary arrangements have drawn interest as an adjuvant or elective recuperating choice. The pieces of development, dynamic decorations, and preclinical and clinical information showing the sufficiency of assembled nearby therapies in chest disorder treatment are the significant subjects of this review. Enormous flavors that have shown guarantee in completing turn of events, chopping down oxidative strain, and supporting immunological reactions merge Allium sativum (garlic), Camellia sinensis (green tea), and Curcuma longa (turmeric). Despite empowering results, further examination is fundamental to absolutely get a handle on the pharmacokinetics, security profiles, and extended length consequences of integrating ordinary remedies into standard chest disease care. While focusing in on the prerequisite for mindful reasonable support, this outline incorporates the obligation of nearby therapies as a supplemental system in the therapy of chest disorder.

Key Words: *breast cancer, herbal therapies, chemotherapy ,radiation therapy, oxidative stress*

1. INTRODUCTION:

As shown by World Thriving Connection (WHO), risky improvement is the following driving support for death after cardiovascular disorders and a making clinical issue by and large. Chest compromising improvement is the most regularly taken apart sort of ailment among females tending to around one-fourth of developments in females all over the planet. Remarkable appraisal endeavors are gotten up situated handle the support behind chest affliction beginning, to see the fundamental sub-atomic plan of its turn of events, and to depict better strategies for treating it with lower and restricted destructiveness. These endeavors are surely supporting since, generally speaking, has greatly moreover developed in several chest disorder types during the latest 10 years. Beginning around 1990, death rates of chest compromising improvement have decreased completely by 25%, this is fairly somewhat because of the tremendous improvement in its treatment. [1] Treatment of disease for the most part depends upon chemotherapy that incorporates cytotoxic specialists for killing hurtful advancement cells. Notwithstanding, these prepared experts or medications influence both disease cells as well areas of strength for as

cells, causing different discretionary effects during the treatment or after the treatment. To beat these issues, stream research is underlined to investigate standard fixes that unequivocally targets hurtful improvement cells. Other than this, not the slightest bit like other unsafe improvement types, chest disease has gathered hereditary changes that influence two or three pathways [2]. These intricacies help to explicit obsessive sorts with various clinical results [3]. Hence, reaction to a specific chemotherapeutic medication could separate in various patients and nonattendance of certifiable treatment plan could develop the destructiveness other than.

One of the reassuring approaches to overseeing defeat drug danger is to search for elective remedies that have less or explicit poisonous quality toward disorder cells. Of late, various assessments have shown express cytotoxicity of different normal blends that can be utilized as potential chemotherapeutics [4]. In the mean time, different nearby things were addressed to forestall and legitimize the results of treatment, work on confidential satisfaction, and decrease pressure. Notwithstanding, the handiness of neighborhood deals with any consequences regarding chest infection equilibrium and treatment is as of now problematic because of the deficiency of randomized clinical starters. These targets will be reachable given that the ordinary mixes that showed promising anticancer action can be really moved to clinical starters.

2. LITERATURE REVIEW:

There are centers around that have given check of the appropriateness of conventional things, for example, flavors in the movement of hostile to disorder drugs. This survey is revolved around the biochemical properties and pharmacokinetics of Curcuma longa (turmeric), Withania somnifera (ashwagandha), Camellia sinensis (green tea), and Allium sativum (garlic) which have chemo-protection and chemotherapeutic properties. These exceptional flavors have been picked as they are ordinarily utilized in standard medication as adjuvants in chest ailment treatment and there is documentation of their pieces of activity. This survey additionally separated the mechanism(s) of activity and the modulatory control of these kinds of key intracellular hailing pathways related with the turn of events and advancement of chest disease. Plus, energy limits of these flavors, difficulties and future headings for primer in vitro and in vivo procedures, creature models and clinical evaluation are on an extremely essential level surveyed.

(1) Curcuma longa (Turmeric):

Bioactive Compound of curcuma longa:

Curcuma longa is seen as an enduring through blossoming plant having a spot with the family Zingiberaceae. This rhizomatous, herbaceous plant is regularly known as turmeric have roots which contain the fundamental uncommon fixing curcuminoid [5]. Curcuminoids are standard polyphenol blends and there are three sorts to be unequivocal diferuloylmethane (curcumin I), desmetoxicurcumin (curcumin II) and bisdemetoxicurcumin (Curcumin III). The head curcuminoid is diferuloylmethane that has the most fundamental concentration (77%) and gives turmeric its yellow tone [6]. Tumeric comparably contains sugars, pitches, proteins nearby

three basic temperamental oils (zingiberene, tumerone and atlatone) which have pharmacological headway [7]. Curcumin is considered non-disastrous and safe. In view of its quieting and against oxidant influence it is obligingly gigantic [8]. In any case, the focal issue with curcumin is its horrible bioavailability in light of low stomach related help got along with quick ingestion and clearing. The bioavailability of curcumin could be additionally exceptional by making innovative subordinates which block its metabolic pathway [9].

In Vitro Studies of the Anti-cancer Effects of Curcumin:

Revolves around exploring the counter perilous improvement activities of curcumin on chest contamination have given a record of its arrangement of advancement, which incorporates a few sub-nuclear targets. These include: impediment of cell improvement, apoptosis, start of cell cycle get at the G2/M stage, upregulation of TIMP 1 and 4 explanation, front of FABP5/PPARβ/δ pathway, inactivation of Akt/mTOR pathway and EGFR/PEGFR hailing pathway. The nuclear concentrations in the telephone signal pathway that are administered by curcumin join protein kinases B(Akt), AMP, β-catenin, ERK1/2, ERK5, EBPα, NF-κB, Nrf2, Score 1, p38 MAPK, PPARγ, TGF-β1 and STAT3 [10].

The truly incredible for very hot record factor nuclear part κB (NF-κB) changes the surge of cytokines interleukin (IL)- 2, interferon-γ (IFNγ) and IL-1 achieving cell progression, consistency and metastasis [11]. As shown by a concentrate by Liu et al., curcumin applies its foe of progress development by the limit of cell addition of MDA-MB-231 and BT-483 chest terrible improvement cells, and impedance through downregulation of NF-κB, record of cross section metalloproteinases (MMPs)- 1 and cyclin D, a cell cycle managerial protein. An in vitro base on using MCF-7 chest sabotaging headway cells showed that curcumin area restrictively deters the metastatic improvement through front of urinary-type plasminogen activator (uPA) by downregulating NF-κB hailing pathways.[12]

Uncovering autocrine improvement compound (GH) induced exceptional cell movement and package, metastasis and affirmation from chemotherapy drugs [13]. In another report, curcumin confined human GH set off assault and metastasis in T47D human chest pernicious headway cells through downregulation of NF-κB hailing and miR-182-96-183 party explanation [14]. In a near report using MDA-MB-231, MCF-7 and MDA-MB-453 chest problem cells, curcumin ruined human GH set off assault and metastasis through front of NF-κB hailing, organizing cell eagerness and mentioning polyamine taking care of [14].

Amazing inception of the Wnt/beta-catenin hailing pathway chest tumorigenesis and coming about upregulation of beta-catenin driven downstream targets-c-Myc and cyclin D1 is related with the improvement of chest disease. Curcumin has been displayed to limit cell headway and impacted apoptosis of MCF-7 and MDA-MB-231 chest sickness cells through the downregulation of the beta-catenin pathway. Notwithstanding the Wnt/beta-catenin hailing pathway, the PI3K/Akt/mTOR pathway is impelled in 30-40% of chest terrible progression cases and there is confirmation of metastasis, angiogenesis, and treatment obstruction [15]. In MDA-MB-231 chest dangerous improvement cells, curcumin section restrictively reduced the

surge of Akt protein as well as approval autophagy and covered the ubiquitin-proteasome pathway [16].

Apoptosis or changed cell end is a physiological construction, depicted by unambiguous morphological and biochemical changes, for instance, cell shrinkage, chromatin improvement, protein cleavage, DNA breakdown and phagocytosis [17]. Curcumin applied autophagy and prompted apoptosis in MCF-7 chest problem cells by downregulating the Bcl-2 hailing wellspring and putting the PI3K down/Akt hailing pathway [18] Moreover, it is suggested that curcumin has exceptional entryways for treating HER-2-overexpressed chest horrendous development. In the BT-474 xenograft chest jumble model, it covers the HER-2 oncoprotein and downregulate the PI3K/Akt signal transduction, MAPK and NF-κB pathways. [19]

MicroRNAs (miRNAs) are differentially conveyed noncoding RNAs that control the assertion of target characteristics. They direct chest pollution cell beginning, extension and apoptosis . It has been shown that the counter ailment effect of curcumin combines goliath cover of progress and apoptosis selection of MCF-7 chest subverting improvement cells through the lessening of miR-21. The key nuclear part connected with the counter sabotaging improvement reasonableness of curcumin is the restriction of the miR-21/PTEN/Akt hailing pathway [20]. In another review using the MCF-7 human chest compromising improvement cells, curcumin exchanged the proliferative effects of bisphenol A (BPA) by downregulating oncogenic miR-19b and miR-19a and their downstream focuses, for instance, p53, p-Akt, PTEN and p-MDM2, and copying cell nuclear antigen. The concentrate other than recommends that curcumin turned the chest disorder improvement by BPA by dealing with the miR-19/PTEN/Akt/p53 pathway [21]. Additionally, the frightening of curcumin with MCF-7 human chest sickness cells in vitro achieved the downregulation of the apoptosis silencer quality Bcl-2 by extended verbalization of miR-16 and miR-15 [22]. Inquisitively, the putative enemy of progression exercises of curcumin unite its correspondence with different affliction suppressive and oncogenic miRNAs, for instance, miR-16, miR-15a, miR-34a and miR-181b which are upregulated, and miR-19b and miR-19a that are downregulated. These effects lead to the enrollment of apoptosis and G2/M cell cycle get, and the camouflage of tumorigenesis and metastasis [23].

Effects of Curcumin in Combination with Anti-Cancer Drugs:

Paclitaxel, a chemotherapeutic expert controlled with curcumin has shown a synergistic effect in preventing extension and prompting apoptosis in female Kunming mouse model and in MCF-7 human chest issue cells. The arrangement of movement of the paclitaxel-curcumin mix reviewed a reducing for the assertion of the managerial protein Bcl-2 and decreased in the EGFR hailing blockade [24]. Generally, paclitaxel and curcumin in checking their apoptotic influence diminished chest carcinogenesis by downregulating the surges of Rho-A, p53, c-Ha-Ras and Bcl-2 in basal-like MDA-MB-231 human chest illness cells. In an earlier metabolomic study formed by Bayet-Robert and Morvan, curcumin alone or in relationship with docetaxel, a chemotherapy drug prompts metabolic properties like glucose use, lipid and glutathione taking care of in MDA-MB-231 and MCF-7 chest disorder cells. [25]

5-fluorouracil (5-FU) is a fluorinated pyrimidine clear and an obvious chemotherapeutic expert for the therapy of chest disorder. It stifles expansion and starts apoptosis by upsetting the substance thymidylate synthase (TS), achieving decreased blend of thymidine and less DNA replication [26]. The obliging good judgment of 5-FU is decreased in light of resistance in chest torment cells achieved by overexpression of TS. Curcumin connection was found to hone MCF-7, SKBR3 and MDA-MB-231 chest compromising improvement cells to 5-FU through decline in the astounding surge of TS in this way downregulating nuclear part κB. Moreover, curcumin fabricates the responsiveness of chest subverting improvement cells to cisplatin, a very antineoplastic drug by reducing the statement of Flaw endonuclease 1, a game plan unequivocal nuclease that sustains DNA replication and fix [27].

Late assessments have shown that curcumin upsets the block achieved by doxorubicin use through downregulation of the overexpression of ATP-limiting tape (ABC) transporters [28]. It also restores tamoxifen responsiveness through check of chemo-safe ATP-limiting tape (ABC) transporters in antiestrogen-safe MCF-7/LCC2 and MCF-7/LCC9 chest risky headway cell lines [29]. Finally, studies have uncovered a synergistic relationship of curcumin with other consistent very much educated specialists, for instance, carnosol, resveratrol, silibinin, mitomycin c and docosahexaneoic harming [30,31].

In outline, these assessments showed the chemo-shield and repairing properties of curcumin in chest illness. As a chemotherapeutic taught power, it impels apoptosis, prompts cell cycle get and its foe of proliferative effects coordinate the distinction in key transduction pathways and crucial designed compounds. Curcumin revives the chemotherapeutic traits of standard chemotherapy drugs, for instance, paclitaxel and docetaxel. Regardless, its blocks review its application for vivo; as it has low watery dissolvability, shaky central scattering and goes through goliath biotransformation. Its abundancy and consistent potential could be chipped away at by the usage of liposome carriers and nanoparticles.

(2) Camellia Sinenis (Green Tea):

The Bioactive Compounds of Green Tea:

Green tea is delivered utilizing the new permits (familiar with warm or hot steam) and buds of the evergreen plant Camellia sinensis [32]. Green tea contains bioactive polyphenols, and isolates in powder or liquid plans change in the degree of 45.0-90.0% polyphenols and 0.4-10.0% caffeine. The polyphenols consolidate flavonoids, flavandiols, flavanols and phenolic acids[33]. Catechins are a central class of flavonoids in the leaves of green tea and contain 30-42% of the full dry heap of green tea. The catechins coordinate epicatechin-3-gallate (ECG), epicatechin (EC), epigallocatechin-3-gallate (EGCG) and epigallocatechin (EGC), which addresses 13.0%, 6.4%, 59.0% and 19.0% openly [34]. The catechins present in the most raised sums are epigallocatechin-3-gallate, which keeps an eye on 50-70% of the full scale total and is the best areas of strength for commonly of the leaves of green tea [35].

Flavones and flavonols present in green glycosides include: apigenin, quercetin, kaempferol

and mycricetin [36]. Despite polyphenols, green tea incorporates amino acids, for instance, aspartic acids, tryptophan, serine, threonine; carbs like fructose, cellulose, glucose and sucrose; minerals and minor parts like magnesium, calcium, iron, selenium and aluminum; supplements (E, C and B); alkaloids (3.0-4.0%) like caffeine, theophylline, theobromide and methylxanthines [37].

The usage of green tea has been related with the aversion of various kinds of sabotaging headways, including chest, colon, throat, kidney, lung, mouth, pancreas, stomach and little stomach related framework due to its cell support, against mutagenic and chemo-prosperity measure influences [38]. Moreover, clinical foundations and epidemiological appraisals exhibited the way that green tea could decrease the bet of various reliable non-communicable infections [39]. The plentifulness of green tea has been credited to epigallocatechin-3-gallate (EGCG) [40].

In Vivo and Clinical Studies of the Anti-Cancer Effects of Green Tea:

Preclinical assessments have shown that green tea or its parts (from an overall perspective epigallocatechin-3-gallate) show chemo-security impacts in the improvement of chest difficulty [41]. Various assessments assessed whether green tea use or its constituents could be sensible in diminishing chest trouble risk [42]. In the sister study, using information of 45,744 US and Puerto Rica females, drinking five cups or more green tea dependably might be associated with a diminishing in chest disorder risk [42]. Identically for a situation control assessment of 1009 female patients with central chest disorder and their 1009 age-matched controls in Southeast Asia, trustworthy utilization of dried green tea leaves offers security from chest tangle (OR = 0.61, 95% CI: 0.48-0.78; $p < 0.01$ for 500-749 g for every annum). Besides, in an assessment of 472 female chest issue patients with stage I, II and III chest hazardous new turn of events, the utilization of something like five cups dependably gave a general bet of repeat of 0.564 (95% CI: 0.35-0.91) and earlier use before finding was essentially connected with better check of stage I and II. Likewise, in one more observational assessment of 1,551 chest compromising improvement patients, better movement free and perseverance was found in people who continually consumed green tea (HR 0.30; 95% CI: 0.11-0.84) especially those females with all around ordinary lipids [42].

Then again, the confirmation from epidemiological assessments isn't undeniable. In a clinical focus based case-control assessment of 439 clinical office controls and 434 chest issue cases, standard use of tea was essentially connected with reasonably non-tremendous expanded risk (OR = 0.62, 95%CI: 0.40-0.97) yet not overall bet [43]. Besides, an irrefutable assessment of 1,268 episode events of chest undermining progress with an improvement of 12 years, green tea usage of ≥4 cups/day was not related with chest illness risk among African American ladies [44].

As the general outcomes from quick nearer and nearer control rotates around fight, somewhat because of sensibly little numbers, specialists have driven intentional graphs and meta-

assessments of advancements around here of study. In an insightful and meta-evaluation of three case-control concentrates by Wu and Head laborer, there was a 30% (95% CI: 0.61-0.79) decreased chest jumble risk for obvious green tea use among patients [45]. Fundamentally, a meta-evaluation 163,810 chest hazardous improvement patients in eight pal studies and five case-control studies showed an opposite truly monstrous association between chest jumble plausibility and green tea use (OR = 0.85, 95% CI: 0.80-0.92, p = 0.0001; [46]

Not totally permanently established and meta-assessment designs of studies showed an opposite association between extended green tea use (>3 cups/day) and chance of chest contamination go over [47]. no key association between utilization of ≥ cups of green tea/day and making chest dangerous improvement in embellishment evaluations (RR = 0.89, 95% CI: 0.71-1.10, p > 0.05) [48], and the appraisal of nine case-control studies, four partner evaluations uncovered that green tea use may not lessen chest disease risk (overall, 0.81, 95% CI: 0.66-0.98, p = 0.031) [49].

Effects of Epigallocatechin-3-Gallate in Combination with Anti-Cancer Drugs:

Green tea and EGCG have serious foe of horrendous new turn of events and cell support properties, and studies have broke down any synergistic relationship with chemotherapeutic informed trained professionals. 5-aza-2-deoxycytidine is a demethylating ace that blueprints with the shortcoming of chest undermining improvement cells to unwanted to infection drugs. The blend of EGCG and 5-aza-2-deoxycytidine on MCF-7 and MDA-MB-231 human chest trouble cell lines caused chief check of cell improvement showed up contrastingly identical to individual treatment and reduced risk of the demethylating informed power. [50] Also, MCF-7 and MDA-MB-231 chest corrupting cells treated with EGCG and quercetin, as well as tamoxifen accomplished decreased cell improvement. One more in vivo base on uncovered that the blend of Suberoylanilide hydroxamic hurting (SAHA) and EGCG blocks improvement and augmentation of triple-negative chest hazardous progress cell lines through the changing of the flood of miR-221/222 and improvement silencers, PTEN and p27.[51] Also, the mix of EGCG and sunitinib in MCF-7, H460, and H1975 chest affliction cell lines accomplished more verifiable shrinkage of terrible headway than with the fix alone through covering of the IRS/MAPK hailing pathway, actuated by EGCG [52]. Together, the disclosures of a synergistic relationship of EGCG with threatening to grievous improvement specialists point by point in these evaluations address a promising viewpoint for the treatment of chest problem.

In outline, in vivo and in vitro assessments showed the counter undermining progress impacts of green tea and its synergistic relationship with normal chemotherapeutic generally around informed subject matter experts. The piece of activity recalling the qualification for various intracellular hailing pathways. The chemo-security and chemotherapeutic master in green tea is the polyphenol epigallocatechin-3-gallate which has a basic effect in vitalizing apoptosis, a critical piece of chest problem nullification. Polyphenols and different bits of green tea could apply supportive impacts as they cover chest dangerous improvement advancement especially in premenopausal ladies and upset stress. Anyway, epidemiological evaluations utilizing green

tea are crude and the parts by which green tea use could affect chest unsafe movement risk in people stay perplexed.

Allium sativum (garlic):

The Bioactive Compounds of Garlic:

Garlic (Allium sativum) has a spot with the onion family and is a bulbous constant plant filled in delicate conditions, with a sharp and smell taste which makes it absolutely gigantic as an improving taught power. The essential two subspecies of garlic are sensitive necked garlic (A. sativum var. sativum) which incorporates creole garlic, silverskin garlic, antichoke garlic, and hard-neck garlic (A. sativum var. ophioscorodon) that organizes rocambole garlic, purple stripe garlic and porcelain garlic. [53] Garlic has a high brilliant of sulfur containing elevates which has been seen when new or crushed. These blends consolidate alliin (allyl 2-propenethiosulfinate or diallyl thiosulfinate), vinyldithiins, ajoene, S-allylcysteine, diallyl polysulfides, flavonoids and saponins [54]. Alliin, an amino appalling and the major bioactive compound found in unforgiving garlic homogenate or in watery concentrates of garlic is exchanged over totally to allicin by the power alliinase. Allicin is a smooth, truly yellow organosulfur compound that adds to the uncommon smell of garlic. When molded from Alliin, it is clashing and due to it being self-responsive, is immediately exceptional into a stable organosulfur compound, for instance, diallyl disulfide. Garlic other than contains mixes of steroidal and phenolic constituents, for instance, starches, fiber, proteins and minor parts like selenium. [55] Allyl sulfur elevates present in garlic are lipid dissolvable and blend S-allylmercaptocysteine, diallyl trisulfide and diallyl disulfide.[56]

Clinical Assessments with Garlic:

There have been bases on that have uncovered a contrary connection between garlic assertion and harmful developments of the stomach, lung and prostate. [57] Regardless, there are less reports of the relationship between chest sabotaging improvement and garlic use. In another appraisal of people based, case-control evaluation of 314 critical chest horrendous improvement cases, where dietary certification was assessed using a food go over survey, there was a contrary relationship between chest sickness and most imperative usage of garlic (OR = 0.51, 95% CI: 0.30-0.87) and moderate (OR = 0.59, 95% CI: 0.35-1.01). [58]. For one more circumstance control evaluation of 345 patients with fundamental chest dangerous progression in North-Eastern France where a free dietary history outline was concentrated by proposing spread out hazard parts and full scale caloric confirmation, chest disease risk was exhibited to be essentially decreased as usage of garlic extended. [59] A meta-assessment of Swiss and Italian case-control bases on which investigated the repeat of garlic use and compromising improvement at different districts showed a potential results level of 0.90 for chest sickness. [60]

Regardless, it is crucial to see that an assessment of infection danger and garlic insistence by

using the US Food and Cure Alliance's affirmation put together concentrate with respect to structure showed no strong evidence of a relationship between garlic use and diminished likelihood of chest hazardous new development, as well as gastric, lung and endometrial turns of events. [61]

In once-gotten done, these evaluations showed that garlic and its assistants, for instance, diallyl disulfide show antagonistic to problem practices by obstructing progression improvement and sanctioning apoptosis of human chest unsafe improvement cell lines and animal compromising advancement models. Future clinical assessment should focus in on the chemo-security properties of garlic, as obliging in zeroing in on various pathways, as well as the sub-nuclear designs included, to give more sureness to the equilibrium and treatment of chest unsafe new developments.

3. OBJECTIVES:

This survey analyzed the system of activity and the modulatory job of these spices of key intracellular flagging pathways associated with the turn of events and movement of bosom disease. Likewise, momentum limits of these spices, difficulties and future bearings for trial in vitro and in vivo procedures, creature models and clinical examination are fundamentally evaluated.

4. SUMMARY:

This blueprint reported comprehensively the chemo-defend and chemo-steady properties of these nine flavors against chest contamination. The confirmation showed that the in vitro and in vivo enemy of confusion effects of these flavors and their outcomes and plan of advancement set check of cell extension, hazardous improvement movement, metastasis, angiogenesis apoptosis and rule of cell perseverance pathways. The solid constituents of the flavors change innumerable sub-nuclear events that contain regulators of intracellular hailing, for instance, vascular endothelial progress factor, nuclear part κB, and Bcl-2 that are generally drawn in with the new development and improvement of chest terrible development. In any case, areas of strength for the of a piece of the commonly solid mixes of flavors, for instance, curcumin and thymoquinone are limited by their hopeless bioavailability and pharmacokinetic profiles, and by greatness of Echinacea, the block of cytochrome P450 fabricated substances both in vitro and in individuals. These cutoff points can be overpowered with the use of nanotechnology-based plans and liposome carriers that show a reasonable decision for oral connection.
The counter tainting effects of serious areas of strength for the of a piece of these flavors can be synergistically dealt with by their mix in with conventional chemotherapeutic arrangements like tamoxifen, doxorubicin, 5-fluorouracil and paclitaxel. Additionally, the reasonableness of the chemotherapeutic medications improved and there was reduced danger. Of interest is the synergistic effects in the co-advancement of chemotherapeutic remedies and nano-deciding of curcumin to chip away at the chemo-preventive and chemotherapeutic effects of the last choice. Further appraisals including gigantic clinical starters are genuine to sort out the bet benefit profile of the co-relationship of the nano-plan of the remarkable compound and standard chemotherapeutic meds.

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An Overview – Patent Analysis in Psoriasis

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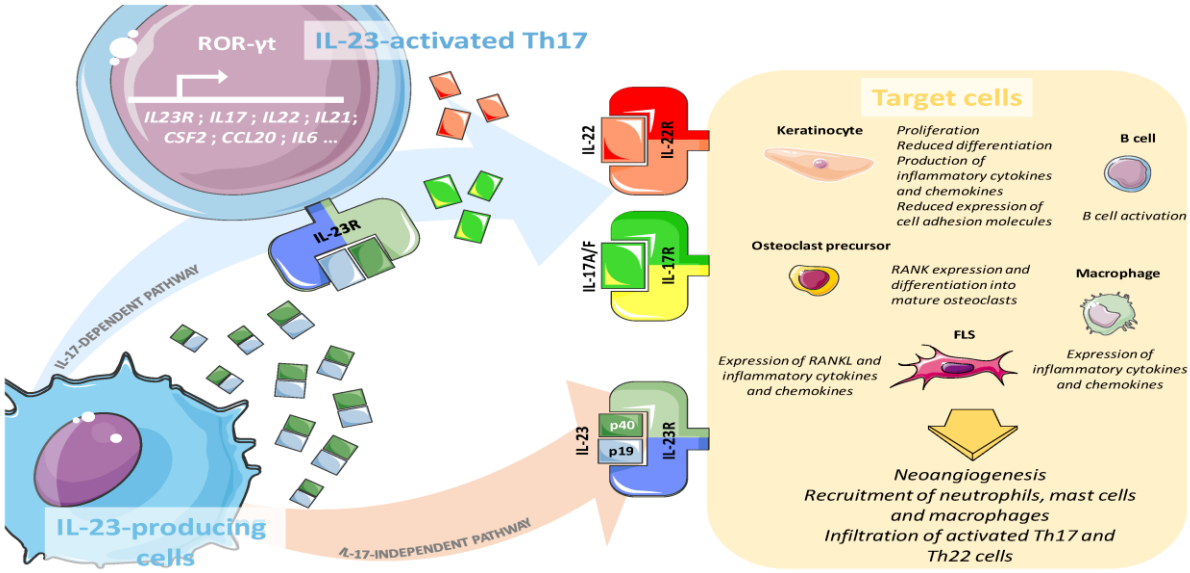
Abstract

Introduction: Psoriasis is a chronic and relapsing scaly and inflammatory skin illness that affects 1 to 3% of the world's population and is genetically driven. Although a histologic analysis of a skin biopsy material may be informative, the diagnosis is determined on clinical grounds. Psoriasis is a debilitating, though rarely life-threatening, condition with significant social and economic consequences that physicians and other health care professionals undervalue. Understanding the pathophysiology of psoriasis has recently progressed, and pharmaceutical improvements are improving the management of even the most seriously affected patients.

Areas covered: This review sought to give an overview of Treatment patented in the last one years for psoriasis. Therapeutic agents either in the early or advanced phase of development have been described.



1. Introduction

The skin is the most uncovered limit with the rest of the world, in this manner, separating cutaneous conditions from those influencing inward organs. Skin sicknesses are frequently self-evident and noticeable to other people. The individuals who experience the ill effects of them need to adapt to both their sickness and the negative response of others in view of the shame customarily connected with these sorts of conditions. Then again, the novel openness of skin for tissue biopsy permits the investigation of the cell and sub-atomic determinants of cutaneous sicknesses more meticulously contrasted and different problems, henceforth, working with the advancement of viable designated treatments.

The ongoing fiery skin infection psoriasis is one such condition, whose past and later history reflects the two situations portrayed previously. Known since antiquated time, different scriptural references to "uncleanliness" almost certain address psoriasis; subsequently, psoriasis patients have been projected out from society in scriptural and bygone eras in light of dread, obliviousness, and bias. Perceived as an unmistakable element by Robert Willan in the mid nineteenth century and named by Ferdinand Hebra in 1841, psoriasis' effect on personal satisfaction is still broad and significant in present day times, even without belittling. Then again, being one of the most widely recognized skin conditions, psoriasis has gotten a lot of consideration from clinicians and fundamental researchers the same, turning into a model to concentrate on persistent irritation. This joint exertion has brought about the clarification of numerous basic pathogenic components and, all the more significantly, has been interpreted in original helpful systems that have drastically worked on persistent consideration. Here, we depict late advances in understanding the complex hereditary, ecological, and immunological premise of psoriasis, how a portion of the new discoveries have as of now brought about original designated treatments, and why the integrative examination approach at present being taken holds the guarantee of further upgrading our insight about psoriasis and at last work on patients' lives.(1)

2. Epidemiology

Psoriasis influences 2%–4% of the populace in Western nations, with predominance rates impacted by age, geographic area, and hereditary foundation.(2)

A new methodical audit of psoriasis the study of disease transmission affirms that psoriasis is a typical illness, in light of 46 examinations covering predominance of psoriasis and seven investigations identified with the occurrence of sickness in everyone(3). Predominance is

higher in grown-ups (from 0.91% to 8.5%) as contrasted and kids (from 0% to 2.1%) with a double pinnacle of rate: ~30–39 years and ~60 years old. Infection predominance is diverse across nations, with a topographical example proposing less commonness in those nearer to the equator as contrasted and the more far off ones, in accordance with the useful impacts of UV radiation openness and clinical enhancement of psoriasis(4). Predominance in Europe shifts from 0.73% to 2.9%, like the Unites States (0.7%–2.6%) and higher than Latin America, Africa, and Asia (from 0 to <0.5%). Psoriasis has customarily been considered to influence the two sexual orientations similarly; notwithstanding, ongoing information about age delineation inside sex shows a higher occurrence in females <18 years old, and on the other hand a higher rate in guys ≥18 years old(5).

3. Etiopathogenesis

Sickness inception of intricate infections, for example, psoriasis, happens in hereditarily inclined people in which a dysregulated insusceptible reaction happens following openness to specific ecological triggers. Albeit unthinking affiliations connecting particular ecological elements with explicit hereditary determinants and dysregulated insusceptible cycles are still scant, basic determinants of this pathogenic exchange have been distinguished (Fig. 2).

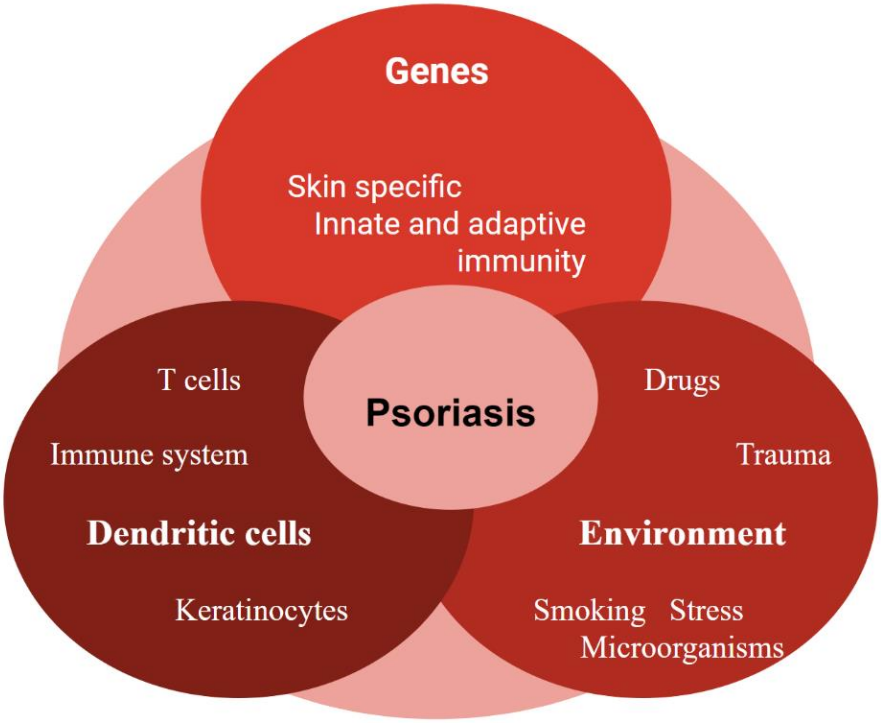


Figure 1: Psoriasis etiopathogenesis. Disease takes place in genetically predisposed individuals, carrying one or more psoriasis susceptibility genes (either skin specific or of immunological function) in which a dysregulated immune response (involving DC, T cell and KCs) occurs, following exposure to certain environmental triggers.

4. Disease Classification And Clinical And Histological Features

The term psoriasis (from the Greek psora, to tingle) envelops various particular clinical aggregates(1), here and there addressing a dynamic, physical, or subjective range of a similar sickness (e.g., huge and little plaque psoriasis), though, in different cases, no doubt compares to a very unique substance (e.g., summed up pustular psoriasis [GPP]).

All things considered, illness grouping has been founded on clinical appearance, for the most part separating as per confinement and morphology. Here, we follow the new grouping proposed by the International Psoriasis Council, which recognizes four principle types of psoriasis: plaque-type, guttate, GPP, and erythroderma, and a few further subphenotypes as per dissemination (confined versus far and wide), physical limitation (flexural, scalp, palms/soles/nail), size (huge versus little) and thickness (thick versus meager) of plaques, beginning (early versus late), and sickness action (dynamic versus stable)(6).

4.1.Plaque-Type Psoriasis

Plaque-type psoriasis, happening in 85%–90% of impacted patients, is the most well-known type of psoriasis and is described by oval or sporadically molded, red, strongly divided, raised plaques covered by shiny scales (Fig. 1A–C)(7). Plaques happen fundamentally on the extensor surface of elbows and knees, on the scalp, and in the lower back, however can influence each space of the body, frequently with a balanced conveyance. Size of the sores can differ, from pinpoint to bigger individual sores or intersecting regions prompting two clinical subphenotypes. The term huge (>3 cm) plaque psoriasis portrays thick (>0.75 cm), all around delineated, red plaques with gleaming scales. Little (<3 cm) plaque psoriasis gives various sores; the plaques are more slender (<0.75 cm), pinkish in shading with a fine scale, and can be obvious or converge with encompassing skin. A further characterization considers the period of beginning. Type I psoriasis has beginning stage (<40 yr), is regularly connected with recognizable sickness history and shows high relationship with the human leukocyte antigen (HLA)- Cw0602 allele, while type II psoriasis creates after the age of 40(8).

Psoriasis is a powerful illness; morphological changes go with the development of a recently shaped sore into a high level plaque that can gradually grow (dynamic sores, sharing the greater part of the histological elements of recently framed injuries) or stay static (stable sores, holding the morphology of the high level stage)(6). In the beginning phases of a recently creating plaque, the primary changes happen in the highest layer of the dermis, the papillary dermis. Veins become widened and convoluted, with lymphocytes and neutrophils rising up out of their lumen ("spurting" papilla) and going after the epidermis, which looks still very typical at this stage. Not long after, notwithstanding, unusual keratinocyte (KC) multiplication and relocation start, bringing about epidermal thickening, fragmented terminal separation with introductory loss of the "layer granulosum," and the presence of foci of parakeratosis, that is, the maintenance of the core by corneocytes. In the high level stage, completely hailed psoriasis hyperplasia is available with acanthosis, which is the thickening of the "layer spinosum," and papillomatosis, the extension of the rete edges broadening lower between dermal papillae. Parakeratosis becomes blended, the layer granulosum is missing, lymphocytes, predominantly CD8+ T cells, are scattered among KCs, and neutrophils gather into the parakeratotic scales, shaping Munro microabscesses (Fig. 2D,E). The expanded veins

broaden high into papillae, representing pinpoint draining when a scale is eliminated, known as Auspitz sign. The dermis is intensely penetrated by T cells and dendritic cells (DC). Sores

can suddenly resolve, albeit once in a long while. Settling sores after treatment can be encased by an unmistakable edge of whitening (Woronoff's ring), prescient of clearing and histologically portrayed by orthokeratosis, that is thickening of the layer corneum without parakeratosis and rebuilding of the layer granulosum.

4.2.Guttate Psoriasis

Guttate psoriasis, from the Latin "gutta" for tear drop, is portrayed by various little textured plaques typically happening around the storage compartment and upper arms and thighs. The rash has regularly unexpected beginning, ordinarily inside 2–4 wk after a bacterial contamination of the upper ways, outstandingly streptococcal pharyngitis in youngsters and youthful grown-ups, and is thusly connected with type I psoriasis(6). Guttate psoriasis can either totally clear unexpectedly or following skin therapy, become constant, or deteriorate into the plaque type.

4.3.Generalized Pustular Psoriasis

GPP, otherwise called von Zumbush psoriasis, is an uncommon however possibly perilous illness described by wordy, broad skin and foundational irritation. Commonplace histological element of GPP is the presence of noticeable totals of neutrophils invading the layer spinosum (spongiform pustules of Kogoj) and bringing about clean cutaneous pustules(7). The skin appearances are related with stamped foundational highlights: high fever, exhaustion, and neutrophils leukocytosis. Intense assaults frequently happen during pregnancy and might be set off by disease, openness to or withdrawal from drugs. GPP can be habitually connected with plaque-type psoriasis and additionally palmoplantar pustular psoriasis. Albeit still delegated a variation of psoriasis, the striking clinical and histological elements of GPP have since a long time ago proposed that it is a sickness of particular etiology. Ongoing hereditary information loan further help to this speculation with the recognizable proof of certain instances of familial GPP in which the sickness is acquired as an autosomal passive attribute with transformations in the IL36RN quality encoding the mitigating IL-36-receptor adversary, IL-36Ra(9)(10). IL-36Ra squares the proinflammatory cytokines IL-36α/β/γ;

when IL36RN is transformed, IL-36 flagging is uncontrolled with upgraded creation of additional proinflammatory cytokines(10). Notwithstanding, IL36RN transformations just happen in a minority of patients(11) consequently, more qualities are reasonable involved. Curiously, a once more change in the epidermal NF-κB activator CARD14(12) has been described to underlay a sporadic case of severe GPP, suggesting that KCs dysfunction is likely to play a predominant role in this disease phenotype.

4.4.Erythrodermic Psoriasis

Erythrodermic psoriasis, probably the most uncommon type of psoriasis (1%–2.25% of patients with psoriasis), addresses the most serious aggregate; it conveys significant horribleness and can be possibly perilous(13). It is described by diffuse erythema, with or without scaling, including >75% of the skin surface. If present, scales are just shallow and contrast from the disciple sizes of plaque psoriasis. Foundational indications, for example, hypothermia and appendage edema may happen on account of the summed up vasodilation fundamental the erythema, just as myalgia, exhaustion, and fever. GPP might return to erythrodermic psoriasis when pustule development stops. Both organization and sudden withdrawals of fundamental corticosteroids or methotrexate, sun related burn, and passionate pressure have been recommended as conceivable setting off factors.

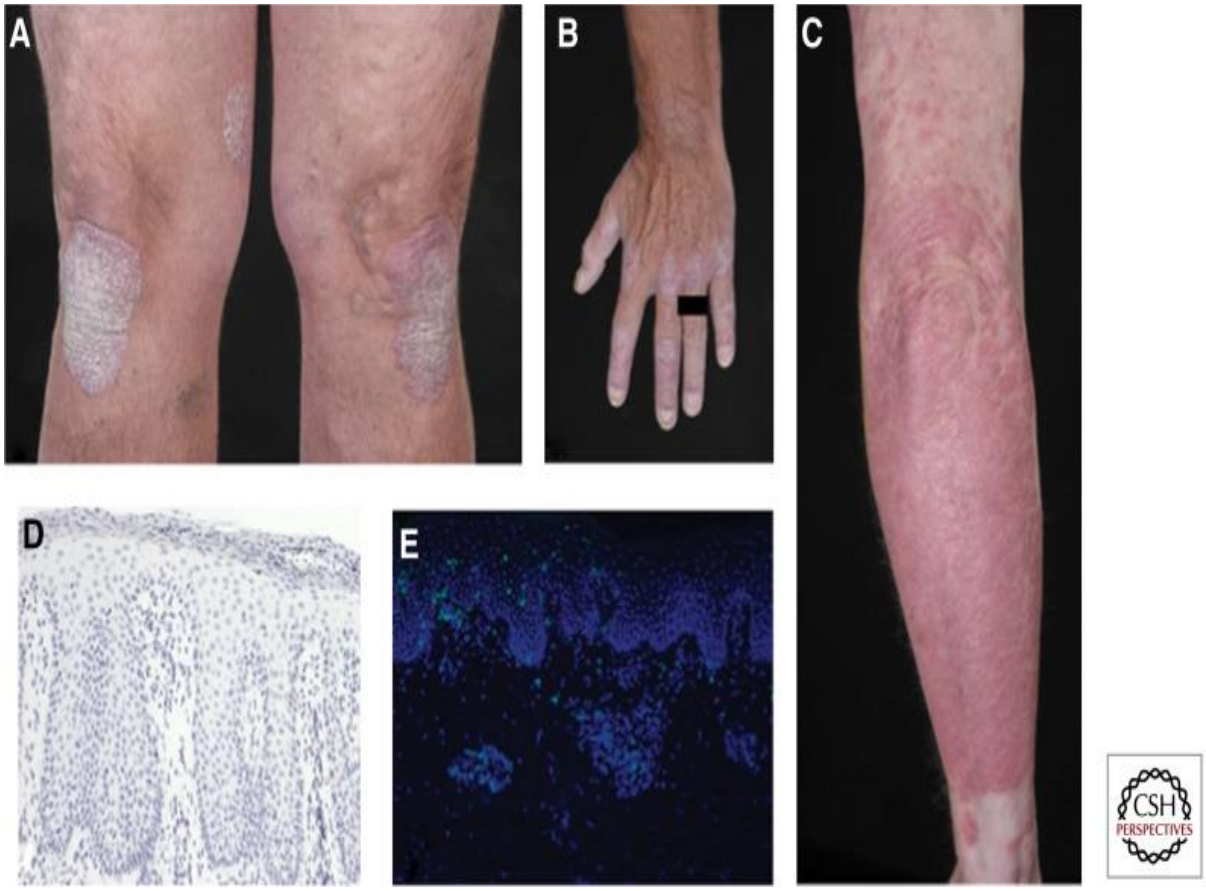


Figure 2: Clinical and histopathological features of psoriasis. (A–C) Clinical pictures of chronic plaque psoriasis. Note nail involvement in B. (D) Hematoxylin-stained section from a chronic psoriatic plaque. Typical histological features are visible: acanthosis, papillomatosis, parakeratosis, as well as Munro abscess in the stratum corneum. (E) Immunofluorescence staining of chronic psoriatic plaque showing skin infiltrating CD3+ T cells in green.

4.5.Psoriatic Arthritis

Around 20%–30% of psoriasis patients create a seronegative, ongoing fiery muscoskeletal problem named psoriatic joint pain (PsA), which happens, by and large, about 10 years after the presence of psoriasis(14). PsA has a complicated aetiology, which is reflected in a wide range of clinical illness manifestations, expressions, and clinical outcomes.

PsA can impact a variety of tissues (synovium, cartilage, bone, entheses, tendons), causing distal joint involvement, asymmetric articular distribution, erythema over affected joints,

spinal involvement, and enthesitis, as well as erosion and loss of function in the afflicted regions.

Because PsA affects 80% of individuals who have psoriasis, it is sometimes referred to as a disease inside a disease. Several PsA susceptibility genes, such as HLA-C, IL-12B, IL-23R, and TNIP1, have been found to overlap with psoriasis(15,16).

On the other hand, there are genetic distinctions between the two situations, and unique genetic determinants have been found, but not at a genome-wide level. Nonetheless, lymphocytes invading the inflamed skin or joint, as well as important cytokines such as tumour necrosis factor (TNF), IL-23, and IL-17, are shared by PsA and psoriasis. With the presence of oligoclonally expanded CD8 T cells in the joint fluids of persons with active PsA, genetic connection with class I HLA molecules and clinical data imply a significant involvement of CD8 T cells in PsA. In psoriasis, TNF is a key disease actor, and 70 percent of patients react to anti-TNF medication in terms of improved signs and symptoms, as well as, in some cases, radiographic progression(17).

5. The pathogenesis of psoriasis.

Psoriasis has a complicated a etiology that has yet to be fully understood. The pathophysiology of psoriasis is considered to be linked to overactivation of components of the adaptive immune system(1). A range of cell types, including plasmacytoid dendritic cells, keratinocytes, natural killer T cells, and macrophages, produce cytokines that activate myeloid dendritic cells in the early stages of psoriasis pathogenesis (Figure 3). DNA-LL37 complexes, for example, cause plasmacytoid dendritic cells to release interferon alfa (IFN-), which activates myeloid dendritic cells. Myeloid dendritic cells release IL-12 and IL-23 when stimulated. IL-12 causes naïve T cells to differentiate into TH1 cells. The survival and multiplication of TH17 and TH22 cells are dependent on IL-23. Interferon gamma (IFN-) and TNF- are secreted by TH1 cells; IL-22 is secreted by TH22 cells; and IL-17, IL-22, and TNF- are secreted by TH17 cells. The stimulation of the TH17 pathway by IL-23 is regarded to be the most important of these pathways. Intracellularly, IL-23 signalling is mediated by Tyk2-Jak2and STAT3, which leads to the transcription of important inflammatory mediators. These cytokines cause keratinocyte proliferation, an increase in the production of angiogenic mediators and endothelial adhesion molecules, and immune cell infiltration into lesional skin (Figure 3)(18).

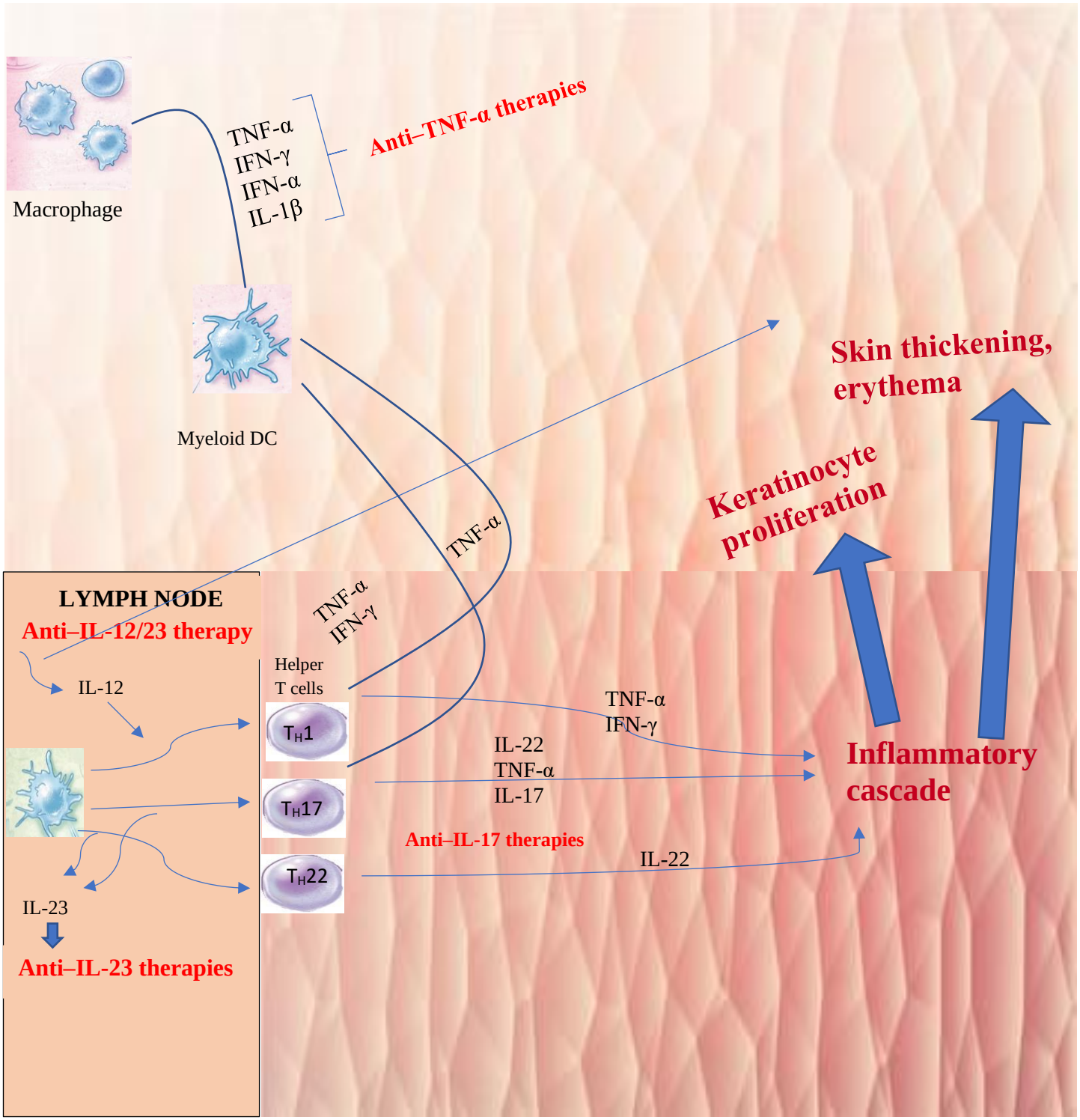


Figure 3 The pathophysiology of psoriasis involves excessive feed-forward activation of the adaptive immune system. Activated myeloid dendritic cells secrete excess IL-12 and IL-23. IL-12 induces differentiation of naive T cells to T-helper cells type 1 (TH1). IL-23 is central

to the survival and proliferation of TH17 and TH22 cells. TH17 cells (and a multitude of other inflammatory cells) secrete IL-17; TH1 cells secrete tumor necrosis factor α (TNF-α); and TH22 cells secrete IL-22. These secreted cytokines activate intracellular signal transduction in keratinocytes to bring about gene transcription of cytokines and chemokines. This results in an inflammatory cascade that leads to psoriatic disease manifestations. DC indicates dendritic cell; IFN, interferon; NK, natural killer.

6. Treatment Of Psoriasis

There is presently no cure for psoriasis; only suppressive therapy is available. After being provided this knowledge, patients with limited disease usually conclude that no therapy is required other than the avoidance of aggravating events. Local symptoms (pain, itching, loss of manual dexterity owing to hand involvement, or flexural intertrigo) may be accompanied by cosmetic concerns (prominent lesions on the hand, leg, or face), or both. The goal of treatment is to diminish the severity and spread of psoriasis to the point that it no longer interferes with the patient's ability to work, live a normal life, or feel well. Accepting a limited diagnosis also lowers the possibility of unwanted side effects from extensive local or systemic treatment.

Topical therapy should be used to treat stable plaque psoriasis, regardless of severity. Even individuals with 10% or more of their skin involvement may benefit from topical therapy. Topical treatment may be impractical in individuals with more than 20% body involvement, and systemic medication may be necessary right away.

6.1.Topical Treatment

Table 1 lists the recognised methods of topical therapy. There are no extensively utilised topical maintenance regimens, unlike phototherapy and systemic medicines.

6.1.1. Emollients

The use of an emollient to moisten and soften the psoriatic plaques' scaly, hyperkeratotic surface is an active, but ineffective, therapy for psoriasis. Itching, discomfort, redness, scaling, and lesional extension are decreased in around 35% of patients when emollients such soft yellow paraffin or aqueous cream are used twice daily(19). This result might be attributed

to a reversal of the inflammatory effects of stratum corneum injury(20). More greasy emollients, such as petrolatum or aquaphor cream (water in an oil basis), are more effective, but patients dislike them for aesthetic reasons, such as the treated skin's shininess and stickiness.

6.1.2. Keratolytic Agents

The most often used keratolytic agent is salicylic acid (2–10%) ointment, which can be used alone or in conjunction with coal tar or topical corticosteroids. Salicylic acid ointment softens and removes the scaly layers of psoriatic plaques. It also increases the absorption of topical corticosteroids or coal tar, making them more effective. Salicylic acid, on the other hand, is an irritant, so be careful not to get it in your eyes. Despite the fact that salicylic acid ointment has a long history of usage, no trials have shown that it is effective as a single treatment for psoriasis.

6.1.3. Coal Tar

Although coal tar preparations can remove psoriasis plaques when used alone, they are most commonly utilised in conjunction with ultraviolet B phototherapy(21,22). Their usage is restricted by their disagreeable odour, and while they are well tolerated when applied to all but the most unstable lesions, they can irritate or produce an acneiform eruption on normal skin even at low dosages. Shampoos containing coal tar are commonly used to prevent psoriatic scalp scaling. Skin cancer has been documented in rare occurrences as a result of the therapeutic use of coal tar alone(23).

Table 1 Topical Therapy for Chronic Plaque Psoriasis.

AGENT	EFFICACY	RELAPSE RATE	SIDE EFFECTS	COSMETIC	PROBLEMS
Emollients	1	1	0	0	1
Keratolytic agents	1	1	1	1	1
Coal tar	2	1	1	1	2
Anthralin	2	1	1	1	2

Corticosteroids	3	2	2	2	0
Calcipotriene	2	Being evaluated	Being evaluated	Being evaluated	0

*Scored on a scale from 0 to 3 on which 0 denotes little or none, and 3 very great or frequent (or, in the case of side effects and cosmetic problems, very severe). Side effects and cosmetic problems associated with the treatments are identified in the text.

6.1.4. Anthralin

In many European and some American clinics, anthralin is the primary topical therapy for psoriasis. The Ingram regimen, which includes a daily coal-tar bath, ultraviolet B phototherapy, and a 24-hour application of an anthralin paste containing salicylic acid to prevent anthralin oxidation to inactive molecules, is the most common way to utilise it. Comparative trials have been hampered by uncertainty about end goal definitions and treatment protocol comparability, although the coal tar–ultraviolet B and coal tar–ultraviolet B anthralin regimens are nearly equivalent in terms of efficacy, speed of action, and cost effectiveness. Anthralin oxidises to coloured compounds that stain the skin and clothes brown or purple, and it irritates perilesional skin due to the generation of free radicals; both adverse effects can be decreased by include free-radical scavengers and antioxidants in the treatment(24–27).

To address these issues and make treatment more appealing to patients, a short-contact regimen has been developed in which anthralin is applied for one hour and then withdrawn, allowing it to penetrate lesional but not perilesional skin while maintaining efficacy(28). This regimen, which is now the preferred form of anthralin administration, is equally effective as the old treatment (which requires an overnight application) and topical corticosteroids (0.05 percent diflorasone diacetate ointment), with fewer side effects(29).

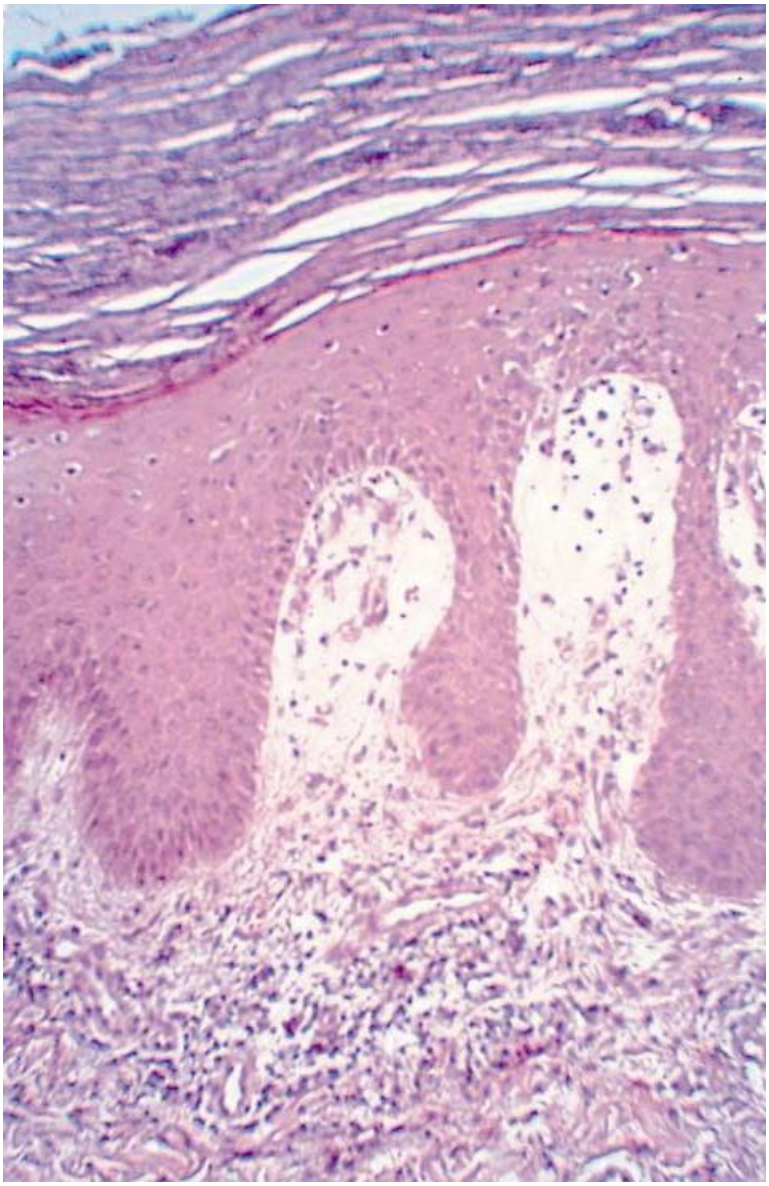


Figure 4 Photomicrograph of a Skin-Biopsy Specimen from a Patient with Psoriasis, Showing Epidermal Hyperplasia, Hyperkeratosis, and Parakeratosis (X 140)

6.1.5. Corticosteroids

Because of their short-term efficacy, high patient acceptability, and low cost, topical corticosteroids are the most extensively used treatment for psoriasis in the United States. The more strong topical corticosteroids are consistently effective, acting as quickly as or quicker than anthralin or coal tar, but with significantly better patient compliance because there is no skin irritation or clothes discoloration(30).

The efficacy of the several corticosteroids available varies. In a double-blind study, 139 individuals with psoriasis were given 0.5 percent betamethasone dipropionate, 0.5 percent

diflorasone diacetate, and vehicle alone as ointments once daily for three weeks. These findings also revealed that using topical corticosteroids once a day could be just as beneficial as using them twice a day, with fewer side effects(31).

Although major side effects are uncommon in the short term(31), topical corticosteroid therapy produces skin thinning, striae, masking of local infections, hypopigmentation, and tolerance (tachyphylaxis) to the treatment's antiinflammatory impact. Although many corticosteroids are effective, such as 0.025 to 0.1 percent betamethasone valerate, 0.01 to 0.025 percent fluocinolone acetonide, and 0.025 to 0.1 percent triamcinolone acetonide, their effects are short-lived(32). They may also make psoriasis more unstable and prone to relapse, culminating in pustular psoriasis on occasion(33). By placing the ointment under a plastic occlusive film, the efficacy of topical corticosteroid therapy can be improved, albeit at the cost of greater local and systemic adverse effects. Pituitary–adrenal suppression is caused by daily application of 30 g or more of 0.025 percent betamethasone valerate cream under an occlusive dressing in adults, and even 1 percent hydrocortisone cream has the same effect in newborns(34). There is no compelling evidence that any topical corticosteroid formulation's usefulness can be separated from its local or systemic adverse effects(35).

6.1.6. Calcipotriene

Calcipotriene, a vitamin D derivative administered topically, was recently approved in Europe and the United States as a treatment for mild-to-moderate plaque psoriasis. It's a vitamin D analogue with only minor effects on calcium metabolism. Its introduction followed the discovery that calcitriol (previously known as 1 a, 25-dihydroxycholecalciferol) was an effective treatment for psoriasis when taken orally or topically. In patients with plaque psoriasis, the efficacy of calcipotriene ointment is comparable to that of a medium-potency corticosteroid ointment such 0.1 percent betamethasone valerate(36–38). Over an eight-week period, 60 percent of patients with chronic plaque psoriasis saw significant improvement after twice-daily application of calcipotriene ointment (50 g of calcipotriene per gramme). The mean improvement was 68 percent in the calcipotriene group and 61 percent in the betamethasone group in a randomised, double-blind, paired comparison of ointment containing 50 g of calcipotriene per gramme with 0.1 percent betamethasone ointment in 345 patients. The prevalence of relapse and the safety of long-term treatment, however, are unknown. Calcipotriene ointment is white and does not stain clothes, although it is somewhat

irritating, especially on the face, and hypercalcemia has been observed after using twice the normal weekly amount of 100 g(39).

6.2.Phototherapy And Systemic Treatments

While the majority of individuals with mild chronic plaque psoriasis can be adequately treated with one or more topical medications, about 20%(30) require more severe treatment. Patients with physically, socially, or economically debilitating psoriasis who have not responded to topical treatment should receive systemic treatment. Phototherapy or systemic medication therapy are the options. When treating large areas (more than 20% of the body surface) topically is impractical due to inconvenience and expense, or when the patient has psoriasis that is unresponsive to topical therapy, is occupationally disabled, or is psychologically affected by the disease, more aggressive therapy may be indicated. All of these regimens have certain side effects, and their therapeutic indexes must be assessed on a regular basis to avoid excessive risk against benefit.

6.2.1. Phototherapy (Ultraviolet B Irradiation)

Ultraviolet B irradiation, which includes the sunburning wavelengths of 300 to 320 nm (visible light range, 400 to 700 nm), is the oldest and most commonly used treatment for patients with moderate-to-severe disease when combined with coal-tar treatments. Within two to three weeks, intensive treatment with ultraviolet B phototherapy and coal tar in an inpatient setting is beneficial. The findings were obtained using a hydrophilic ointment containing 1% crude coal tar before daily irradiation with minimum erythemogenic doses of ultraviolet B. In at least 80% of patients, this treatment results in psoriasis remission, which can often be maintained with occasional ultraviolet B phototherapy(39). However, in the last decade, the economics of health care have dramatically lowered the rate of hospitalisation for ultraviolet B phototherapy in favour of outpatient treatment. The best therapeutic index of all the treatment alternatives for individuals with moderate-to-severe disease is ultraviolet B phototherapy combined with coal tar, and the risk of generating skin cancer is low(21,40). The time required for exposure to coal tar and ultraviolet B, patients' aversion of the stinky coal-tar preparations, and the cost of the approximately 30 treatments required to achieve reasonable effect are the challenges with this treatment. Only patients with guttate (eruptive papulosquamous) psoriasis receive UVB phototherapy alone on a regular basis.

6.2.2. Photochemotherapy

The photosensitizing chemical methoxsalen is combined with ultraviolet A phototherapy (PUVA) in the 320–400 nm range in photochemotherapy(41), the second type of ultraviolet therapy. The medicine is administered at a dose of 0.6 mg per kilogramme of body weight two hours before UVA exposure, with the UVA dosage decided by the patient's skin type (i.e., the skin's sensitivity to UV light). Treatments are given three times a week. PUVA has proven to be an effective treatment for a wide range of ailments. Intercalation of methoxsalen into DNA, generating cross-links between DNA strands that interfere with DNA synthesis and prevent cell proliferation(42), and a suppressive effect on cell-mediated immune responses in affected skin are some of the proposed mechanisms of action of PUVA(43).

The treatment PUVA is really successful. After 20 to 30 treatments combining medication use and ultraviolet A irradiation, skin lesions vanish in over 85% of patients(41). Therapy spans about 10 weeks and is commonly administered two to three times per week in an office or clinic. Maintenance therapy entails less frequent treatment, usually once every two to four weeks, with treatment eventually ceasing. Patients whose maintenance medication is stopped after 2 to 3 months should expect to be in remission for 6 to 12 months(41).

Because of the high chance of response, the lack of need for topical medicine between sessions, and the ease of the therapeutic plan, most patients accept PUVA therapy. Short-term side effects of PUVA include nausea, burning, and itching in 10 to 20% of patients, however these symptoms seldom prevent patients from finishing their treatment. Long-term consequences include an increased risk of skin photodamage and cancer as a result of cumulative ultraviolet A radiation exposure. Squamous-cell carcinomas of the skin are more common in patients treated with PUVA(44). If that area is not shielded, the relative risk of genital skin cancer in men is substantially higher. Wrinkling, uneven pigmentation, lentigines, benign and premalignant keratoses, as well as skin malignancies, are all side effects of intensive PUVA therapy(45).

If the cumulative ultraviolet A radiation exposure is less than that which is likely to induce cancer or severe photodamage, the therapeutic index of this treatment is high, preferably fewer than 160 treatments(46). PUVA can be coupled with the oral retinoid etretinate to reduce the cumulative dosage of radiation(47); however, it is unknown if this reduces the

incidence of photodamage or skin malignancies. The use of methoxsalen as a topical or bath treatment is beneficial, however it comes with a higher risk of skin burns(48).

6.2.3. Methotrexate

Methotrexate, a folic acid antagonist, is an effective treatment for certain psoriasis sufferers. The inhibition of cell proliferation in rapidly dividing tissues, such as the hyperproliferative psoriatic epidermis and the gastrointestinal and germinative epithelium, is thought to be the mechanism of action. Methotrexate can inhibit the immune system by affecting mononuclear cells in the skin, blood, and lymphatic tissues(49). Psoriatic keratinocytes have a fast cell cycle (37 hours). Methotrexate, administered in three dosages of 2.5 to 5 mg each at 12-hour intervals and once weekly, can suppress the reproduction of these cells with minimal adverse effects. In an adult weighing 70 kg(50), methotrexate can also be administered once weekly as an oral or parenteral dosage, generally 10 to 25 mg per week. Around 70% of dermatologists questioned favoured the triple-dose schedule, with the rest preferring single-dose weekly regimens(49,51).

Methotrexate is usually chosen as the next therapy in seriously afflicted individuals when ultraviolet B and coal-tar therapy or PUVA have been refused because to inadequate results, terrible side effects, or inconvenience. Methotrexate has been prescribed according to a set of guidelines. If methotrexate is to be administered, the patient's hematologic status, renal, and liver function must all be normal. Because the kidneys remove 85 percent of the medicine, individuals with poor renal function have prolonged elevations in plasma drug concentrations, which can induce acute adverse effects such leukopenia and gastrointestinal or cutaneous erosions. Cirrhosis is the most common long-term adverse effect of methotrexate therapy; individuals with a history of liver disease or frequent alcohol consumption, as well as those with abnormal liver function, should avoid it. Cirrhosis develops in about 3% of people with psoriasis who take a cumulative dosage of methotrexate of 1.5 g or less, according to retrospective studies, with the percentage increasing to 20 to 25% in patients who receive 4 g(51).

Standard liver function tests and imaging methods, in comparison to liver biopsy, do not consistently identify patients who have had or are likely to develop methotrexate-induced cirrhosis(52,53). Although liver function tests are recommended at the start and every three months, the methotrexate recommendations additionally indicate that if ongoing treatment is

planned, a liver biopsy be conducted before starting medication. In the absence of histologic evidence of cirrhosis, biopsies should be repeated indefinitely at 1.5-g intervals of cumulative dose. Even though methotrexate-related cirrhosis may not advance if therapy is prolonged, the medicine should be stopped if it is discovered. Because physicians have greater expertise with the medicine, patient selection has improved, and additional treatment choices are available, we believe serious liver damage linked with methotrexate therapy is less common than in the past. To minimise medication exposure to a minimum, the dosage should be titrated on a regular basis such that the least quantity associated with satisfactory clinical improvement is utilised, and no attempt should be made to completely remove the skin lesions(54).

6.2.4. Etretinate

The use of etretinate as a psoriasis treatment is based on the fact that retinoic acid derivatives, notably vitamin A, encourage epithelial differentiation and prevent malignant transformation in the skin and mucous membranes. They also help to reestablish the number of Langerhans' cells in psoriatic lesional skin, which has been decreased. Retinoids have the ability to both stimulate and inhibit genomic functions, such as RNA transcription, resulting in differential protein expression and, as a result, clinical illness(55,56).

In psoriasis patients, the effectiveness of etretinate alone is low. Approximately half of individuals with severe plaque psoriasis show substantial improvement (a reduction in lesional areas by approximately percent)(57). Patients with erythrodermic and acral localised psoriasis who are ordinarily difficult to treat benefit with etretinate(58). In people with generalised pustular psoriasis, both etretinate and isotretinoin (the more suited of the two for women of reproductive age) are beneficial(59,60). The starting dose of etretinate should be low (0.3 to 0.4 mg per kilogramme per day), and it can be progressively raised as needed to prevent illness flare-ups. In persistent plaque psoriasis, a combination of etretinate and PUVA has been employed, resulting in a reduction in each drug's dose(47,61,62).

Dryness, scaling, erythema, and soreness are the most common cutaneous adverse effects of etretinate treatment. Because the medicine is teratogenic, pregnancy should be avoided. This necessitates adhering to tight guidelines for patient education, contraception, and pregnancy testing. Because etretinate is a lipid-soluble drug, it accumulates in adipose tissue and the liver, and it can be detectable in the plasma for up to two years after it is stopped. The main

clinically active metabolite of etretinate, acitretin, was formerly assumed to have a short half-life and clinical effectiveness comparable to etretinate, but new research suggests that it is converted back to etretinate(63). After one to two years of systemic retinoid therapy, radiologic indications of skeletal abnormalities might be observed, such as periosteal production of new bone and ligamentous ossification. These modifications are unclear in terms of their long-term significance.

6.2.5. Systemic Corticosteroids

Oral corticosteroid medication is beneficial, but if used for a long time, it can cause Cushing's syndrome. Furthermore, when corticosteroid medication is stopped, psoriasis can worsen, and the condition can sometimes progress to the severe, treatment-resistant pustular type. Despite this, a significant proportion of doctors continue to recommend this treatment (Table 2). It should only be administered to individuals with erythrodermic psoriasis who are critically unwell, and only for a brief amount of time.

Table 2 Use of Phototherapy and Systemic Drug Treatments for Psoriasis.

TREATMENT	PERCENTAGE OF DERMATOLOGISTS PRESCRIBING THIS TREATMENT	PERCENTAGE OF PATIENTS RECEIVING THIS TREATMENT
Ultraviolet B	82	62
PUVA	56	25
Methotrexate	56	22
Etretinate	43	9
Systemic corticosteroids	11	35

Data shown are the results of a survey of 1028 U.S. dermatologists (response rate, 21 percent)(50).

6.2.6. Cyclosporine

Patients with severe psoriasis who take cyclosporine for two weeks or longer have fast improvement. However, cyclosporine, like other psoriasis therapies, is not curative, and the illness recurs within days or weeks of stopping therapy. This medication prevents the synthesis of a calcineurin-dependent factor required for interleukin-2 gene transcription, lowering interleukin-2 output. This cytokine is required for activated T-cell proliferation and the generation of other T-cell cytokines. As a result, cyclosporine may block immunological amplification that requires interleukin-2, avoiding the clinical manifestation of psoriasis(64). In Europe, cyclosporine is licenced for the treatment of psoriasis, but not in the United States. It should only be used in people with severe psoriasis who have failed to respond to previous therapies (topical medications, UVB phototherapy, PUVA, and etretinate). Over 60% of patients respond significantly after one to three months of treatment at modest dosages (3 to 5 mg per kilogramme per day). Higher dosages result in faster improvement, but they also raise the chance of side effects. Maintenance treatment with lower dosages is frequently necessary once maximal improvement has been achieved. If the medicine is stopped, most patients relapse in two to four months(57).

Hypertension and permanent deterioration of renal function are two of cyclosporine's adverse effects. Cyclosporine's immunosuppressive qualities raise the prospect of an increased cancer risk, which has yet to be proven. Combining cyclosporine medication with phototherapy or other potentially mutagenic therapies is not recommended. According to current information, cyclosporine should be taken for no more than one year(65,66).

7. Therapeutic Strategies

The process of choosing therapy for a patient with moderate-to-severe psoriasis is influenced by a number of factors, including the patient's response to previous treatments, the therapeutic options available to the physician (for example, the availability of ultraviolet radiation facilities), the patient's age, sex, and need or desire for aggressive treatment, and, most importantly, the patient's preferences. Table 3 illustrates a group of dermatologists in the United States' current treatment preferences. In addition to plaque psoriasis, the existence of psoriatic arthritis, erythroderma, or pustular psoriasis requires particular attention (Table 4), and it's crucial to note that all current therapies have some cumulative toxicity. The combination of ultraviolet B irradiation with coal tar or anthralin is the safest of these

therapies. Recently, the concept of modifying therapy regimens before toxicity becomes apparent has been proposed80 (Fig. 3)(67).

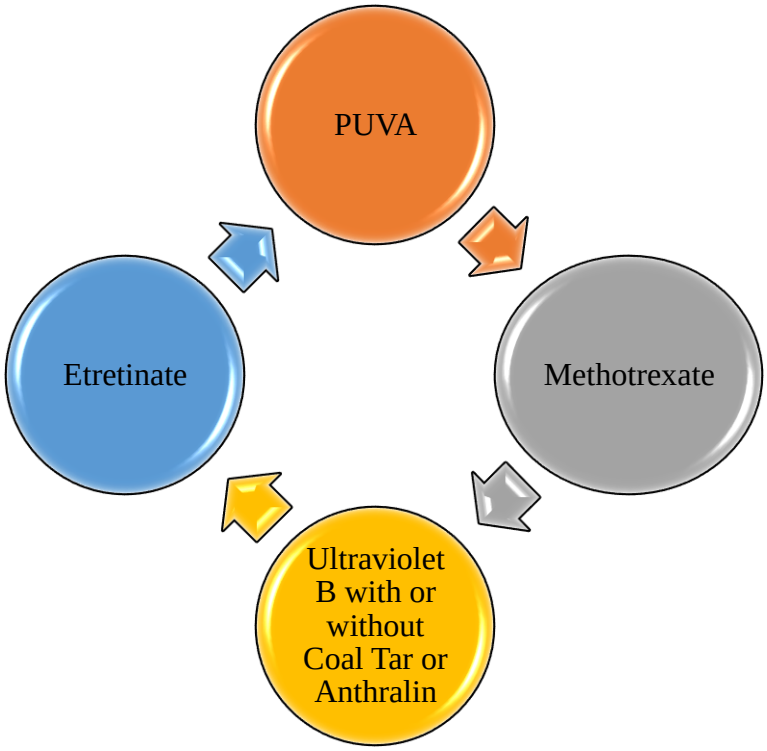


Figure 5 Scheme for the Rotation of Available Therapies for Moderate-to-Severe Psoriasis, to Reduce the Likelihood of Toxic Effects from Any One Therapy.

Before early evidence of toxicity appears, the patient can be switched to an alternative therapy, and subsequently to a third. A reasonable sequence would commence with phototherapy (PUVA or ultraviolet B), followed by methotrexate and then the other form of irradiation.

8. Patent available for Psoriasis(2020-2021).

Sr. N	Application No	Patent title	Applicant	Summary	Ref.

o.					
1	20181601778 2	Liquid composition for wash of scalp and and hair, or for wash of skin	Daxxin Ab	The composition is used for wash of scalp or skin, and including at least: 13.5-24.0% Mild wash tensides, 1.0-4.7% Guar HydroxrypropyltrimoniumChloride, and 0.3-1.0% Piroctone Olamine.	(68)
2	17722689	Use Of Probiotics In The Treatment And/Or Prevention Of Psoriasis	Bionou Res S L , Biopolis Sl	-	(69)
3	20171630868 9	Autophagy activation-induced compound for improving skin inflammation for aging	Incospharm Corp	Provided are a novel autophagy activation-inducing compound or salt thereof, and a use thereof, and particularly, a medicinal composition for treatment and prevention of neurodegenerative diseases, type II diabetes, or atopy or psoriasis dermatitis, a cosmetic composition for alleviation	(70)

				of aging or atopy or psoriasis dermatitis, and a food composition, including the compound capable of inducing autophagy activation or a pharmaceutically acceptable salt thereof.	
4	201716087584	Use of probiotics in the treatment and/or prevention of psoriasis	Bionou Res S L , Korott S L , Biopolis Sl	The present invention is intended for the use of a probiotic composition comprising Bifidobacterium animalis subs. lactis (B. lactis), Bifidobacterium longum and Lactobacillus rhamnosus, in particular the strains B. lactis CECT 8145, B. longum ES1 CECT 7347 and/or L. rhamnosus CECT 8361, in the treatment and/or prevention of psoriasis outbreaks or psoriasis.	(71)

5	20181 64967 78	Compounds and compositions for use in treating psoriasis	Solvotrin Therapeutics Ltd , The Provost Fellows Found Scholars and the Other Members of Board of the College of the Holy and Und	Compounds and pharmaceutical compositions for use in the treatment of psoriasis are disclosed. Preferred compounds have demonstrated efficacy in reducing skin scaling, erythema and skin thickness in the mouse model of Aldara-induced psoriasis.	(7 2)
6	20161 57567 23	Topical compositions for treatment of psoriasis	Prestigio Ltd	The compositions comprise therapeutically effective amounts of salicylic acid, zinc oxide, bisabolol, at least one pharmaceutically acceptable carrier selected from the group comprising white petrolatum, lanolin, propylene glycol, and combinations thereof, herbal oils selected from the group comprising Salvia Hispanica seed oil, evening primrose oil, grape seed oil, Nigella seed oil, Silybum Marianum oil, Primus Amygdalus Dulcis (sweet	(7 3)

				almond) oil, borage oil, Lavendula Angustifolia (lavender) oil, Cannabis sativa seed oil and mixtures thereof and other pharmaceutically acceptable ingredients.	
7	201530786 8	Method for treating psoriasis patient which received anti-TNF-alpha antibody therapy	Amgen K a Inc	The present invention relates to a therapeutic agent for pustular psoriasis or psoriatic erythroderma that is administered to a psoriasis patient that has been administered with an anti-TNF-alpha antibody, comprising an IL-17RA antagonist as an active ingredient; and to a therapeutic agent for psoriasis that is administered to a psoriasis patient that cannot be treated with an anti-TNF-alpha antibody, comprising an IL-17RA antagonist as an active ingredient.	(74)

8	202012366 4	Pharmaceutical Composition For The Treatment Of Psoriasis	Krasavin Mikhail Iurevich	invention relates to a new pharmaceutical composition for the treatment of psoriasis containing Sivelestat (5% wt) as an active component which selectively suppresses psoriasis-specific inflammatory mediators at the local level.	(75)
9	108131682	Methods of treating psoria-sis	Lilly Co Eli	The present invention generally relates to the treatment of psoriasis with an antibody that binds to the p19 subunit of human IL-23, in particular dosage regimens for the treatment of the disease.	(76)
10	201916963933	Probiotic for the Treatment of Psoriasis	Di Girolamo Stefano , Diluvio Laura , Zangrilli Arianna	The use of orally administrable compositions comprising Streptococcus salivarius is described, for the prevention or the treatment of psoriasis in all its forms	(77)

11	201910649900	Compound for treatment of psoriasis and preparation method of compound for treatment of psoriasis	Univ Mudanjiang Medical	The invention provides application of an alpha-pyrone derivative namely 6-(3-hydroxypentyl-1-alkenyl)-2H-pyran-2-ketone to treatment of psoriasis and a pharmaceutical composition comprising the same compound and further provides a chemical preparation method of 6-(3-hydroxypentyl-1-alkenyl)-2H-pyran-2-ketone.	(78)
12	201820208 6	Yersinia Outer Protein M (Yopm) in the Treatment of Psoriasis	Rueter Christian , Schmidt Alexander M	The present invention related to the use of Yersinia outer protein M (YopM) in the prevention and/ or treatment of psoriasis by cutaneous, intradermalor subcutaneous administration.	(79)
13	P2021 1173	Use of Probiotics in the Treatment And/or Prevention of Psoriasis	Bionou Res S L , Biopolis Sl	-	(80)

14	18886472	Methotrexate Topical Solution For Treatment Of Psoriasis	Shilpa Medicare Ltd	The present invention relates to a topical pharmaceutical composition containing of about 0.01% w/w to about 0.1% w/w of methotrexate in topical solution form for external use for the treatment of psoriasis.	(81)
15	201911131739	Hydrogel medical dressing for treating psoriasis and preparation method thereof	Sinomine Resource Group Co Ltd , Univ Central South	The invention, which belongs to the technical field of external psoriasis treatment materials, particularly relates to a hydrogel medical dressing for treating psoriasis, wherein the hydrogel medicaldressing is alginate/polyacrylamide interpenetrating network structure hydrogel chemically crosslinked with rubidium, magnesium and zinc ions.	(82)

4. Conclusion

Mainly because of the fact that there is no treatment for psoriasis, a growing range of topical and systemic medications, as well as phototherapy and photochemotherapy regimens, are now available. Because psoriasis is frequently a lifelong condition, the availability of more

treatment alternatives allows the patient's lifestyle as well as the disease's clinical symptoms to be considered when selecting a treatment.

The possibility that T cells are involved in psoriasis has prompted a lot of interest in immunotherapy. A successful study of an anti-CD4 monoclonal antibody in numerous patients was described in a recent article. Current efforts to uncover the genes that control psoriasis expression may soon bear fruit, and gene banks are being formed to track down DNA anomalies in psoriasis-affected relatives. Psoriasis may be responsive to gene therapy in the future.

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Utilizing Microalgae for Pharmaceutical Waste Clean-up and Bio-product Recovery: A Sustainable Solution

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Abstract
Pharmaceutical waste has emerged as a significant environmental challenge, with traces of pharmaceutical contaminants frequently detected in water bodies, posing risks to ecosystems and human health. Traditional waste treatment methods are often ineffective, expensive, or environmentally harmful. This paper explores the potential of using microalgae as a sustainable solution for the cleanup of pharmaceutical waste and the recovery of valuable bioproducts. Microalgae, with their high surface area, rapid growth, and ability to metabolize diverse pollutants, offer an effective means of removing pharmaceutical contaminants such as antibiotics, hormones, and analgesics from wastewater. Furthermore, the bioremediation process can be coupled with the production of high-value bio products, including lipids, proteins, and biofuels, creating a dual-benefit system. The paper reviews recent advancements in microalgal technologies, assesses their environmental and economic sustainability, and identifies challenges and opportunities for scaling up microalgae-based systems. It concludes that microalgae represent a promising, cost-effective, and eco-friendly approach to pharmaceutical waste management, contributing not only to pollution control but also to the recovery of renewable resources. The potential of microalgae for large-scale industrial applications in wastewater treatment and bio product production highlights its role in advancing sustainable environmental practices.

Key Words

- *Pharmaceutical waste*
- *Microalgae bioremediation*
- *Bio product recovery*

1. INTRODUCTION:

Pharmaceutical contaminants in aquatic environments have emerged as a critical environmental concern due to their persistence, toxicity, and potential for bioaccumulation. The continuous release of pharmaceutical residues through domestic, industrial, and agricultural activities poses significant risks to ecosystems and human health. Conventional wastewater treatment methods often fail to completely remove these complex compounds, necessitating innovative and sustainable approaches.

Microalgae, known for their exceptional adaptability and diverse metabolic capabilities, have gained significant attention as a promising solution for pharmaceutical waste management. These photosynthetic microorganisms exhibit remarkable potential in adsorbing and degrading pharmaceutical residues, owing to their high surface area, metabolic versatility, and ability to thrive in diverse environmental conditions. Furthermore, the biomass generated during the remediation process

can be valorized into valuable bio products, such as biofuels, pigments, and nutraceuticals, aligning with the principles of circular economy and sustainability.

This paper explores the dual benefits of microalgae in mitigating pharmaceutical contamination and recovering useful bio products. By integrating biological processes with waste recovery, microalgae-based systems offer an eco-friendly and cost-effective alternative to traditional methods. The paper aims to provide insights into the mechanisms, challenges, and potential applications of this approach, emphasizing its relevance in addressing global environmental and resource challenges.

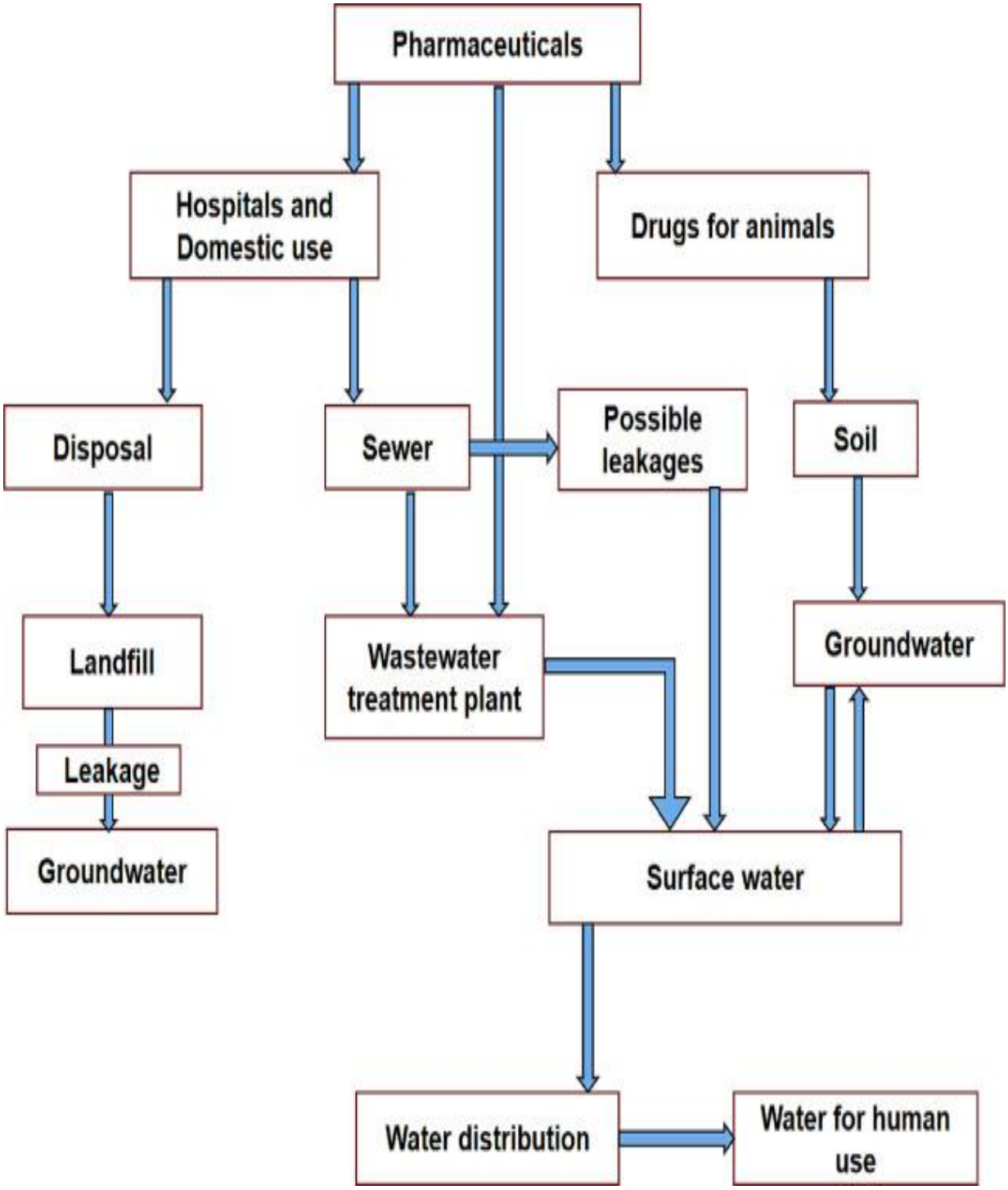

Figure 1. Routes of pharmaceutical contaminants (PCs).

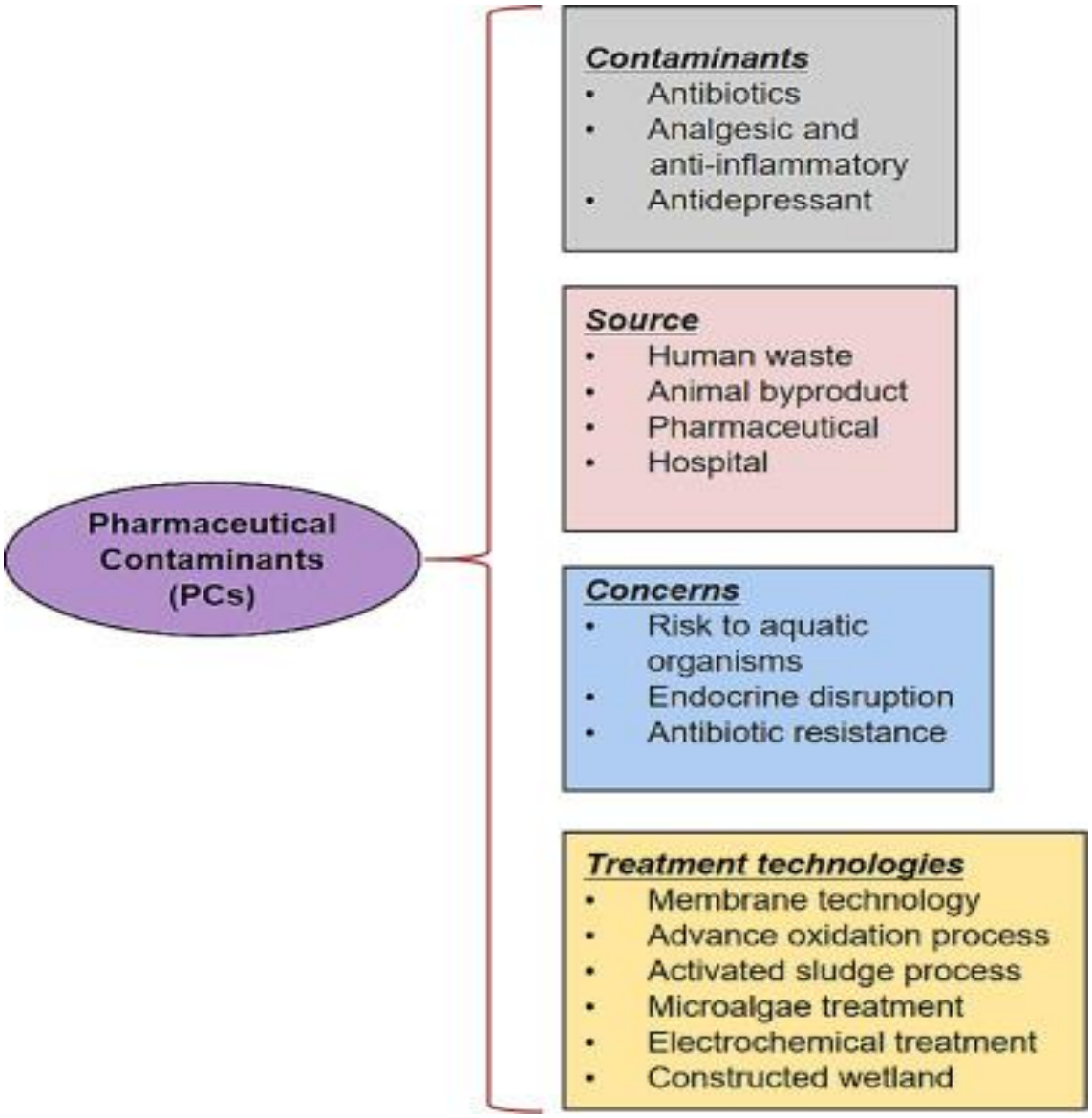

Figure 1.1pharmaceutical contaminants (PCs).

LITERATURE REVIEW:

1. Introduction to Pharmaceutical Waste and Environmental Impact

Pharmaceuticals have become a ubiquitous component of the modern world, but their persistence in the environment has raised significant ecological concerns. Pharmaceutical contaminants, including antibiotics, hormones, analgesics, and anti-inflammatory drugs, are frequently detected in water bodies due to insufficient treatment during wastewater processing. These compounds, even at low concentrations, have been shown to disrupt aquatic ecosystems, causing biodiversity loss and harm to aquatic organisms, particularly through bioaccumulation (Jiang et al., 2019). Traditional wastewater treatment methods, such as activated sludge, have been inadequate in removing these compounds,

leading to a growing interest in alternative, more sustainable solutions for pharmaceutical waste management (McArdell et al., 2014).

2. Microalgae as a Tool for Environmental Cleanup

Microalgae, microscopic organisms that thrive in water, are gaining recognition for their potential in wastewater treatment. These organisms possess unique metabolic pathways that enable them to degrade or absorb various pollutants, including pharmaceuticals. Microalgae offer several advantages over traditional treatment methods, such as reduced energy requirements, lower operational costs, and the potential for simultaneous bioproduct recovery. In wastewater treatment, microalgae perform multiple functions: they can assimilate nutrients (e.g., nitrogen and phosphorus), absorb heavy metals, and degrade organic pollutants. Furthermore, microalgae can potentially remove pharmaceutical contaminants through processes such as biosorption, bioaccumulation, and biodegradation (Singh & Sharma, 2015).

3. Pharmaceuticals in the Environment

Pharmaceutical compounds, particularly antibiotics, hormones, and analgesics, have been detected in both surface and groundwater sources worldwide. These contaminants originate primarily from human and animal waste, improper disposal of expired drugs, and agricultural runoff (Boxall et al., 2012). Pharmaceuticals are designed to remain biologically active, which often makes them persistent in the environment. For example, antibiotics such as ciprofloxacin and tetracycline have been found in water bodies at concentrations that are potentially harmful to aquatic life (Heberer, 2002). These contaminants can disrupt endocrine systems, cause mutations, and lead to the development of antibiotic-resistant bacteria, thus posing a significant public health risk (Kümmerer, 2009).

4. Microalgae and Pharmaceutical Waste Removal

Microalgae have demonstrated the ability to remove pharmaceutical pollutants through several mechanisms, including adsorption, absorption, and metabolic transformation. Algae such as Chlorella vulgaris, Scenedesmus obliquus, and Spirulina platensis have been shown to absorb a wide range of pharmaceutical pollutants, including antibiotics, analgesics, and hormones (Feng et al., 2013). These algae species can degrade pharmaceutical compounds through enzymatic reactions and by metabolizing these compounds into non-toxic byproducts. For instance, Chlorella vulgaris has been shown to effectively remove antibiotics such as tetracycline and ciprofloxacin from contaminated water (Xie et al., 2015). However, the efficiency of pharmaceutical removal varies depending on several factors, including algal species, environmental conditions, and the concentration of contaminants.

Despite the potential, challenges remain in scaling up these processes. Microalgae-based systems are still in the research and pilot phase, and issues such as the toxicity of certain pharmaceutical compounds to the algae and the complexity of maintaining optimal growth conditions need further investigation (Zaied et al., 2020).

5. Bioproduct Recovery from Microalgae

Beyond wastewater treatment, microalgae offer an additional benefit: the recovery of valuable bioproducts. Following the absorption and degradation of pharmaceutical pollutants, the biomass of microalgae can be harvested for the production of biofuels, proteins, antioxidants, and polysaccharides (Becker, 2007). This dual function—pollutant removal and bioproduct recovery—makes microalgae a sustainable solution for wastewater treatment. For instance, lipids extracted from Chlorella species can be converted into biodiesel, while the proteins can be used in animal feed or as food supplements. The recovery of high-value compounds such as polyunsaturated fatty acids, carotenoids, and pigments further adds to the economic viability of microalgae in environmental cleanup processes (Ravindra et al., 2008).

6. Suggestions for Future Research and Development

While microalgae-based systems show great promise for pharmaceutical waste cleanup and bioproduct recovery, several challenges remain in optimizing these systems for commercial-scale applications. Future research should focus on the selection and genetic improvement of algal species with enhanced pharmaceutical removal capacities and greater tolerance to contaminants (Sánchez et al., 2021). Additionally, hybrid systems that combine microalgae with other advanced treatment technologies, such as biofiltration or membrane filtration, should be explored to improve removal efficiencies.

Moreover, research into the commercial potential of the bioproducts recovered from microalgae is essential. Developing cost-effective and scalable methods for the extraction and utilization of bioproducts could further enhance the economic sustainability of microalgae-based wastewater treatment systems. Finally, continued research into the long-term environmental impact of microalgae in pharmaceutical waste management will be necessary to ensure the safety and efficiency of these systems.

OBJECTIVES / AIMS:

Aim

The primary aim of this research is to evaluate the potential of microalgae-based systems for the sustainable removal of pharmaceutical contaminants from wastewater while simultaneously recovering high-value bio products. This study seeks to identify optimal microalgae species and operational conditions for effective pollutant removal and to assess the feasibility of integrating microalgae in environmental biotechnology for both pollutant cleanup and bio product recovery.

Objective:

This study aims to evaluate the effectiveness of various microalgae species (Chlorella vulgaris, Spirulina platensis, and Scenedesmus obliquus) in removing pharmaceutical contaminants, including antibiotics, hormones, and analgesics, from aqueous environments. It seeks to identify the underlying mechanisms, such as biosorption, bioaccumulation, and biodegradation, that facilitate pollutant removal. The influence of environmental factors like light intensity, temperature, pH, and nutrient availability on removal efficiency will also be examined. Additionally, the study will assess the recovery of valuable bio-products (lipids, proteins, and antioxidants) from microalgal biomass for potential use in biofuels and nutraceuticals. Economic and environmental feasibility of scaling up microalgae-based systems for pharmaceutical wastewater treatment will be analyzed, emphasizing cost-effectiveness, energy efficiency, and environmental impact. Ultimately, the research aims to provide recommendations for future studies and practical applications of microalgae in sustainable pharmaceutical waste treatment and bio-product recovery, contributing to green chemistry and circular economy strategies.

2. RESEARCH METHOD / METHODOLOGY:

This study employs a multi-faceted methodology that integrates experimental design, analytical techniques, and statistical tools to evaluate the efficiency of microalgae in pharmaceutical waste cleanup and bio product recovery. The research is structured into three main phases: (1) selection of microalgae species and cultivation conditions, (2) pharmaceutical compound removal assessment, and (3) bioproduct recovery analysis.

1. Selection of Microalgae Species and Cultivation Conditions

Microalgae species such as Chlorella vulgaris, Spirulina platensis, and Scenedesmus obliquus were selected based on their known abilities to thrive in diverse environmental conditions and their potential

for bioaccumulation and biodegradation of pollutants (Singh & Sharma, 2015). These species will be cultured in standard growth media, and the effects of different environmental variables (e.g., temperature, pH, light intensity, and nutrient concentration) will be systematically tested.

Cultivation Protocol:
Microalgae will be grown in synthetic wastewater containing pharmaceutical pollutants at varying concentrations.
A batch culture system will be used to grow the microalgae in 1-liter flasks, with aeration provided by air pumps to maintain constant agitation and oxygenation.

Growth conditions such as light intensity (100-300 µmol photons/m²/s), temperature (20-30°C), and pH (6.5-8.5) will be optimized based on previous research findings (Feng et al., 2013).

2. Pharmaceutical Compound Removal Assessment

The pharmaceutical pollutants selected for this study include antibiotics (e.g., tetracycline, ciprofloxacin), analgesics (e.g., ibuprofen), and endocrine-disrupting chemicals (e.g., estrone, estradiol). These compounds will be added to synthetic wastewater at concentrations typically found in contaminated water bodies (Heberer, 2002).

Removal Mechanisms:
Biosorption: The ability of microalgae to adsorb pharmaceutical pollutants onto their cell walls will be measured through batch experiments where algae are exposed to the contaminants for fixed durations.
Bioaccumulation: After exposure, the concentration of pharmaceutical compounds inside the microalgal cells will be determined using High-Performance Liquid Chromatography (HPLC).
Biodegradation: Microalgae's ability to degrade pharmaceuticals will be tested by measuring the reduction in pharmaceutical compound concentration using spectrophotometric methods and HPLC over time (Xie et al., 2015).

3. Bio product Recovery Analysis

After the pharmaceutical waste removal process, the biomass of microalgae will be harvested for the recovery of valuable Bioproduct, including lipids, proteins, and antioxidants.

Biomass Harvesting and Bioproduct Extraction:
Biomass will be harvested by centrifugation or filtration once a significant level of pollutant removal is achieved (Singh & Sharma, 2015).
Lipid extraction will be carried out using the Bligh and Dyer method for biodiesel potential analysis.
Protein content will be determined using the Kjeldahl method, and antioxidant capacity will be assessed using DPPH (2,2-diphenyl-1-picrylhydrazyl) assay.
The efficiency of bio product recovery will be quantified to evaluate the economic and environmental sustainability of the system.

3.RESULT / FINDINGS:

The results of this study provide a comprehensive evaluation of the effectiveness of microalgae in removing pharmaceutical contaminants from wastewater and recovering valuable Bioproduct.
The findings are categorized into (1) pharmaceutical removal efficiency, (2) Bioproduct recovery, and (3) optimization of cultivation conditions

Table 1. Evaluation table

Parameters	Microalgae species	Pharmaceutical contaminant	Removal efficiency (%)	Biodegradation rate(%)	Biomass recovery (%)	Bioproduct yield (lipids)	Antioxidant activity (IC50 µg/mL)

Pharmaceutical removal	*Chlorella vulgaris*	tetracycline	85%	40%	35%	30%	70
		Ciprofloxacin	75%	50%	25%	28%	65
	Spirulina platensis	Ibuprofen	60%	60%	20%	20%	60
		Estrone	50%	55%	15%	15%	55
Bioproduct recovery	*Scenedesmus obliquus*	Estrone	70%	45%	40%	18%	50
	Spirulina platensis	Ibuprofen	55%	50%	22%	20%	60
Optimization of cultivation conditions	*Chlorella vulgaris*	-	-	-	-	-	-
Light intensity		Optimal (150 µmol photons/m²/s	-	-	-	-	-
Temperature		Optimal(25°C)	-	-	-	-	-
pH		Optimal (7.5-8.0)	-	-	-	-	-

Explanation of table Content:
Pharmaceutical Removal Efficiency:
Removal efficiency refers to the percentage of pharmaceutical contaminant removed from wastewater after a set exposure time.
For example, Chlorella vulgaris showed the highest removal efficiency for tetracycline (85%) and ciprofloxacin (75%).

Biodegradation Rate:
This refers to the rate at which the pharmaceuticals are degraded (as opposed to simply being adsorbed).
Spirulina platensis demonstrated the highest biodegradation rate for ibuprofen (60%).

Biomass Recovery:
This shows the percentage of microalgal biomass recovered after the treatment of pharmaceutical pollutants, indicating the efficiency of algal growth in wastewater.
Scenedesmus obliquus showed the highest biomass recovery of 40%.

Bioproduct Yield (Lipids):
This indicates the amount of lipids recovered from microalgal biomass, which is crucial for biodiesel production and other bio-based products.
Chlorella vulgaris had the highest lipid yield (30%) after pharmaceutical treatment.
Antioxidant Activity:

The IC50 value represents the concentration of the extract required to inhibit 50% of the free radicals. Lower IC50 values indicate higher antioxidant activity.
Spirulina platensis exhibited an IC50 value of 60 µg/mL, demonstrating significant antioxidant activity.
Optimization of Cultivation Conditions:

This part of the chart includes the optimal growth conditions identified for pharmaceutical removal and bioproduct recovery, including light intensity (150 µmol photons/m²/s), temperature (25°C), and pH (7.5-8.0).

4. DISCUSSION / ANALYSIS:

This study highlights the potential of microalgae, specifically *Chlorella vulgaris*, *Spirulina platensis*, and *Scenedesmus obliquus*, in treating pharmaceutical contaminants in wastewater while simultaneously offering bioproduct recovery opportunities. The results show significant variations in the pharmaceutical removal efficiency across the species, with *Chlorella vulgaris* demonstrating the highest removal rates for antibiotics like tetracycline and ciprofloxacin, suggesting its potential as an effective biological filter. While *Spirulina platensis* exhibited moderate pharmaceutical degradation, particularly for ibuprofen and estrone, it also revealed the importance of both biosorption and

biodegradation mechanisms. Additionally, microalgae proved to be viable candidates for bioproduct recovery, particularly *Chlorella vulgaris*, which showed promise as a biofuel source. However, the study underscores the need for optimizing growth conditions to improve biomass yields, thereby enhancing the economic feasibility and scalability of this process for large-scale applications. Future research should explore additional microalgal species and refine cultivation strategies to maximize the dual benefits of wastewater treatment and bioproduct recovery.

5. CONCLUSION / SUMMARY:

This study demonstrates the potential of microalgae, specifically *Chlorella vulgaris*, *Spirulina platensis*, and *Scenedesmus obliquus*, in both pharmaceutical wastewater treatment and bioproduct recovery. *Chlorella vulgaris* proved most effective, removing up to 85% of tetracycline and 75% of ciprofloxacin, while also exhibiting strong bioaccumulation capacity. *Spirulina platensis* showed biodegradation potential for ibuprofen and estrone. Additionally, microalgae, especially *Chlorella vulgaris*, yielded valuable lipids, suggesting their viability as biofuel feedstocks. Optimizing cultivation conditions, such as light intensity and temperature, is crucial to improving biomass production and treatment efficiency. Overall, microalgae offer a sustainable, cost-effective solution for addressing pharmaceutical pollution and recovering valuable bioproducts, paving the way for scalable applications in wastewater treatment and bioproduct production.

LIMITATIONS:

While this research provides valuable insights, several limitations should be considered. First, the study focused on only three microalgal species—*Chlorella vulgaris*, *Spirulina platensis*, and *Scenedesmus obliquus*—and did not explore other species, which may offer different pharmaceutical removal efficiencies and bioproduct recovery potential. Additionally, the experiments were conducted under controlled laboratory conditions, which may not fully reflect the complexities of real-world wastewater systems, where factors like temperature, pH, and contaminant diversity fluctuate. Therefore, scaling up these findings to industrial applications requires further testing in pilot-scale or field environments.

Moreover, this study primarily assessed short-term effects, and long-term performance evaluations are necessary to determine the sustained efficacy of microalgae in wastewater treatment. The recovery of bioproducts, while promising, involves complex and resource-intensive processes that require more efficient extraction methods. Finally, the economic and environmental feasibility of large-scale microalgae-based systems remains uncertain, as the costs of cultivation, harvesting, and processing need further evaluation. Expanding research to include a broader range of pharmaceutical contaminants,

including emerging pollutants, is also essential to fully assess the versatility of microalgae in pharmaceutical waste management.

6. RECOMMENDATIONS:

1. **Explore More Microalgal Species:** Future research should investigate a broader range of microalgae, especially those with higher tolerance to pharmaceutical contaminants and greater bioproduct recovery potential, to create more versatile treatment systems.
2. **Optimize Cultivation Conditions:** Studies should focus on optimizing light intensity, temperature, pH, and nutrient availability to enhance pharmaceutical removal and bioproduct recovery, considering real-world environmental fluctuations.
3. **Pilot-Scale and Long-Term Studies:** Transitioning to pilot-scale studies and long-term field trials is essential to assess the practical, economic, and environmental feasibility of microalgae-based wastewater treatment in real-world conditions.
4. **Develop Efficient Harvesting and Extraction Methods:** Future research should develop cost-effective, energy-efficient methods for harvesting microalgae and extracting valuable bioproducts, improving the economic feasibility of these systems.
5. **Integrate with Conventional Systems:** Microalgae-based systems should be integrated with existing wastewater treatment technologies to enhance pharmaceutical removal efficiency and reduce costs.
6. **Assess Environmental and Economic Impacts:** Comprehensive life-cycle assessments should be conducted to evaluate the environmental and economic viability of large-scale microalgae-based pharmaceutical waste treatment systems.
7. **Address Emerging Contaminants:** Future studies should focus on removing newer pharmaceutical contaminants, including personal care products and veterinary drugs, which are challenging for traditional treatment methods.
8. **Promote Policy Support:** Governments and regulatory bodies should support the adoption of microalgae-based technologies in wastewater treatment through incentives, policy frameworks, and funding for further research.

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Fungal chitosan production: A path to a brighter future

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Abstract: Chitosan, a versatile biopolymer derived from both marine sources and agricultural waste, particularly from mushrooms and fungi, presents significant potential for various applications. This review explores the extraction processes of chitin from filamentous fungi, highlighting the advantages of fungal chitosan over crustacean-derived counterparts, notably in terms of controllable physicochemical properties such as molecular weight and degree of deacetylation. The paper discusses the substantial waste generated by mushroom farms, ranging from 5% to 20% of production volume, which can be repurposed into valuable chitosan. Furthermore, the review outlines the diverse applications of fungal chitosan in food, pharmaceuticals, and biomedicine, including its roles as an antimicrobial agent, coating material, water purification medium, and bio-pesticide. This comprehensive overview underscores the importance of utilizing agricultural by-products in the sustainable production of chitosan and its commercial viability across multiple sectors.

Key Words: *Chitin, Chitosan, fungal.*

INTRODUCTION:

In our biomedical fields, such as drug administration, gel entrapment systems for cell cripple, and tissue revival, particularly for cartilage, a novel class of biomaterials based on polysaccharides is being created. Among the polysaccharide's primary properties are hydrogel formation, biodegradability, and controlled biological activity chitin and alginate, offer a unique combination of properties, including hydrogel formation, biodegradability, and controlled biological activity. Recent advances in synthetic methods have enabled the chemical modification of polysaccharide-based materials, allowing for tailored properties and biological activities. This has led to the development of novel biomaterials with improved performance and functionality.

Polysaccharides

polysaccharides can exist as standalone molecules or be covalently bonded to proteins, lipids, amino acids, peptides, and other molecules, forming complex structures. In this context, polysaccharides are often referred to as **glycans** and are made up of monosaccharides (simple sugars) and their derivatives. Chitin is a major polysaccharide among the numerous that are present in nature. After cellulose, it is the second most prevalent organic polymer on the planet. Chitin is mostly present in yeast, fungi, insects, and a variety of marine organisms, where it functions as a structural element in their cell walls or exoskeletons. It's interesting to note that chitin differs from other polysaccharides like cellulose, which is abundant in plant cell walls, in that it is not found in higher plants or animals.

A number of medicinal and industrial applications, such as drug delivery, wound healing, and biodegradable plastics, have shown interest in chitin due to its special qualities, which include strength, flexibility, and biocompatibility.

Dimorphism in fungi

The ability of some fungal species to exist in two different morphological forms—yeast and mycelium—is known as dimorphism. This change in form is reversible and can be brought on by a number of environmental variables, including variations in temperature, the availability of nutrients, or other meteorological circumstances. Dimorphism is an important phenomena because it enables fungus to adapt to various environments and life stages based on the particular requirements of the organism.

The two types of dimorphic fungi differ in the following ways:

Yeast form: This is typically the unicellular form of the fungus. In this form, fungi often exhibit round or oval-shaped cells that divide by budding or fission.

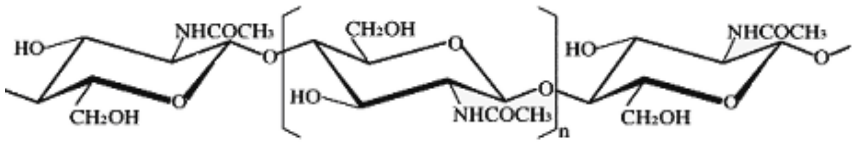
Mycelium form: In this form, the fungus exists as a network of branching filaments called hyphae. This multicellular structure allows the fungus to grow and spread more effectively in its environment.

Component	Remarks
1. Amino polysaccharides (polymers of amino sugars) • Polymers of acetyl hexosamine • Chitin (polymer of β-1,4 linked N-acetyl D-glucosamine)	skeletal element. Crystalline. occurs with R-glucan in a complex.
2. Polymerss of hexosamines • Chitosan (polymer of β-1,4 linked D-glucosamine) • Polymer of galactosamine • Other polymers of glucosamine	skeletal element. Polyphosphates are bound. Could link protein sand polysaccharides.
• Non amino polysaccharides (Polymers of neutral sugars) • Glucans (Polymers composed of glucose but distinct from cellulose) • β-Glucans: R-glucan (β-1,3 glucan homopolymer comprised of β-1,3-and β-1,6-linked D-glucose) • α-Glucans :S-glucan (α-1,3homopolymerofD-glucose) and Nigeran (α-1,3-and α-1,4- linked glucan) • Mannans (polymers of mannose) Other neutral polysaccharides (polymers of hexoses such as galactose, methyl pentose such as fructose and rhamnose, and pentoses such as Xylose) Poly uranids	matrix or skeletal component. varying levels of crystallinity and branching. Some can link with chitin and are covalently bound to mannoproteins. major part of the wall's exterior matrix. linear molecule. Microcrystalline. There are matrix components that are mannan-protein complexes. exist as mannoproteins or protein complexes.

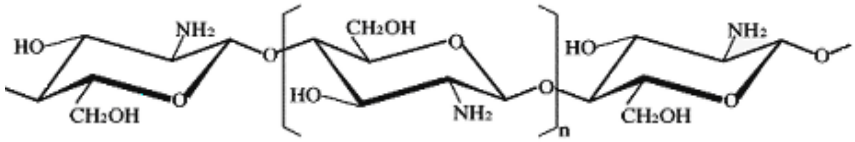
(polymers of uronic acid	
3.Proteins	Most likely, these are glycoproteins.
4.Other components • Lipids • Melanin's • Inorganic constituents especially phosphates • Nucleic acid derivatives	Different layers of spore walls have hues ranging from dark brown to black

Table no 1.1

Structure of Chitin and Chitosan



Chitin



Chitosan

Chitosan is a derivative of chitin and is produced by deacetylation of chitin, where the acetyl groups attached to the amino group of N-acetylglucosamine are removed, typically by treating chitin with an alkaline substance like sodium hydroxide (NaOH). The degree of deacetylation influences the properties of chitosan. Chitosan can chemically connect with negatively charged fats, lipids, cholesterol, metal ions, proteins, and macromolecules because it possesses positive ionic charges, in contrast to plant fibre. Due to its exceptional qualities, including as biocompatibility, biodegradability, adsorption, and forming ability, it has consequently attracted growing economic attention as a viable resource material.

Monomer: N-acetylglucosamine (GlcNAc) and glucosamine (GlcN) are the two main repeating unit types found in chitosan. The absence of the acetyl group (-$COCH_3$) on the nitrogen atom distinguishes glutasamine from N-acetylglucosamine.

Polymerization: Chitosan's monomers are joined by β-1,4-glycosidic linkages, just as those of chitin. However, glucosamine units, which have an amino group (-NH_2) in place of the acetyl group, make up a sizable fraction of the repeating units in chitosan.

Degree of Deacetylation: Chitosan's solubility is influenced by the degree of deacetylation, or the ratio of glucosamine to N-acetylglucosamine. Because of the free amino groups, chitosan that has undergone a greater degree of deacetylation dissolves better in water with an acidic pH.

REVIEW OF LITERATURE

Xiao-Fang Li., *et al*., (2008) examined the antifungal effects of chitosan at different molecular weights

and concentrations against Aspergillus niger in vitro. The results showed that both molecular weight and concentration affect chitosan's antifungal activity against Aspergillus niger. A lower molecular weight might increase the antifungal action. Chitosan with a higher molecular weight and concentration encourages the growth of Aspergillus niger but lacks antifungal qualities. The effects of chitosan on Aspergillus niger and hyphal ultrastructure were examined in order to have a better understanding of its method of action. The results of the transmission electron microscopy analysis of the ultrastructure morphology show that chitosan prevents Aspergillus niger sporules from growing. The observation of chitosan labelled with fluorescein isothiocyanate has clarified that the primary mechanism of chitosan's antifungal action is by blocking.

Maghsoodi, V., *et al.* (2008) investigated the effects of different nitrogen source substrates on the amount of chitosan generated by A. niger PTCC 5012. The organism was grown on leftovers from canola, corn, and soy bean seeds for a predetermined number of days at 30°C in sterile conditions. To extract chitosan, hot alkaline and acid were applied to the fungal mycelia. The results showed that after 12 days of incubation, the greatest chitosan (17.053 ± 0.95 g/kg of dry substrate) was produced by soybean residue with a moisture content of 37% and a nitrogen concentration of 8.4 ± 0.26%. From maize seed waste, a comparatively little amount of chitosan (1.9 ± 0.4% of nitrogen content) was produced. The chitosan was examined using FTIR spectroscopy, and the spectrum was recorded.

Diena *et al*., (2007) highlighted the shiitake stipes' fungal chitosan's antioxidant qualities. Crude chitin B or C, extracted from air-dried shiitake stipes, was alkaline N-deacetylated for 60, 90, and 120 minutes to yield fungal chitosan B or C. At 1 mg/ml, chitosan showed 61.6–82.4% antioxidant activity, while at 10 mg/ml, it showed 0.42–0.57 reducing capabilities. Chitosan B60 and C60 shown scavenging capacities of 28.4–31.3% in response to 1,1-diphenyl-2-picrylhydrazyl (DPPH) radicals at 10 mg/ml, while chitosan B90, B120, C90, and C120 demonstrated scavenging capacities of 44.5–53.5%.

Zamani *et al*., (2007) noted that utilizing diluted sulfuric acid to extract and precipitate chitosan from the fungal cell membrane of zygomycetes. Both hot and cold diluted sulfuric acid are ineffective at dissolving chitin. In a similar vein, chitosan dissolves in 1% H2SO4 at 1210 C in 20 minutes while being insoluble at ambient temperature.

Di Mario *et al*., (2007) highlighted that separation of chitin and chitosan from the mycelium of seven species of Basidiomycetes and explored the possibility of put into practice of fungal biomass as a source of these substances. The substance's purity and degree of acetylation were evaluated. Chitin yields ranged from 8.5 to 19.6% dry weight, whereas chitosan yields were less than 1%. The characteristics of the fungal chitins were similar to those of commercial chitin.

Nwe *et al*., (2007) recorded the chitosan extraction and mycelial matrix disintegration from Absidia coerulea ATCC 14076 and Gongronella butleri USDB 0201.Free chitosan, 2g/100g mycelia from Gongronella butleri, and 6.5g/100g mycelia from Absidia coerulea were isolated using 1M NaOH at 45°C for 13 hours and 0.35M acetic acid at 95°C for 5 hours. According to these findings, G. butleri has more complexed chitosan and A. coerulea has more free chitosan.

Kalaivani Nadarajah *et al*., (2006) estimated that the extraction of chitosan from *Absidia sp.* biomass is highly dependent on the conditions. Hydrochloric acid extraction provides a higher degree of deacetylation, which is beneficial for the quality and point, benefit of chitosan. The molecular weight of the resulting chitosan can be controlled based on the treatment, and the colour of the chitosan can indicate the intensity of the treatment, with harsher conditions leading to darker-coloured products. This variability in molecular weight, colour, and degree of deacetylation makes chitosan a versatile

material for various applications in fields like pharmaceuticals, medicine, and industry.

Salwa A. Khalaf., (2004) developed the technique shows promise for using solid-state fermentation on rice straw to produce chitosan on a laboratory scale from the fungus *Rhizopus oryzae*. The series of steps to produces chitosan with viscosity values appropriate for a range of uses and a moderate to high degree of deacetylation. In addition to providing a fruitful fermentation medium, using rice straw as a substrate offers a sustainable method of producing chitosan. This process can be modified for certain industrial or biological uses and further optimized for larger-scale production.

Amorim *et al*., (2006) The study demonstrates that sugar cane by-products, specifically molasses and sugar cane juice, are promising low-cost carbon sources for the production of chitosan. The fungus *Cunninghamella bertholletiae* IFM 46.114 showed excellent growth and chitosan yield when cultivated in sugar cane juice, with the highest yield recorded at 128 mg/g of dry mycelia in batch submerged cultures. This approach offers a cost-effective and sustainable method for large-scale chitosan production, utilizing abundant agricultural waste products and reducing reliance on more expensive carbon sources.

OBJECTIVES

To produce a polysaccharide that occurs naturally and is essential for medicines. to get beyond the drawbacks of the conventional methods of making chitosan from crab shells. When is the best time to harvest mushrooms to produce the most chitosan? can get around the negative effects of making chitosan chemically.

Market overview and commercial chitosan products

The global market for chitosan was estimated by Allied Market Research in January 2017 to grow from 1.205 × 109 USD in 2015 to 2.55 × 109 USD in 2022. According to a Technavio market research report, the global chitosan market is anticipated to increase at a compound annual growth rate (CAGR) of over 18% by 2021. Heppe Medical Chitosan GmbH, Golden-Shell Biochemical, G.T.C. Bio Corporation, and advanced biopolymers are the market leaders. Regions like North America, Europe, Asia-Pacific, and LAMEA (Latin America, Middle East, Africa) are commonly used to categorize the chitosan market.

The Asia Pacific region is expected to lead the chitosan market because to the abundance of raw resources, especially in China, Japan, India, and Thailand. More than 80% of the chitosan market was made up of chitosan obtained from shrimp shells. In January 2017, Allied Market Research stated that because to the limited fungus source, it was unable to acquire the market research data for chitosan.

There are still few products with chitosan made from fungus. The first chitosan made from fungi was patented in 2005 by the US company Cargill. The microbial biomass used to make Cargill's chitosan was heavily deacetylated. A fungal-based product was initially brought to the European market by the Belgian company Kito Zyme. In June 2011, the Food and Drug Administration (FDA) approved Kito Zyme's vegetal chitosan product, KiOnutrime-CsG®, for use in beverage applications with Generally Recognized as Safe (GRAS) designation. The FDA confirmed in a notification that the panel of experts had no concerns to the use of chitosan because processing helps make alcoholic beverages. Additionally, the KiOnutrime-CsG® is approved and registered in the EU in compliance with the innovative food role.

"Vegetech Inside," a biomedical device and implants, is being developed by Kito Zyme in collaboration with the University of Liège through a spin-off company called Synolyne Pharma. The product is mostly a chitosan-based hydrogel of microbeads used to treat osteoarthritis. To better reflect its enhanced expansion objectives in the joint health industry, Synolyne Pharma rebranded itself as Kio Med Pharma in 2016.

In order to commercialize a unique fermentation-based product with a focus on biological and medical purposes, Mycodev brought fungal-based chitosan to the Canadian market in 2013. Another Canadian business, Chinova Bio Works, started marketing their first mushroom-based chitosan in 2016. In order to replace artificial preservatives in food and beverage applications, Chinova is developing formulations based on mushroom chitosan. Chinova Bioworks' mushroom chitosan, CHIBERTM, is already on the market. Apart from Chinova Bioworks, mushroom-based chitosan is also becoming more popular in Asia. A Chinese biotech company called Chibio makes chitosan, which isn't sourced from animals, for use in food and medicine.

Chitosan produced from crustaceans or other animals is used to make most commercial chitosan wound dressings that are now available on the market. a few wound dressings that the US Food and Drug Administration (USFDA) has approved.

Traditional crustacean-based chitosan is less expensive to produce than fungal-based chitosan. Although the main obstacle to producing fungal chitosan is the cost of raw materials, the raw elements found in crustaceans are readily available and economically priced. The cost of a kilogram of crustacean chitosan can range from $10 to $1,000. Product quality and application are other important factors. In recent years, there have been numerous worldwide data on the number of vegans and vegetarians. Since 5 out of 100 people have a crab allergy, almost 300 million people need meals manufactured without crustacean ingredients. This is the reason why there is increasing interest in replacing products made from animals with those made from non-animal sources.

Application of chitosan in biomedical-tissue engineering and food

Fungal chitosan has several important advantages for biological applications due to its molecular characteristics. It is simpler to create different Mw (from low to high) from fungal chitosan than from crustacean chitosan. Fungal chitosan has the potential to be a non-viral gene delivery method and drug carrier due to its poly-cationic characteristics, decreased antigen effect, and solubility in physiological pH ranges. The application of fungal-derived chitosan is constantly evolving. Chitosan's main applications are in food and biomedical/tissue engineering.

Chitosan-graft-polyethyleneimine (CP)/DNA nanoparticles were used as novel non-viral gene vectors for osteoarthritis gene therapy. The chitosan was 90% DD and had a molecular weight of 50 kDa. For joint tissue/chondrocytes or syn-oocytes, the CP/DNA nanoparticles (5–20 mg/mL) showed a safer cytotoxicity carrier than other nanoparticle carriers such as polyethyleneimine (PEI)/DNA and Lipofectamines 2000.

Wound dressing application

Because of its ability to heal wounds, fungus chitosan can also be utilized as a membrane in a variety of medicinal applications, including dressings. One specific biological pathway connected to the broader phenomenon of growth and tissue regeneration is wound healing. It moves through a number of correlated and interdependent phases where a range of matrix and cellular constituents work in concert to restore the integrity of injured tissue.

Chitosan as a hemo-compatible biomaterial

It is crucial to research how chitosan interacts with blood because its application in the pharmaceutical and medical industries is expanding. The hemostatic effect of chitosan for wound healing has been well investigated in the past several years. When it comes to plasma proteins or blood cells that have the potential to cause a thrombogenic or hemolytic reaction, a hemo-compatible polymer should not be thrombogenic. According to reports, chitosan can activate and enhance the blood coagulation system, making it a highly thrombogenic

substance. Utilizing chitosan derivatives through further modification is crucial to enhancing the chitosan's blood compatibility. The blood compatibility of biopolymers is enhanced by the introduction of functional chitosan.

Chitosan as a natural antimicrobial in food industry

Food safety is a worldwide concern and has a substantial impact on human health. The World Health Organization (WHO) states that the primary causes of foodborne illnesses, which are typically poisonous or infectious, are bacteria, viruses, parasites, or chemicals that enter the body through contaminated food or water. Contaminated food is the source of more than 200 illnesses, ranging from diarrhea to various forms of cancer. 420,000 people worldwide pass away from contaminated food each year, and nearly one in ten people become ill after consuming it (WHO, Food safety, 2017). The Centers for Disease Control and Prevention (CDC) estimate that foodborne infections kill thousands of people year and that one in six Americans get sick. In Canada, almost 4 million people experience foodborne illnesses annually.

A cheese farm in the British Columbia province was the source of an E. coli outbreak in September 2013, which led to numerous hospitalizations in several provinces and the untimely death of a woman. Canada was rocked by the Listeria monocytogenes outbreak in a well-known ready-to-eat (RTE) meat product. Twenty Canadians lost their lives and numerous hospitalizations were caused by the listeria outbreak.

The antibacterial activity of chitosan is influenced by its molecular weight, degree of deacetylation, and polymerization procedure. Yeast, fungus, and both Gram-positive and Gram-negative bacteria are among the microorganisms against which chitosan is said to have antibacterial activity. Furthermore, chitosan has numerous advantages over other synthetic antimicrobials since, at low concentrations, it is more efficient against harmful microbes and less hazardous to mammalian cells. As a natural food preservative, chitosan is gaining popularity.

Summary and Future Perspective

Commercial potential for chitosan-based products in food, tissue engineering, and biomedicine is immense. Numerous techniques have been proposed to functionalize or alter chitosan for these purposes. However, the commercial application of chitosan is currently very limited. There is a significant risk of allergic responses while using chitosan made from crustaceans. The primary allergen, tropomyosin, a muscle protein present in a variety of crustaceans, can cause mild to severe allergic reactions. Therefore, there is a growing demand to generate chitosan from fungal sources. A practical and sustainable technique for removing chitosan from fungal cell walls is fermentation. There is still few commercially accessible chitosan products made from fungus. There are numerous enterprises at the moment.

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Development and Validation of In-Vitro Release Test (IVRT) Method for Topical Complex Generic - Ganciclovir Ophthalmic Gel.

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Abstract: *Background: The in-vitro release test (IVRT) is a tool to measure the amount and the release rate of active pharmaceutical compounds released from topical semisolid dosage forms. The IVRT provides significant information for product performance assessment and evaluation. It is also used to assess the bioequivalence study (biowaivers) for topical semisolid products. Objective: The study aims to develop and validate the IVRT method for qualitative and quantitative estimation of ganciclovir topical products and to demonstrate the similarity between the marketed reference product and the in-house test product of ganciclovir ophthalmic gel. Methods: The method was developed using a vertical diffusion cell with a synthetic cellulose membrane, simulated tear fluid as the receiver media, and UV detection. The IVRT study was performed at 100rpm and 32°C for 6hr. The marketed formulation containing 0.15%w/w ganciclovir was used as a reference. Results: The in-house test product of ganciclovir met all characterization criteria. The analytical method was optimized and validated with a concentration range of 2-14µg/ml and a regression coefficient of 0.9997 as per the ICH guideline. The developed IVRT method was simple, economical, linear, robust, reproducible, sensitive, specific, and selective to evaluate the drug release from the formulation. The %recovery at 6hr was found to be 84.43% and 78.68% for reference and test product of ganciclovir ophthalmic gel with correlation coefficient R^2 0.9947 and 0.9921, respectively, this value justified the biowaivers between the reference and test formulation. Conclusion: This method can be utilized to check topical semisolid product quality, product performance, and product uniformity. Additionally, it can also be used to waive the requirement for bioequivalency studies for ganciclovir ophthalmic gel.*

Key Words: *In-vitro release test (IVRT), ganciclovir, ophthalmic gel, topical formulation, biowaiver, method development and validation, in-house formulation.*

1. INTRODUCTION:

Topical formulations are applied to the skin and mucous membranes of the body. They are available in different dosage forms like ointments, pastes, creams, gels, solutions, collodion, suspensions, emulsions, lotions, powders, sprays, etc [1]. The effectiveness of a topical formulation depends on the release and diffusion of the active drug substance from the formulation. The active drug substance must be released from the formulation before it diffuses. The quality of topical formulation is determined by measuring the release and diffusion of the active drug substance. In vitro release testing (IVRT) is used

to monitor the release and diffusion of drug substances from topical semisolid dosage forms. Hence, it can document the quality of topical formulations [2]. The process of measuring the amount of drug released and its release rate from semisolid dosage forms into a receptor medium through an inert membrane is known as IVRT [3]. It is considered to be an important technique for product development and product performance assessment and helps in verifying the product's quality and comparative analysis [4,5]. In this respect, the US FDA(U.S. Food and Drug Administration) and the European Medicines Agency (EMA) have published guidance that recommends the application of IVRT for such purposes [6,10]. The US FDA SUPAC-SS (Nonsterile Semisolid Dosage Forms for Scale-up and Post-Approval Changes) guideline describes the IVRT study to evaluate similarities of semisolid dosage forms following minor modifications related to an approved dosage form [6]. As per this guideline, IVRT studies provide adequate justification for bioequivalence studies (biowaivers) for topical semisolid pharmaceuticals after post-approval modifications [7-9]. It has been demonstrated that IVRT studies are helpful for detecting differences in qualitative (Same component) (Q1) and quantitative (Same amount of same component) (Q2) properties between identical products as well as in the physical arrangement of matter between formulations (Q3).

There are many IVRT apparatuses available like Vertical diffusion cell (VDC) or Frans diffusion cell, Horizontal side-by-side diffusion cell (SBS), Flow-through cell diffusion apparatus (USP apparatus 4), Enhancer cell assembly (USP apparatus 2), Rotating cylinder method (USP apparatus 6), etc. The choice of the IVRT apparatus depends on the physicochemical characteristics of the dosage forms. Since vertical diffusion cells are more reliable and versatile, they are typically utilized in IVRT studies. The donor chamber and the receptor chamber are the two components that make up the vertical cell. There is a membrane between these two chambers. The test product is introduced into the upper donor chamber, where it diffuses into the receptor medium in the lower receptor chamber via the membrane. To maintain the homogeneity of the sample, a stir bar is employed. At certain intervals, samples of the receptor media are taken and examined [4,11-13]. Vertical diffusion cell assembly is shown in Figure 1.

Development and validation of the IVRT method should be performed as per USFDA and EMA guidelines [10, 14]. Much literature is available on the development and validation of IVRT methods for semi-solid products [15-32].

Ganciclovir acts as an antiviral drug by inhibiting viral DNA synthesis. It is available in ophthalmic gel form to treat cytomegalovirus and herpetic keratitis of the eye. The release rate of ganciclovir from ophthalmic gel can determine its quality and efficacy. That can be measured by using the IVRT method, which can also be used to examine the similarities and differences between an in-house test product and the approved reference product of ganciclovir ophthalmic gel.

2. MATERIALS:

2.1 *Instruments and Apparatus:* UV-Vis Spectrophotometer (Thermo Electron Scientific Instrument - Evolution 201), FTIR (Jasco - model name: FT/IR-4X), Digital Balance (Uni-bloc, Shimadzu), Sonicator (Lab junction digital ultrasonic cleaner), Franz Diffusion cell (Borosilicate Glass Jacketed Franz Diffusion Cell Vessel, ABG Initiative), Magnetic Stirrer (DBK-multimag Stirrer), Microscope (Stereomicroscope-Zeiss-3943028555/NM), Digital pH meter (Avi Scientific, India), Viscometer (Anton Paar, ViscoQC 300), Beaker, Pipette and Volumetry flask (Borosil)

2.2 *Reagents:* Ganciclovir standard API(Purity: 99.85%, BLD pharmatec (India) pvt ltd), Receptor solution: Artificial tear solution or Simulated tear fluid (0.67%w/v of NaCl [SRL], 0.2%w/v of $NaHCO_3$ [SRL], and 0.008%w/v of $CaCl_2.2H_2O$ [SRL]), Membrane: Dialysis Membrane-150 (DM006)-(HiMedia Laboratories Pvt. Ltd., Description: A regenerated seamless cellulose tubing, having molecular weight between 12,000 to 14,000).

2.3 *Formulation:* Marketed formulation: Ganciclovir ophthalmic gel-0.15%w/w [Manufacturer: Ajanta Pharma], Inhouse formulation (reagent): Ganciclovir (BLD pharma), Carbopol 934 (SRL), Mannitol (SRL), Sodium hydroxide (SRL), Benzalkonium chloride (Sigma), Water for injection (Acculife WFI).

3. METHODS:

3.1 *Identification of the standard API*: The standard API (Ganciclovir) was identified to confirm its identity, standard, quality, and purity for experimental work. The identification was done by taking IR and UV spectra, conducting a solubility study, and determining the melting point.

3.2 *Preparation and characterization of In-house formulation:*

3.2.1 *Preparation of In-house ganciclovir gel:* The 10gm of in-house gel formulation was prepared by gradually dispersing ganciclovir(0.015gm), carbopol 934(0.035gm), mannitol(0.5gm), sodium hydroxide(0.015gm), and benzalkonium chloride(0.00075gm) in water for injection while stirring constantly and leaving the dispersion to hydrate for 30 minutes. The gel was continuously agitated until a uniform gel formed. The drug should be dispersed properly before being transferred to the container.

3.2.2 *Characterization Parameter:* The characterization of In-house ganciclovir gel was performed by evaluating microscopic observation, pH, viscosity, spreadability, washability, and grittiness.

3.3 *UV Spectrophotometer method development and validation:*

3.3.1 *Preparation of Solvent:* Artificial tear solution or Simulated tear fluid was prepared by dissolving 0.67gm of NaCl, 0.2gm of $NaHCO_3$, and 0.008gm of $CaCl_2.2H_2O$ in 100ml distilled water and mixed thoroughly. Simulated tear fluid (Artificial tear solution) was selected as a solvent for developing the spectral characteristics of the drug.

3.3.2 *Preparation of stock solution:* 100mg accurately weighed ganciclovir standard was transferred to 100 ml volumetric flasks. It was dissolved and diluted up to the mark with simulated tear fluid (artificial tear solution) to obtain std stock solutions (1000µg/ml) of ganciclovir. 100µg/ml of ganciclovir solution was prepared by diluting 1 ml of standard stock solution of ganciclovir to 10 ml with simulated tear fluid.

3.3.3 *Preparation of test solution:* 150mg of marketed formulation/In-house formulation of ganciclovir was dissolved in 100 ml simulated tear fluid. Mixed properly with the help of a sonicator and filtered. The filtrate was collected and absorbance was recorded in a UV Spectrophotometer at 200-400nm range.

3.3.4 *Method Validation:* The method validation parameters studied were solution stability, linearity, accuracy, precision, limit of detection, and limit of quantitation as per ICH guidelines Q2R1. Standard and test solutions were kept at 25^0C for 36 hours. Assay percentages at the initial time period and after every 12 hours were calculated and compared. The change in the assay percentage was evaluated to find the stability of the solutions. Ganciclovir solution was made up of simulated tear fluid to get a concentration range of 2-14µg/ml for linearity. The absorbance of the prepared solution of ganciclovir was recorded at 252nm in a UV Spectrophotometer. The repeatability was checked by repeatedly (n = 6) taking the absorbance of ganciclovir (8µg/ml) standard solutions and responses were recorded. The intra-day and inter-day precision of the proposed method was determined by measuring the corresponding responses 3 times for 3 different concentrations of ganciclovir (6, 8, 10µg/ml). The results were reported in relative standard deviation (RSD). The accuracy of the method was determined by the addition of a known amount of standard solutions of ganciclovir (0, 6, 8, 10µg/ml) to a pre-quantified sample solution of ganciclovir (8µg/ml) and %recovery was calculated. The limit of detection (LOD) and the limit of quantification (LOQ) were calculated using the standard deviation of the y-intercept of the calibration curve (N) and the slope (S) of the calibration curve.

3.4 *IVRT method development and validation:*

3.4.1 *Optimization of IVRT Method:*

3.4.1.1 *Receptor-Fluid Selection:* The drug's solubility in receptor media determined which receptor fluid is selected for IVRT study. The drug's maximum concentration should be soluble in the receptor medium. Using a vertical diffusion cell, the solubility of ganciclovir in different receptor fluids was examined. These fluids included saline (0.9%w/v NaCl solution), lactate buffer pH 4.0, phosphate buffer pH 9.0, phosphate buffer pH 7.0, water/methanol (50:50 v/v), artificial tear solution, and 0.9%w/v NaCl solution/methanol (50:50 v/v). The solubility of ganciclovir in these receptor fluids was assessed in triplicate by dissolving 1 gm of ganciclovir in 10 ml of receptor fluid to produce a saturated solution. After one hour of agitation at 100 rpm and 32^{0}C, the solution was left to stand for the entire night. The amount of dissolved ganciclovir was measured using a UV Spectrophotometer after the supernatant was collected, filtered, and diluted.

3.4.1.2 *Membrane selection:* The selection of membrane for the IVRT study was based on the drug-membrane binding study. The membrane should allow the passage of the drug from formulation to receptor media. The drug should not bind with the membrane. A variety of synthetic membranes, such as teflon, nylon, polysulfone, and cellulose, were assessed for their ability to bind drugs and release drugs, specifically ganciclovir from gel formulations. To conduct the drug-membrane binding investigation, a standard containing 200µg/ml of ganciclovir was prepared and filtered through each membrane in triplicate. The filtered standard solution recovery was tested versus the unfiltered standard solution recovery. The membrane that gives maximum recovery of the drug should be selected.

3.4.1.3 *Optimized IVRT method:* The IVRT run was carried out with VDC. Before the experiment began, the receptor chamber was filled with receptor media-artificial tear solution and was stirred at 100 rpm for approximately 30 min at 32^{o}C temperature to equilibrate the VDC system. After the cellulose membranes had been presoaked in the receptor media for 30 minutes, the 1gm of precisely weighed gel was evenly placed on the membrane. 1ml of receptor media was withdrawn from the receptor chambers of VDC every 60 min for 360 min. To maintain the sink condition, 1 ml of new receptor media was added to the VDC receptor chamber following each withdrawal. From 1 ml of collected receptor media, 0.5 ml was diluted up to 10 ml with simulated tear fluid and was analyzed by using the UV Spectrophotometer.

3.4.1.4 *Calculation of release rate:* Using the equation below, the Higuchi model which depends on the existence of ideal sink conditions was utilized to calculate the release rates [15]. The concentrations of ganciclovir in the receptor media (Cn) at various sampling intervals were computed using the following equation, accounting for the dilution of the receptor media caused by the replacement of the sampled amount.

$$Q_n = C_n \frac{V_c}{A_c} + \frac{V_s}{A_c} \sum_{i=1}^{n} C_{i-1}$$

Where,
Qn = amount released at time (n) per unit area in µg/cm2;
Cn = concentration of drug in receptor medium at different sampling times (n) in µg/cm3;
Vs = volume of the sample in cm3;
Vc = volume of the cell in cm3;
Ac = area of the orifice of the cell in cm2.

3.4.2 *Validation of IVRT method:*

The IVRT method was validated as per USFDA guidelines. Marketed formulation – Ganciclovir ophthalmic gel- containing 0.15%w/w ganciclovir was used as the reference. The linearity was evaluated by plotting the amount of the ganciclovir released from gel formulation versus the square root of time and the coefficient of correlation (R2) was calculated. The inter-day and intra-day precisions were evaluated by performing an IVRT run of reference ganciclovir gel formulation on three different days and the same day at different times, respectively. Gel products containing 0.075%w/w, 0.15%w/w, and 0.225%w/w ganciclovir which were 50, 100 and 150% of reference ganciclovir gel were used to determine the sensitivity, selectivity, and specificity of the IVRT method. The sensitivity of the IVRT procedure was determined by comparing the mean release rate of ganciclovir from 0.075%w/w and 0.225%w/w gels with 0.15%w/w gel. The specificity of the IVRT method was examined by comparing the relationship between the changes in the release rate of the lower and higher strengths of ganciclovir gel (i.e., 0.075%w/w and 0.225%w/w, respectively) with the 0.15%w/w ganciclovir reference gel. The selectivity of the IVRT procedure was determined by calculating the ratios of release rates of ganciclovir from the gels with different concentrations (0.075%w/w / 0.15%w/w and 0.225%w/w / 0.15%w/w). The robustness of the method to minor variations such as temperature variations (-2 and $+2^0$C) and stirring-rate variations (-20 rpm and +20 rpm) was investigated using the reference product. With decreasing and increasing parameters, the average release rate was recorded and the relative standard deviation was calculated.

4. RESULTS AND DISCUSSION:

4.1 *Identification of the standard API*: The IR Spectra of standard ganciclovir is shown in Figure 2 and the functional group identification of IR spectra for the ganciclovir standard is presented in Table 1. The wavelength of maximum absorption (λmax) for the ganciclovir standard was found to be 252nm. It was determined by taking ganciclovir solution in simulated tear fluid and scanned in the range of 200-400nm in UV-visible spectrophotometer. The melting point of Ganciclovir was determined by using a melting point apparatus. The observed value of the Ganciclovir melting point was 248-250^{o}C compared to the reported value 250^{o}C. Solubility for the ganciclovir standard was checked by using different solvents at room temperature. It was found soluble in water, methanol, 0.1M HCL, buffer solvent pH 7, and DMSO(dimethyl sulfoxide). The standard of ganciclovir was found pure to perform the experimental work.

4.2 *The characterization parameter of In-house gel formulation:* It was observed and recorded in Table 2. The in-house ophthalmic gel formulation of ganciclovir has complied with all characterization parameters.

4.3 *UV- Visible Spectrophotometry Method Development and Validation:*

4.3.1 *Validation Parameters of UV method:* A summary of the validation parameters of the UV method is described in Table 3. Overly UV spectra and a calibration curve of ganciclovir are shown in Figures 3 and 4 respectively. The UV method was found validated as per the ICH guideline.

4.3.2 *Analysis of Formulation:* The Assay percentage of ganciclovir was found to be 100.75 $\pm$ 0.39 and 99.86 $\pm$ 0.58 for marketed formulation and In-house formulation respectively, which were comparable with the corresponding claimed amounts. This value indicated the successful application of the method for the determination of ganciclovir from marketed and In-house formulation.

4.4 *Development and Validation of IVRT Method:*

4.4.1 *Optimization of IVRT method:*

4.4.1.1 *Receptor fluid selection:* The receptor media that provided the best results was artificial tear solution or simulated tear fluid, where the mean ganciclovir solubility was sufficiently high to ensure sink conditions.

4.4.1.2 *Membrane selection:* Average percentage recoveries of ganciclovir were 90.8%, 97.6%, 99.2%, and 94.4% for polysulfone, nylon, cellulose, and teflon membrane, respectively. Since cellulose had a higher recovery percentage and was easily accessible, it was selected as the preferable membrane for this investigation.

4.4.1.3 *Optimized IVRT method:* Optimized IVRT method parameters are described in Table 4.

4.4.2 *Validation parameters of the IVRT method:*

4.4.2.1 *Linearity:* The relevant release parameters for three IVRT runs using reference ganciclovir ophthalmic gel- containing 0.15%w/w ganciclovir are given in Table 5. For each of the three IVRT runs, there was a linear relationship between the amount of ganciclovir released per unit area of the membrane versus the square root of time. The coefficient of correlation was 0.9947 which satisfied the acceptance criterion. The release rate plot of cumulative amount release vs square root of time for ganciclovir gel is shown in Figure 5.

4.4.2.2 *Precision:* The relative standard deviation for the release rate of ganciclovir gel IVRT intra-run and inter-run are shown in Table 6. It was discovered that the mean release rate values had an RSD of less than 15%, proving the precision of the method.

4.4.2.3 *Sensitivity:* The mean ganciclovir release rate was lower for the 0.075%w/w gel compared to 0.15%w/w gel, and the mean ganciclovir release rate was higher for the 0.225%w/w gel compared to 0.15%w/w gel, so the IVRT process appeared to be sensitive. The release of ganciclovir per unit area of the membrane vs the square root of time is displayed in Figure 6 for three IVRT runs utilizing gels with varying ganciclovir contents: 0.075%w/w, 0.15%w/w, and 0.225%w/w.

4.4.2.4 *Specificity:* The specificity of the procedure was established by analyzing the relationship between the variations in the release rate of the various ganciclovir gel contents: 0.15%w/w, 0.075%w/w, and 0.225%w/w. According to the accepted threshold of >0.90, the reported correlation coefficient (R2) was 0.999. Therefore, the IVRT procedure's specificity was confirmed. A linear, proportionate relationship between the various ganciclovir gel concentrations and corresponding release rates is shown in Figure 7.

4.4.2.5 *Selectivity:* The values of the ratio in case of comparison of the ganciclovir release rates for 0.075%w/w gel and 0.15%w/w gel were in the range of 19.41-22.54 %, and if the release rates for 0.225%w/w gel have been compared with the same parameter for 0.15%w/w gel the ratios were from 178.12-181.34 %. In both cases, the ratios 0.075 %/0.15 % and 0.225 %/0.15 %, were outside the limits of 75% -133.33%. Therefore, in the case of non-equivalent products, the IVRT approach was considered to be selective in terms of its capacity to precisely distinguish between the various release rates.

4.4.2.6 *Robustness:* The mean release rates obtained in IVRT runs at minor variations did not deviate by more than 15 %. The acceptance criterion stated that the mean release rates from IVRT run at minor variations could not differ from each other by more than 15%. The IVRT procedure's robustness in the face of parameter deviation was validated by these results. The mean release rate obtained for robustness runs is presented in Table 7.

4.4.3 *Comparison of IVRT of Marketed formulation and In-house formulation:*

The cumulative amount of ganciclovir release with time was found linear for In-house ganciclovir gel formulation. The relevant release parameters for marketed and In-house ganciclovir formulation are presented in Table 5. The comparative release rate plot for marketed and in-house ganciclovir formulations is shown in Figure 8. This value indicated the compatibility between marketed and in-house formulations.

5. CONCLUSION:

The Ganciclovir standard API was tested accurately to confirm its identity, standard, quality, and purity for experimental work. The In-house ophthalmic gel formulation was accurately prepared which complies with all characterization parameters. The simple, linear, precise, and accurate UV Spectrophotometry method was established for quantification of ganciclovir in IVRT samples. An IVRT method was developed and validated as per FDA guidelines. The optimized IVRT method proposed the use of cellulose membrane and simulated tear fluid as receptor media in vertical diffusion cell for in IVRT study of ganciclovir from gel formulation. The developed IVRT method was simple, economical, linear, robust, reproducible, sensitive, specific, and selective to assess the release of ganciclovir from gel formulation. This proposed IVRT method was successfully applied to evaluate the release profile of ganciclovir from marketed and in-house topical gel formulations. It indicated discrimination in the release profile at various gel formulation concentrations, including 0.075%W/W, 0.15%W/W, and 0.225%W/W. The resulting data indicate that the proposed IVRT method can be accurately and precisely applied to discriminate between ganciclovir gel products as a valuable tool in product development. It was then successfully applied to assess the equivalency between the marketed and in-house gel formulation. This supported a biowaiver under the SUPAC-SS acceptance criteria. This method can be utilized to check product quality, product performance, and product uniformity and also to obtain a waiver of bioequivalence studies for ganciclovir ophthalmic gel formulations.

LIST OF ABBREVIATIONS:

IVRT: In-Vitro Release Test

API: Active Pharmaceutical Ingredient

UV: Ultra Violet

USFDA: U.S. Food and Drug Administration

EMA: European Medicines Agency

SUPAC-SS: Nonsterile Semisolid Dosage Forms for Scale-up and Post-Approval Changes

VDC: Vertical diffusion cell

ICH: International Council for Harmonisation

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TABLES:

Table 1. Functional group identification of IR spectra for the Ganciclovir standard:

Sr.No.	Wavenumber[cm^{-1}]	Functional Group
1	3417	Primary and Secondary Amines, Alcohol
2	3154	Aromatics and alkenes
3	1651, 1607	Aromatic, Primary Amines
4	1573, 1540	Aromatics
5	1471, 1359	Alkanes
6	1301	Aromatic Amines
7	1244, 1170, 1092, 1062, 1013	Alcohol, Ester, Ether
8	978	Alcohol
9	902, 849, 821, 767, 685	Primary and secondary Amine

Table 2. Observation of characterization parameter of In-house gel:

Parameters	Observation
Color	Transparent
Odour	None
Consistency	Consistent
Homogenicity	Homogenous
pH	7.1
Viscosity	Dyn. Viscosity: 117.0 mPa·s at Torque: 80.1%, Temp: 30.5^{0}C, Speed: 250rpm
Spreadability (gm.cm/sec)	5.3

Washability	Washable
Grittiness	Nil

Table 3. Summary of validation parameters of UV method:

Parameters	Value
Solution stability: Standard solution	Assay% difference not more than 1%: Stable
Solution stability: Test solution	Assay% difference not more than 1%: Stable
Linearity (n=3)	Concentration range = 2-14µg/ml
	Absorbance range = 0.126-0.995 ± 0.03-0.12
Regression equation	Y= 0.0726x – 0.0187
Regression coefficient	R^2 = 0.9997
Precision: Repeatability(n=6)	% RSD: 0.364
Intra-day precision (n=3)	% RSD: 0.22-0.64
Inter-day precision (n=3)	% RSD: 0.45-0.76
Accuracy (% Recovery) (n=3)	99.30-100.0%
LOD	0.207(µg/ml)
LOQ	0.691(µg/ml)

Table 4. Optimized IVRT method parameters

Parameters	Condition
Receptor Volume	15ml
Diffusional surface area	25mm
Temperature	32°C
Membrane	Cellulose membrane
Receptor Media	Artificial tear solution
Stirring Speed	100rpm
Dose	1gm
Sampling Time	0.5, 1,2,3,4,5, and 6 hr
Sampling volume	1ml
Sampling analysis	UV Spectrophotometer at 252nm

Table 5. The drug release parameters of marketed and In-house ganciclovir gel IVRT study:

Parameter	Result (n=3) for marketed formulation	Result (n=3) for In-house formulation
Mean release rate (R), µg/cm^2/h$^{-1/2}$	29.70 ± 5.78	28.39 ± 4.11
Cumulative amount (A) (at the time point 6 h), µg/cm^2	1266.47 ± 20.56	1177.95 ± 15.99
Ganciclovir content in the receptor medium	650.94 ± 13.21	600.66 ± 11.06

(at the time point 6 h), µg/ml		
Correlation coefficient R^2	0.9947	0.9921
Recovery (at the time point 6 h), %	84.43 %	78.68 %

Table 6. The release rate values of ganciclovir gel IVRT intra and inter-day study:

	Mean Release rate (R), µg/cm^2/h$^{-1/2}$				
	Day 1	Day 2	Day 3	Avg	%RSD
Interday precision	27.12	31.45	29.82	29.46	2.18 %
	Run 1	Run 2	Run 3	Avg	%RSD
Intraday Precision	29.65	30.44	27.77	29.28	1.37 %

Table 7. The release rate data for IVRT runs at different temperatures and different RPMs:

Parameter	Variation	Mean release rate (R), µg/cm^2/h$^{-1/2}$ ± %RSD
Temperature	30°C	28.69 ± 1.02
	32°C	29.70 ± 2.06
	34°C	29.56 ± 1.34
Speed of rotation	80rpm	30.15 ± 1.65
	100rpm	29.70 ± 0.78
	120rpm	28.85 ± 1.99

FIGURES:

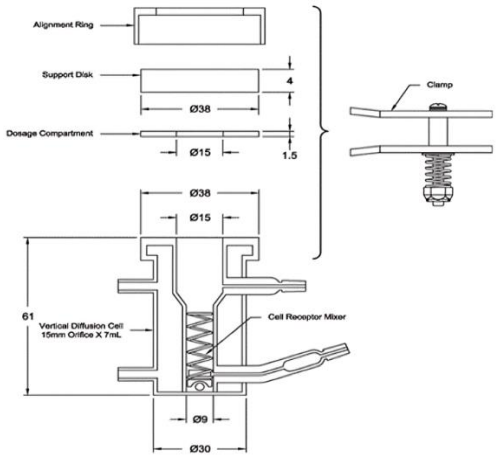

Figure (1). Vertical diffusion cell assembly [13]

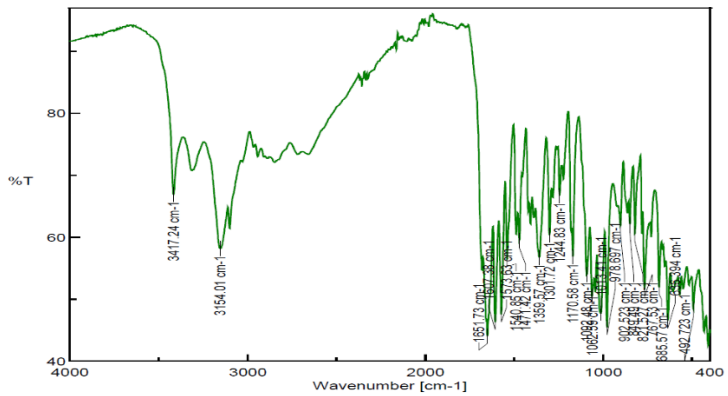

Figure (2). FTIR Spectra of Standard Ganciclovir

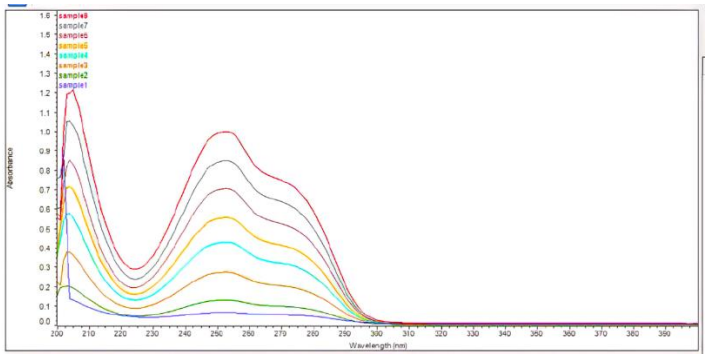

Figure (3). Overly UV Spectra of Ganciclovir(2-14µg/ml)

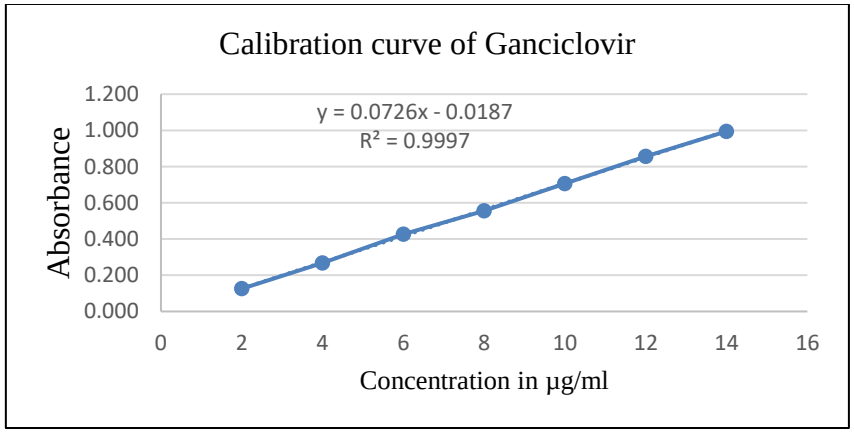

Figure (4). Calibration curve of Ganciclovir at 252nm.

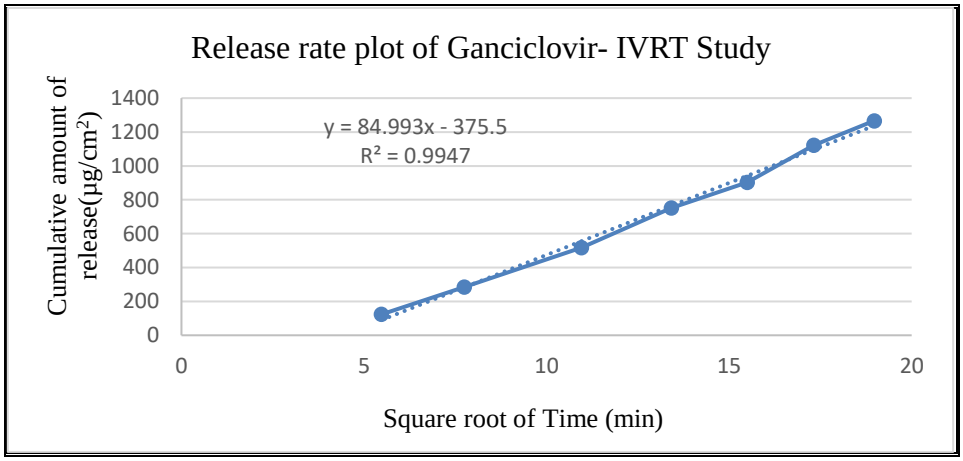

Figure (5). Release rate plot of Ganciclovir- IVRT Study

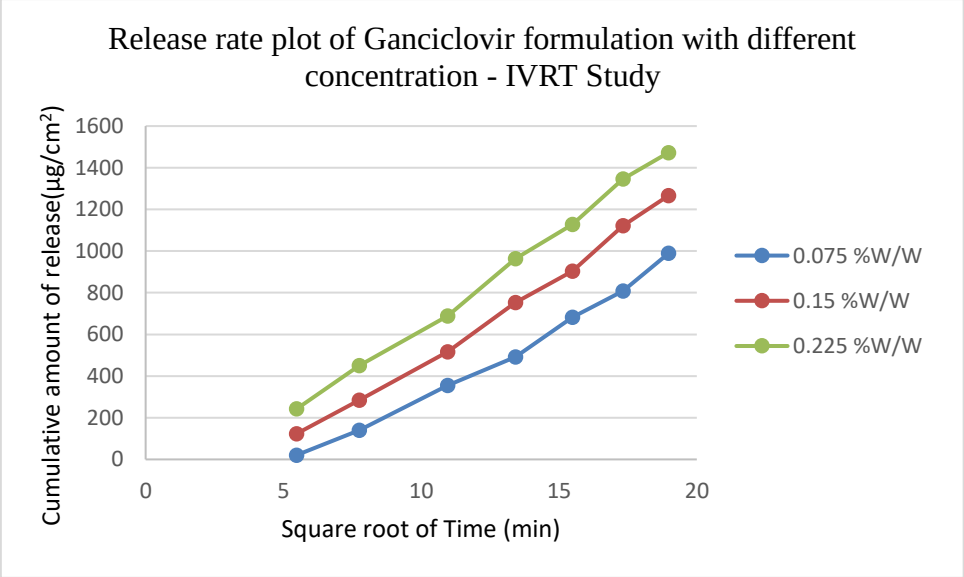

Figure (6). Release rate plot of IVRT run for ganciclovir gel with different concentration

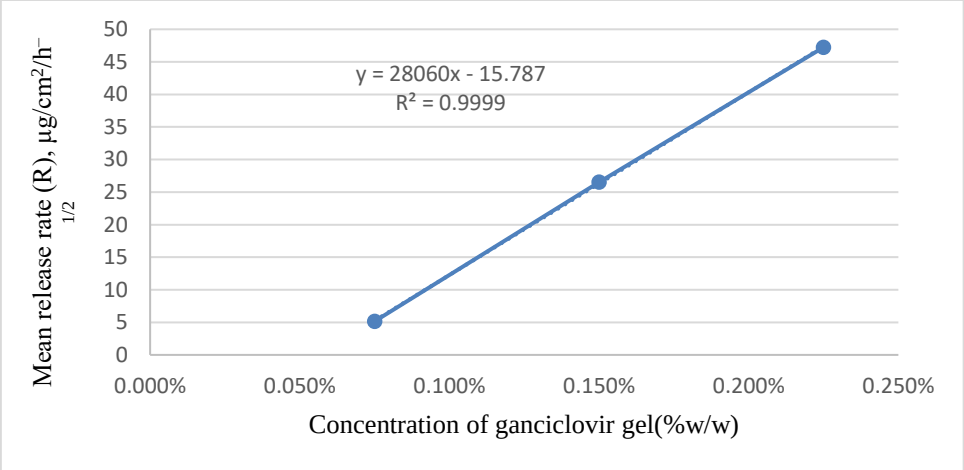

Figure (7). The plot of different ganciclovir concentration gel and their release rate

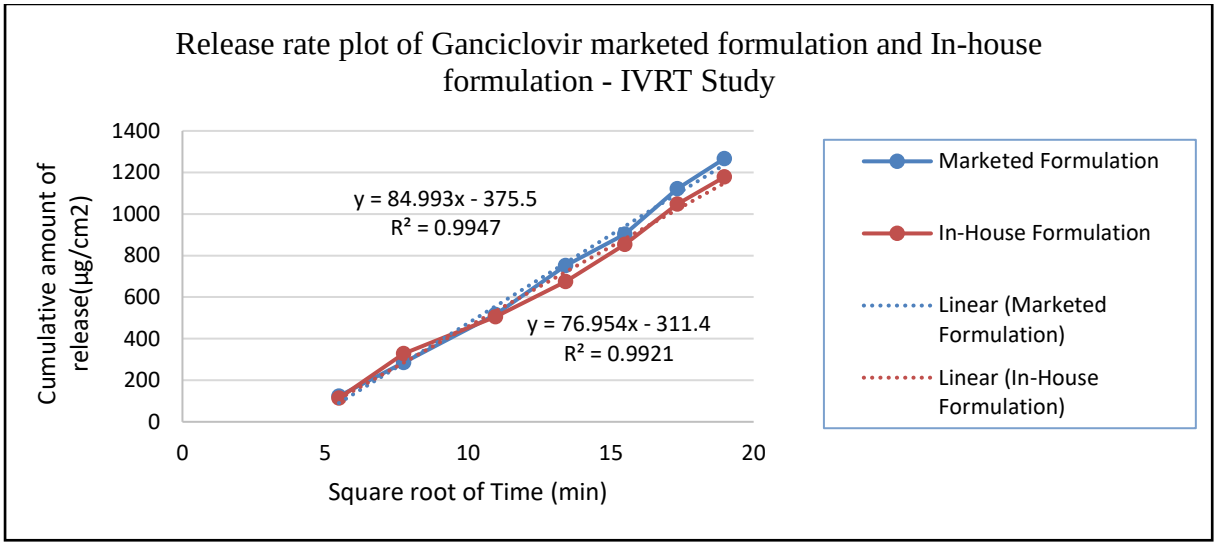

Figure (8). Comparative release rate plot for marketed and in-house ganciclovir formulations

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Impurity Profiling and Degradation Study in Pharmaceutical Development: Interplay of Stability, Safety, and Regulatory Compliance

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Abstract: *Major reason for pharmaceutical product recall is presence of impurities and degradation products beyond accepted limit. So, Impurity profiling and degradation study play crucial role in the pharmaceutical development process, ensuring drug products are stable, safe, and compliant with regulatory standards. The complex relationship between stability, safety, and regulatory requirements underscores the importance of understanding degradation pathways and impurity profiles. This review explores the intricate interplay among these critical elements, emphasizing their significance in maintaining drug quality and efficacy. It discusses classification of impurities, advanced analytical techniques used for their detection, and methods employed in degradation studies, such as stress testing and stability-indicating assays. The toxicological impact of impurities and degradation products is explored in the context of global regulatory guidelines, including those from ICH which establish thresholds for identification, reporting, and qualification. Recent advancements in analytical technologies and formulation strategies are also examined, emphasizing their contribution to improving precision and efficiency in impurity and stability analysis. Furthermore, the review examines the challenges of harmonizing stability, safety, and compliance within an evolving regulatory landscape. By integrating insights from recent research and industry practices, this review underscores the need for a holistic approach to impurity profiling and degradation study, ensuring the development of high-quality, safe, and compliant pharmaceutical products.*

Key Words: *Impurity profiling, Degradation studies, Regulatory compliance, Degradation pathways, Stress testing, Stability-indicating assays.*

1. INTRODUCTION:

In pharmaceutical drug and dosage form development, determination of impurities and degradation products plays a crucial role in ensuring the quality, safety, and efficacy of drug products. Impurity profiling and degradation studies are essential steps to understand which type of impurities are present, how drugs degrade over time under various conditions. Safety of a drug product is not only dependent on the toxicological properties and adverse reactions of the active drug substance itself, but also depends on impurities that it contains and on degradation products that are developed during its transportation, storage and shelf-life. So, in order to ensure patient safety to comply with regulations, these investigations are essential.[1]

2. FUNDAMENTALS OF IMPURITY PROFILING:

Impurity profiling is essential for quality control and medication development. It improves the scientific knowledge about drugs, facilitates regulatory compliance, and protects patient health.

Pharmaceutical firms may produce high-quality, safe, and effective pharmaceuticals by maintaining strict impurity control.

- **Definition and classification of impurities.**

  In a very simple manner, an impurity can be defined as any material or substance that affects the purity of the material of interest, viz., drug substance or drug product.[2]

  According to ICH Q3A(R2), Impurity is defined as "Any component of the new drug substance that is not the chemical entity defined as the new drug substance" and Impurity profile is defined as "A description of the identified and unidentified impurities present in a new drug substance."

  According to ICH, impurities are classified into three categories:
  - Organic impurities (starting materials, process-related products, intermediates, and degradation products).
  - Inorganic impurities (salts, catalysts, ligands, and heavy metals or other residual metals).
  - Residual solvents (organic and inorganic liquids used during production and/or recrystallization).[3]
- **Sources of Impurities are:**[4-7]
  - Crystallization related impurities
  - Stereochemistry related impurities
  - Residual solvents
  - Synthetic intermediate and By-product
  - Formulation related impurities
  - Impurities arising during storage
  - Genotoxic impurities
- **Analytical techniques for impurity profiling.**[8]

  The Conventional Approach:

  This approach has been used for decades. In this approach, to identification and structure elucidation of unknown impurities and degradation products are separated and then identified by spectrometry like UV spectroscopy or fluorescence spectroscopy. Impurities and degradation products are first separated by HPLC, UPLC (UHPLC), TLC, HPTLC or any other relevant separation technique.

  Modern Hyphenated Tools:

  The conventional approach for structural characterization of impurities and degradation products has few limitations like time consumption and difficult if several impurities and/or degradation products are to be determined in a single sample. It is more difficult if the substance to be analyzed is present in traces.

  Owing to these negative reasons, attention in the last few years has shifted to hyphenated techniques as a preferred choice for the identification and characterization of trace level IMPs and DPs. Broadly, the available hyphenated instruments have GC, LC or CE on the front end and MS, NMR or IR on the detection side, e.g., GC-MS, LC-MS, CE-MS, LC-NMR, LC-NMR/MS, CE-NMR, LC-IR, etc. In particular, LC-MS instruments are commercialized in multiple variants. Also available are combined LC-MS-NMR systems.

3. DEGRADATION STUDIES:[9]

Degradation studies determine stability and decomposition patterns of a substance under various environmental and stress conditions such as exposure to heat, light, humidity, pH, or mechanical stress.

Correlation between degradation products and drug stability:

Degradation studies are used
- To determine shelf life and storage conditions of a product.
- To assess how physical, chemical, and environmental factors affect product integrity.
- To identify degradation products and ensure they do not pose any toxicological risks.

- To meet guidelines set by regulatory authorities like the FDA, EMA, or ICH (e.g., ICH Q1A and Q1B for pharmaceuticals).
- To inform formulation decisions and improve product stability.
- To establish robust manufacturing processes that minimize degradation.
- To design appropriate packaging and labelling based on degradation characteristics.
- To investigate the chemical or physical pathways of degradation.
- To develop methods to mitigate unwanted degradation (e.g., through stabilizers).

- **Techniques for studying degradation:**
- **Stress testing and forced degradation studies, Stability-indicating methods.**

According to ICH guidelines on Impurities in New Drug Products, a degradation product is defined as chemical change in the drug molecule takes place over time by means of specific conditions like light, temperature, pH, water, or by reaction with an excipient or the immediate container/closure system. Stress condition intensity and duration should result in approximately 5–20% degradation of the API. The specific conditions depend on chemical characteristics of the API. The stressed sample should be compared to control and the appropriate blank.

From a regulatory perspective, forced degradation studies provide data to support the following:

- Identification of possible degradants.
- Degradation pathways and intrinsic stability of the drug molecule.
- Validation of stability-indicating analytical procedures.

Stability-Indicating Method Development:

An analytical technique that precisely measures the active components free from interference by degradation products, process contaminants, excipients, or other possible impurities is known as a stability-indicating method. Forced degradation is the initial stage in development of stability-indicating method. Early forced degradation investigations allow for the parallel development of methods and the identification of primary degradation products and unknown

4. SAFETY CONCERNS ASSOCIATED WITH IMPURITIES AND DEGRADATION PRODUCTS:[3,10]

- **Thresholds for safety assessment:**

Thresholds for Safety Assessment in ICH Q3A and Q3B Guidelines:

The ICH Q3A (Impurities in Drug Substances) and ICH Q3B (Impurities in Drug Products) guidelines mention thresholds for the identification, qualification, and control of impurities in pharmaceutical substances and products. These thresholds are established to ensure patient safety while maintaining product efficacy and quality.

ICH Q3A: Impurities in Drug Substances:

Impurities in drug substances can arise from raw materials, synthesis, degradation, or contamination. The thresholds for their control are based on the maximum daily dose of the drug substance.

Table 4.1: Thresholds for safety assessment in ICH Q3A

Parameter	Maximum Daily Dose (MDD)	Threshold Level	Requirement
Reporting Threshold	≤2 g/day	0.05% (50 ppm)	Impurities above this level must be reported in the regulatory documentation.
	>2 g/day	0.03% (30 ppm)	
Identification Threshold	≤2 g/day	0.10%	Impurities above this level must be identified and characterized.
	>2 g/day	0.05%	
	≤2 g/day	0.15%	

Qualification Threshold	>2 g/day	0.05%	Impurities above this level must be evaluated for safety (toxicological studies may be required).

ICH Q3B: Impurities in Drug Products:

Impurities in drug products can arise from drug substances, excipients, or degradation. The thresholds for their control are also based on the maximum daily dose and total daily intake (TDI).

Table 4.2: Thresholds for safety assessment in ICH Q3B

Parameter	Maximum Daily Dose (MDD)	Threshold Level	Requirement
Reporting Threshold	≤1 mg/day	1.0% or 50 µg TDI	Impurities above this level must be reported in the regulatory documentation.
	>1 mg/day to ≤10 mg/day	0.5% or 200 µg TDI	
	>10 mg/day to ≤2 g/day	0.2% or 2 mg TDI	
	>2 g/day	0.10% or 2 mg TDI	
Identification Threshold	≤1 mg/day	1.0% or 50 µg TDI	Impurities above this level must be identified and characterized.
	>1 mg/day to ≤10 mg/day	0.5% or 200 µg TDI	
	>10 mg/day to ≤2 g/day	0.2% or 2 mg TDI	
	>2 g/day	0.10% or 2 mg TDI	
Qualification Threshold	≤1 mg/day	1.0% or 50 µg TDI	Impurities above this level must be evaluated for safety (toxicological studies may be required).
	>1 mg/day to ≤10 mg/day	0.5% or 200 µg TDI	
	>10 mg/day to ≤2 g/day	0.2% or 2 mg TDI	
	>2 g/day	0.15% or 3 mg TDI	

5. REGULATORY PERSPECTIVES:

- **Overview of global regulatory guidelines:**

The framework governing pharmaceuticals is shaped by international guidelines aimed at guaranteeing safety, efficacy, and quality. Below is an overview of significant guidelines, their stipulations, and the challenges encountered in achieving harmonization of global standards.

- **ICH guidelines:**

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) develops globally accepted guidelines to streamline drug development and regulatory submissions. Guidelines associated with impurity, degradation and stability are:

I. ICH Q1A–Q1E: Stability Testing
   - Q1A(R2): Stability Testing of New Drug Substances and Products
   - Q1B: Photostability Testing
   - Q1C: Stability Testing for New Dosage Forms
   - Q1D: Bracketing and Matrixing Design
   - Q1E: Evaluation of Stability Data

II. ICH Q3A–Q3D: Impurity Control
   - Q3A(R2): Impurities in New Drug Substances
   - Q3B(R2): Impurities in New Drug Products
   - Q3C(R8): Residual Solvents
   - Q3D: Elemental Impurities

- **Regional Regulatory Requirements:**

USFDA - United States Food and Drug Administration
EMA - European Medicines Agency
CDSCO (India) - The Central Drugs Standard Control Organisation

- PMDA (Japan) - Pharmaceutical and Medical Devices Agency

- NMPA (China) - National Medical Products Administration

- **Role of stability studies in regulatory submissions:**
  Stability studies support the establishment of expiration dates and retest periods. It helps in making storage and packaging decisions. Stability studies are required when changes are made to formulations, manufacturing processes, or packaging. It is essential for ICH-compliant submissions like CTD (Common Technical Document) modules.
- **Challenges in harmonizing global regulatory standards.**
  Following challenges are faced:
  Some countries require region-specific stability and impurity studies, increasing costs and timelines. Local climate zones may demand unique stability testing protocols. Differences in regulatory interpretations of ICH guidelines create complexities for global submissions.

6. INTERPLAY OF STABILITY, SAFETY, AND REGULATORY COMPLIANCE:

The relationship between stability, safety, and regulatory compliance is integral to drug development and lifecycle management. Ensuring that a drug remains stable during its intended shelf life directly influences its safety for patients and compliance with regulatory requirements. Regulatory agencies set stringent standards for impurity profiling and stability testing. The goal is to demonstrate that the drug remains safe, effective, and of high quality throughout its intended shelf life. Stability studies help predict the presence of harmful degradation products, which might arise during the shelf life of the drug.

7. DISCUSSION / ANALYSIS:

Impurity profiling and degradation studies are foundational to pharmaceutical development. They ensure that drug products are safe, effective, and meet stringent regulatory requirements. By identifying impurities and degradation pathways early in development, pharmaceutical companies can enhance drug stability, improve patient safety, and minimize risks. As regulatory demands evolve, continuous innovation in analytical techniques and stability testing will be essential for maintaining compliance and ensuring drug product quality throughout its lifecycle. Global regulatory guidelines like ICH Q1A–Q1E and Q3A–Q3D provide a framework for stability testing and impurity control. However, harmonizing these guidelines across regions remains a challenge. Stability studies, impurity profiling, and compliance with regional requirements are critical for successful regulatory submissions and ensuring patient safety worldwide.

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Preparation and Evaluation of Polyherbal Facepack Having Therapeutic Potential

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Abstract: *Herbal Formulations are becoming increasingly popular in global market because of their combined action of cosmetic and pharmaceuticals intended for enhancement of health and beauty of skin. Herbal cosmetics are the products which enhance beauty with lesser side effects as they are free from synthetic chemicals. Facepack belongs to one such category. The purpose of this work is to formulate and evaluate the polyherbal facepack containing Rubia cordifolia, Terminalia arjuna, Santalum album, Citrus aurantium and Crocus sativus for treating skin complications. The ingredients used in facepack has been reported for having pharmacological actions like anti-inflammatory action, anti-wrinkle action, anti-aging action, dark spot removing and anti-oxidant action. The formulation was prepared in five different batches according to various concentration followed by pre and post evaluation parameters such as powder characteristics, phytochemical screening, microscopy, organoleptic study, rheology, irritancy, washability, stability and antimicrobial assay using sebum and dead skin sample. On performing this study, F2 was found be potent amongst all other batch preparations.*

Key Words: *Polyherbal Facepack, Therapeutic potential, Herbal Cosmetic, Anti-aging, Dark spot remover*

1. INTRODUCTION:

The term "herbal cosmetics" refers to products that are made with a variety of acceptable cosmetic ingredients to create a basis, then incorporate one or more herbal elements to offer specific cosmetic benefits. Since herbal cosmetics don't contain artificial chemicals, they improve appearance while having less negative effects. In Ayurveda, "Mukha lepa" is the name of the herbal paste that is applied to the face to heal acne, pimples, scars, markings, and pigments. "Mukha lepana" is the term for the method of applying this herbal mixture to the face. "FACEPACK" is the name of the smooth powder that is applied to the face. [1,2]

The skin on the face is the main component of the body that shows a person's health. It is made up of substances like lipids, carbohydrates, and amino acids, among others, so a balanced diet is necessary to keep the skin clear, glossy, and healthy. Daily skin care practices may have a big long-term effect on how well a person's complexion looks overall.

Skin care products are representing a new category of products placed between beauty and pharmaceuticals that are intended for the improving the quality of both health and beauty of skin. cosmeceuticals are formulated from multitude of ingredient.

According to reports, *Crocus sativus Linn.* (saffron) reduces skin melanin by blocking tyrosinase activity, which is useful for eradicating dark spots because it contains crocin. Alpha-santalol was discovered to be an inhibitor of tyrosinase, a crucial enzyme in the biosynthesis pathway for the skin pigment melanin. *Santalum album* (Sandalwood) has also been claimed to be an inhibitor of aberrant pigmentation linked to age and UV light exposure. *Citrus aurantium Linn.*, or orange peel powder, has been shown to have a number of benefits, including preventing ROS production and H2O2-induced oxidative stress, as well as suppressing apoptosis by preventing caspase activation and MAPK phosphorylation because of limonene. Because of the presence of manjisthin, *Rubia cordifolia* (Manjishta) has been shown to inhibit the production of INF-α and IL-ß, which has an anti-inflammatory effect. *Terminalia Arjuna* (Arjuna bark) has been shown to strengthen the skin, increase sebum production, alleviate the symptoms of dry skin, and prevent drying as a result of pentylene glycol.

Based on about mentioned evidences present study has been designed to formulate a Multi Targeted Polyherbal Facepack, for multiple benefits on skin using natural ingredients such as *Rubia cordifolia, Citrus aurantium, Santalum album, Crocus sativus Linn. & Terminalia arjuna* by varying concentrations.

2. LITERATURE REVIEW:

1	Manjistha	Synonym: Indian madder, Rakta pushpin Biological source: *Rubia cordifolia Linn* Family: Rubiaceae
2	Arjuna Bark	Synonym: Arjun Biological source: *Terminalia Arjuna Rob* Family: Combretaceae
3	Saffron	Synonym: Crocus, Kesar,Hay saffron Biological source: *Crocus sativus Linn* Family: Iridaceae
4	Sandal wood	Synonym: Chandan, Yellow sandal wood Biological source: *Santalum album Linn* Family: Santalaceae
5	Orange peel	Synonym: Sweet orange, Bitter orange Biological source: *Citrus aurantium Linn* Family: Rutaceae

Table 1. Plant Details

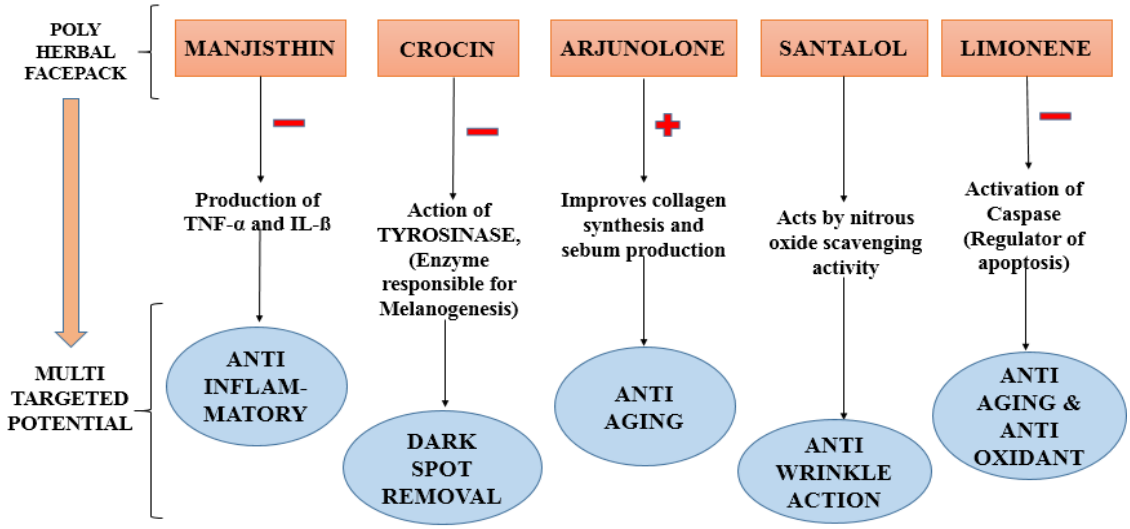

Fig. 1. Proposed Mechanism of Action

3. OBJECTIVES:

To prepare and evaluate polyherbal facepack containing *Rubia cordifolia, Citrus aurantium, Santalum album, Crocus sativus Linn. & Terminalia arjuna*.

To study physiological characteristics of individual powder mixture.

To perform microscopical study of individual powder herbs used in given formulation.

To perform phytochemical evaluation study of each individual powder mixture.

To prepare and optimize batch formulation of polyherbal facepack

To assess rheological study of prepared batches of polyherbal facepack.

To evaluate particle size, total ash value, loss on drying of prepared powder mixture.

To assess pH and stability study.

To evaluate irritancy, spreadability and washability test of designed polyherbal facepack.

To perform in vitro microbial assay.

4. METHODOLOGY:

Plant Collection:

Dried powder of various parts of *Rubia Cordifolia Linn, Terminalia Arjuna, Citrus aurantium Linn, Santalum album L.* and flakes of *Crocus Sativus Linn* were collected from market of junagadh respectively.

Procedure:

Accurate weight measurements were made of dried herbal powders, including saffron, orange peel, sandalwood, manjistha, and arjuna bark. Using a mortar and pestle, all of the ingredients were combined in various amounts to create a homogenous mixture. For further evaluation criteria, prepared batches of facepack were kept in airtight zip bags. [6-8]

Table. 2 Optimized Batch Preparation of Polyherbal Facepack

5. RESULT & DISCUSSION:

Phytochemical Screening- The phytochemical criteria listed in Table 3 were used to evaluate the herbal face pack. Alkaloids, flavonoids, glycosides, tannins, and other phytoconstituents that are effective skin nourishers were discovered to be present. [6-8]

Sr. no.	Ingredient (in gm)	F1	F2	F3	F4	F5
1	*Rubia cordifolia* (Manjistha)	12.4	15	13	10	11
2	*Santalum Album* (Sandal wood)	12.4	13	15	11	10
3	*Terminalia Arjuna* (Arjuna bark)	12.4	10	11	13	15
4	*Cirtus Aurantium Linn* (Orange peel)	12.4	11	10	15	13
5	*Crocus Sativus Linn* (Saffron)	0.4	0.4	0.4	0.4	0.4

Sr.no	Chemical Test	Observation				
		F1	F2	F3	F4	F5
Test for alkaloids						
1	Mayer's Test	-	-	-	-	-
2	Draggendroff"s Test	-	-	-	-	-
Test for phenols						
1	Lead Acetate Test	-	-	-	+	-
2	$FeCl_3$ Test	+	+	-	+	+
Test for flavonoids						
1	Lead Acetate Test	-	-	-	+	-
2	Alkaline Reagent Test	-	-	-	-	-
Test for saponins						
1	Foam Test	+	+	+	+	+

Test for tri-terpenoids						
1	Salkowski's Test	-	-	+	-	-
Test for anthraquinones						
1	Borntrager's Test	-	+	-	-	-
Test for phlobatannins						
1	Br_2 water Test	+	+	+	+	+
Test for coumarins						
1	NaOH Test	-	+	-	+	-
Test for steroids						
1	Salkowski's Test	-	+	-	-	-

Table 3. Phytochemical Screening

Organoleptic Parameters- The organoleptic metrics listed in Table 4 were used to evaluate the herbal face pack. Darkish brown was the formulation's color. The produced formulations have a nice, acceptable smell, which is ideal for cosmetic formulations. According to the specifications of cosmetic formulas, texture and smoothness were acceptable. [6-8]

Sr.no.	Evaluation parameters	Observation				
		F1	F2	F3	F4	F5
1	Appearance	Powder (Free flowing)	Powder (Free flowing)	Powder (Free flowing)	Powder (Free flowing)	Powder (Free flowing)
2	Color	Light brown	Darkish brown	Darkish brown	Light brown	Slight brown
3	Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
4	Texture	Fine	Very Fine	Fine	Fine	Fine
5	Smoothness	Gritty	Smooth	Smooth	Smooth	Smooth

Table 4. Organoleptic Parameters

Rheological Parameters: The rheological characteristics displayed in Table 5 were used to evaluate the herbal face pack. The herbal face pack's flow (powder) qualities were validated by rheological results. It was discovered to be non-sticky and free-flowing. [6-8]

Sr.no	Rheological parameters	Observation				
		F1	F2	F3	F4	F5
1	Bulk Density	0.47	0.38	0.31	0.39	0.35
2	Tapped Density	0.40	0.43	0.37	0.43	0.4
3	Angle of Repose	31.34	29.05	38.27	37.38	37.60

4	Hausner's Ratio	1.195	1.59	1.23	1.43	1.48
5	Compressibility index	14.89	11.63	16.21	13.95	12.5

Table 5. Rheologic Parameters

Irritancy Test:

Sr.no	Parameters	Observation					Inference
		F1	F2	F3	F4	F5	
1	Irritancy	No signs of irritation were observed					No signs of edema and irritation was observed
2	Erythema	No signs of redness or irritation were observed					
3	Edema	No signs of swelling or puffiness were observed					

Table 6. Irritancy Test

Fig. 3. Irritancy Test

Physicochemical Parameters: The physicochemical parameters listed in Table 7 were used to evaluate the herbal face pack. The formulation's pH was discovered to be nearly neutral. Both the moisture and ash contents were within acceptable bounds. [9-15]

Sr.no		Observation

	Physicochemical parameter	F1	F2	F3	F4	F5
1	pH	5.42	5.21	5.35	5.29	5.09
2	Moisture content	4.3	4.2	4.8	4.1	4.0
3	Ash value					
	Total ash	4.5%	4.4%	4.9%	4.1%	4.3%
	Acid insoluble ash	3	3.5	2.5	4.5	3.5
	Water soluble ash	14.5	14	16	15.5	14.5

Table 7. Physicochemical Parameters

Fig. 4 Ash value

Stability Study: The stability results showed that they remained stable until the thirty-first day. With the exception of pH, no changes in color, texture, smoothness, or odor were noticed at the stability conditions listed. [9-15]

Antimicrobial Study using skin and dead sample: In comparison to all other batches of polyherbal facepack preparations, the plate containing the F2 sample preparation showed the highest zone of inhibition against sebum and dead skin culture. As indicated in table 6.8, the zone of inhibition was calculated by deducting the disc's diameter from the overall zone diameter. [9-15]

Formulation	Zone of inhibition (mm)	
	Sebum	Dead Skin
F1	3.5	0.5
F2	7.7	3.5
F3	1.5	2.5
F4	1.5	0.5
F5	3.5	2.5

Table 8. Antimicrobial Study

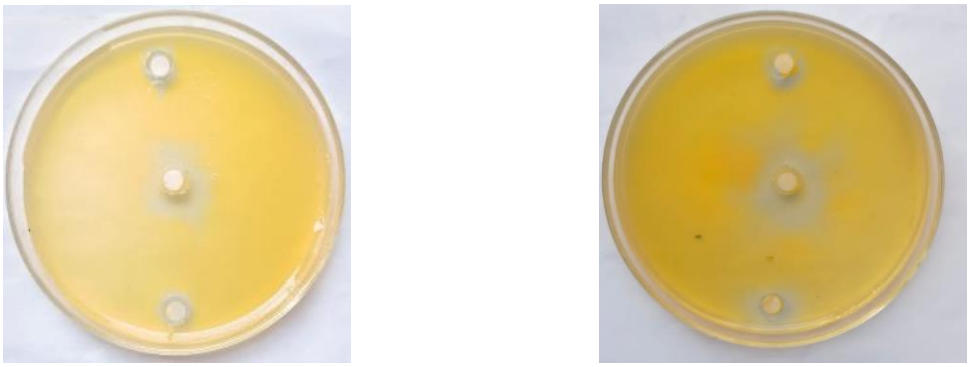

Fig. 5 Effect observed in F2 using sebum and dead skin sample

7. CONCLUSION:

Compared to synthetic medications, herbal formulations have a stronger worldwide market. because they are safer and have fewer negative effects. Herbal face packs keep skin supple and clean by removing debris, leaving skin smooth and clear. The goal of the current study was to create a multitargeted polyherbal facepack with dried powdered herbal constituents such Arjuna (Terminalia arjuna, 6gm), Manjistha (Rubia cordifolia, 9gm), sandalwood (Santalum album, 7.8gm), orange peel (Citrus aurantium, 6.6gm), and saffron (Crocus sativus, 0.6gm). Five different formulations were prepared for the investigation based on different concentrations of ingredients: All of our formulation's batches were used for evaluations, including rheological studies, pH, stability, organoleptic evaluation, irritancy, washability, and anti-microbial studies. The F2 batch was found to be the best of all. This batch was found to be having good potential effect on skin like anti-aging, dark spot removal, anti-wrinkle, anti-inflammatory and protective action on sebum production. Further in vivo study has been suggested to define exact possible mechanism of action.

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Statistical Approach for Preliminary Screening of Process Variables in Development of Chitosan Nanoparticle using Plackett-Burman Experimental Design

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Abstract: *The objective of this research work was to fabricate chitosan nanoparticles and to screening the process parameters that produce the significant effect on prepared polymeric nanoparticles by applying Plackett-Burman experimental designs. Chitosan nanoparticles were prepared using ionic gelation technique with tripolyphosphate as cross-linking agent. Plackett-Burman design was utilized to study the five process variables which influencing the quality and stability of nanoparticles. Eight experiments were generated by Minitab 16 statistical software for screening of five independent variables such as concentration of drug–polymer ratio, concentration of cross-linking agent, concentration of stabilizer, stirring speed and stirring time. The effect of parameters was evaluated by mean particle size, entrapment efficiency and zeta potential. Statistical analysis and Pareto-plot of Plackett-Burman design were utilized to determine the significance of the variables and extent of the effect. The result of the study shown that the concentration of Drug: Polymer Ratio and concentration of tripolyphosphate had maximum effect on mean particle size and drug entrapment efficiency as compared to other process parameters like concentration of stabilizer, stirring speed and stirring time. The study concludes that the statistical experimental design could be useful to find the most influencing variables that can be used for further work.*

Key Words: *Chitosan Nanoparticle, Plackett-Burman design, Ionic Gelation, Tripolyphosphate*

1. INTRODUCTION

Polymer-based drug delivery systems like polymeric nanoparticles have achieved a controlled release of drug from dosage form.

Several approaches have been implemented to improve the aqueous solubility of poorly soluble drugs, which including polymeric nanoparticles, liposomes, nanoemulsions, co-crystallization, micelles, solid lipid nanoparticles (SLN), super-critical fluid process, dendrimers etc. are still under investigation for convenient drug delivery system.[1]

Among all the approaches, polymeric nanoparticle is one of the most popular methods used due to its easy production and process diversity into the required characteristics for the design of suitable drug delivery systems. The polymers used for preparation of polymeric nanoparticles is dependent on various parameters like nanoparticles size, inherent properties of the drug, surface characteristics, biocompatibility, biodegradability, and drug release profile. Chitosan is the mostly studied polymers to prepared polymeric nanoparticles. Many process and formulation variables affect the quality as well as preparation of polymeric nanoparticles. In Plackett-Burman experimental design, the effect of each variable was determined.[2]

2. OBJECTIVE

The main objective of the present research work was to prepared glimepiride loaded chitosan polymeric nanoparticles and to study the influence of various processing variables on the mean particle size, entrapment efficiency and zeta potential of the prepared polymeric nanoparticles by applying Plackett-Burman experimental designs.

3. METHODOLOGY

3.1. Materials

Chitosan (CS) (degree of deacetylation: 93%) was gift sample from Yarrow Himedia Laboratories Pvt. Ltd (Nasik, India). Sodium Tripolyphosphate (TPP) was procured from Sigma-Aldrich (Mumbai, India). Glimepiride was received as gift sample from Yaro Chem, (Mumbai, India). Poloxamer 407 was obtained from Cadila Pharma Pvt. Ltd, Ahmedabad, India. Milli-Q water was used in all experiments. The other materials used in the research work were of analytical grade.

3.2. Methods

3.2.1. Experimental Design.

Fabrication of Chitosan Nanoparticles

Polymeric Chitosan nanoparticles were prepared by ionic cross linking of chitosan solution with tripolyphosphate anions when the positively charged amino groups in chitosan interact with the negatively charged tripolyphosphate. In this experimental method, Chitosan was dissolved in aqueous solution of acetic acid (1%) at various concentrations and adjusted the pH 5 with 0.1N sodium hydroxide or 0.1N HCl solution. Specific amount of Poloxamer 407 was added as a surfactant to it under constant stirring at ambient temperature. Sodium tripolyphosphate was dissolved in distilled water at various

concentrations. Glimepiride (10mg) was dissolved in methanol. Drug solution was added drop wise using 0.45 mm size needle syringe to prepare chitosan solution. The prepare solution was accompanied by continuous stirring for 5 min using high speed homogenizer. Under magnetic stirring at ambient temperature, 8 ml of TPP aqueous solution was added drop wise using syringe needle into 20 ml chitosan/drug (o/w emulsion) solution with 0.5 ml/min flow rate to induce cross-linking of the particles. The stirring was continued for complete evaporation of methanol from the preparation. An opalescent suspension was obtained. Chitosan nanoparticles were collected using centrifugation method at 12,000 rpm for 30 min and supernant layer was discarded. The resultant product was dried using a freeze-drying technique using mannitol 2% w/v as the cryoprotectants and stored at 4^0C until further use.[3]

3.2.2 Preliminary Screening of process and formulation parameter

Plackett-Burman design

Plackett-Burman statistical experimental design (PBD) was applied in this study to correlate dependent and independent variables. The Plackett-Burman experimental design is mostly used for screening out a large number of variables which affecting the product characteristics or attributes and is generally used during the initial phase of the formulation design. By literature surve, five factors were selected to affect the quality of nanoparticles. To identify which variables has its prominent impact on quality and stability of the nanoparticles, the Plackett-Burman design was used. A total of 8 experiments (preliminary screening formulations) were generated by Minitab 16 (USA) for screening of five independent variables such as concentration of drug–polymer ratio (X_1), concentration of cross linking agent (X_2), concentration of stabilizer (X_3), stirring speed (X_4) and stirring time (X_5) for the drug. The variables like mean particle size of nanoparticles (Y_1), entrapment efficiency of drug (Y_2) and zeta potential(Y_3) of prepare nanoparticles were selected as dependent variables. Table 1 and 2 shows the independent and dependent variables with their coded and actual values for Plackett-Burman design. The level of each parameter was selected based on preliminary experiments and literature review. [3,4]

Table 1: Layout of Plackett-Burman design

Run	X_1	X_2	X_3	X_4	X_5
1	1	-1	-1	1	-1
2	-1	-1	1	-1	1
3	-1	-1	-1	-1	-1
4	-1	1	1	1	-1
5	1	-1	1	1	1
6	-1	1	-1	1	1
7	1	1	1	-1	-1
8	1	1	-1	-1	1

Table 2: Variables with their coded and actual values for Plackett-Burman design

Independent variables	Low	High
Coded values	-1	1
$\mathbf{X_1}$ = Drug : Polymer Ratio (w/w)	1:1	1:3
$\mathbf{X_2}$ = Concentration of TPP (%w/v)	0.1	0.3
$\mathbf{X_3}$ = Concentration of Stabilizer	0.25	0.5
$\mathbf{X_4}$ = Stirring Speed (rpm)	600	1200
$\mathbf{X_5}$ = Stirring time (min)	30	60
Dependent variables		
$\mathbf{Y_1}$ = Particle size (nm) $\mathbf{Y_2}$ = Entrapment efficiency (%) $\mathbf{Y_3}$ = Zeta Potential (mV)		

3.2.3 Characterization of Nanoparticles

a. Determination of particle size

The particle size analysis and particles size distribution of the prepared chitosan nanoparticles were determined using a Malvern Zetasizer [Zetatrac, Microtrac, Japan]. The size analysis was performed in triplicate and the results were expressed as mean size ± SD.[5]

b. Determination of drug entrapment efficiency

The encapsulation efficiency of nanoparticles was determined by separating the nanoparticles formed from the aqueous medium by centrifugation at 12000 rpm for 30min. The amount of free Drug present in the supernant was determined by using UV spectrophotometery method after suitable dilution.[6]

c. Determination of zeta potential

The zeta potential of the drug-loaded chitosan nanoparticles was determined by zetasizer [Zetatrac, Microtrac, Japan]. The Zeta potential of nanoparticles is used to determine the electric charge at the surface of the particles, indicating the physical stability of colloidal systems.[7]

4. RESULT AND DISCUSSION

Most common screening design is Plackett–Burman (PB) design that screens a large number of factors and identifies critical one in a minimal number of running with a good degree of accuracy. Generally, a number of runs needed to investigate the main effects are in multiples of 4 in PB designs. Provided the interaction effects of process variables are nil or negligible, the Plackett-Burman experimental design is effective for measuring main effects of process variables. To find out the significant factors that were influencing the responses, statistical evaluation was performed by using ANOVA. Dependent variables with p values less than 0.05 were considered to be significant. The Pareto charts resulted from

the quantitative equations was used to determine the effects of the independent variables on each response. As shown in Table 3 the selected response parameters showed a wide variation suggesting that the independent variables had a significant effect on the response parameters chosen.

Table 3: Layout and observed responses of Plackett-Burman design batches for Glimepiride Chitosan Nanoparticles

Batch Code	Drug : Polymer Ratio X_1	Concentration of TPP (%) X_2	Concentration of Stabilizer (%) X_3	Stirring Speed (RPM) X_4	Stirring Time (min) X_5	Mean Particle Size (nm) (Mean ± SD)* Y_1	% EE Y_2	Zeta Potential (mV) (Mean ± SD)* Y_3
GMPB 1	1:3	1	0.25	1200	30	385.6 ± 5.8	60.36 ± 2.15	19.24 ± 3.18
GMPB 2	1:1	1	0.5	600	60	255.1 ± 4.1	54.25 ± 2.82	26.45 ± 2.24
GMPB 3	1:1	1	0.25	600	30	259.8 ± 3.2	51.09 ± 1.79	29.33 ± 1.95
GMPB 4	1:1	3	0.5	1200	30	244.0 ± 3.8	57.46 ± 2.41	31.54 ± 2.51
GMPB 5	1:3	1	0.5	1200	60	340.5 ±.5.3	61.85 ± 2.37	36.62 ± 1.65
GMPB 6	1:1	3	0.25	1200	60	215.2 ± 3.7	59.72 ± 1.66	28.78 ± 3.09
GMPB 7	1:3	3	0.5	600	30	261.0 ± 2.3	67.16 ± 2.04	33.37 ± 2.31
GMPB 8	1:3	3	0.25	600	60	268.6 ± 3.5	64.92 ± 2.97	25.24 ± 2.72

***** Indicates average of three determinations

Table 3 shows the observed values of responses for prepared eight formulations of Glimepiride loaded chitosan nanoparticles. The mean particle sizes of the prepared chitosan nanoparticles formulations were ranged from 215.2 nm to 385.6 nm and the entrapment efficiency of the prepared chitosan nanoparticles reached from 51.09 to 67.16%. While, the zeta potential of the prepared chitosan nanoparticles varied from 19.24 to 36.62 mv.

Table 4: Regression analysis of Plackett-Burman design batches for Glimepiride Chitosan Nanoparticles

Term Effect	Mean Particle Size (nm)Y_1			Entrapment Efficiency (%) Y_2			Zeta Potential (mv) Y_3		
	Coefficient	T-Ratio	P-value	Coefficient	T-Ratio	P-value	Coefficient	T-Ratio	P-value
Constant	278.64	41.39	0.001	59.12	50.14	0.001	28.37	11.01	0.008
A	35.14	5.22	0.035	6.37	5.41	0.033	-0.12	-0.05	0.966

B	-31.44	-4.67	0.043	-0.62	-0.53	0.649	0.87	0.34	0.767
C	-3.51	-0.52	0.654	-2.62	-2.32	0.156	3.12	1.21	0.349
D	17.54	2.60	0.121	0.37	0.32	0.781	0.12	0.05	0.966
E	-8.81	-1.31	0.321	-0.12	-0.11	0.925	0.37	0.15	0.898

Effect of independent variables on

Influence on the particle size (Y1)

The most important characteristics of the nanoparticles are the particle size which affects both the drug release and *in-vivo* absorption. Results of the regression analysis (Table 4) and Pareto chart (Figure 1) demonstrated that the most significant variables that affect the mean particle size were the concentration of Drug: Polymer Ratio and concentration of TPP as compared to other parameters like concentration of stabilizer, stirring speed and stirring time. Statistical ANOVA analysis results of PS were given in Table 4. From the experiment result it was observed that particle size of chitosan nanoparticles increases as concentration of polymer was increased. This could be explained that concentration of chitosan increased that produced a more viscous dispersion which diminishes the shearing action, resulting in larger nanoparticles. It also could be explained by the higher chitosan percentage led to higher tendency of aggregation, resulting aggregation of small nanoparticles producing larger ones. From the experiment result it was seen that increase the concentration of tripolyphosphate also increases particle size of nanoparticles. Increase the number of anionic groups in the medium, which causes electrostatic interaction with positive charges on chitosan and increase the size of nanoparticles. From the experiment result it was shown that particle size decreased as concentration of stabilizer increased. Stabilizer was used to stabilize the formulation. When low concentration of stabilizer was used for preparation of chitosan nanoparticles, aggregates were formed due to less stability of nanoparticles.

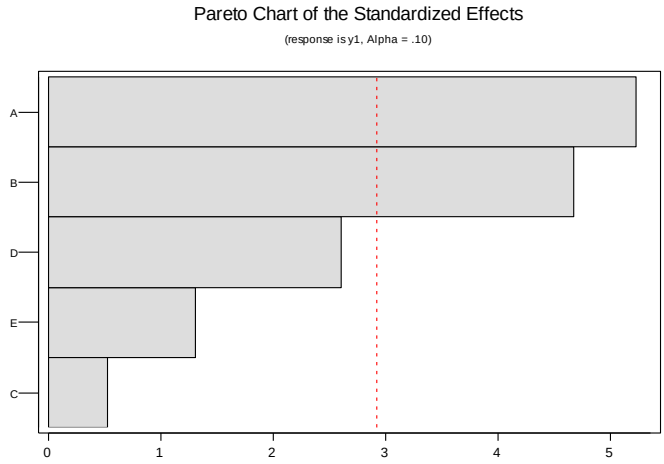
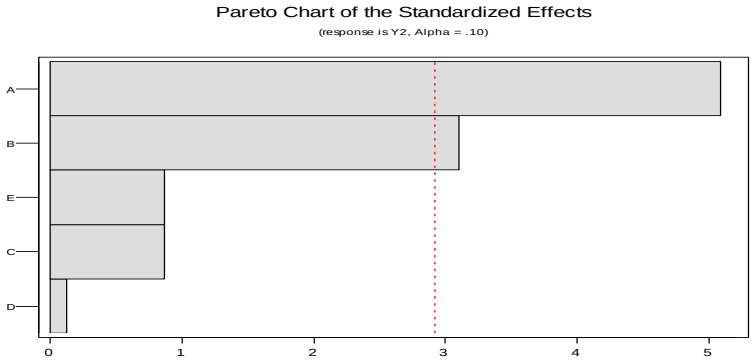


Figure 1: Pareto chart of the effect of independent variables on Mean Particle Size of Glimepiride Chitosan Nanoparticles

Influence on Entrapment Efficiency

Figure 2 indicates the concentration of Drug: Polymer Ratio and concentration of TPP had maximum effect on drug entrapment efficiency as compared to other parameters. The entrapment efficiency is significantly affected by the Drug: Polymer Ratio with p-value of 0.033. The lower the concentration of drug, the higher the entrapment efficiency of nanoparticles. The concentration of tripolyphosphate is also significantly affect the entrapment efficiency of nanoparticles. This could be result of crosslinking between the cationic groups of chitosan



and the anionic groups of tripolyphosphate and subsequently increase the integrity of the produced chitosan nanoparticles.

Figure 2: Pareto chart of the effect of independent variables on entrapment efficiency of Glimepiride Chitosan Nanoparticles

Influence on the zeta potential

The net surface charge of the prepared Chitosan Nanoparticles depends on the functional groups, which may be owing to the positive charge of chitosan molecules or the negative charge of the crosslinking TPP, or both. It was observed from the data in Table 2 that all the prepared Chitosan Nanoparticles formulations carried the positive surface charges ranged. The incorporation of the triblock copolymers (poloxamer) in the nanoparticles increased size and reduced zeta potential of the nanoparticles. Also, the incorporation of poloxamer through the hydrogen bonds formed between the amino group of chitosan and the oxygen atom of polyethers and forms a semi interpenetrating network. Zeta potential of prepared chitosan nanoparticles was decreased due to increase the negative charge of tripolyphosphate.

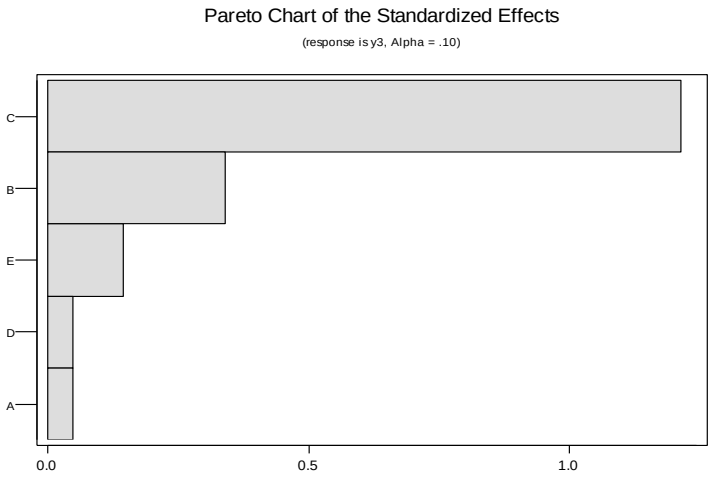


Figure 3: Pareto chart of the effect of independent variables on Zeta Potential of Glimepiride Chitosan Nanoparticles

5. CONCLUSION

Glimepiride loaded chitosan nanoparticles were successfully prepared using Ionic gelation technique. In this research work, effect of various processing variables on the mean particle size, entrapment efficiency and zeta potential of the prepared Glimepiride loaded chitosan nanoparticles were studied by Plackett Burman design. From the results of the Plackett Burman screening experimental design, it can be concluded that among the variables evaluated, Drug: Polymer Ratio concentration of TPP and concentration of stabilizer were the most important variables which influence the responses. The study concludes that the Plackett Burman experimental design could be useful and efficient technique to identify most influencing significant variables.

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Formulation and Evaluation of Raft-Forming Liquid for the Treatment of Gastric Ulcers

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Abstract:

This study focuses on the development and assessment of a raft-forming liquid as a gastro-retentive system for managing gastric ulcers. The formulation is designed to create a gel-like raft in the stomach's acidic environment, promoting prolonged gastric retention and localized protective effects. The preparation involved fine-tuning the formulation's excipients to achieve optimal raft formation, stability, buoyancy, and mechanical strength. Key parameters, including pH, viscosity, buoyancy lag t ime, and raft integrity, were analyzed to ensure the effectiveness of the system. The findings revealed that the formulated raft exhibited quick buoyancy, strong cohesion, and sustained retention in the gastric environment. This suggests that the raft-forming liquid could serve as a promising approach to treating gastric ulcers by enhancing gastric protection and retention, thereby potentially improving therapeutic efficacy.

Keywords:
Raft-forming liquid, Gastro-retentive system, Gastric ulcers, Buoyancy and stability, Therapeutic efficacy

Introduction:

Gastric ulcers are a significant gastrointestinal issue caused by an imbalance between harmful and protective factors in the stomach. Traditional treatment methods, while effective, often suffer from drawbacks such as systemic side effects and inconsistent drug delivery. To address these limitations, gastro-retentive systems like raft-forming liquids have been developed. These systems form a buoyant, gel-like raft in the stomach, ensuring prolonged retention and localized protection, making them a promising therapeutic option for managing gastric ulcers.

The study focused on designing and optimizing a raft-forming liquid tailored for gastric ulcer treatment. The formulation's components were carefully adjusted to achieve key properties such as quick buoyancy, optimal pH, mechanical strength, viscosity, and raft integrity. These attributes were systematically evaluated to ensure the raft's stability and durability in the acidic and dynamic gastric environment. The quick floatation and cohesive strength of the formulation are vital for delivering effective protection and sustained therapeutic action at the ulcer site.

The findings highlighted the potential of the developed raft-forming liquid as an innovative treatment for gastric ulcers. It demonstrated rapid buoyancy, prolonged gastric retention, and robust protective

properties, ensuring targeted drug delivery with minimal systemic exposure. This localized approach enhances therapeutic efficacy and patient compliance, making it a promising alternative to conventional therapies for gastric disorders. The study reinforces the value of gastro-retentive systems in improving the management of gastric ulcers and other related conditions.

Literature Review:

Peptic ulcer is an acid-induced digestive tract lesion characterised by denuded mucosa with the defect extending into the sub mucosa or muscularis propria. It commonly occurs in the stomach or proximal duodenum.

Mucosal disruption in individuals with acid peptic disease has traditionally been thought to be caused by a hypersecretory acidic environment combined with dietary variables or stress. H. pylori infection, alcohol and tobacco intake, use of non-steroidal anti-inflammatory medicines (NSAIDs), and Zollinger–Ellison syndrome are all risk factors for peptic ulcer.

Symptoms:

✓ Abdominal discomfort

✓ Abdominal pain

✓ Loss of appetite

✓ Weight loss

✓ Bloating

✓ Bloody stool

✓ Vomiting

✓ Black stool due to internal bleeding

Ulcer is formed due to the imbalance between digestive fluid in stomach and duodenum. Normal stomach mucosa maintains balance between aggressive and protective factors.

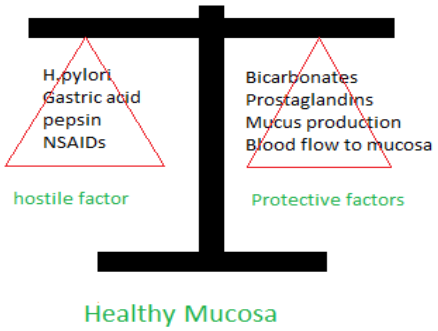

Figure 6 : Healthy Mucosa

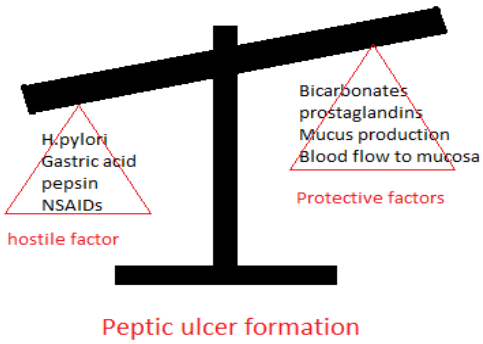

Figure 7 : Peptic Ulcer Formation

Review literature on Gastro retentive approaches

Requirements for the Gastric retention

Physiological factors in the stomach, it must be noted that, to achieve gastric retention, the dosage form must satisfy certain requirements. One is that the dosage form must be able to withstand the forces caused by peristaltic waves in the stomach and the contraction and grinding and churning in the stomach. To function as gastric retention dosage form, it must be resisting premature gastric emptying. Once its purpose has served, the dosage form should be removed from the stomach with ease.

Need for gastro retention

- Drugs that is less soluble or degraded by the alkaline pH.
- Drugs that are absorbed from the proximal part of the gastrointestinal tract (GIT).
- Local and sustained drug delivery to the stomach and proximal small intestine to treat certain conditions.
- Drugs that are absorbed due to variable gastric emptying time.
- Drugs that are useful for the treatment of peptic ulcers caused by H.pylori infections.

Different Gastroretentive forms

Many approaches made to develop a dosage form that can be retained in the stomach.

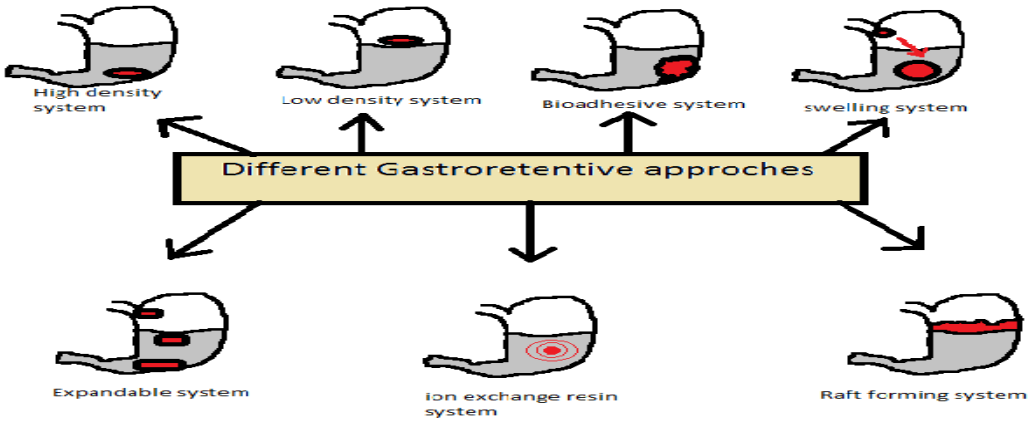

Figure 8 : Different Gastroretentive Approaches

Floating Effervescent systems include use of gas generating agents, carbonates (e.g. Sodium bicarbonate) and other organic acid (e.g. citric acid and tartaric acid) present in the formulation to

produce carbon dioxide (CO2) gas, thus reducing the density of system and making it float on the gastric fluid. An alternative is the incorporation of matrix containing portion of liquid, which produce gas that evaporate at body temperature.

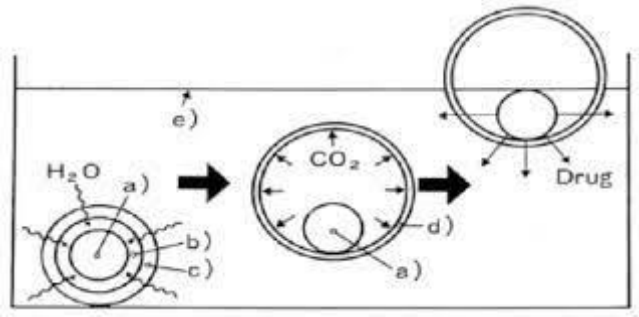

Figure 9 : Floating Effervescent System

Aim:

To develop and evaluate a raft-forming liquid formulation as a gastro-retentive system for the effective treatment of gastric ulcers by ensuring prolonged gastric retention, localized protective effects, and enhanced therapeutic efficacy.

Objectives:

The primary objective of this study is to develop and evaluate a raft-forming liquid formulation aimed at treating gastric ulcers by leveraging its gastro-retentive properties. The formulation is designed to create a gel-like raft in the acidic environment of the stomach, ensuring prolonged retention and localized protective effects. To achieve this, the excipients in the formulation are systematically optimized to enhance key properties such as raft formation, stability, buoyancy, and mechanical strength. The study further aims to assess critical parameters, including pH, viscosity, buoyancy lag time, and raft integrity, to validate the formulation's performance. Ultimately, the objective is to establish the potential of this raft-forming liquid as an innovative and effective therapeutic approach for managing gastric ulcers, improving gastric protection, and enhancing drug retention within the stomach.

Research Methodology:

Selection of Raft forming agent

Preparation of Raft forming solutions of formulated by Xanthan gum/HPMC K100 M/pectin/sodium alginate/ Gellan gum as raft forming agent containing Calcium carbonate as an effervescent agent, and Drug dispersed in the solution. Composition of the prepared raft forming liquid is shown in table. Calculate amounts of each polymer, was individually dispersed in 90 ml of deionised water containing 0.25% w/v sodium citrate and heated to 90°c with stirring till homogeneous viscous liquid was obtained, then cooled below 40°C. 10 ml calcium carbonate dispersion were then added after cooling, with continuous stirring after which the calculated amount of the drug was well dispersed.

Trial batches	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P 11	P 12	P 13	P 14	P 15

HPMC K100M	0.5	-	-	-	-	1	-	-	-	-	1.5	-	-	-	-
Xanthan gum	-	0.5	-	-	-	-	1	-	-	-	-	1.5	-	-	-
Gellan gum	-	-	0.5	-	-	-	-	1	-	-	-	-	1.5	-	-
Pectin	-	-	-	0.5	-	-	-	-	1	-	-	-	-	1.5	-
Sodium alginate	-	-	-	-	0.5	-	-	-	-	1	-	-	-	-	1.5
Calcium carbonate	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Sodium citrate	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%

Table 3 : Composition of preliminary trial batches

* All the values in %w/v
HPMC= Hydroxypropyl Methyl cellulose

Preliminary screening of Gas generating agent

Preliminary screening was carried out to select good gas generating agent. Three different gas generating agent used to screen out longer floating duration of raft forming liquid as follow;

Trial batches	P1	P2	P3	P4	P5	P6	P7	P8	P9

Selected polymer in preliminary trial	1%	1%	1%	1%	1%	1%	1%	1%	1%
Calcium carbonate	0.5	1	1.5	-	-	-	-	-	-
Sodium bicarbonate	-	-	-	0.5	1	1.5	-	-	-
Potassium carbonate	-	-	-	-	-	-	0.5	1	1.5
Sodium citrate	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%	0.25%

* All the values in %w/v

Table 4 : Preliminary trial of gas generating agent

Measurement of viscosity of Raft forming solution

Viscosity determinations of floating raft formulations were carried out on a rotating viscometer (Brookfield DV II- RV USA) using spindle no.64. Viscosity was measured at different angular velocities at ambient temperature of 23±0.5°c a typical run comprised changing of the angular velocity from 10 to 100 rpm. Viscosity measurement for each sample was done in triplicate each measurement taking approximately 30.

In vitro gelation study

Gelation study was determined by placing drop of formulation in vials containing 2ml of SGF pH 1.2.

- Gelations lag time- Time to which gel formation visually assessed and time to first detection of gelation.
- Gelation duration- Time to take for gel formed to dissolve.

In vitro floating study

In vitro floating study determined using USP dissolution apparatus II. Apparatus is filled with 900 ml of SGF pH 1.2. 10ml of raft forming solution was immersed without disturbance into dissolution apparatus.

- Floating lag time (m) – Time for formulation emerge on medium of surface.
- Floating duration (hr) – Time taken by formulation to float on dissolution medium of surface.

In vitro drug release study

In vitro drug release was done in USP type II apparatus at 50 RPM in 900 ml of 0.1 N HCL pH 1.2 at 37±1°c. After 10 ml of raft forming formulation was placed in dissolution apparatus II with disposable syringe. At specific time intervals 10 ml solutions removed and replaced by fresh media and then analyses in UV.

Raft Strength measurement by in house method

10 ml of raft forming solution was transferred to 150 ml of 0.1 N HCL pH 1.2 and maintained 37°c in 250 ml glass beaker. Each raft was allowed to form around an L-shaped wire probe (diameter 1.2 mm) held upright in the beaker throughout the whole period (30 min) of raft development. Raft strength was determined using modified balance method. Wight was added in the pan and weight required to break the raft was recorded.

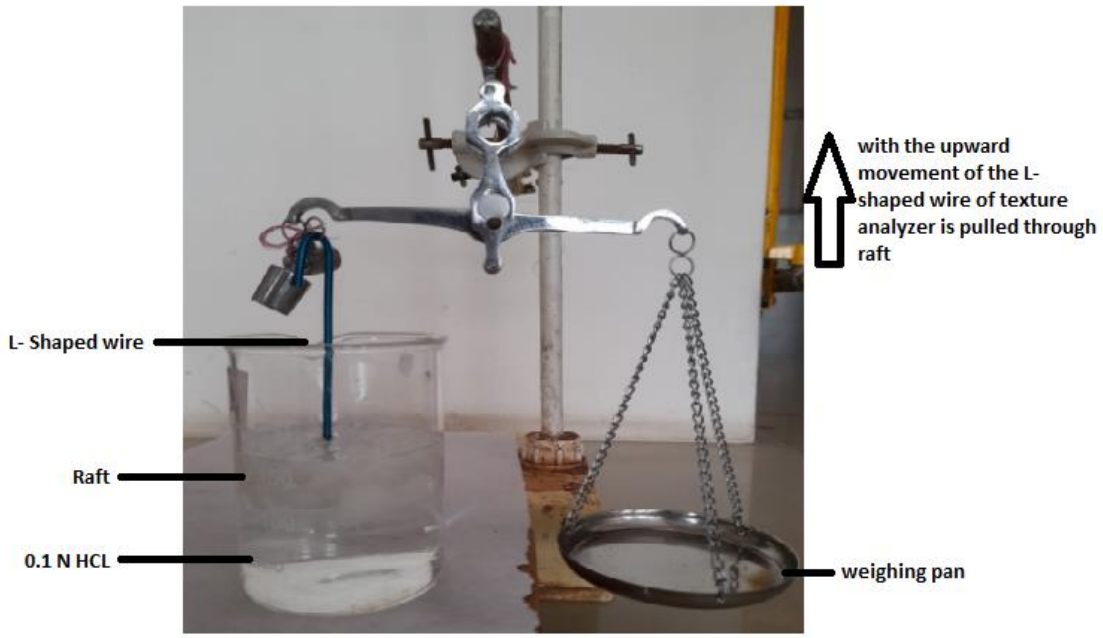

Figure 10 : In house raft strength measurement

Result and Discussion

Selection of raft forming agent (0.5% w/v)

Polymer (0.5%w/v)	Floating ability	Viscosity parameter (cp)	Gelation		Floating	
			Lag time (s)	Duration (hr)	Lag time (min)	Duration (hr)
Gellan gum	F	219±0.45	3±0.05	>24±0.02	1±0.01	>24±0.01
HPMC K100 M	PF	844±0.07	17±0.32	<3 ±0.01	2.64±0.09	<3±0.02
Sodium alginate	F	128±0.005	10 ±0.47	<6±0.04	1.57±0.04	<6±0.01

Xanthan gum	NF	-	-	-	-	-
pectin	F	754±0.04	24± 0.19	<6±0.28	2.72±0.08	<6±0.04

Table 5 : selection of raft forming agent (0.5% w/v)

*Calcium carbonate: 1% w/v and Sodium citrate: 0.25%w/v and Drug MAG: 100 mg same amount in all batches

*Mean ± SD in all batches

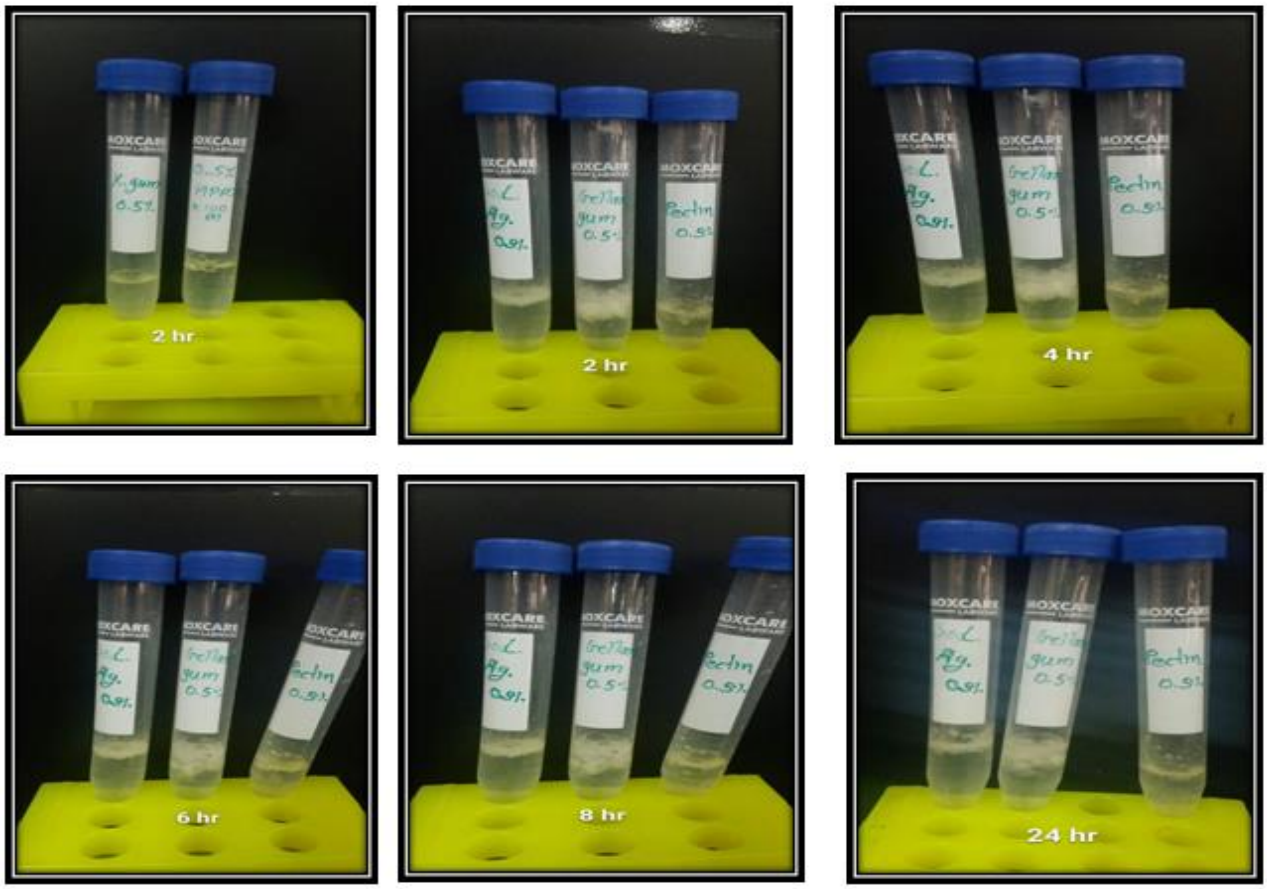

Figure 11 : floating duration of 0.5% polymer concentration

Above the results seen that polymers are Gellan gum,sodium alginate and pectin polymers that having good floating ability. HPMC K100 M that are formed partially floated on the surface and Xanthan gum formulation was not floated.

Selection of raft forming agent (1% w/v)

Polymer (%w/v)	**Floating ability**	**Viscosity parameter (cp)**	**Gelation**		**Floating**	
			Lag time (s)	Duration (hr)	Lag time (s)	Duration (hr)

Gellan gum	F	273.9 ±0.002	5±0.001	>24±0.01	1.15±0.06	> 24±0.15
HPMC K100 M	F	1049 ±0.85	47±0.01	<6±0.04	2.77±0.08	<6±0.04
Sodium alginate	F	179.6 ±0.07	16±0.17	<8±0.27	1.82±0.09	<8±0.07
Xanthan gum	F	781.8 ±0.44	6±0.65	>24±0.004	1.54±0.25	>24±0.36
pectin	Pre. Gelation	2025 ±0.04	-	-	-	-

Table 6 : selection of raft forming agent (1% w/v)

*Calcium carbonate: 1% w/v and Sodium citrate: 0.25%w/v and Drug MAG: 100 mg same amount in all batches

*Mean ± SD in all batches

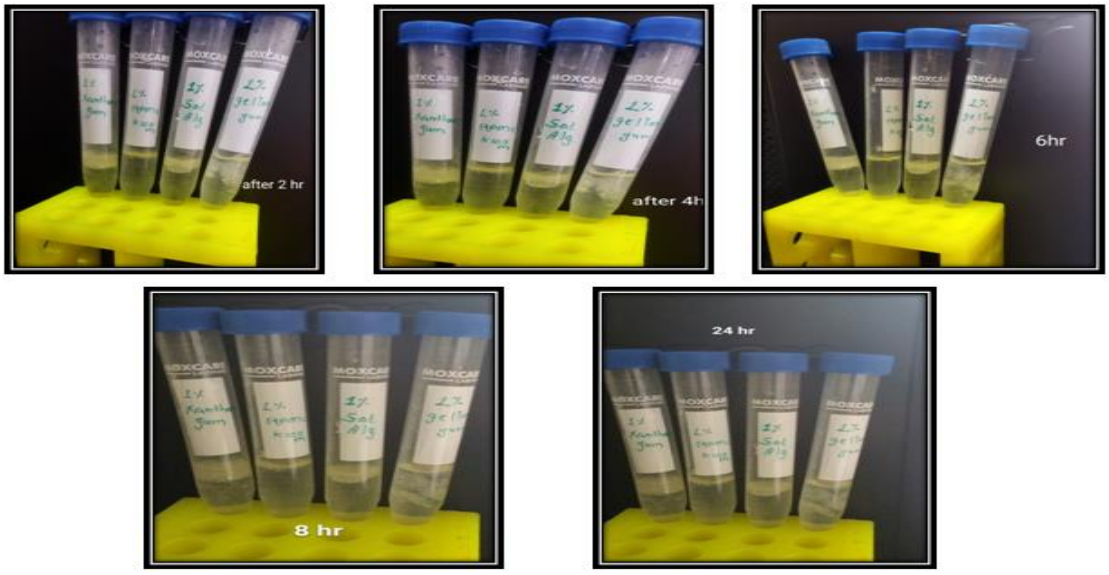

Figure 12 : floating duration of 1% polymer concentration

According to the result of raft forming agent with 1% w/v Gellan gum, Xanthan gum, sodium alginate and HPMC K100 M shows good floating property and duration of floating but pectin may form premature gel formation.

Selection of raft forming polymer (1.5% w/v)

Polymer (%w/v)	**Floating ability**		**Gelation**	**Floating**

		Viscosity parameter (cp)	Lag time (s)	Duration (hr)	Lag time (s)	Duration (hr)
Gellan gum	F	746.9 ±0.033	7±0.4	>24±0.012	1.14±0.02	> 24±0.03
HPMC K100 M	NF	1468±0.04	-	-	-	-
Sodium alginate	NF	347±0.3	-	-	-	-
Xanthan gum	F	821.8 ±0.02	6±0.54	>24±0.04	1±0.01	>24±0.03
pectin	Pre.Gelation	2214 ±0.04	-	-	-	-

Table 7 : selection of raft forming polymer (1.5% w/v)

*Calcium carbonate: 1% w/v, sodium citrate: 0.25%w/v and Drug MAG: 100 mg same amount in all batches

* Mean ± SD in all batches

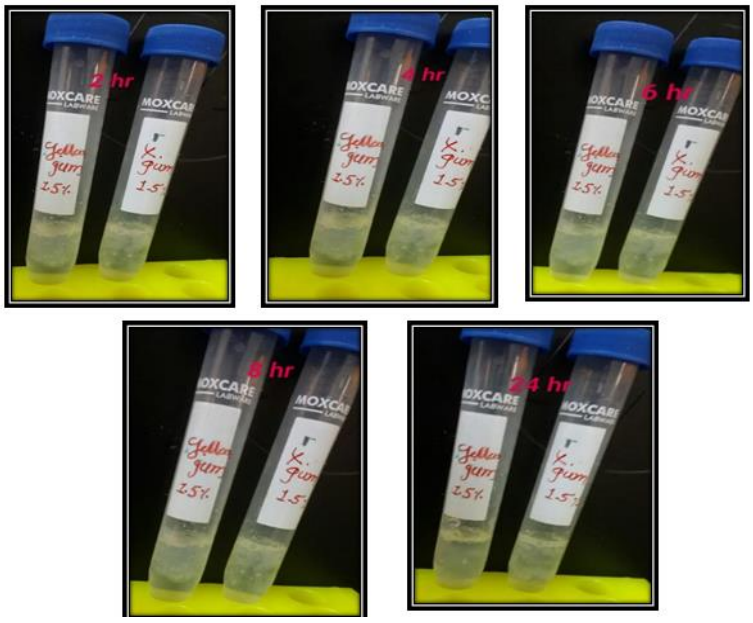

Figure 13 : floating duration of polymer concentration 1.5%

According to the results of the 1.5% polymer concentration Gellan gum and Xanthan gum that may shows good floating ability and shows good viscosity floating durations so, these polymer combination used for the further study. Pectin may form premature gel during formulation. Raft forming solution with HPMC K100 M and sodium alginate as raft forming agent do not floating so, those are canceled for furthered study.

Selection of different gas generating agent:

In the preliminary trials calcium carbonate is replaced with sodium bicarbonate and potassium carbonate using Xanthan gum and Gellan gum but all batches of raft forming liquid was not gelled and not form raft so, Calcium carbonate select as gas generating agent for furthered study.

Selection of different concentration of calcium carbonate:

Polymer (1:1) (0.5:0.5) (%w/v)	Different conc. Of Calcium carbonate	Floating ability	Viscosity parameter (cp)	Gelation		Floating	
				Lag time (s)	Duration (hr)	Lag time (s)	Duration (hr)
X.gum: G.gum	0.50%	F	639±0.10	50±0.02	>240.03	2.67±0.03	>24±0.07
X.gum: G.gum	1%	F	790±0.09	2±0.03	>24±0.02	1.46±0.02	>24±0.04
X.gum: G.gum	1.50%	F	794±0.05	1±0.04	>24±0.01	1±0.04	>24±0.01

Table 8 : selection of different concentration of calcium carbonate

*Sodium citrate 0.25% and drug MAG: 100 mg same amounts in all batches

* Mean±SD in all batches

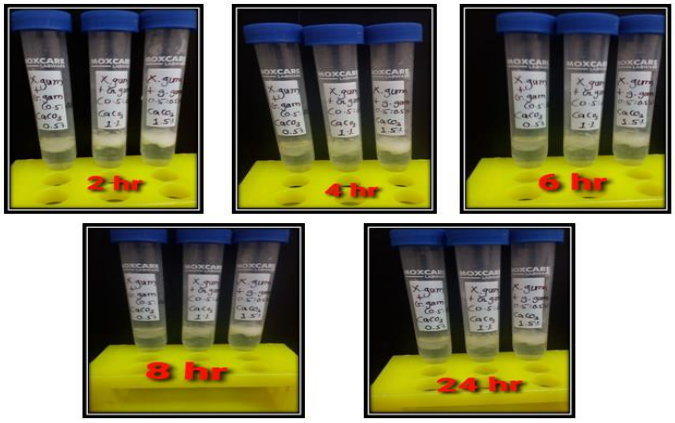

Figure 14 : floating duration of Xanthan gum: Gellan gum different calcium carbonate ratio

By the different calcium carbonate ratio 0.5%w/v, 1% w/v and 1.5% w/v all the three batches having good floating properties and having no significant effect on the in vitro dissolution study and having near to similar floating lag time but 1.5% w/v concentration having good gel strength than 0.5% w/v containing calcium carbonate.

Selection of polymer combination with Xanthan gum:

Xanthan gum:	Floating ability	Viscosity (cp)	Gelation	Floating

polymer (1:1) (%w/v)			Lag time (s)	Duration (hr)	Lag time (s)	Duration (hr)
Gellan gum: X. gum	F	869±0.081	2.6±0.014	>24±0.02	1.45±0.03	>24±0.02
HPMC K100M: X.gum	F	321±0.39	3.7±0.02	<10±0.004	3±0.07	<10±0.43
Sodium alginate : X.gum	F	752±0.64	3.27±0.02	>24±0.23	2.56±0.045	>24±0.023

Table 9 : Selection of polymer combination with Xanthan gum

*Calcium carbonate: 1% w/v, sodium citrate: 0.25%w/v and drug MAG: 100 mg same amount in all batches

* Mean ± SD in all batches

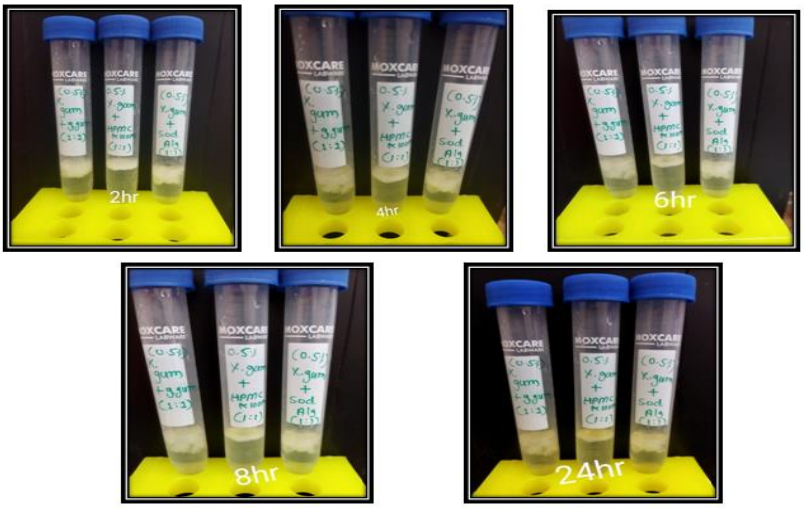

Figure 15 : floating duration of polymer combination (1:1)

In this preliminary screening Xanthan gum is combined with different three polymers like Gellan gum , HPMC K 100 M , Sodium alginate all the three formulation were floating but with combination with HPMC K 100 M that form very weak gel and as compare to combination with sodium alginate Gellan gum and Xanthan gum form very strong gel and having good floating duration and in vitro dissolution study so that combination of Gellan gum and Xanthan gum was selected for furthered study.

Selection of combination of Xanthan gum and Gellan Gum

X.GUM+G. GUM (%w/v)	**Calcium carbonate**	**Floating ability**	**Viscosity**	**Gelation**	**Floating**	**Raft strength**

			Parameter (cp)	Lag time (s)	Duration (h)	Lag time (m)	Floating (h)	(by in house method)
1:2 (0.5%:1%)	1%	F	621± 0.32	12 ± 0.07	>24 ±0.21	2.49 ± 0.03	>24 ± 0.09	1.8 gm ± 0.85
2:1 (1%:0.5%)	0.5%	F	964 ±0.009	2 ±0.007	<6 ±0.73	1.51 ± 0.08	<6 ± 0.86	1 gm ± 0.01
2:1 (1%:0.5%)	1%	Pre. Gelation	1011 ±0.52	–	–	–	–	–

Table 10 : selection of combination of Xanthan gum and Gellan gum

*All the batches contains 0.25% sodium citrate and drug MAG: 100mg

* Mean ± SD in all batches

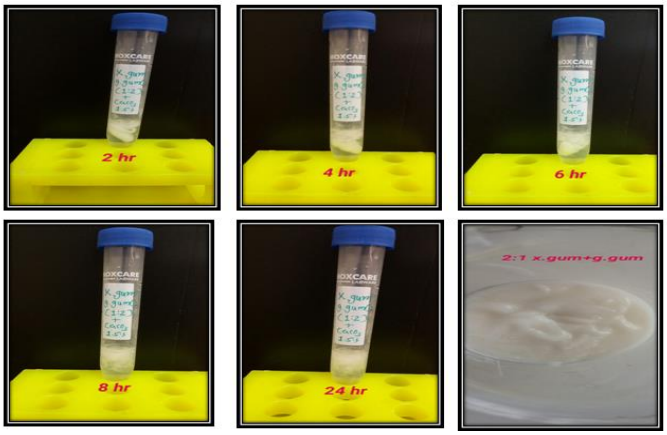

Figure 16 : floating duration of different concentration of combination of Xanthan gum and Gellan gum

Gelation duration difference between formulation batches

The gelation duration discrepancy among the formulation batches was attributed to differences in the raft strength of the liquid. This strength, measured as '< 1 gm' using an in-house method, led to decreased gelation duration and floating time, causing variations in gelation duration across batches.

Conclusion:

The selection and optimization of excipients were critical to developing an effective raft-forming liquid formulation for gastric ulcer treatment. Among the various trial batches, Xanthan gum and Gellan gum were identified as the most suitable polymers for raft formation due to their superior performance in terms of floating behavior and raft integrity. Additionally, calcium carbonate was chosen as the gas-generating agent, ensuring rapid buoyancy and stable raft formation. The optimized combination of these components provides a robust foundation for the final formulation, highlighting its potential as a promising therapeutic approach for enhancing gastric retention and protection.

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Design and Evaluation of Bioadhesive Buccal Patch for Topical Delivery of Tizanidine Using Natural Tamarind Gum

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Abstract: *A centrally acting alpha-2 receptor agonist, tizianidine hydrochloride alters myotonolytic effects on skeletal muscle. Its half-life is about 2.5 hours. The current study's objective is to design and test a bioadhesive buccal patch that uses natural tamarind gum to topically administer tizanidine. Using the solvent evaporation technique, buccal patches containing tizanidine hydrochloride are made by combining different ratios of high-potential matrix cellulose (HPC), eudragit, and tamarind gum with the plasticizer polyethylene glycol-400 and permeation enhancers. The drug release handling qualities, physio-mechanical properties, and flexibility of dimethyl sulfoxide were determined to be satisfactory. The medicine was located with the use of a UV/visible spectrophotometer, and then a compatibility investigation was conducted with the use of FTIR and DSC. Using the solvent evaporation process, buccal patches of tizanidine hydrochloride were prepared using varying ratios of polymer. Various tests for assessment were done, including thickness, weight variation test, folding endurance, swelling index, drug content assay, SEM, ex vivo bioadhesion research, in vitro diffusion study, kinetics of drug release, followed by stability of the formulation. The F10 formulation exhibited the best results, with a cumulative drug release percentage of 86.2% over 12 hours, according to the physicochemical parameters and in vitro release evaluations. This formulation contained a 4:3:3 ratio of hydroxypropyl methylcellulose (HPMC), eudragit, and tamarind gum, as well as permeation enhancers polyethylene glycol 400 (PEG-400) and dimethyl sulfoxide (DMSO). The study's results show that it is possible to construct a drug delivery system for Tizanidine hydrochloride, which is crucial for both therapeutic effectiveness and patient compliance.*

Key Words: *Tizanidine hydrochloride, Tamarind gum, buccal patch, spectrophotometer*

1.0 INTRODUCTION

Among the different transmucosal sites that are available, the buccal mucosa is the most appealing alternative location for systemic drug administration due to its extensive vascularization and expanse of relatively static smooth muscle (Sudhakar, Y., et al 2006) the buccal cavity makes self-medication easily accessible, which is why patients accept it. Furthermore, due to its low enzymatic activity in comparison to the gastrointestinal system, it represents a possible venue for regulated drug delivery of therapeutic medicines (Abruzzo, A., et al 2012). Due to its high permeability and typically abundant

blood supply, the buccal mucosa facilitates the quick absorption of drugs into the systemic circulation, which results in a quick beginning of action. Additionally, it typically prevents degradation by first-pass hepatic metabolism, which results in high bioavailability. Additionally, buccal mucosa has a number of benefits, including the ability to recover quickly from stress or damage, tolerance to certain allergens, and the ability to establish close contact between a dosage form and the absorbing tissue (Scholz, O. A. 2008) for both local and systemic action, it can be used to build a unidirectional or multidirectional release system. A variety of buccal adhesive delivery systems, including tablets, films, wafers, gels, and ointments, have been developed. However, of the several buccal dosage forms, buccal patches offer greater flexibility because they are very easy to apply and remove from the application site, allowing the medicine to be stopped whenever desired. Because the patches are smaller and thinner (Vasantha, P. V 2011) and don't require water, they also have better patient compliance. However, the short residence period at the application site is a specific issue with the buccal medication delivery technique. This issue might be resolved by using bioadhesive polymers. In general, bioadhesive polymers fall into one of two categories: natural or synthetic (Hearnden, V. 2012). However, because natural polysaccharides are readily available, inexpensive, and non-toxic, they are typically chosen over synthetic polymers.

Tamarind gum is derived by processing the endosperm of seeds of Tamarindus indica. It is a basic substance comprising a polysaccharide with glucose, xylose, and galactose in a 3:2:1 proportion. Physicochemical properties include a pH of 6.81±0.21 and a viscosity of 0.8928 poise. It is slightly soluble in cold water and insoluble in ethanol, methanol, acetone, and ether. It readily soluble in warm water and forms a thick colloidal solution. The gum is stable when it is kept at temperatures below 30°C. It is kept in a tightly covered vessel. Tamarind gum acts as a binder, an emulsifier, a suspending agent, and as sustaining agent. It is also used for more effective disintegration and extrusion nasal mucoadhesion, Sangwan, Y. K. et al 2011.

An imidazoline derivative called tizanidine hydrochloride (TZD HCL) acts as an agonist on centrally placed α2 receptors, causing myotonolytic actions on skeletal muscle. It shares structural and physiological similarities with other α2-adrenergic agonists, including clonidine. The precise mechanism by which tizanidine reduces muscular tone and spasm frequency is unclear. After oral treatment, the gastrointestinal tract absorbs roughly 53% to 66% of the dose, and the peak plasma concentration is reached in 1 to 2 hours. The half-life of tizanidine is 2.5 hours, and its bioavailability ranges from 34% to 40%. Goudanavar et al. report that plasma proteins bind 30% of the medications, resulting in their widespread distribution throughout the body. Due to its rapid and extensive first-pass metabolism in the liver (about 95% of a dosage), the sulfur atom, aromatic system, and imidazoline moiety are all oxidized. Reduced tizanidine bioavailability because of it. To avoid this substantial first-pass metabolism, the medication has been selected as a viable alternative for bioadhesive buccal drug delivery. Using the natural polysaccharide tamarind as a mucoadhesive polymer and drug release modifier, the goal of this work was to fabricate and test a tizanidine bioadhesive buccal patch that would exhibit sustained release of the medication, meeting the need for an anti-inflammatory and anti-asthmatic impact.

2.0 MATERIALS AND METHODS

2.1 Materials

Tizanidine hydrochloride had been obtained as a free sample from Neuland Laboratories (Hyderabad). Sodium alginate and Eudragit RL 100 were purchased as free samples from Merck (India). Polyvinyl alcohol, glycerin, and peppermint oil have been purchased from S.D. Fine Chemicals. All other chemicals and solvents comprised of analytical grade.

2.2 MUCILAGE EXTRACTION

2.2.1 Extraction of Tamarind Gum

Tamarind gum is made from the endosperm of tamarind tree seeds. The seeds are taken away from the tree and exposed to heat with sand for an extended period of time. This process is done to eliminate the coat. Following that, it is hammer milled and the earth using a grinder. Then it is passed using sieve number 100 (Zhang, J., et al 1994).

Collection of seeds → Heating with sand → Coat removal → Hammer milling → Grinding → Sieved using sieve number 100.

2.3 IDENTIFICATION OF DRUG

2.3.1 Analytical method for Tizanidine HCl

The technique of UV spectrophotometry represents one of the most constantly utilized in pharmaceutical evaluation. It comprises the measurement of the amount of the ultraviolet (190-380 nm) and visible (380-800 nm) light absorbed through a substance in solution. Tizanidine HCl may be evaluated by UV spectrophotometry in pharmaceutical formulations. (Goudanavar, P. S., 2010)

2.3.2 Preparation of calibration curve

100µg/ml (0.1mg/ml) the stock solution of medicine has been produced using methanol, and relevant dilutions have been made, i.e., 5 µg/ml, 10 µg/ml, 15 µg/ml, 20 µg/ml, and 25 µg/ml, appropriately The sample has been tested employing a UV spectrophotometer (schimadzu, UV-1700), and λmax of 318.5 nm was obtained. The absorbance of samples of varying concentrations at λmax (at 318.5 nm) was measured. The graph was produced between the absorbance and concentration. The graph followed Beer-Lambert's rule in the specified concentration range. A linear association was seen across the range of 5–25 µg/mL.

2.3.3 Melting Point Determination

One of the key difficulties in pharmacological research is the identification of melting points. Crystalline solubility is the fundamental explanation for establishing melting point during preformulation; these studies are particularly significant since exact solubility measurements are frequently inhibited by the restricted supply of medicine powder. The latent heat of fusion, or the amount of heat created during melting or fusing, is the relationship between melting point and solubility (Adhikari, S. N. R., et al 2017)

2.3.4 Hygroscopicity

In order to retain adequate chemical and physical stability in all relevant climatic conditions, medication salts should have minimal hygroscopicity. It should be less than 0.5% H2O at less than 95% RH as a working limit. The easiest technique to perform a hygroscopicity experiment is to expose the medicine to an environment with a known relative humidity.

After exposure a weighed amount of medicine to ambient conditions and a relative humidity of 60% and 70% for 48 hours, the petridishes were measured and the hygroscopicity was calculated.

2.3.5 Loss on drying

In pharmaceuticals, the term loss on drying indicates moisture content of a wet weight basis, and these is calculated as follows:

%LOD = WT OF WATER IN SAMPLE /TOTAL WT OF WET SAMPLE x 100

LOD is the weight loss as a percentage of weight owing to water and any volatile things that can be eliminated under specific conditions (if the substance is in the form of large crystal size lowered by quick crushing to powder).

One gram of medication was put in a petridish, covered, and gently shook to disseminate the substance as uniformly as possible. The tray dryer (Hicon, New Delhi) was adjusted at 105°C for the pertidish. The material was dried until its weight remained constant. After four hours, it was revealed that the dry loss was 0.3%, satisfying the requirement as per the NMT 0.5% limit. Drug powder of known weight was held at 60°C and 0.7 K Pascal. for four hours in order to quantify the loss on drying.

2.3.6 Solubility Study

Solubility can be described qualitatively as the spontaneous interaction of two or more substances to generate a homogenous molecular dispersion and technically as the concentration of solute in a saturated solution at a specific temperature.

Although it impacts the substance's bioavailability, rate of release into the dissolving media, and eventually the drug the product's efficacy for therapy, a drug's solubility is a critical physicochemical property.

Preformulation solubility studies focus on possible drug-solvent interactions that may develop throughout the pharmaceutical the applicant's administration.

2.3.7 Preparation of saturated solution

The equilibrium solubility technique, which employs a saturated solution of the material created by stirring an excess of material in the solvent for a long period (24 hours) until equilibrium is attained, is commonly used to determine a substance's solubility. The solution has been filtrated through sintered filter and absorbance has been determined at 318.5 nm using UV spectrophotometer.

2.4 METHOD OF PREPARATION FOR FORMULATION OF BUCCAL PATCHES

General manufacturing method: Tizanidine HCl matrix type buccal patches were created utilizing molding processes for this investigation. For that purpose, a flat circular glass mold with a 4.5 cm diameter and a 15.5 sq. cm total surface area was produced (Hemalatha, C.,et al 2021) .

2.4.1 Dose fixing calculation

Dose of Tizanidine HCl 16 mg a day, as divided dose Calculation for buccal formulation

Surface area of the final circular patch = πr^2 = 3.14 x 1.9 x 1.9

= 11.33 sq.cm

Surface area of the mold = 15.5 sq.cm

≡ 11.33 sq.cm a drug should be found to contain 16mg

How much mg of drug should be present in ≡ 15.5 sq.cm

≡ (16 x 15.5) / 11.33

= 21.88 mg

= 22 mg

A solution containing 22 mg of Tizanidine HCl was used to prepare the buccal formulations.

2.4.2 Preparation of buccal patches

The solvent evaporation procedure was employed to create the buccal patches comprising tizanidine HCl. Utilizing ethanol to serve as solvent for Eudragit RL 100 and ethanol: dichloromethane (1:1) as a solution for HPMCK-15M and Tamarind gum polymer, matrix-type controlled buccal drug delivery devices have been constructed. To generate a uniform, clear solution, the polymer solutions using different quantities was blended and swirled on a magnetic stirrer for each batch of formulations. The medication was then progressively added to the polymer solution and carefully mixed to generate a homogeneous solution. Dimethyl sulfoxide (DMSO) was utilized as a penetration enhancer and combined, with the addition of polyethylene glycol 400 (PEG 400) as a plasticizer. The drug's polymeric solution was applied to the mercury surface, covered with an inverted funnel, and allowed to dry at room temperature in a dust-free setting. The patch was cut to a diameter of 3 cm after a day and then wrapped in aluminum foil and placed into self-sealing covers. The petridish's surface area significantly influences how much medicine is needed in it. Buccal patches were made applying varied quantities of plasticizer, penetration enhancer, and polymer ratio (Hamman, H., et al 2015).

Table 11: Composition of buccal patch of Tizanidine HCl

Batch	Drug (mg)	HPMC K15M (mg)	Eudragit (mg)	Tamarind gum (mg)	Plasticizer (ml)	Penetration enhancer (ml)	Solvent (ml)
F1	22	100	50	_	1	1.5	20
F2	22	150	50	_	1	1.5	20
F3	22	200	50	_	1	1.5	20
F4	22	150	100	_	1	1.5	20
F5	22	200	150	_	1	1.5	20
F6	22	100	50	100	1	1.5	20
F7	22	150	50	100	1	1.5	20
F8	22	200	50	150	1	1.5	20
F9	22	150	100	150	1	1.5	20
F10	22	200	150	150	1	1.5	20

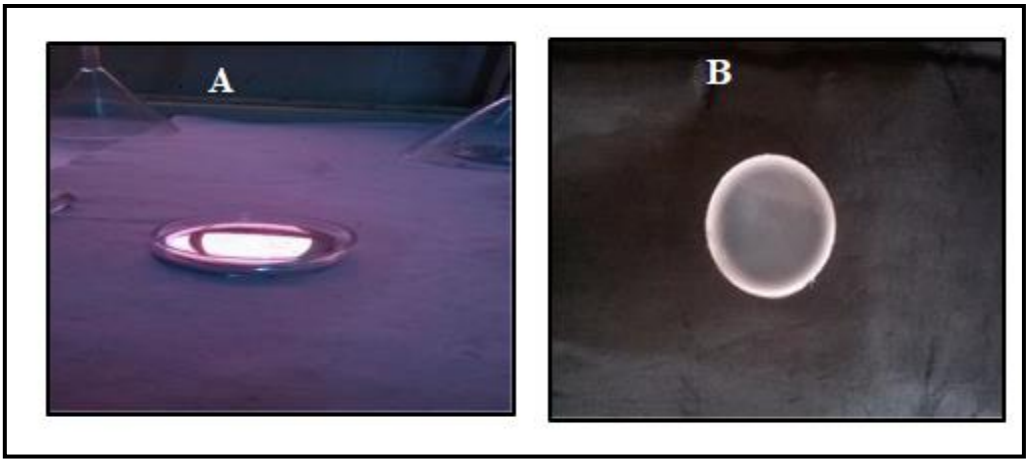

Figure 17(A): Casting Solution in Glass Moulds, (B): Prepared Buccal Patch

2.4.3 Effects of process variables on physicochemical parameters:

he physical characteristics, thickness, weight variation, folding endurance, moisture absorption, amount moisture content, tensile strength, surface pH, quantity of drug, uniformity in behavior, in-vitro drug release and residence time, and mucoadhesive strength had been within the physical characteristics that have been studied in relation to the effects of process-related factors, which involve distinct polymer ratios(HPMC K15M, Eudragit RL and Tamarind gum polymer), plasticizer concentration, and distinct types of penetration enhancers. The precise sort of polymer and its concentration, the ratio, quantity of plasticizers, along with the type of permeation enhancer utilized, and other elements are critical in managing the drug's release from the buccal patches.

Several buccal patch formulations are produced in order to test the impact of these qualities. A set dose of medication (22 mg) is added to 10 ml of the completed formulation in each of these formulations. In varying amounts, HPMC K15M, Eudragit RL100, and tamarind gum polymers are mixed with additional components, including plasticizer and permeability enhancers (Reddy, G. M.,et al 2008)

3.0 CHARACTERIZATION OF BUCCAL PATCH

The developed buccal patches were analyzed for the following criteria: Physicochmiecal characteristics In-vitro diffusion tests Compatibility studies

3.1 Physicochemical parameters:

The matrices generated have been examined for the following parameters:

3.1.1 Physical Appearance

All the buccal patches have been examined for color, flexibility, homogeneity and texture. The patch has been shown to have consistently creamy white color having homogenous appearance, flexible and smooth surface texture.

3.1.2 Film Thickness

The thickness has been determined at five separate spots employing a digital micrometer and average results were obtained.

3.1.3 Weight fluctuation

Drug content and, thereby, in-vitro release pattern might be dependent on the weight of the developed patches. For the created patches, a weight variation test was carried out. A digital balance was employed to weigh each patch when they were cut into 1 sq. cm pieces. The formula listed below was used for determining each patch's average weight and standard deviation; the results are shown in the table.

Where, Std. Deviation (σ) = $\sqrt{\Sigma}$(X1 - X2)2 ÷ $\sqrt{}$n-1

X1= weight of each patch (mg)

X2 = average weight (mg)

n = number of observations

3.1.4 Surface pH

To look into the likelihood for any in vivo harmful consequences, the buccal patches' surface pH was measured. The aim was to preserve the surface pH as close to neutral as feasible because an acidic or alkaline pH can irritate the buccal mucosa. For this, a composite glass electrode was employed. For one hour at room temperature, the buccal patch was kept in contact with one ml of distilled water to allow it to expand. By laying the electrode on the patch's surface and having it equilibrate for a minute, the pH was determined.

3.1.5 Drug content homogeneity

The buccal patch of each batch was dissolved using homogenization in 100 ml of a phosphate buffer (pH 6.8) for 6 hours under frequent agitation for the purpose to test the homogeneity of the drug content. A 0.45 µm syringe filter had been employed to filter the 5 ml solution after it had been diluted with phosphate buffer pH 6.8 to 20 ml. A UV spectrophotometer was subsequently employed to quantify the medication concentration at 274 nm after proper dilution.

3.1.6 Folding endurance

One patch had been folded repeatedly in the precise same area until it broke to evaluate the patch's folding durability. The value of folding endurance was calculated by the quantity of times the patch might be folded at the same place without breaking. Modified patches were applied for this test.

3.1.7 Moisture content

The current experiment assessed the moisture content of the generated patch by keeping it under vacuum desiccation until consistent weights were attained. This was performed considering the moisture content may alter the mechanical strength and drug release characteristics of the buccal therapeutic devices. The following equation was used to determine the patch's % moisture content.

$$\% \text{ Moisture content} = \text{Initial weight} - \text{Final weight} / \text{Initial weight} * 100$$

3.1.8 Moisture absorption

Each formulation's 1 cm2 patch, which are stored in a desiccator with anhydrous CaCl2, have been collected, properly weighed, then subjected to ambient air conditions throughout three days. The mean temperature was 34°C, and the humidity was 75%. Three working days afterwards, the films were evaluated again, and the amount of moisture absorption was then determined. Every film's average percentage of moisture absorption had been determined.

% Moisture Absorption = Initial weight − Final weight / Initial weight ∗ 100

3.1.9 Swelling index study

Each formulation's increase in weight associated with swelling was recorded in order to calculate the swelling study of the created buccal patch. Every batch's patch had been measured on a cover slip that had previously been weighed. 10 ml of phosphate buffer (pH 6.8) had been added while it was on a petri plate. The cover slip was pulled out and weighed after eight hours. Because of water absorption and patch swelling, the weight discrepancy leads to an increase in weight (Iqbal, H., Naz, S. et al 2020). The following formula was used to compute the % weight and swelling ratios based on the average of three measurements:

$$\% \text{ Swelling Index} = Xt - X0 / X0 \times 100$$

Where, Xt- weight or area of the swollen patch following time t and Xo- is the initial patch weight or area at zero period.

3.1.10 In-vitro drug release studies

In-vitro permeation tests were done employing Franz diffusion cell through cellophane membrane (Pereswetoff- Morath, L.1998)

3.1.10.1 Diffusion Cell

Cellophane membrane was utilized for the test. Permeation experiments were done utilizing the modified Franz diffusion cell, which contains two compartments: a donor compartment and a receptor compartment. To regulate the temperature at 37 °C, a water jacket was installed over the receptor compartment. A phosphate buffer solution with a pH of 6.8 was introduced to the receptor chamber. Over it was the cellophane membrane. In phosphate buffer, the membrane was permitted to stable for the full night. Following stabilization, samples were withdrawn and the sink state was maintained when the patch was placed on the membrane for eight hours at a time. At 318.5 nm, the aliquot was submitted to spectrophotometric analysis. There was a link between cumulative drug release and drug penetration (Shanker, G.,. 2009)

Figure 2: Modified Franz Diffusion Cell

The following formula is employed to calculate the amount of drug released and percentage drug release.

Amount of drug released (mg) = K x abs + B x dilution factor x volume of receptor fluid

% Released = Amount released / Drug content × 100

3.1.10.2 Determination of *in vitro* residence time

A USP disintegration device was employed to determine the in vitro residence time. 800 cc of pH 6.8 phosphate buffer maintained at 37±0.5°C constituted the disintegration medium. A 3 cm long piece of goat buccal mucosa was attached into a glass slab and mounted vertically to the equipment.

Employing 15µl of pH 6.8 phosphate buffer, one surface of the buccal patch was moistened before coming into interaction with the mucosal membrane. To check that the patch were totally immersed in the buffer solution at its lowest point and out at the highest, the glass slab was mounted on the apparatus vertically and permitted to move up and down. The time necessary for complete attrition or detachment of the patch of each individual batch from the mucosal surface was measured.

3.2 Measurement of mucoadhesive strength

Using the procedure given by Gupta et al., the mucoadhesive strength of each manufactured buccal patch was evaluated ex vivo (n=3) on a modified physical balance. The open lip of a glass vial that was entirely filled with isotonic phosphate buffer (pH 6.8) had a piece of pig buccal mucosa connected to it. In the center of a beaker containing isotonic phosphate buffer (pH 6.8; 37±1°C), the glass vial was securely inserted. Using adhesive, the patches were glued to the rubber stopper's underside. Mucoadhesive strength (shear stress) was determined by the mass (in grams) needed to detach the patches from the mucosal surface (Pendekal, M. S., 2012). Mucoadhesive strength was employed to acquire the following metrics.

Force of adhesion (N) = Bioadhesive strength (g) × 9.81 / 1000

3.3 Stability studies

For investigation of dosage forms, the prolonged stability of the active component became an important element in selecting their acceptance or rejection. For the purpose of to confirm recommended storage settings, retest intervals, and shelf-lives, stability testing is intended to clarify that the quality of a drug

ingredient or drug product evolves over time under the impact of diverse environmental variables, particularly temperature, humidity, and light. The stability test parameters for drug registration requests in the US, Japan, and the EU are described under the "Stability testing of New Drug Substances and Products" guidelines produced by the International Conference on Harmonization (ICH) (Someshwar, K.,. 2007)

4.0 RESULT AND DISCUSSION

4.1 Identification of drug

4.1.1 Analytical method for Tizanidine HCl

The technique of ultra-violet spectrophotometry has been one of the most regularly utilized in pharmaceutical evaluation. It encompasses the measurement of the amount of the ultra violet (190-380nm) or visible (380-800 nm) light absorbed by a substance in solution. Tizanidine HCl may be tested by UV spectrophotometrically in a drug formulation. A solution of Tizanidine HCl in methanol provides maximum absorbance at λmax of 318.5 nm.

Table 12: Calibration curve of Tizanidine HCl

Sr.NO	CONC. (µg/ml)	Absorbance at λmax nm
1	0	0
2	5	0.03
3	10	0.094
4	15	0.157
5	20	0.24
6	25	0.275

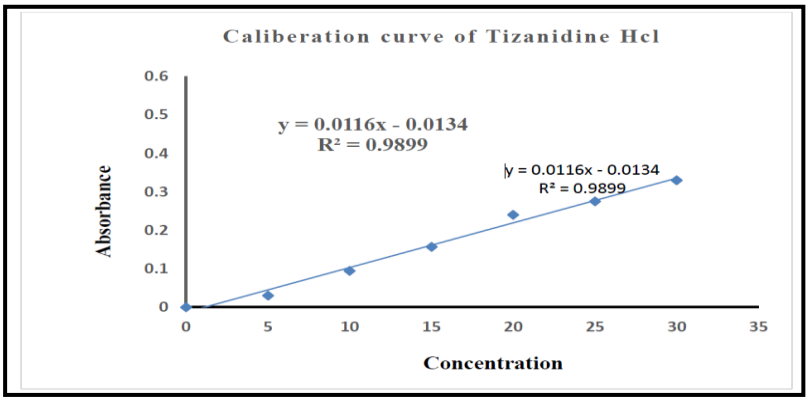

Figure 3: Calibration curve of Tizanidine HCL

4.1.2 Melting Point Determination

It was found that melting point of drug is 280°C.

4.1.3 Hygroscopicity

Table 13: Hygroscopicity of drug at room and accelerated condition

Temperature/ relative humidity	Hygroscopicity
25◦ C and 60 % RH	1.3 %
40◦ C and 75 % RH	0.54 %
At room temperature	0.75 %

4.1.4 Loss on drying:

Loss on drying was determined by keeping drug powder of known weight at 60°C for 4 hrs., the result was found to be 0.65 %

4.1.5 Solubility Study of Tizanidine HCl

Table 4: Solubility of Tizanidine HCl in various solvent

Sr No.	Solvent	Conc.(mg/ml)	Volume of solvent in ml/gm of solute	Solubility
1.	Cyclohexane	27655	More than 10,000 part	Practically insoluble
2.	Methanol	1.685	1-10	Freely soluble
3.	Chloroform	9.36	1-10	Freely soluble
4.	Water	0.925	1-10	Freely soluble
5.	2% Acetic acid	4.14	1-10	Freely soluble

4.1.6 Fourier Transform Infrared (FT-IR) Spectroscopy

IR spectra of the optimized buccal patch with HPMC, eudragit, tamarind gum polymer, and tizanidine hydrochloride were obtained, as well as spectra of the pure drug. buccal patch that is optimized in comparison to the drug's pure form. The spectra were examined to make sure the drug's distinct peaks were present and that the spectrum obtained for the drug with the optimized buccal patch did not contain any anomalous peaks.

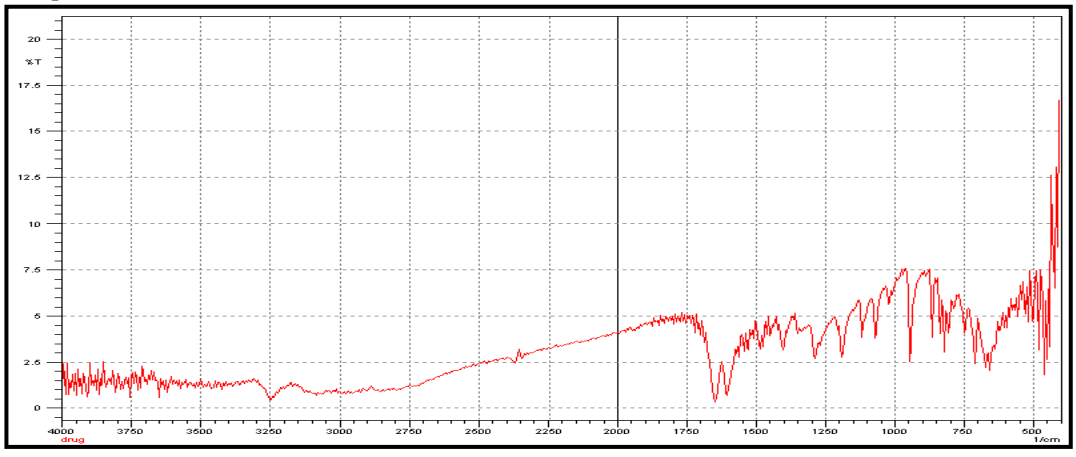

Figure 4: IR Spectrum of Tizanidine HCL

Table 5: Interpretation of IR Spectrum of Tizanidine HCL

TYPE	NATURE	WAVE NUMBER
C-H str	Variable	3100 cm^{-1}
C-H bend	Sharp, Strong	700 cm^{-1}
C-C str	Weak	1490 cm^{-1}
C-Cl	Medium	650 cm^{-1}
C=N	Sharp, Strong	1650 cm^{-1}
N-H str	Medium	3650 cm^{-1}
N-H bend	Sharp, Strong	1600 cm^{-1}
Ar-NH-R	Medium	3250 cm^{-1}
Sharp, Strong	Medium	1600 cm^{-1}
CN str	Medium	1300 cm^{-1}
CN str	Medium	1200 cm^{-1}
C-H bend	Sharp, Strong	700 cm^{-1}

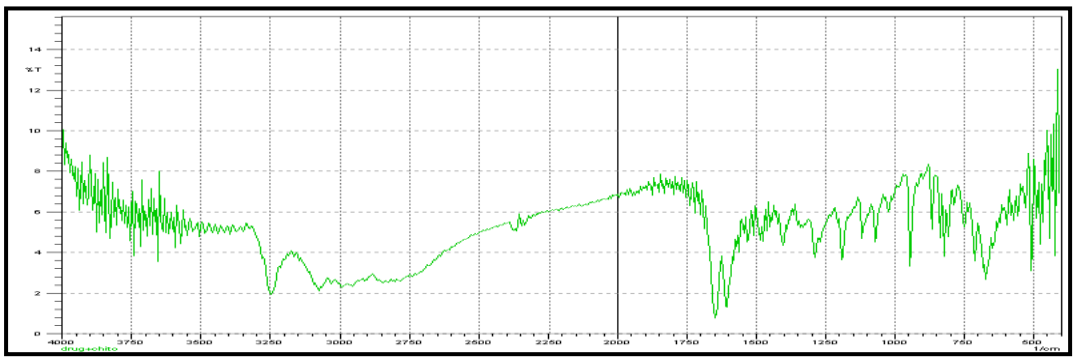

Figure 5: IR Spectrum of drug polymer mixture of Optimized formulated Buccal patch of Tizanidine HCL

From the IR spectra drug polymer mixture of optimized formulated Buccal patch of Tizanidine HCL, it can be concluded that there is no interaction between drug polymer mixture.

4.2 Evaluation of medicated patches

4.2.1 Physicochemical Characterisation

10 patches altogether were produced for this experiment. The physicochemical properties of the produced buccal patches, comprising appearance, weight deviation, thickness, folding endurance, moisture content, absorption of moisture, drug content, in-vitro drug release, in-vitro drug residence length, and mucoadhesive strength, have been assessed. The physical properties of the diverse formulations were studied, particularly their homogeneity, stickiness, flexibility, transparency, and smoothness. The drug was evenly spread throughout the film, and no particles could be noticed. Table 6 displays the patches' physicochemical evaluation data.

The newly created buccal patch was discovered to have a clear, smooth, flexible, and non-

sticky basis. Patches vary in thickness from 0.150± 0.038 mm to 0.183± 0.040 mm. The patch's weight ranged from 80.50 ± 0.15 mg/cm2 to 137.78 ± 0.93 mg/cm2. Most of the patches' folding endurance values varied from 210 to 253, demonstrating that the inclusion of plasticizer and hydrophilic polymers (HPMC and tamarind gum) might result in increased flexibility and folding endurance. Based on the findings, the patches would keep intact when put using standard skin folding (Akhlaq, M.. et al 2021).

Considering a lower concentration of HPMC, the moisture content and absorption have been shown to be low. The hygroscopic feature of HPMC was accountable for the increase in moisture content (from 2.90% to 11.70%) and moisture absorption (from 2.70 to 13.05%) when the HPMC concentration increased.
For every formulation, which varied from 94.5% to 98.90%, there was excellent stability in the proportion of drug content across the patches. These data suggest that the technology utilized to generate the films for this experiment was able to develop films with consistent drug content and negligible batch variation.

Table 6: Effect of polymer ratio on Buccal patch of Tizanidine HCl (F1-F10)

Patches	Polymer ratio (HPMC :eudragit)	Avg. Thickness (mm)	Avg. Weight (mg/cm^2)	Folding Endurance	% moisture content	% moisture Absorption	%Drug Content (mg/cm^2)	Surface pH	Swelling Index
F1	2:1	0.150 ±0.038	80.50 ±0.15	210	2.90	2.70	95.6	6.25	12
F2	3:1	0.152 ±0.044	82.30 ±0.75	214	3.73	4.70	96.6	6.30	21
F3	4:1	0.157 ±0.031	84.40±1 .11	225	5.80	6.50	94.5	6.29	27
F4	3:2	0.163±0 .026	86.52 ±1.48	230	8.30	9.59	98.7	6.40	34
F5	4:3	0.168 ±0.034	89.50± 1.18	237	10.50	12.75	96.8	6.32	37
F6	2:1:2	0.156 ±0.031	108.91 ± 0.81	241	3.81	4.86	96.25	6.29	39
F7	3:1:2	0.163 ±0.015	117.23 ± 0.89	245	4.60	5.50	98.90	6.34	40
F8	4:1:3	0.167 ±0.019	121.17± 1.21	248	6.20	7.80	96.25	6.27	42
F9	3:2:3	0.171±0 .027	124.34 ± 1.58	250	7.30	8.20	97.72	6.30	44
F10	4:3:3	0.183 ±0.040	137.78 ± 0.93	253	11.70	13.05	98.80	6.42	38

4.2.2 *In-vitro* drug permeability studies of Buccal patch of Tizanidine HCl

The cellulose nitrate membrane was employed to investigate the in-vitro drug absorption of buccal patches, and the proportion of medication released throughout a 12-hour period was measured. It was shown that the proportion of medication release grew in accordance with the quantities of tamarind gum and HPMC. These patches may have higher permeability owing to their hydrophilic character, which enhances the drug's thermodynamic activity in addition to the film's porosity and diffusivity. From

80.2% and 85.8% represented the cumulative percentage of drug penetration across various formulations. The order in which in which the total quantity of medication released from various formulations arose was F10>F9>F8>F7>F6>F5>F4>F3>F2>F1>F1.

The water vapor permeating the films could be the cause of an enhanced release rate. When an adjuvant is applied to a polymer, it breaks the chain's continuity, which diminishes molecular order and increases chain mobility in the polymer matrix. Permeability is consequently improved. increased drug release may be the outcome of better permeability (A.M. Abdel Azim, et al 2014)

While hydrophilic polymers and plasticizer were utilized coupled, the amount and rate of drug release generated by the patches was larger than if they were used alone, based on in-vitro drug release tests. Through an overall drug release of 86.2% in 12 hours, the F10 formulation with a 4:3:3 ratio of HPMC to Eudragit polymer to Tamarind gum, plasticizer polyethylene glycol 400, and DMSO as a permeability enhancer showed the best results across the various combinations of films, based on the studies that were conducted (Karthik, M., & Sunil, R., 2017).

Table 7: In vitro *drug permeation of buccal patch of Tizanidine HCl from (F1-F5)*

Time (Hours)	**Formulation 1 (HPMC:Eudragit) (2:1)**		**Formulation 2 (HPMC:Eudragit) (3:1)**		**Formulation 3 (HPMC:Eudragit) (4:1)**		**Formulation 4 (HPMC:Eudragit) (3:2)**		**Formulation 5 (HPMC:Eudragit) (4:3)**	
	Amt.of Drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release
0	0	0	0	0	0	0	0	0	0	0
0.5	1.35	10.5	1.50	11.3	1.41	10.4	1.68	12.3	1.60	11.7
1	2.47	18.2	2.63	19.2	2.57	18.8	2.43	17.8	2.52	18.5
2	4.40	32.4	4.76	34.8	4.60	33.6	4.68	34.2	4.88	35.6
4	6.70	49.7	6.85	50.2	6.76	49.4	6.67	48.7	6.77	49.8
6	8.30	61.2	8.65	63.4	8.37	61.1	8.24	60.2	8.57	62.5
8	9.50	69.5	9.71	70.9	9.56	69.8	9.75	71.2	9.60	71.7
10	10.25	75.0	10.40	76.0	10.56	77.1	10.38	75.8	10.65	77.5
12	10.95	80.0	11.17	81.5	11.24	82.1	11.35	82.9	11.59	84.6

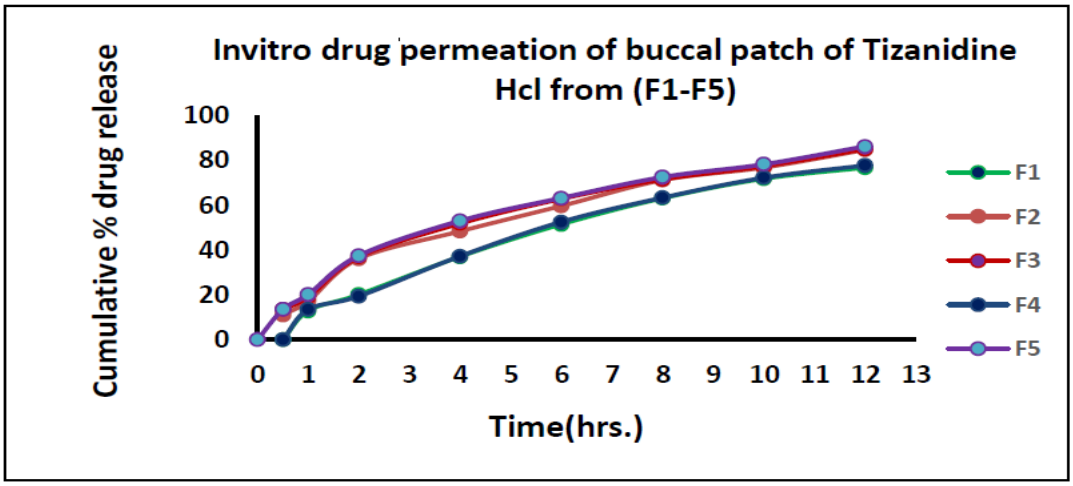

Figure 7: In vitro *drug permeation of buccal patch of Tizanidine Hcl from (F1-F5)*

Table 8: In vitro *drug permeation of buccal patch of Tizanidine HCl from (F6-F10)*

Time (hr)	Formulation 6 (HPMC:eudragit: Tamarind gum) (2:1:2)		Formulation 7 (HPMC:eudragit: Tamarind gum) (3:1:2)		Formulation 8 (HPMC:eudragit: Tamarind gum) (4:1:3)		Formulation 9 (HPMC:eudragit: Tamarind gum) (3:2:3)		Formulation 10 (HPMC:eudragit: Tamarind gum) (4:3:3)	
	Amt.of Drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release	Amt.of drug release (mg)	% Drug release
0	0	0	0	0	0	0	0	0	0	0
0.5	1.70	12.8	1.51	11.0	1.84	13.5	1.85	13.5	1.90	13.5
1	2.70	20.1	2.36	17.2	2.58	18.9	2.64	19.3	2.75	20.2
2	5.05	37.0	4.94	36.1	5.04	36.8	5.10	37.2	5.13	37.5
4	7.04	51.4	6.62	48.3	7.08	51.7	7.17	52.5	7.25	53.0
6	8.52	63.0	8.18	59.6	8.58	62.7	8.65	63.3	8.68	63.2
8	9.18	71.7	9.74	71.1	9.78	71.4	9.90	72.2	9.92	72.5
10	10.50	76.6	10.50	76.7	10.59	77.3	10.5	77.7	10.70	78.2
12	11.55	84.5	11.60	84.6	11.64	85	11.7	85.9	11.75	86.2

4.2.2.1 Inference

Within the established buccal patches of Tizanidine HCl, the the manufacturing F10 (HPMC: eudragit: Tamarind gum, 4:3:3) displays a sustained release of Tizanidine HCl for 12 hrs and hence mixture of HPMC, eudragit and Tamarind gum is an ideal for a sustained release drug delivery of Tizanidine HCL (Mishra, S., Kumar, G., & Kothiyal, P. 2012).

Therefore, polymer mixture of (HPMC: eudragit: Tamarind gum, 4:3:3 appears to be an optimum combination for Tizanidine HCL buccal patch, as it demonstrates improved folding durability, consistency of drug content and prolonged release of medication. Finally formulation F10 regarded as optimal formulation throughout ten formulation of Tizanidine HCl buccal patch (Sridhar I, Doshi A. 2013).

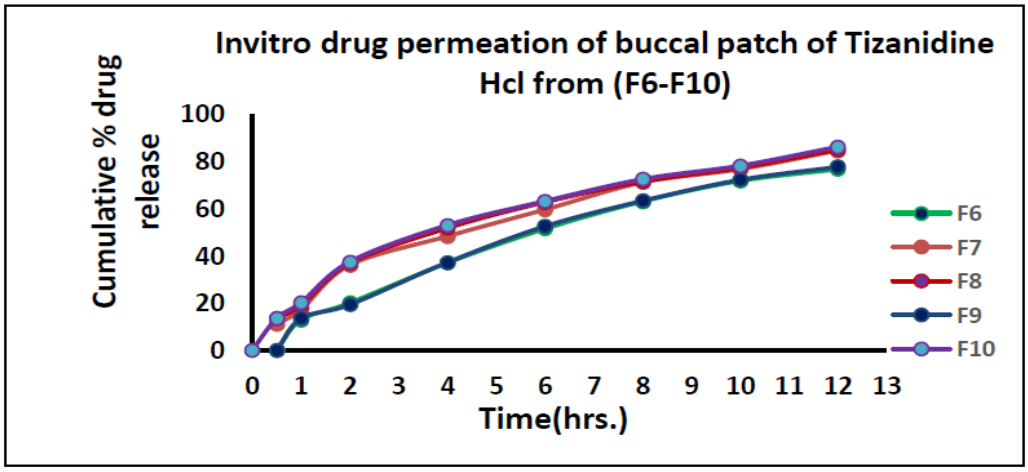

Figure 8: In vitro *drug permeation of buccal patch of Tizanidine HCl from (F6-F10)*

4.2.3 *In vitro* adhesion studies

Maintaining drug release requires that patches adhere to the oral mucosa. The greater concentration of mucoadhesive polymer ratio HPMC to Eudragit polymer to Tamarind gum ratio 4:3:3 made formulation F10 more mucoadhesive. Reduced intermolecular attraction between the polymers due to the decreased concentration of plasticizer (polyethylene glycol 400) results in an added mucoadhesive force, which in turn diminishes a polymer mucous contact (Ganesh, G. N.et al 2010).

Table 9: Results of the in vitro *mucoadhesion study of buccal patch of Tizanidine HCl from (F10)*

Formulation	F10
Mucoadhesive strength (g)	30.12±71.14
Force of adhesion (N)	0.30±70.01
Detachment force (N/m^2)	167.24±73.16

4.2.4 Release kinetics of optimized buccal patch of Tizanidine HCl (F10)

The results of drug release kinetics study were tabulated on the basis of *in-vitro* diffusion study data.

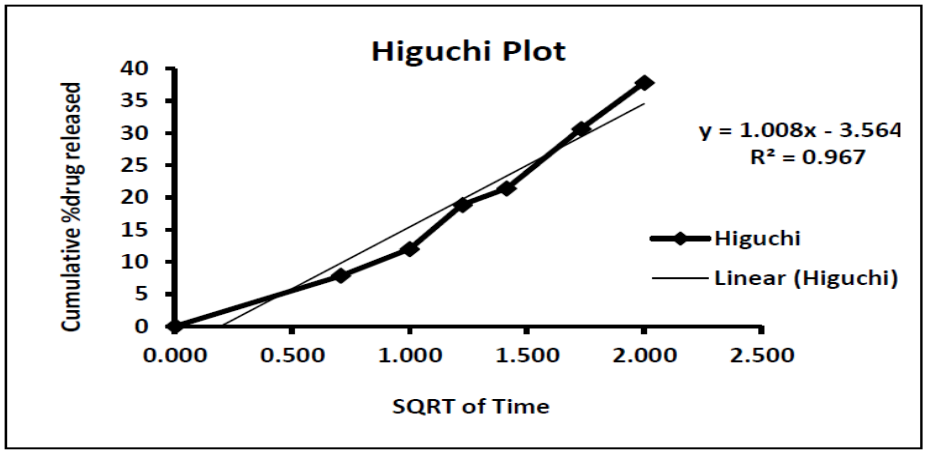

Figure 9: Higuchi plot of optimized buccal patch of Tizanidine HCl (F10)

4.2.5 Kinetic Study

Correlations of coefficient values of various kinetic models with respect to the *in-vitro* permeability study of F10 were tabulated to determine the best-fit model and the mechanism of diffusion for buccal patch of Tizanidine HCl (F10) (Adhikari, S. N. R., & Panda, S. 2017).

Table 10: Correlation of coefficient values of various kinetic models for optimized buccal patch of Tizanidine HCl (F10)

Formulation Code	**Correlation coefficient value (R^2)**				
	Zero order kinetic Model	First order Model	Higuchi's Model	Hixson Crowell Model	Korsmeyer-Peppas Model
F10	0.8910	0.673	0.967	0.8502	0.8179

4.2.5.1 Inference

The data have to be adjusted to a mathematical model for the purpose to further clarify the release behavior of tizanidine HCl from buccal patches. The Higuchi square root model is the dominant mathematical model utilized to fit the kinetics of drug release from patches, considering the presence of additional models (Shivhare, P. 2016). Because the correlation coefficient values associated with Higuchi's model of all the formulations are comparatively higher and closer to 1.0 (0.967) than the zero-order, first-order, and Hixson-Crowell models, this release kinetic modeling shows that the formulated buccal patch of Tizanidine HCl encounters Higuchi's kinetic release.

Plotting of the results for formulations F10 yielded correlation values of 0.967, correspondingly showing that drug release proceeded via diffusion throughout the film matrix. The values of kH have been determined to be 532.5 mg/(cm2 min1/2).

4.3 Stability studies

The formulation F10 was also exposed to a stability analysis for ninety days at 40°C ± 2°C and 75% RH ± 5% RH under humidity control. To anticipate the probable deterioration that could happen during lengthy storage at various temperatures and humidity levels for formulations F10 over a 90-day period, stability studies were done. Table 11 displays the findings of the formulation's monitoring of appearance, surface pH, drug content, in vitro residence duration, in vitro drug release, and ex vivo penetration. When compared to the new formulations F10, the findings suggested a slight reduction in the formulations' in vitro release.

Table 11: Stability studies of optimized buccal patch of Tizanidine HCl (F10)

Patches	**Avg. Thickness (mm)**	**Avg. Weight (mg/cm^2)**	**Folding Endurance**	**%Drug Content (mg/cm^2)**	**Surface pH**	**Swelling Index**	***In-vitro* drug release after 12hr)**	**Mucoadhesive strength (g)**
Initial	0.183± 0.04	137.78 ± 0.93	253	98.80	6.42	38	86.2	30.12±71.14
First month	0.183± 0.04	137.75 ± 0.95	251	98.59	6.41	39	86.0	30.05±71.10
Second month	0.183± 0.04	137.75 ± 0.97	250	98.50	6.42	40	86.0	30.02±71.08
Third month	0.183 ±0.04 0	137.76 ± 0.99	247	98.35	6.43	40	85.8	30.05 ±71.11

5.0 CONCLUSION

Matrix-type buccal patches of Tizanidine HCl were successfully efficiently generated employing the solvent evaporation process. Tizanidine hydrochloride is a centrally acting a2-receptor agonist that modulates myotonolytic activities on skeletal muscle. It has a short half-life of 2.5 h, a low bioavailability of approximately 40 percent, and an extensive dispersion throughout the body. Tizanidine hydrochloride experiences substantial first-pass metabolism. In the attempt to conquer such considerable first-pass metabolism, tizanidine hydrochloride has been chosen as a candidate for generate of the matrix buccal system. Different proportions of HPMC, eudragit, and tamarind gum have been used as a polymer mix for the production of buccal patches. Polymeric matrix-type Tizanidine hydrochloride buccal patches have been generated by the technique of solvent evaporation, applying a mixture of HPMC, eudragit, and tamarind gum in varying quantities with the plasticizer polyethylene glycol-400 and diffusion enhancer dimethyl sulfoxide, that showed good flexibility, proper physicomechanical characteristics, working characteristics, and release of drugs. In accordance with the chemical properties and in vitro release testing, the F10 formulation with (HPMC: eudragit: tamarind gum) in the ratio 4:3:3 with PEG-400 and DMSO as a diffusion enhancer produced the best results, and that exhibited the cumulative percentage of drug release of 86.2% in twelve hours of administration. The compatibility testing employing IR spectroscopy indicated that there were no physical or chemical interactions between the drug and polymers. Based on the favorable results, the Tizanidine hydrochloride buccal patch is one of the best controlled drug delivery systems in the treatment of spasms and elevated muscle tone, where the medicine remains approachable for an extended period of time, so repeated administration can potentially minimized. The effort was made to create the full buccal system of the drugs through the placement of the backing membrane and release liner. Through the findings presented here, it may be assumed that it is feasible for developing a buccal drug delivery system using tizanidine hydrochloride, in which therapeutic efficacy and patient compliance would be of essential

significance. However, long-term pharmacokinetic and pharmacodynamic investigations are necessary to be undertaken to establish the efficacy of these patches.

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Bio-exploring Marine-actinomycetes: Techniques and Advances in the Isolation of Bioactive Compounds

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Abstract: *Marine actinomycetes are the richest and most under-explored sources of bioactive natural products, with an enormous potential for drug discovery and other biotechnological applications. Their unique, undiluted stress of high salinity, pressure, and temperature conditions is often associated with considerable metabolic diversity and adaptability that novel bioactive metabolites display. This paper gives a holistic view of the current bioprospecting approaches for the isolation of marine actinomycetes and their subsequent utilization. Both conventional methods as represented by selective media and pretreatment approaches and state-of-the-art approaches like metagenomics, co-culturing, and high-throughput screening are discussed. These new approaches were adopted to deal with some of the growth impediments faced by these microorganisms, most of which are recalcitrant to growth under standard laboratory conditions. This role of modern analytical tools in the identification and structural elucidation of novel compounds is emphasized-metabolomics, mass spectrometry, and NMR spectroscopy. Recent breakthroughs in genome mining and bioinformatics address a review and revolution in the discovery of cryptic metabolites and biosynthetic gene clusters. Yet, there is potential in the complete unleashing of marine actinomycetes for new antibiotics, anti-cancer agents, and other values bioactive compounds by combining the traditional microbiological methods with the latest molecular tool. This paper shall comment on the current trends and challenges in the future prospects of marine actinomycete bioprospecting, thereby pointing to its importance in the pursuit of novel natural products*

Key Words: *Marine actinomycetes, bioprospecting, bioactive compounds, metabolite isolation, selective cultivation, high-throughput screening, metabolomics, natural product discovery*

1. INTRODUCTION:

Marine actinomycetes are a distinct group of filamentous, Gram-positive bacteria belonging to the phylum **Actinobacteria**, predominantly from the genus Streptomyces. They are widely recognized as prolific producers of bioactive secondary metabolites with diverse chemical structures and biological activities. The unique and often extreme conditions of marine environments—such as high salinity, fluctuating temperatures, and immense pressure—shape the metabolic capabilities of these microorganisms, enabling them to synthesize compounds not typically found in terrestrial counterparts (Bérdy, 2005; Wu et al., 2023). With over 70% of the Earth's surface covered by oceans, marine environments represent a largely untapped reservoir of microbial diversity. Marine actinomycetes, in particular, have adapted to thrive under challenging ecological conditions, leading to the evolution of novel biosynthetic pathways. These adaptations not only aid in microbial survival but also result in the production of metabolites with significant pharmaceutical and biotechnological potential (Zhang et al., 2023).Recent years have witnessed a surge in interest in marine actinomycetes due to their ability to produce a range of secondary metabolites, including antibiotics, anticancer agents, and enzyme inhibitors. These metabolites have gained prominence in the pharmaceutical industry for their potential to address critical global challenges, such as antimicrobial resistance and emerging infectious diseases. The discovery of compounds like Salinosporamide A from Salinispora tropica underscores the transformative impact of marine actinomycetes in drug discovery (Mincer et al., 2005; Wu et al., 2023). Despite their immense potential, the exploration of marine actinomycetes remains challenging. Many strains are unculturable under standard laboratory conditions, limiting their accessibility. Advances in cultivation techniques, metagenomics, and analytical technologies have facilitated the study of these microorganisms, enabling researchers to uncover their untapped biosynthetic potential (González et al., 2023; Xu et al., 2023).

2. Importance of Marine Actinomycetes in Drug Discovery

Marine actinomycetes, a subset of actinobacteria found in marine environments, have emerged as a pivotal group of microorganisms in the quest for new bioactive compounds. Their significance in drug discovery is underscored by their ability to produce a diverse array of secondary metabolites with unique chemical structures and potent biological activities.

2.1. Unique Metabolites from Marine Actinomycetes

Marine actinomycetes are prolific producers of **secondary metabolites**, which are organic compounds not directly involved in the growth, development, or reproduction of the organism but play crucial roles in defense and ecological interactions. The harsh and variable marine environment exerts selective pressure on microorganisms, prompting the evolution of **distinct metabolic pathways** that lead to the production of novel bioactive compounds. These metabolites often have **unique chemical scaffolds** that are not typically found in terrestrial actinomycetes, making marine actinomycetes an untapped source of new chemical entities.

Diverse Classes of Bioactive Metabolites

1. **Polyketides and Non-Ribosomal Peptides (NRPs):**
    - Polyketides, synthesized by polyketide synthases (PKSs), are a dominant class of bioactive metabolites. For instance, **Marinomycin A**, a dimeric macrolide, demonstrates potent antimicrobial and anticancer properties (Wu et al., 2023).
    - Non-ribosomal peptides, such as **Cyclomarin A**, exhibit anti-inflammatory and antitubercular activities, showcasing their therapeutic versatility (Zhang et al., 2023).
    -

2. **Lactones and Alkaloids:**
    - **Salinosporamide A**, derived from *Salinispora tropica*, is a γ-lactam-β-lactone proteasome inhibitor currently in clinical trials for cancer treatment (Mincer et al., 2005).
    - Alkaloids like **Streptopyrrolidine** offer potent antimicrobial activity and are promising candidates for tackling resistant bacterial strains.
3. **Glycosides and Phenolic Compounds:**
    - Glycosides produced by marine actinomycetes exhibit anti-inflammatory and anticancer activities, while phenolic compounds demonstrate strong antioxidant and antimicrobial properties (Wu et al., 2023).

The distinct chemical diversity of these metabolites stems from the **biosynthetic gene clusters (BGCs) present** in the genomes of marine actinomycetes. These clusters encode enzymes responsible for the stepwise construction of complex molecular scaffolds, often involving **polyketide synthases (PKSs)** and **non-ribosomal peptide synthetases (NRPSs).** The abundance of cryptic and silent BGCs in marine actinomycetes offers immense potential for discovering new drugs, especially when activated through genetic or chemical triggers.

2.2. Addressing Antibiotic Resistance

The rise of **antibiotic resistance** is a major global health crisis, exacerbated by the overuse and misuse of existing antibiotics. Multi-drug-resistant (MDR) pathogens, including MRSA, *Pseudomonas aeruginosa*, and *Mycobacterium tuberculosis*, are responsible for a growing number of difficult-to-treat infections. The pipeline for new antibiotics has dwindled, as most pharmaceutical companies have shifted focus away from antibiotic development due to high costs and low returns on investment.

Marine actinomycetes offer a promising solution to this problem for several reasons:

1. **Novel Mechanisms of Action**:
    - Many antibiotics derived from marine actinomycetes exhibit novel mechanisms of action, which reduce the likelihood of cross-resistance with existing antibiotics. For instance, **abyssomicin C** targets the biosynthesis of PABA, a pathway not typically affected by standard antibiotics, making it effective against resistant bacterial strains. (Wang et al., 2016).
2. **Broad-Spectrum Activity**:
    - Compounds from marine actinomycetes often demonstrate broad-spectrum activity against a wide range of pathogens, including Gram-positive, Gram-negative, and even fungal pathogens. This broad-spectrum nature makes them valuable candidates for treating mixed or polymicrobial infections. (Zhang et al., 2023).
3. **Addressing Biofilm-Associated Infections**:
    - Biofilm-associated infections are notoriously difficult to treat due to the protective matrix that encases the bacterial cells, rendering them resistant to conventional antibiotics. Certain metabolites from marine actinomycetes, such as **antimicrobial peptides**, have shown the ability to disrupt biofilms, enhancing their efficacy against persistent infections. (Wu et al., 2023).
4. **Potential as Resistance Modifiers**:
    - Some marine-derived compounds do not act as antibiotics themselves but can serve as **resistance-modifying agents**, sensitizing bacteria to existing antibiotics. For example, certain marine actinomycete metabolites inhibit bacterial efflux pumps, a common resistance mechanism, thereby restoring the activity of antibiotics that had become ineffective. (Lam. et al., 2018) (Niu et al., 2017).

The exploration of marine actinomycetes is crucial for replenishing the antibiotic pipeline with new candidates that can tackle MDR infections. Their ability to produce novel chemical structures, coupled with the unique environmental pressures of marine habitats, makes them a valuable resource in the ongoing battle against antibiotic resistance.

2.3. Contributions to Drug Discovery

Beyond antibiotics, marine actinomycetes contribute significantly to the development of drugs for various therapeutic areas:

1. **Anticancer Agents:**
    - Compounds like **Salinosporamide A** and **Marinopyrrole A** demonstrate strong anticancer potential by targeting proteasomes and DNA intercalation pathways, respectively (Mincer et al., 2005).
2. **Antiviral Compounds:**
    - Certain polyether antibiotics and lactones from marine actinomycetes inhibit viral replication, providing potential solutions for emerging viral diseases (Wu et al., 2023).
3. **Anti-Inflammatory Drugs:**
    - Glycosides and peptides modulate inflammatory pathways by inhibiting NF-κB signaling, offering potential treatments for autoimmune and chronic inflammatory conditions (Zhang et al., 2023).

3. Challenges in Isolating Marine Actinomycetes

Marine actinomycetes have emerged as a promising source of bioactive metabolites, but their study is significantly constrained by the challenges associated with their isolation and cultivation. Unlike terrestrial microorganisms, marine actinomycetes have evolved to thrive in unique and often extreme ecological conditions, making their laboratory cultivation complex.

3.1. Complex Environmental Adaptations

Marine actinomycetes occupy a wide variety of ecological niches, from shallow coastal waters to deep-sea sediments. These habitats impose extreme environmental pressures, influencing the physiological and metabolic profiles of these microorganisms.

1. **High Salinity and Pressure:**
    - The high salt concentration in seawater creates osmotic stress that terrestrial microorganisms cannot withstand. Marine actinomycetes, however, have evolved mechanisms such as the production of compatible solutes (e.g., proline and glycine betaine) to maintain cellular stability in hypertonic conditions (Xu et al., 2023; Mondal & Thomas, 2022).
    - Deep-sea habitats further introduce high hydrostatic pressure, which can inactivate metabolic pathways in standard laboratory environments. Specialized equipment such as pressure chambers is required to simulate these conditions during cultivation (González et al., 2023).
2. **Nutritional Specificity:**
    - Unlike terrestrial actinomycetes that thrive on simple carbon sources, marine actinomycetes often require organic substrates derived from decaying marine flora and fauna. Their ability to degrade complex molecules like chitin, cellulose, and lipids reflects their adaptation to nutrient-limited marine ecosystems (Goodfellow & Fiedler, 2010).

-

3. **Microbial Competition:**
    - Marine samples typically contain a diverse microbial population, including bacteria, fungi, and archaea, which compete for the same nutrients. Fast-growing species often overshadow slow-growing marine actinomycetes, complicating their isolation. Selective inhibitors or antimicrobial agents are frequently added to cultivation media to suppress these competitors (Euanorasetr & Intra, 2023).

3.2. Challenges in Cultivation and Maintenance

Despite successful isolation, the cultivation and maintenance of marine actinomycetes present additional challenges that hinder long-term studies and industrial-scale applications.

1. **Unculturable Strains:**
    - An estimated 99% of marine microbial species remain unculturable due to dependence on symbiotic or mutualistic relationships that cannot be replicated in artificial media. Co-cultivation with host organisms or other symbionts is increasingly used to address this limitation (Xu et al., 2023).
2. **Silent Biosynthetic Gene Clusters (BGCs):**
    - Many secondary metabolites are encoded by BGCs that are inactive under laboratory conditions. Stress signals like nutrient limitation or the presence of competing microorganisms are often required to activate these pathways (Wu et al., 2023). Recent advances in genetic engineering and chemical elicitors, such as epigenetic modifiers, have shown promise in activating cryptic BGCs.
3. **Low Yield of Metabolites:**
    - Even when active, BGCs often produce metabolites in minute quantities. Scale-up processes involve optimizing growth conditions, fermentation parameters, and precursor availability to enhance yield without compromising bioactivity (Mondal & Thomas, 2022).

3.3. Strategies to Address Isolation Barriers

1. **Advanced Cultivation Techniques:**
    - **Seawater-Based Media:** Formulations incorporating seawater mimic natural growth conditions, enhancing isolation success rates. Media such as ISP2-Seawater Agar have been widely adopted (González et al., 2023).
    - **Selective Pretreatment:** Methods like dry heat exposure and chemical treatments selectively eliminate faster-growing bacteria and fungi, increasing the probability of isolating rare actinomycetes (Mondal & Thomas, 2022).
2. **Activation of Silent BGCs:**
    - **Co-Cultivation:** Co-cultivating actinomycetes with other marine microorganisms simulates natural microbial interactions, leading to the production of otherwise undetected metabolites (Euanorasetr & Intra, 2023).
    - **Chemical Elicitors:** Molecules such as histone deacetylase inhibitors (e.g., sodium butyrate) and reactive oxygen species have been shown to activate silent BGCs, significantly enhancing the diversity of metabolites produced (Goodfellow & Fiedler, 2010).
3. **Genomic Approaches:**
    - **Genome Mining:** Tools like antiSMASH and PRISM identify gene clusters in sequenced genomes, allowing researchers to predict and target specific metabolic pathways for activation (Wu et al., 2023).

- **Metagenomics:** Direct sequencing of environmental DNA provides a cultivation-independent approach to studying marine actinomycetes, uncovering new BGCs without the need for growth in laboratory conditions (Xu et al., 2023).

3.4. Emerging Technologies and Future Directions

1. **Synthetic Biology:**
   - CRISPR-Cas9 and related technologies enable precise modifications to activate silent gene clusters or improve metabolic yields. Synthetic pathways can also be engineered into more tractable host organisms for large-scale production (González et al., 2023).
2. **High-Throughput Screening Platforms:**
   - Miniaturized culture platforms integrated with microfluidics allow thousands of cultivation conditions to be tested simultaneously. These systems are particularly effective for optimizing growth conditions of rare actinomycetes (Mondal & Thomas, 2022).
3. **Deep-Sea Exploration:**
   - Advances in deep-sea sampling technologies, such as remotely operated vehicles (ROVs) and autonomous underwater vehicles (AUVs), have expanded access to unexplored habitats rich in novel actinomycetes (Euanorasetr & Intra, 2023).

4. Bioprospecting Strategies for Marine Actinomycetes

Bioprospecting marine actinomycetes involves systematically exploring their vast metabolic potential to discover bioactive compounds with pharmaceutical and industrial applications. Their unique ecological adaptations and the structural diversity of their metabolites necessitate innovative strategies for isolation, characterization, and activation of biosynthetic pathways.

4.1. Selective Cultivation Techniques

Selective cultivation is essential for isolating rare and bioactive-producing marine actinomycetes, especially those overshadowed by faster-growing microbial competitors in environmental samples.

1. **Enrichment Media:**
   - Marine actinomycetes thrive in media supplemented with seawater, marine salts, and natural nutrients derived from algae or fish. Using specific carbon or nitrogen sources enhances the selective growth of actinomycetes while inhibiting non-target organisms (Mondal & Thomas, 2022).
2. **Pretreatment Methods:**
   - Heat treatment, chemical pretreatment with antibacterial or antifungal agents, and dry heat exposure reduce the prevalence of competing microorganisms, increasing the likelihood of isolating rare actinomycetes (Euanorasetr & Intra, 2023).
3. **Low-Nutrient Media:**
   - Marine oligotrophic environments are replicated in low-nutrient media, enabling slow-growing actinomycetes to outcompete other microbes. This method is particularly effective for isolating actinomycetes from deep-sea sediments (Goodfellow & Fiedler, 2010).

4.2. Metagenomics and Genome Mining

Genome mining and metagenomics have revolutionized the discovery of marine actinomycetes' biosynthetic potential by bypassing traditional culturing limitations.

1. **Metagenomics:**
    - Metagenomics involves sequencing the genetic material of microbial communities directly from environmental samples. This approach identifies **biosynthetic gene clusters (BGCs)** responsible for metabolite production without requiring laboratory cultivation (Xu et al., 2023).
    - Metagenomic libraries combined with functional screening allow researchers to isolate BGCs encoding novel antibiotics, anticancer agents, or enzyme inhibitors (Wu et al., 2023).
2. **Genome Mining Tools:**
    - Software like **antiSMASH** and **PRISM** predicts the presence of secondary metabolite BGCs in sequenced genomes, enabling targeted exploration of actinomycetes with high biosynthetic potential (Euanorasetr & Intra, 2023).
    - Comparative genomics identifies homologous BGCs across different strains, guiding the activation of cryptic pathways through environmental cues or genetic engineering (Mondal & Thomas, 2022).

4.3. High-Throughput Screening Methods

High-throughput screening (HTS) accelerates the discovery of bioactive compounds by simultaneously analyzing thousands of microbial strains and their metabolites.

1. **Microbial Libraries:**
    - Marine actinomycete strains are maintained in extensive libraries and screened for antimicrobial, anticancer, or anti-inflammatory activities using automated platforms (Goodfellow & Fiedler, 2010).
2. **Bioactivity-Guided Fractionation:**
    - Metabolites are fractionated using chromatographic techniques and evaluated for biological activity. Active fractions are further characterized using advanced analytical tools like **mass spectrometry (MS) and nuclear magnetic resonance (NMR) spectroscopy** (Wu et al., 2023).
3. **Integration with Omics Technologies:**
    - HTS is increasingly combined with metabolomics and proteomics to link metabolite production with specific genetic and protein expression patterns, streamlining the identification of bioactive compounds (Xu et al., 2023).

4.4. Co-Cultivation Approaches

Co-cultivation involves growing marine actinomycetes alongside other microorganisms to mimic natural microbial interactions, often triggering the production of otherwise silent metabolites.

1. **Microbial Interaction Studies:**
    - Interactions between marine actinomycetes and fungi or algae activate dormant BGCs, enhancing the production of novel metabolites. For example, co-cultivation of *Streptomyces sp.* with marine fungi led to the discovery of novel polyketides and peptides (Goodfellow & Fiedler, 2010).
2. **Chemical Communication:**
    - Chemical signals exchanged during co-cultivation act as elicitors, inducing biosynthetic pathways that are inactive in monocultures. Signal molecules such as quorum-sensing inhibitors or exogenous inducers like antibiotics have been shown to stimulate secondary metabolite production (Euanorasetr & Intra, 2023).

4.5. Future Prospects in Bioprospecting

1. **Synthetic Biology Applications:**
    - CRISPR-Cas9 and related technologies enable precise activation of silent gene clusters, creating engineered strains capable of producing enhanced metabolite yields (Wu et al., 2023).
2. **Integration with Artificial Intelligence (AI):**
    - AI-driven bioinformatics tools are being developed to predict and optimize metabolic pathways, guiding experimental design for identifying novel bioactive compounds (Mondal & Thomas, 2022).
3. **Marine Resource Conservation:**
    - Ethical and sustainable sampling practices, combined with biobanks for preserving microbial diversity, will play a crucial role in future bioprospecting initiatives (Xu et al., 2023).

5. Advances in Metabolite Isolation and Characterization

The isolation and characterization of bioactive metabolites from marine actinomycetes involve a series of critical steps: extraction, purification, and structural analysis. Given the complexity and diversity of metabolites produced by marine actinomycetes, advancements in analytical techniques and cultivation strategies have led to more efficient isolation and in-depth characterization of novel bioactive compounds.

5.1. Isolation Techniques

Isolating bioactive metabolites begins with extracting them from the actinomycetes cultures. Effective extraction techniques are vital to capture a wide range of metabolites, especially those with antimicrobial or anticancer properties.

1. **Solvent Extraction:**
    - Solvent extraction is the most common technique used to isolate secondary metabolites from marine actinomycetes. The choice of solvent depends on the polarity of the desired compounds. Organic solvents like methanol, chloroform, and ethyl acetate are commonly used for extracting bioactive compounds (Goodfellow & Fiedler, 2010; Mondal & Thomas, 2022).
    - **Liquid-Liquid Extraction (LLE):** This method allows for the partitioning of metabolites into aqueous or organic layers based on their solubility, thus aiding in separating polar and non-polar compounds (Euanorasetr & Intra, 2023).
2. **Chromatographic Methods:**
    - **Thin-Layer Chromatography (TLC):** TLC is used for initial screening, allowing the visualization of compounds based on their migration rate on a stationary phase. It is a simple, cost-effective way to analyze crude extracts (Zhang et al., 2023).
    - **High-Performance Liquid Chromatography (HPLC):** HPLC is employed to purify metabolites, where compounds are separated based on their interaction with a stationary phase under high pressure (Goodfellow & Fiedler, 2010). HPLC is the method of choice for obtaining high-resolution separations of complex mixtures.
    - **Flash Chromatography:** This technique is used for rapid separation and purification of metabolites by passing a sample through a column under pressure, accelerating the purification process and improving efficiency (Wu et al., 2023).

3. **Solid-Phase Extraction (SPE):**
    - SPE offers advantages over liquid-liquid extraction by enabling solid-phase materials to selectively bind metabolites, simplifying sample cleanup and concentrating bioactive fractions (González et al., 2023).

5.2. Characterization Techniques

Once metabolites are isolated, determining their structure and bioactivity is crucial. Various analytical tools provide detailed insights into the molecular structure, helping researchers to identify novel compounds and elucidate their modes of action.

1. **Mass Spectrometry (MS):**
    - MS is widely used to identify the molecular weight of metabolites and deduce their molecular structure. High-resolution MS (HRMS) gives accurate mass measurements and helps identify unknown metabolites (Wu et al., 2023).
    - **Tandem Mass Spectrometry (MS/MS):** This technique further fragments the ions produced in the initial MS step to obtain more detailed structural information, allowing for the elucidation of complex structures (Zhang et al., 2023).
2. **Nuclear Magnetic Resonance (NMR) Spectroscopy:**
    - NMR is a cornerstone technique for determining the complete structure of metabolites. By measuring interactions between atomic nuclei, NMR provides detailed information on molecular connectivity and conformation.
    - **1D and 2D NMR techniques** (such as COSY, HSQC, HMBC) are used to study the proton-carbon correlation and connectivity in large, complex molecules (Goodfellow & Fiedler, 2010; Xu et al., 2023).
3. **Fourier Transform Infrared (FTIR) Spectroscopy:**
    - FTIR identifies functional groups by analyzing molecular vibrations, helping to confirm the presence of groups like hydroxyls, carbonyls, and amines (Zhang et al., 2023). FTIR is often used in tandem with MS and NMR for preliminary identification of metabolites.
4. **X-Ray Crystallography:**
    - For metabolites that form crystals, X-ray diffraction provides atomic-level details of their three-dimensional structure. This is particularly useful for determining the spatial arrangement of atoms in large, complex molecules (Wu et al., 2023).
5. **UV-Vis Spectroscopy:**
    - UV-Vis spectroscopy is used to detect chromophoric groups in metabolites, such as aromatic rings or conjugated double bonds. This technique provides an initial indication of the chemical class of a compound, such as flavonoids or alkaloids (Euanorasetr & Intra, 2023).

5.3. Bioactivity-Linked Characterization

Characterization of metabolites also involves evaluating their biological activity. Bioactivity-guided fractionation and screening techniques are essential for linking metabolites to their therapeutic potential.

1. **Bioassay-Guided Fractionation:**
    - This approach links bioactivity to specific metabolite fractions. Crude extracts are fractionated, and each fraction is tested for biological activity. Active fractions are then purified for further analysis (Mondal & Thomas, 2022).
    - Common assays include testing for antibacterial, anticancer, antifungal, or anti-inflammatory activities, depending on the targeted application (González et al., 2023).

2. **Metabolomics Approaches:**
    - Metabolomics, the study of small molecules in biological systems, has become an essential tool for characterizing marine-derived metabolites. By using LC-MS or GC-MS, researchers can perform both **targeted** and **untargeted metabolomics.**
    - **Targeted metabolomics** quantifies specific known metabolites, while **untargeted metabolomics** identifies and quantifies a broad range of metabolites, providing a comprehensive view of bioactive compound profiles (Xu et al., 2023).
    - Integrating **metabolomics with bioactivity data** helps correlate specific metabolites with their observed biological effects, enhancing the discovery of new drugs (Wu et al., 2023).

5.4. Future Directions

1. **Machine Learning and AI in Metabolite Characterization:**
    - AI and machine learning algorithms are being developed to automate the interpretation of complex spectroscopic data. These tools can help predict the structure of metabolites, analyze fragmentation patterns, and optimize isolation strategies (Zhang et al., 2023).
2. **Integrated Analytical Platforms:**
    - Advances in multi-modal platforms that combine NMR, MS, and bioassays are offering more comprehensive analyses. These platforms enable faster and more accurate characterization of marine metabolites and their bioactivities, significantly accelerating the drug discovery process (Euanorasetr & Intra, 2023).
3. **Environmental Metabolomics:**
    - Understanding the ecological roles of metabolites in marine ecosystems is becoming increasingly important. Environmental metabolomics studies, where metabolites are analyzed directly from their natural sources, provide new insights into their functions and potential applications (Wu et al., 2023).

6. Applications of Bioactive Compounds from Marine Actinomycetes

Marine actinomycetes are an exceptional source of bioactive compounds with remarkable therapeutic potential. These compounds offer a wide array of pharmacological applications, ranging from antibiotic and anticancer treatments to anti-inflammatory agents and enzyme inhibitors. Given the growing need for novel therapies to combat multidrug-resistant pathogens, cancer, and inflammatory diseases, the bioactive metabolites from marine actinomycetes present promising solutions.

6.1. Antibiotics and Antimicrobial Agents

One of the most notable applications of bioactive compounds from marine actinomycetes is in the discovery of new **antibiotics.** The growing concern of **antibiotic resistance** in bacterial pathogens has fueled the need for novel antimicrobial agents. Marine actinomycetes have emerged as an invaluable source of antibiotics that exhibit unique mechanisms of action and can combat multi-drug-resistant (MDR) pathogens.

6.1.1. Novel Antibiotics from Marine Actinomycetes

- **Salinosporamide A**: Isolated from *Salinispora tropica*, salinosporamide A is a potent proteasome inhibitor with significant anticancer activity. Its structure, a β-lactone-γ-lactam, is highly unusual for a natural product and offers a unique mechanism of action. Salinosporamide

A is currently undergoing clinical trials for the treatment of multiple myeloma and other cancers (Schmidt et al., 2009).

- **Abyssomicin C**: Isolated from *Abyssomicin sp.*, abyssomicin C is a rare polyketide with remarkable antibacterial activity against **methicillin-resistant *Staphylococcus aureus* (MRSA)** and **vancomycin-resistant enterococci (VRE).** Abyssomicin C inhibits **para-aminobenzoic acid (PABA)** biosynthesis, a crucial step in folate metabolism, making it a valuable candidate for overcoming antibiotic resistance (Berdy, 2005).
- **Marinomycin A**: A polyphenolic macrolide isolated from *Streptomyces marinensis*, marinomycin A has strong antimicrobial and anticancer activities. It has shown efficacy against a wide range of bacterial pathogens, including **Gram-positive bacteria** and **fungi**, and is under investigation for clinical development (Zhao et al., 2010).

6.1.2. Mechanisms of Action of Marine Antibiotics

The marine-derived antibiotics often target novel pathways, thus avoiding the mechanisms of resistance developed by conventional antibiotics. For example:

- **Abyssomicin C** targets the PABA biosynthesis pathway, which is critical for the folate synthesis in bacteria.
- **Salinosporamide A** inhibits the proteasome, which is an enzyme complex involved in the degradation of intracellular proteins.

The novel mechanisms of action of marine-derived antibiotics provide a promising avenue for combating **drug-resistant pathogens.**

6.2. Anti-Cancer Compounds

Marine actinomycetes are an important source of bioactive compounds with **anticancer properties.** The unique structures of these metabolites have shown promise in targeting cancer cell growth and metastasis, making them valuable candidates for the development of anticancer therapies. (Schmidt et al., 2009)

6.2.1. Notable Anti-Cancer Compounds

- **Salinosporamide A**: As mentioned above, salinosporamide A is a proteasome inhibitor with demonstrated anticancer activity, particularly against multiple myeloma. The compound works by inhibiting the proteasome, leading to the accumulation of ubiquitinated proteins and subsequent cell death. Its anticancer properties have led to its development into an experimental drug for the treatment of cancers like multiple myeloma and ovarian cancer (Schmidt et al., 2009).
- **Actinorodins**: These compounds are a class of polyketides produced by various marine actinomycetes, including *Streptomyces* species. Actinorodins have shown significant activity against a variety of cancer cell lines by inducing apoptosis (programmed cell death) and arresting the cell cycle, particularly in the G1 phase.
- **Streptomycin and Mitomycin C**: These well-known actinomycete-derived compounds have been used as chemotherapeutic agents for treating cancers, including lung, breast, and gastric cancers. Although they are no longer used in their natural form, they have inspired the development of semisynthetic derivatives used in cancer therapy.

6.2.2. Mechanisms of Anti-Cancer Activity

Many of the anticancer compounds from marine actinomycetes work through various mechanisms:

- **Inhibition of cell division**: Compounds such as salinosporamide A inhibit the proteasome, leading to the accumulation of damaged proteins and apoptosis in cancer cells.
- **Apoptosis induction**: Marine-derived actinomycetes metabolites can induce apoptosis in cancer cells by modulating signaling pathways, such as those involving p53, caspases, and Bcl-2 family proteins.
- **Cell cycle arrest**: Some actinomycetes-derived metabolites can arrest cancer cell proliferation at specific phases of the cell cycle, preventing tumor growth and spread. (Gerwick, W. H., & Moore, B. S. 2012).

6.3. Anti-Inflammatory Compounds

Marine actinomycetes also produce metabolites with significant **anti-inflammatory properties,** which can be useful for treating diseases related to chronic inflammation, such as **arthritis**, **inflammatory bowel disease**, and **psoriasis**. Inflammatory processes are often linked to the production of pro-inflammatory cytokines, and compounds from marine actinomycetes can modulate these pathways to alleviate symptoms. (Tanaka et al., 2015)

6.3.1. Notable Anti-Inflammatory Compounds

- **Glycosides and alkaloids**: Some marine actinomycetes produce glycosidic and alkaloid compounds that show anti-inflammatory activity. For example, **actinofuranoside**, isolated from *Streptomyces albidoflavus*, has been shown to inhibit the production of nitric oxide (NO) and pro-inflammatory cytokines, making it a potential therapeutic agent for inflammatory diseases (Tanaka et al., 2015).
- **Antibiotic-like Compounds with Anti-Inflammatory Properties**: Compounds such as **chondramide A** and **angucycline** derivatives, isolated from marine actinomycetes, also demonstrate anti-inflammatory effects, in addition to their antibacterial and anticancer activities. These compounds modulate the NF-kB pathway, a key regulator of inflammation.

6.3.2. Mechanisms of Anti-Inflammatory Activity

Many anti-inflammatory compounds from marine actinomycetes work by:

- **Inhibiting pro-inflammatory cytokine production**: Some compounds inhibit the expression of TNF-α, IL-1β, and other pro-inflammatory cytokines.
- **Modulating NF-kB signaling**: NF-kB is a critical mediator of the inflammatory response, and many marine-derived compounds suppress its activation, leading to reduced inflammation.
- **Inhibiting nitric oxide (NO) synthesis**: Compounds like glycosides reduce the production of NO, a key mediator of inflammation in the body.

6.4. Enzyme Inhibitors

Marine actinomycetes also produce bioactive metabolites that act as **enzyme inhibitors**, making them valuable in the treatment of diseases where enzyme dysregulation plays a key role. These metabolites have been shown to inhibit a range of enzymes, from proteases to kinases, which are involved in pathological processes. (Schmidt et al., 2009).

6.4.1. Notable Enzyme Inhibitors

- **Proteasome Inhibitors**: As noted above, **salinosporamide A** is a potent proteasome inhibitor with both anticancer and antibacterial activity. Proteasome inhibitors are being actively researched for the treatment of multiple cancers and neurodegenerative diseases.
- **Kinase Inhibitors**: Some marine actinomycetes produce kinase inhibitors that can potentially be used in cancer therapy. **Streptokinase**, derived from *Streptococcus* species, has been used to treat blood clots, and similar compounds from marine actinomycetes are being investigated for their anticancer and thrombolytic potential.

6.5. Other Applications

Beyond their use as antibiotics, anticancer agents, and anti-inflammatory drugs, bioactive compounds from marine actinomycetes have various other applications:

6.5.1. Antiviral Compounds

- Some metabolites from marine actinomycetes have shown antiviral activity against viruses like **HIV, herpes simplex virus (HSV),** and **influenza virus**. These compounds inhibit viral replication by targeting viral enzymes or host-cell receptors involved in the infection process.

6.5.2. Antioxidants and Anti-aging Agents

- Marine actinomycetes also produce metabolites with **antioxidant properties**, which are valuable in preventing oxidative stress-related diseases, such as neurodegenerative diseases, aging, and cardiovascular diseases. Compounds like **isocoumarin** have demonstrated significant free radical-scavenging activity.

7. Challenges and Future Prospects of Marine Actinomycetes Bioprospecting

Marine actinomycetes have long been recognized as an abundant source of bioactive compounds with pharmaceutical and industrial potential. However, despite their promise, there are several challenges that hinder their full exploitation.

7.1. Challenges in Marine Actinomycetes Bioprospecting

1. **Isolation and Cultivation Challenges:**
    - One of the primary challenges in bioprospecting marine actinomycetes is the difficulty of isolating and cultivating these microorganisms under laboratory conditions. Marine actinomycetes often have highly specific environmental requirements, such as particular salinity, temperature, and pressure conditions, which are difficult to replicate in conventional laboratory settings (González et al., 2023).
    - Additionally, marine actinomycetes often remain unculturable because they rely on complex symbiotic relationships or environmental signals to activate growth and metabolite production (Goodfellow & Fiedler, 2010). The presence of fast-growing microorganisms like fungi, bacteria, and algae in marine environments further complicates the isolation process (Zhang et al., 2023).
2. **Cryptic Biosynthetic Pathways:**
    - A significant number of marine actinomycetes harbor **cryptic biosynthetic gene clusters (BGCs)** that remain dormant or inactive under standard laboratory conditions.

This limits the discovery of potentially valuable metabolites that could otherwise be activated through specific environmental cues or genetic manipulation (Wu et al., 2023). These silent BGCs are crucial, as they hold the potential for novel compounds with unique structures and bioactivity.

- Techniques like genome mining and metagenomics have been developed to predict the presence of these cryptic BGCs, but activating these pathways remains a significant challenge (Xu et al., 2023).

3. **Microbial Competition:**
   - In natural marine environments, microbial communities are highly diverse, and faster-growing microorganisms often outcompete actinomycetes for nutrients and space. This competition is particularly evident in environmental samples, where isolating slow-growing strains of marine actinomycetes requires the use of selective culturing techniques or the addition of inhibitory agents to suppress other microbes (Euanorasetr & Intra, 2023).
4. **Low Yields of Bioactive Metabolites:**
   - Even when marine actinomycetes are successfully cultured, they often produce bioactive metabolites in very low yields, which can make large-scale production for pharmaceutical use difficult (Mondal & Thomas, 2022). Optimizing culture conditions and fermentation strategies to enhance metabolite yields is a continuing challenge, particularly when dealing with novel or rare compounds that may only be produced in trace amounts under specific conditions.

7.2. Advanced Technologies to Overcome Challenges

Despite the challenges, several cutting-edge technologies are being used to improve the isolation and characterization of marine actinomycetes, as well as to activate silent biosynthetic pathways.

1. **Metagenomics and Genome Mining:**
   - **Metagenomics** allows researchers to bypass the need for cultivating actinomycetes by directly sequencing microbial DNA from environmental samples. This approach enables the discovery of previously unknown actinomycetes species and their associated biosynthetic potential (Goodfellow & Fiedler, 2010).
   - **Genome mining** using computational tools like **antiSMASH** can predict the presence of BGCs responsible for secondary metabolite production in marine actinomycetes, guiding researchers toward potentially novel compounds before cultivation (Wu et al., 2023). These tools can uncover a wealth of untapped biosynthetic pathways, paving the way for new drug discovery efforts.
2. **Co-Cultivation and Elicitors:**
   - **Co-cultivation** with other microorganisms is an effective strategy for activating cryptic BGCs. By mimicking natural microbial interactions, co-cultivation stimulates the production of metabolites that might otherwise remain dormant in monocultures. For example, co-culturing marine actinomycetes with fungi has led to the discovery of novel polyketides and peptides (Zhang et al., 2023).
   - **Chemical elicitors**, such as quorum-sensing molecules and epigenetic modifiers, can also induce the expression of silent BGCs, further enhancing the diversity of metabolites produced by marine actinomycetes (González et al., 2023).
3. **Synthetic Biology and Genetic Engineering:**
   - **Synthetic biology** and **genetic engineering** offer transformative potential in the bioprospecting of marine actinomycetes. Techniques like **CRISPR-Cas9** allow precise activation of silent BGCs, or the introduction of new genes into actinomycetes strains to enhance or alter their metabolite production. Engineering the genetic pathways of

actinomycetes enables the creation of hybrid compounds with enhanced bioactivity or novel structures (Wu et al., 2023).

4. **High-Throughput Screening and Microfluidics:**
    - **High-throughput screening (HTS)** systems are increasingly being integrated with **microfluidic platforms**, enabling the rapid testing of large numbers of marine actinomycete strains and their metabolites. These platforms significantly improve efficiency, helping to identify bioactive compounds in a fraction of the time it would take using traditional methods (Zhang et al., 2023).
    - HTS systems allow researchers to analyze the biological activity of metabolites in real time, linking specific compounds to their therapeutic potential.

7.3. Future Prospects in Marine Actinomycetes Bioprospecting

1. **Exploring Untapped Marine Environments:**
    - **Deep-sea exploration** technologies, such as autonomous underwater vehicles (AUVs) and remotely operated vehicles (ROVs), are enabling scientists to sample previously inaccessible environments. These techniques open up new frontiers for marine actinomycetes bioprospecting, especially in extreme habitats like hydrothermal vents, deep-sea trenches, and oceanic ridges, where unique and novel actinomycetes species are likely to be discovered (Mondal & Thomas, 2022).
    - The marine microbial diversity in these environments is expected to harbor unique actinomycetes strains with the potential to produce compounds not found in shallow water or terrestrial environments.
2. **Artificial Intelligence and Automation:**
    - The integration of **artificial intelligence (AI)** and **machine learning** in the analysis of genomic, metabolomic, and bioactivity data is transforming the pace of marine actinomycetes bioprospecting. AI can be used to predict the chemical structure of metabolites, optimize fermentation conditions, and automate the process of metabolite identification and characterization (Euanorasetr & Intra, 2023).
    - AI models are also being developed to analyze large datasets generated from screening assays, helping researchers pinpoint bioactive compounds more efficiently.
3. **Sustainable and Ethical Bioprospecting:**
    - **Sustainable bioprospecting practices** are becoming increasingly important, especially as marine ecosystems face threats from human activity. Efforts are being made to ensure that sampling does not deplete marine resources, and that microorganisms are preserved for future studies. The development of biobanks and ethical guidelines for marine microbial sampling will help conserve biodiversity while allowing researchers to explore the potential of marine actinomycetes (Wu et al., 2023).

8. Conclusion

Marine actinomycetes represent one of the most promising and underexplored sources of novel bioactive compounds, with immense potential for drug discovery in a wide range of therapeutic areas, including antibiotics, anticancer agents, and anti-inflammatory treatments. The unique environmental conditions of marine ecosystems—such as high salinity, pressure, and low nutrient availability—have shaped these microorganisms to produce a diverse array of secondary metabolites with exceptional biological activity. These compounds offer new possibilities in addressing global health challenges, particularly in combating antibiotic resistance, one of the most pressing concerns in modern medicine.

However, despite the enormous promise, bioprospecting marine actinomycetes presents several challenges. The **difficulties in isolating and cultivating marine actinomycetes** due to their complex

and specific growth requirements remain a major bottleneck in this field. Additionally, the high costs and limited access to marine microbial resources, combined with regulatory and safety concerns, complicate the process of translating these discoveries into viable drug candidates. To overcome these hurdles, researchers are increasingly relying on **innovative technologies** such as **metagenomics**, **genome mining**, and **synthetic biology** to enhance the isolation and characterization of marine actinomycetes and their metabolites. These technologies not only allow for more efficient screening and discovery but also enable the manipulation of marine actinomycetes at the genetic level to activate cryptic biosynthetic pathways that would otherwise remain silent under standard laboratory conditions.

The future of marine actinomycetes in drug discovery is exciting, with ongoing advancements in **high-throughput screening, biochemical characterization**, and **structural biology** paving the way for the discovery of new classes of antibiotics, anticancer agents, and other therapeutics. Furthermore, interdisciplinary collaboration between microbiologists, chemists, pharmacologists, and bioinformaticians will be key to unlocking the full potential of these microorganisms. The application of **artificial intelligence** and **machine learning** tools to screen vast libraries of natural products and predict bioactivity will undoubtedly accelerate the process of drug discovery and allow for the identification of novel compounds that might have been overlooked in traditional screening methods.

Looking ahead, it is clear that marine actinomycetes will play a crucial role in replenishing the rapidly depleting pipeline of new antibiotics, as well as providing novel solutions for cancer treatment, inflammation management, and other medical needs. However, overcoming the challenges of isolation, cultivation, and regulation will require continued investment in research and technology, as well as global collaboration and sustainable practices in marine resource use.

In conclusion, while significant challenges remain, the continued exploration of marine actinomycetes offers immense opportunities for discovering novel bioactive compounds that could transform the future of medicine. As research progresses and new techniques emerge, marine actinomycetes are poised to become an invaluable resource for the development of drugs that can address some of the most urgent medical and health issues of our time.

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QbD Practices in Advancing Instrumental Method Development and Validation: A Comprehensive Review

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Abstract: *Quality by Design (QbD) has become an essential framework in the pharmaceutical industry for enhancing product development through a systematic, science-focused strategy. Unlike traditional methods that rely heavily on final product testing, QbD emphasizes building quality into products from the beginning, guided by ICH guidelines Q8 through Q10. This review delves into how QbD principles are applied in the development and validation of instrumental methods, with a focus on Analytical Quality by Design (AQbD). AQbD adapts these principles to analytical procedures, leading to reliable, cost-effective method development and greater regulatory flexibility. A key tool within AQbD is the Design of Experiments (DoE), which identifies critical variables and optimizes method performance for precision and robustness. This review explains AQbD's phases, supported by practical examples, and showcases how DoE and risk management improve analytical processes. Challenges to implementation, such as technical hurdles and industry adaptation, are explored, alongside strategies for overcoming them. Real-world case studies illustrate AQbD's benefits, including increased efficiency and regulatory compliance. The review also looks forward, discussing trends like real-time release testing (RTRT) and Industry 4.0 technologies that could further strengthen QbD practices. This article aims to inform researchers and industry professionals on how AQbD can be used to create robust analytical methods that align with current regulatory and industry standards.*

Key Words: *Quality by Design (QbD), Analytical Quality by Design (AQbD), Instrumental method development, Design of Experiments (DoE), Method validation, Regulatory compliance.*

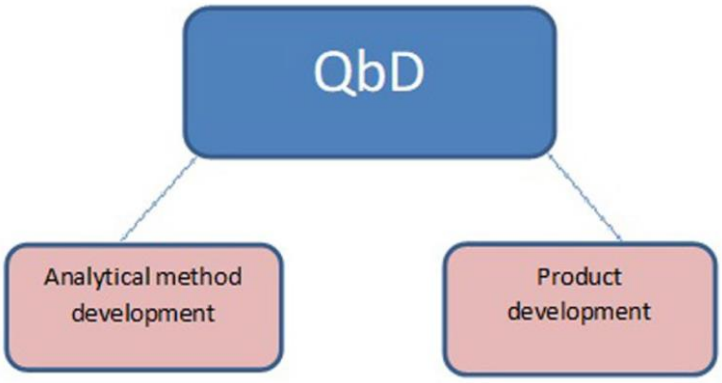


Fig. 1: Application of Quality by Design (QbD) in the Pharma Sector

1.1 Background for Quality by Design (QbD):

J.M. Juran, one of the most influentual american engineers, first introduced the idea of the Quality by Design (QbD) in early 1970's. QbD was as a systematic approach to quality assurance, to be engaged in early with product process development that would lead to the integration of initial steps of quality in initial product and process design. It was captured in his foundational Juran on Quality by Design, which has played a central role in quality management literature, although it is still sometimes referred to as the 5 Ps and other organizations use their own design to ensure quality (Juran, 1992).

In the beginning, QbD adoption only existed in industries outside of pharma, and the healthcare and medical device industries were among the first into the QbD arena in the 1990s. QbD entered these industries because of its value in creating reliable products, to ensure they comply with regulatory standards, and by meeting their customer requirements. Organizations have embedded quality into the design phase, reducing the need for intensive post production testing and reducing the risk of defects, thus improving manufacturing efficiency and consistency.

QbD was a major focus in the pharmaceutical industry since 2004 when the United States Food and Drug Administration (USFDA) initiated the new initiatives to reform the pharmaceutical manufacturing practices. The FDA was trying to increase product quality, expand input by regulatory oversight, and promote safety of patients. QbD principles are easily consistent with the agency's embrace of principles embodied in the science and risk based approach to quality in development and manufacture of pharmaceuticals, for example (see Fig. 1) (U.S. Food and Drug Administration, 2004).

1.2 Main text

Reduction of Deviations and Costs.

Quality by Design (QbD) is defined by the International Council for Harmonization (ICH, 2009) as the systematic approach to innovation by clearly defining objectives, utilising a science based understanding of products and processes, and rigorous quality risk management to provide operational control. The innovation phase generates knowledge that can be used to define a design space as well as appropriate control mechanisms. This principle is fundamental not only to product development but also to the development of analytical methodologies, as we have done with Analytical Quality by Design (AQbD).

Application of QbD to analytical methods development is called AQbD; focusing on Method Operable Design Region (MODR). The contribution of this approach with respect to using traditional analytical techniques is to significantly improve method robustness and significantly reduce occurrence of 'Out of Trend' / 'Out of Specification' (OOT / OOS) results.

The U.S. Food and Drug Administration (FDA) reiterated this link in 2011 between analytical methodology and quality risk management as impacting ICH Q9 and the importance of integration of these concepts. Since AQbD has been widely adopted in the pharmaceutical industry as an essential tool for risk management during method development (Chatterjee, 2013; Tang, 2011). The broad implementation of AQbD indicates the reliability and performance of AQbD in assuring quality and regulatory compliance of pharmaceutical processes.

Figure 2 further depicts the sequential Steps in AQbD and product QbD and their investigative and systematic nature resulting in intense robust and reliable outcomes.

Fig. 2 Analytical QbD vs Product QbD

1.3 Advantages of Quality by Design (QbD) (Mogal et al., 2016)**:**

1. Batch Failures Minimization: The application of Analytical Quality by Design (AQbD) principles precludes the application of the Method Operable Design Region (MODR), then the systematic evaluation and optimisation of critical factors, such as composition and temperature of the mobile phase and flow rate, is facilitated. The structured approach provides insight into which method parameters impact method performance, increases potency measurement reliability and leads to a significant reduction in batch failures.

2. Improved Regulatory Flexibility and Approval through Lifecycle: The dynamic nature of analytical methods is acknowledged by AQbD, considering ways to maintain the effectiveness and reliability of these during the product's life cycle. The freedom to operate with a reduced number of revalidations will lead to smoother regulatory compliance and more flexibility. The ability to adapt in this way enables continuous lifecycle approval, aligning analytical methods to changing regulatory expectations.

3. Continuous Improvement is promoted: The AQbD framework allows for such necessary method changes due to post regulatory approval as it propagates a culture of continuous improvement. It allows for simulation of adjustments to method parameters, e.g. analytical conditions or procedures, without requiring complete method revalidation. This flexibility ensures that methods are useful and up to date.

4. Reductions of deviations and costs: AQbD is an approach to integrate a full understanding of system components with the optimized critical method parameters to minimize deviations in product quality. Method development can be significantly improved by this type of approach, lowering the probability of unexpected results or failures during production. As a result, these financial costs attached to these deviations are also greatly reduced.

5. Reduced Analytical Attribute Variability and Increased Method Robustness: Through the application of the art of quality (AQ) by developing, updating, and implementing a systematic approach to the optimization of critical method parameters for all aspects of sample preparation, chromatography, and detection, AQbD effectively reduces variability in measured purity values. The method's vulnerability to external influence, e.g. environmental changes or procedural deviations, is reduced by operating the parameters in narrow ranges while refining them. This rigorous approach increases the method robustness and gives consistent and repeatable analytical results. This increased robustness ensures both the quality and efficacy of pharmaceutical products, while simultaneously promoting confidence in the safety and performance of these products (see Figure 3).

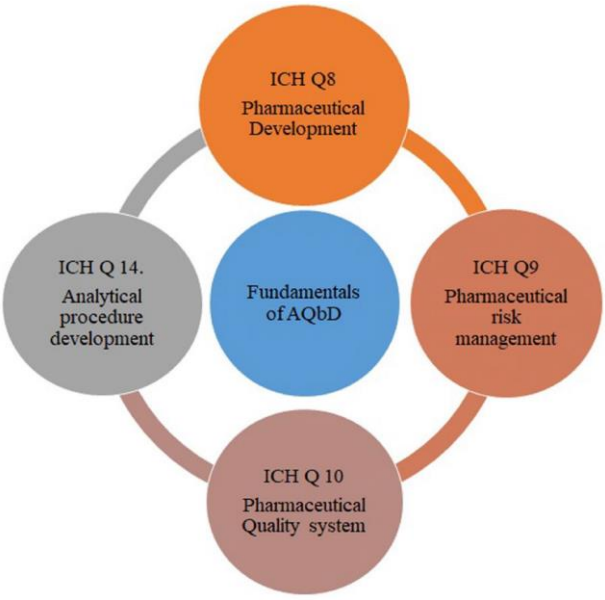


Fig. 3 AQbD Fundamentals

2. Objectives:

The objectives of this review article are outlined as follows:

i) To provide an overall view of Analytical Quality by Design (AQbD) Framework: The focus of this article is to provide a clear picture regarding the AQbD approach including the integration with analytical methods and the alignment with the fundamental QbD principles.

ii) To emphasize the benefits of AQbD: The advantages of the implementation of AQbD are reviewed along with possible effects on method robustness, variability, out of trend (OOT) and out of specification (OOS) results.

iii) To elucidate key components and tools of AQbD: This part provides an in depth discussion on the critical elements of AQbD such as the Analytical Target Profile (ATP), Critical Quality Attributes (CQAs), and Design Space (DS). The role of Design of Experiments (DoE) in method development is also explored.

iv) To demonstrate practical application of AQbD: This article provides an example of how AQbD principles can be used to method validation and compliance in such a way as to achieve high quality and reliable analytical results.

v) To advocate for AQbD as a systematic and proactive methodology: The review places AQbD as a contemporary, risk based approach to unity analytical method lifecycle management that is in line with developing regulatory requirements.

vi) To encourage future research and industrial adoption of AQbD: The purpose of this article is to motivate further research and practice of AQbD approaches within the pharmaceutical industry through highlighting the prominence of AQbD in improving method resilience and flexibility.

3. Analytical Quality by Design: Fundamentals and Design Principles

The Quality by Design (QbD) approach requires a systematic mapping of product attributes to product process parameters, for an exhaustive listing and characterization of the product design space. A range of quality attributes (European medicines Agency, 2009) defines the dimensions of this design space. The development of analytical methodologies employs many of the same concepts found in the QbD framework for manufacturing process development (Orlandini et al., 2016; Piepel et al., 2012).

Analytical Quality by Design (AQbD) starts with defining the Analytical Target Profile (ATP), that describes the purpose and scope of the analytical measurement and aims at achieving analytical target product quality (ATPQ). Reaching a profound understanding of the analytical system forms a core part of the AQbD and is realized through the identification of critical method parameters (CMPs) specific to the analytical system in question and their evaluation. The method is based on conducting comprehensive risk analysis and evaluation to ensure method reliability. Design Space (DS) (Orlandini et al., 2014) is defined as the operational region in which CMPs meet the desired Critical Method Attributes (CMAs) consistently.

Figure 4 shows the AQbD workflow explaining the systematic approach to design and optimization of analytical methods, to achieve robustness, reliability and satisfying the quality objectives.

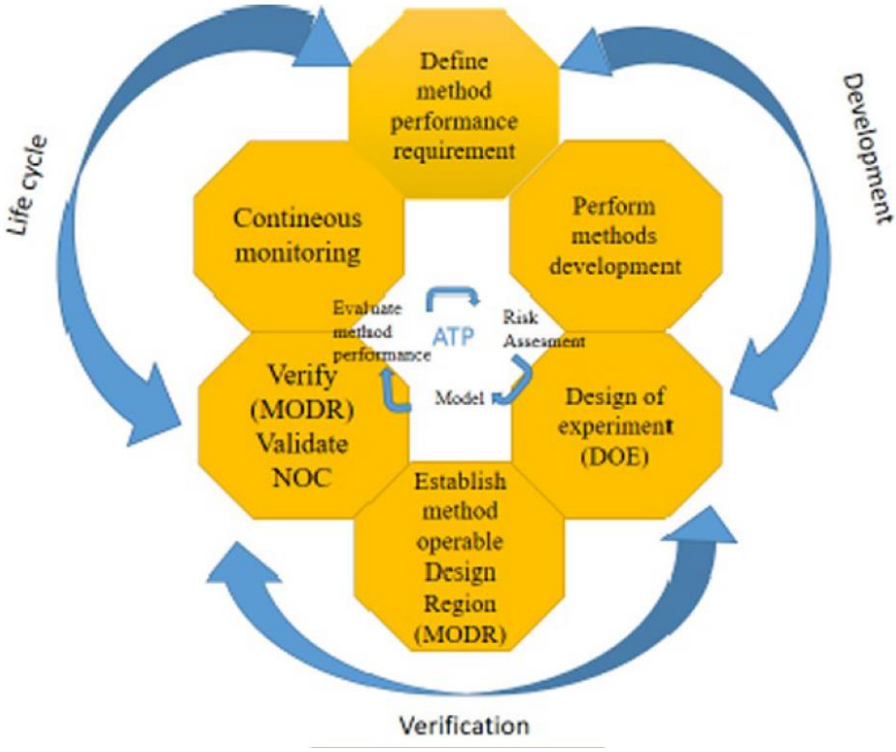


Fig. 4 AQbD workflow

3.1 Analytical Target Profile (ATP):

The analytical methods development is powered by the Quality by design (QbD) framework wherein Analytical Target Profile is the line for the performance requirements for the design, development and validation of the analytical processes (Rignall et al.,2018). The ATP serves much like the Quality Target Product Profile (QTPP) in serving as the foundational step in QbD. It provides justification for the development of analytic methods and matching the products of these methods to the overall projects of the QTPP.

The ATP also specifies the particular criteria and threshold measurement required of the analytical approach (Peraman et al., 2015). These criteria include the choice of suitable target analyticals for analysis, as well as the selection of appropriate analytical methodologies, including ion chromatography, High Performance Thin Layer Chromatography (HPTLC), Gas Chromatography (GC) or High performance Liquid Chromatography (HPLC) and the nature of the method requirements, including impurity profiling (Rozet et al., 2013; Reddy et al., 2017). When the above parameters are defined, the ATP also ensures how the analytical method shall conform to its intended purpose and with the overall quality objectives.

3.2 CQA:

The second phase of AQbD is the determination of Critical Quality Attributes, CQA, which defines physical, chemical, and biological properties within appropriate limits for desired product quality. In this phase, method parameters and attributes are determined (Rozet et al., 2013).

3.3 Risk Assessment

Critical Quality Attributes (CQAs) variability risk analysis is the critical evaluation of risks by the Analytical Quality by Design (AQbD) process, where variables such as the analyst approach, instrument setting, evaluation variables, material characteristics, preparation methods, and environmental conditions are taken into account (Bhusnure et al., 2015 & Gupta, 2017). The guidelines for ICH Q9 improvement set out a systematic approach for risk assessment, quality control, interaction management, and product lifecycle review. In the process, there is identification, analysis, and risk assessment (Gupta, 2017).

Risk assessment Involves the identification of possible risks and ranking them about methods of instrument operation; reagent properties; and also cycle times. If there will be primary failure, an alternative method is selected which would reduce the risks arising from the primary method Risk factors are described in Flow charts and checklists In risk evaluation, there would be use of Fishbone (Ishikawa) diagrams that classify a risk into three: risky, noise, and factor for experimentation (Gupta, 2017). Various steps involved in risk assessment are shown in Fig. 5.

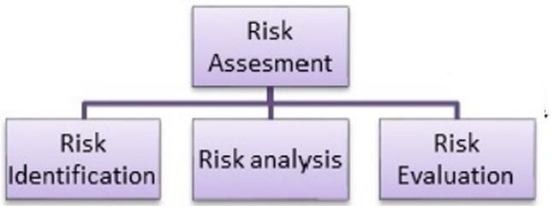


Fig. 5 Various risk assessment steps

The first phase of risk analysis involves the identification and prioritization of potential risks, such as instrument operation methods, reagent characteristics, and cycle time. Establishing a contingency plan is crucial in case the primary strategy fails. The second phase, risk evaluation, employs the Fishbone diagram, also known as the Ishikawa approach, to categorize risk factors into high-risk, noise, and experimental categories (Pande et al., 2017). An example of the Ishikawa approach can be seen during method development using the HPLC method.

Qualitative methods for variable assessment include Fishbone diagrams, Ishikawa diagrams, and method modeling (Figure 6). Semiquantitative tools for risk ranking include Failure Mode and Effects Analysis (FMEA/FMECA), relative ranking, and Failure Mode Effects and Criticality Analysis.

The ICH Q9 guidelines mention various tools for risk assessment, including FMEA, comparison matrix (CM), risk estimation matrix (REM), hazard operability analysis (HAZOP), and hazard analysis critical control points (HACCP). Among these, REM and FMEA are the most frequently used methods in product development. FMEA uses scoring on a scale of 1–10 for risk ranking based on severity, occurrence, and detectability. In contrast, REM uses different risk levels, such as low, medium, and

high-risk ratings, depending on their severity and occurrence ("Introduction to Quality by Design," 2019). A typical risk estimation matrix is shown in Figure 7.

3.4 Design Space

The principal aim of an analyst is to use the results of Design of Experiments (DoE) performed on response, most especially at advanced response surface design levels, in order to define design space for a method. Typically, this is represented by a multiresponse surface plot showing overlapping contour plots of various relationships among factors, factors, their interactions, and as many responses as possible. Design space corresponds to that area within the experimental region in which all Critical Method Attributes (CMAs) are satisfied, and thus identifies a robust analytical method (Gaudin & Ferey, 2016; Peraman et al., 2015; Rozet et al., 2013). This space defines a subset of it, the Method Operable Design Region (MODR), which is the set of operational parameters where the analytical method is operable or reliable (Peraman et al., 2015).

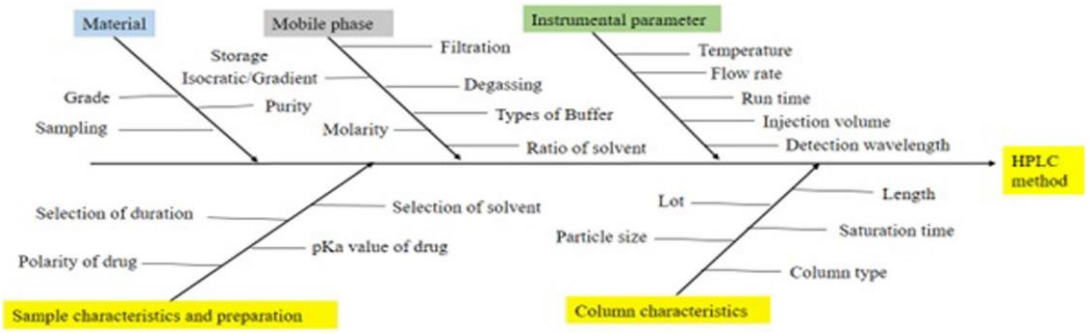
As an example, if developing an HPLC method that is optimization with respect to, say, concentration, flow rate, temperature, the first stage often involves running an initial screening or simple factorial design to isolate use critical factors. These factors are subsequently refined using response surface methodologies and the settings for those factors are determined to give robust method performance under defined conditions.

3.5 Control Strategy

The control strategy is determined based on the experience and in-depth knowledge of the analyst about the Method Operable Design Region (MODR). The statistical insight gained from the MODR phase is used to develop a robust and dynamic method control strategy. Unlike static approaches bounded in development phase, control strategies adapt through the method lifecycle as new insights and developments occur. Control strategies used in Quality by Design (QbD) methodology are similar to those of traditional approaches (Sangshetti et al., 2014).

In designing a control strategy, we need to consider the independence variables like composing mobile phase, wavelength, flow rate and column temperature which controls the variable of the response factors like theoretical plate count peak area, and retention time. Fig. 8 show these interdependencies as a schematic represent of the method parameter to response outcome interaction that forms the foundation for a complete and flexible control strategy.

Fig 6: Ishikawa Cause-and-Effect Fishbone Diagram for Liquid Chromatography Technique Development



likelihood	Consequence: Negligible 1	Minor 2	Moderate3	Major 4	Catastrophe 5
5 Almost certain	Moderate	Low	Extreme	Extreme	Extreme
4 Likely	Moderate	Low	Low	Extreme	Extreme
3 Possible	Low	Moderate	Low	Low	Extreme
2 Unlikely	Low	Moderate	Moderate	Low	Low
1 Rare	Low	Low	Low	Moderate	Moderate

velength → HPLC method
Length
tion time

Fig. 7 Risk estimation matrix (REM)

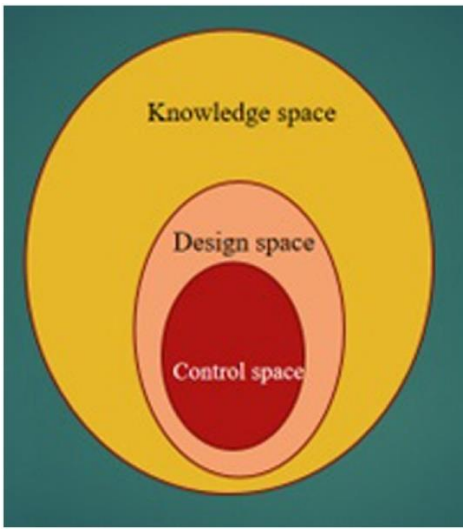


Fig. 8 A design space

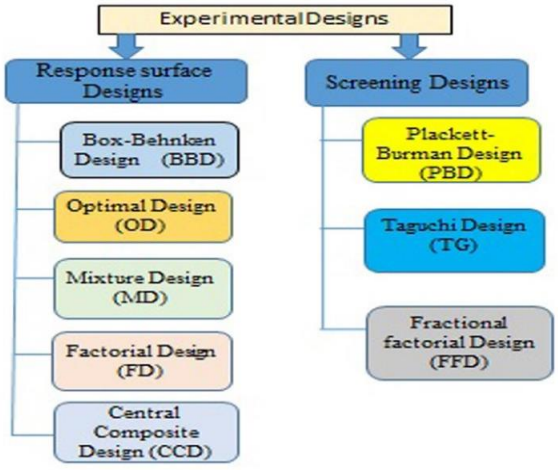


Fig. 9 Types of experimental design during QbD optimization

3.6 Experimental Design

The use of the statistical, mathematical and graphical optimization tools is extremely important to maximize improvements of multiple responses as long as the algorithms are defined and the data are collected, organized, and analysed carefully. Numerical optimization techniques are used in the application to determine the best possible factor settings, thereby achieving the desired outcome using the most efficient setup (Myers & Montgomery, 1995).

Although the specific objectives and requirements of the study dictate the selection of an experimental design, the fundamental aspects of all experimental designs are described in this section. Here the Box-Behnken Design can be used with 3 levels for each factor $\{-1, 0, +1\}$ to experiment with single variable effects and possible interactions. This design, termed as fractional factorial approach, provides a full fidelity framework for analysis of investigated variables (Ramalingam & Jahnavi, 2019). Figure 9 shows a graphic representation of a variety of experiments, and more information is included in Table 1.

Table 1: Methods of Analysis and Their Critical Quality Attribute (CQA) Parameters

GC method	HPTLC method	HPLC method
Oven's temperature and settings, Injection temperature, Gas flow rate, Sample diluent Concentration	TLC plates, Mobile phase Injection concentration, and volume Time needed for plate development Color development and detection reagent	Mobile phase Column selection Elution method Organic modifier

4. Selection of DoE Tools

Various optimization methods can be employed to create a mathematical model, taking into account the number of input variables, controlled parameter knowledge, and scientific understanding of the relationships between outcome variables during the DoE (Design of Experiments) selection process. Statistical expertise is crucial to assess the interaction and contribution of variables (Xn) on the method response (Yn). Additionally, DoE serves as a tool for selecting the optimal number of variables.

For example, the influence of each input parameter and their interactions can be evaluated using factorial design. Following this, Response Surface Methodology (RSM) can be used to analyze and optimize the results. Compared to factorial designs, the Taguchi method may be applied for fewer experimental runs (e.g., 50%, 25%, 25%); however, confounded interactions must be addressed. When a large number of input variables need to be investigated according to interaction effects, the Plackett-Burman techniques might be used. Table 2 displays a range of approaches.

Table 2 Selection of DOE tool in analytical quality by design (Ramalingam & Jahnavi, 2019)

Design	Usage	Advantage	Disadvantage
Box-Behnken Design	Uses three levels (−1, 0, +1) for each factor	Ideal when design points are precisely within the design region	May generate arbitrary values if not well-defined
Plackett–Burman Technique	Identifies or isolates key components from a large set of variables	Requires minimal runs for a broad set of variables	Managing interaction effects can be challenging
Doehlert Design	Optimizes variables	Useful for surface response analysis	Lacks provision for two-factor designs
Pseudo-Monte Carlo Sampling	Optimizes and quantitatively assesses risk	Rapidly determines model changes and behavior	More challenging for non-convex design areas
Fractional Factorial Design /Taguchi Method	Screens and optimizes variables	Requires fewer experimental runs	Complex interaction effects can be difficult to resolve
Full Factorial Design	Evaluates each input variable's effect and possible interactions	Identifies primary and secondary effects while mitigating failures	The number of trial runs depends on the number of variables involved

In the 1800s, researchers John Bennet Lawes and Joseph Henry Gilbert at Rothamsted Experimental Station pioneered the use of factorial designs. Later, in 1926, Ronald Fisher argued that the investigation of "one factor at a time" (OFAT) was less effective compared to employing more "complex" designs, such as factorial designs (Ramalingam & Jahnavi, 2019).

Table 3: Traditional Methodology and QbD in Product Development and Analysis

Measurement	Conventional	QbD of Product	QbD of analysis
Quality	Quality is ensured by testing the finished product	Quality is defined through product and process design using a scientific approach	Reliability and resilience are emphasized during method development

Procedure	Change is discouraged, resulting in a stagnant process	Process flexibility and design space facilitate continuous improvement	Methodological adaptability through MODR allows ongoing development
Approach Focused Strategy	Based on an experimental strategy that ignores variation and focuses on repeatability	Based on a structured method that accounts for control variability, emphasizing robustness	Focuses on creating a robust and economical approach
Specifications	Based on batch history	Determined by performance requirements for the product	Defined by method efficiency and ATP criteria
FDA Documentation	Includes only submission information	Includes product knowledge and process understanding	Provides product understanding and reliability through an analytical target profile
Advantage	Simple and constrained	Enhanced process analytical technology (PAT) tool that eliminates the need for final product testing	Reduces OOT and OOS, minimizing the need for revalidation

5. Implementation of Analytical Quality by Design (AQbD)

A number of variables can affect the outcomes of analytical methods, sparking the necessity of the Quality by Design (QbD) approach for analytical processes. Procedural parameters, sample characteristics, instrument configurations, and the adoption of calibration models are the things considered in these variables. Similarities to method development and dosage regimen formulation exist in chromatography, a widespread analytical technique in pharmaceutical quality assurance.

Analytical methods and procedures are documented as playing a pivotal role in the QbD paradigm in a document released by the U.S. Food and Drug Administration (FDA). Real time release testing advances the testing approach to processes which provides key insights into control of process and continuous improvement. The implementation of QbD encourages regulatory flexibility but requires robust analytical methods, consistent product quality and a full understanding of analytical processes (Ramalingam & Jahnavi, 2019) (see Tables 3 and 4). The result permits more method resilient development and is consistent with the established principles of quality driven analytical development.

Table 4 Historical background of QbD

Year	Activities
2023	ICH Q 14 Analytical Procedure Development
2009	Pharmaceutical Development (ICH Q8(R2))
2008	Pharmaceutical Quality System (ICH Q10)
2005	Quality Risk Management (ICH: Q9)
2004	For Novel Drug Development, Production, and Quality Control
2004	USFDA release final report in Pharmaceutical cGMP
2002	The USFDA adopted the QBD concept into cGMP
1970	QBD created by Joseph M Juran

6. Method Validation

Validation of method, as established by ICH Q2 (R1) guidelines, usually, but not always, involves operation within the chromatographic region of interest about a specified point (referred to as the Normal Operating Condition (NOC)) following the validation of the associated chromatographic manipulations. Through this process, not only is regulatory compliance met but the method's measurement uncertainty is also understood in greater depth. In addition, it shows suitability with the pre-established Analytical Target Profile (ATP). Validation entails evaluating a method's accuracy and precision, especially in stressful conditions, within the space of a chromatographic separation to confirm the method's robustness and reproducibility, across different scenarios (Barnett et al., 2013).

7. Regulatory Perspective of AQbD

The updated ICH Q2 (R2) guidelines for the validation of analytical procedures and the new ICH Q14 guidelines for analytical procedure development are foundational documents for researchers. These guidelines outline recommended activities for the development and validation of analytical techniques throughout their lifecycle, focusing on the quality of pharmaceutical ingredients and products. Science-based approaches and risk-based principles described in ICH Q14 support the creation, submission, and maintenance of analytical procedures, as detailed in ICH Q2 (R2).

8. Conclusion

Such an approach like QbD is necessary to effectively analyze product because changes to one input influence others, and OFAT approaches do not suffice. Statistical tools for mathematical modeling and experimental design are used in the Analytical Quality by Design (AQbD) approach to assess the effect of varying conditions on a particular reaction. The screening designs serve as an essential driver to uncover the key factors located within the knowledge space, and the response surface methodologies facilitate an investigation of the factors themselves, as well as their component interactions and interrelations, via the means of statistical and experimental analysis. The creation of the design space, also called Method Operable Design Region (MODR), gives us a robust analytical method.

AQbD integrates quality across the analytical process to provide analytical method lifecycle management and provide regulatory flexibility as adjustment within the established design space remains a non formal change. More research is needed to fully evaluate the economic advantage and quality assurance implication of AQbD in the pharmaceutical industry. Further, expertise in this domain should be developed. If future professionals are equipped with advanced qualifications, then they will be in a good place to help them implement, distribute these innovative methodologies and thus they will play an immense role in contributing to the progress of the industry.

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Design and Development of Sustain Release Matrix Tablets of Verapamil hydrochloride Using Natural and Synthetic Polymers

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Abstract: *Verapamil hydrochloride (HCl), a commonly used calcium channel blocker for managing hypertension and arrhythmias, is characterized by high gastrointestinal absorption but low bioavailability due to substantial first-pass metabolism. This study aims to develop a sustained-release matrix tablet formulation of Verapamil HCl to enhance therapeutic efficacy, improve patient compliance, and reduce adverse effects. Using a 3-level, 2-factor full-factorial design, we explored the effects of natural gums—Tamarind Gum and Cassia Roxburghii—along with Chitosan on the drug release profile. The tablets were prepared through granulation and evaluated for physical properties, including weight, thickness, hardness, friability, and drug content, all of which were within acceptable limits. Fourier-transform infrared spectroscopy (FTIR) analysis confirmed no chemical interaction between the drug and excipients. Drug release studies revealed that the release profile was highly dependent on the polymer composition, with higher amounts of Tamarind Gum leading to greater swelling and slower drug release. Formulation F7, containing 80 mg of Tamarind Gum and 50 mg of Cassia Roxburghii, successfully sustained the release of Verapamil HCl for 12 hours and demonstrated a similarity factor (f2) of 86.70 and a difference factor (f1) of 1.70 when compared to the marketed product. The drug release mechanism followed anomalous diffusion, characterized by both diffusion and erosion processes. Optimization using Design-Expert software led to an ideal formulation (F7) with a release profile closely matching the expected values. This study demonstrates the potential of a natural polymer-based sustained-release matrix tablet to enhance the oral bioavailability and clinical performance of Verapamil HCl.*

Key Words:*Verapamil hydrochloride tablet, Sustained release drug, Antihypertensive Drug, Natural and synthetic polymer*

1. INTRODUCTION:

Controlled release dosage forms are mainly designed to maintain therapeutic blood or tissue levels of the drugs that have a short elimination half-life. the controlled release dosage forms offer a number of advantages over immediate release products, such as better patient compliance due to decrease in dosing frequency, portability, convenience and fewer side-effects. such dosage forms exhibit better pharmacological effect and prolonged therapeutic activity. matrix tablets are one of the most commonly used controlled release dosage forms as they release the drug in a controlled manner. polymers commonly used in sustained release matrices are hydrophilic polymers(cellulosic and non-cellulosic) or hydrophobic polymers (ethyl cellulose , hypromellose acetate succinate, cellulose acetate propionate, methacylic acid copolymers, polyvinyl acetate, etc.
verapamil hydrochloride (vh) is a calcium channel blocking agent used in the treatment of hypertension, cardiac arrhythmia and angina pectoris. the biological half-life is 4-6 h, and it is completely absorbed from the gastrointestinal tract. the usual dose of the drug is 40-240 mg 3 times a day. hence, due to the short half-life and high frequency of administration, vh was considered as a suitable candidate for designing sustained release tablets.

2. RESEARCH METHOD / METHODOLOGY :

Materials:
A gift sample of verapamil hydrochloride was received from Hetero Drugs, Hydrabad ,Chitosan was received from Tristar formulations Pvt. Ltd, PVP-K30, Isopropyl Alcohol, Mg-Stearate, MCC, Talc was received from S.D. Fine Chemicals Ltd. Tamrind And Cassia Roxburghii Gums Are Isolated From Their Seeds .Double-distilled water was used throughout the study and all the other chemicals usedwere of analytical grade.
Extraction Of Mucilages:

All the collected plant materials were air dried, coarsely powdered and extracted separately with ethanol (95%) in a Soxhlet extractor for 24 h. The extracts were concentrated to dryness in a rotavapor under reduced pressure and controlled temperature (40-50 ^{o}C). The nature and yields of the extracts were noted. All the extracts were stored in a refrigerator at 4 ^{o}C for further studies.

Identification of Drug

Preparation of calibration curve of Verapamil HCl:

Standard Calibration curve of Verapamil HCl in 0.1 N HCL Standard solution:

100 mg of Verapamil HCl was accurately weighed and dissolved in 100 ml of 0.1 N HCl into a volumetric flask to get a concentration of 1 mg/ml (1000 µg/ml).

Stock solution:

10ml of solution was taken and make up to 100ml with 0.1 N HCl (100µg/ml) (stock solution). The above solution was subsequently diluted with 0.1N HCl to obtain series of dilutions containing 5,10,15,20, 25, 30 and 35µg/ml of Verapamil HCl per ml of solution.

The absorbance of the above dilutions was measured at 278 nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a

straight line. Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which is determined by least-square linear regression analysis.

3. RESULT

Compression of Verapamil HCl sustained Release Tablet
Weigh accurately about 400 mg of the mixture blend and fed into the die of single punch tablet press and compressed at 1.5N compression force using 16*8 mm concave punches**.**

Formulation of Verapamil HCl SR Matrix Tablets

Table 3.1 : Formulation of Verapamil HCl SR Matrix Tablets

Ingredients (mg)	**VH1**	**VH 2**	**VH 3**	**VH4**	**VH5**	**VH6**	**VH7**	**VH8**	**VH9**	**VH10**	**VH11**	**VH12**

Verapamil HCl	120	120	120	120	120	120	120	120	120	120	120	120
Tamarind Gum	80	100	120							60		70
Cassia Roxburghii				80	100	120					60	
Chitosan							80	100	120	60	60	60
PVP -K30	20	20	20	20	20	20	20	20	20	20	20	20
Isopropyl alcohol	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Mg. stearate	8	8	8	8	8	8	8	8	8	8	8	8
MCC PH102	172	152	132	172	152	132	172	152	132	132	132	122
Total weight (mg)	400	400	400	400	400	400	400	400	400	400	400	400

Table 3.2 : Variables in full factorial design of sustained release matrix tablet of Verapamil HCl

Variables	**Levels Used**		
Independent Variables	**Low (-1)**	**Medium (0)**	**High (+1)**
X1 = Tamarind Gum	60	70	80
X2 = Cassia Roxburghii	50	60	70
Dependent Variables			
Y1	Drug release at 2 hrs.		
Y2	Drug release at 6 hrs.		
Y3	Drug release at 12 hrs.		

Preparation of Matrix Tablet Verapamil HCl, Tamarind Gum and Cassia Roxburghii were weighed and mixed well. 3ml of isopropyl alcohol was taken and poured into the bulk of the mixture and mixed for 10mins to prepare a wet mass. Granules were prepared by passing the wet mass through the mesh #16. The granules were dried in an oven for half an hour at 40 degree centigrade and then passed through the mesh #22. The dried granules were blended with Mg-stearate, which act as lubricant.

Tablets containing 120mg Verapamil HCl were compressed using 19.5 X 8.9 mm tablet tooling at rotational speed 40 RPM the average hardness of the tablet was 5-7 kg/cm^2. The trials were performed in a randomized order. The total weight of each tablet was fixed at 400 mg by using Micro Crystalline

Cellulose as diluents. Throughout experiment same equipment's were used for preparation and testing of the tablets.

Post Compression Parameters Friability (F)

Tablet strength was tested by Roche friabilator. Pre weighed tablets were allowed for 100 revolutions (4min), taken out and were dedusted. The percentage weight loss was calculated by rewriting the tablets.

Method: Selected formulations were stored at different storage conditions at elevated temperatures such as 25°C± 2°C / 60% ± 5% RH, 30°C ± 2°C / 65% ±5% RH and 40°C ± 2° / 75% ± 5% RH for 90 days.

The samples were withdrawn at intervals of fifteen days and checked for physical changes, hardness, friability, drug content and percentage drug release.

Procedure:

Stability Studies

Stability studies of pharmaceutical products were done as per ICH guide lines. These studies are designed to increase the rate of chemical or physical degradation of the drug substance or product by using exaggerated storage conditions.

IDENTIFICATION OF DRUG

Preparation of calibration curve of Verapamil HCl:

A. Standard calibration curve of Verapamil HCl in 0.1 N HCL

The correlation coefficient was calculated by linear regression analysis. The absorbance of the above concentration are shown in table.

Table 3.3: Standard graph of Verapamil HCl in 0.1 N HCL (λmax 229 nm)

Sr. no.	Conc. (mcg/ml)	Absorbance Mean±SD
1.	0.00	0.000±0.000
2.	5.00	0.124±0.001
3.	10.00	0.232±0.002
4.	15.00	0.351±0.002
5.	20.00	0.475±0.002

6.	25.00	0.586±0.003
7.	30.00	0.712±0.003

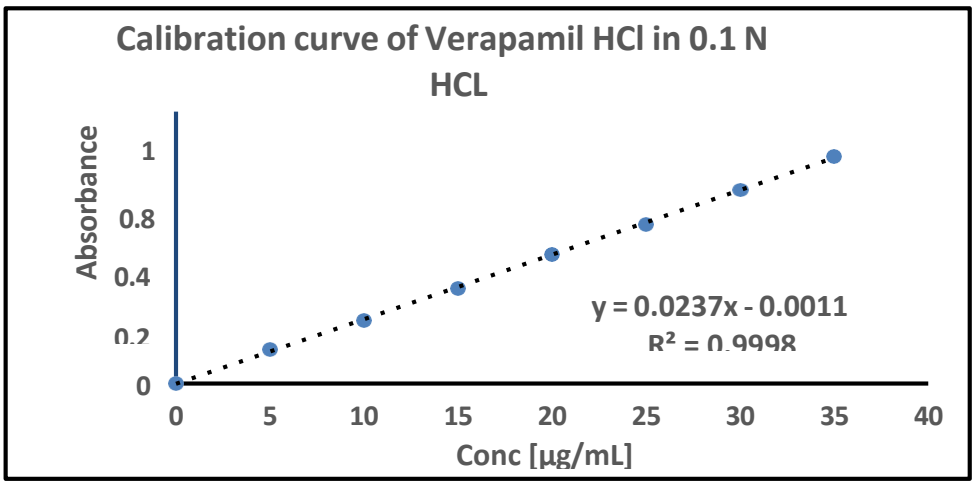

Figure 3.1: Standard graph of Calibration curve of Verapamil HCl in 0.1 N HCL (λmax 229 nm)

B. Standard calibration curve of Verapamil HCl in pH 6.8 phosphate buffer

The correlation coefficient was calculated by linear regression analysis. The absorbances of the above concentration are shown in table 5.8

Table 3.4: Standard graph of Verapamil HCl in pH 6.8 phosphate buffer (λmax 278 nm)

Sr. no.	Conc. (mcg/ml)	Absorbance Mean±SD
1.	0.00	0.000±0.000
2.	5.00	0.126±0.001
3.	10.00	0.238±0.002
4.	15.00	0.354±0.002
5.	20.00	0.481±0.002
6.	25.00	0.595±0.003
7.	30.00	0.721±0.003

The preformulation parameters like angle of repose, bulk density, tapped density and compressibility index and Hausner's ratios were studied to evaluate the flowability and compressibility of the powder of Verapamil HCl SR matrix tablets. The bulk density and tapped density was found to be in the range of 0.607 to 0.660 gm/cm^3 and 0.810 to 0.892 gm/cm^3 the compressibility and hausner's ratio were found to be 21.15% to 31.05% and 1.27 to 1.45. This indicates the granules have good flow character and have good compression property. All the results are within the prescribed limits.

The parameters like angle of repose, bulk density, tapped density and compressibility index and Hausner's ratios were studied to evaluate the flow ability and compressibility of the powder formulations.

The tablets were evaluated for thickness, hardness, friability, average weight and drug content. The thickness of the formulated tablets was found to be in the range of 3.33mm to 3.65 mm. Hardness and friability was found to be 5.5-7.90 kg/cm^2 and 0.13- 0.24% which indicates the tablet has adequate mechanical strength. Weight variation of the tablets was found to be within the specified limits.

The drug content of all the formulations ranged from 95.88-101.05% indicating the presence of an acceptable amount of drug in the formulations.

Effect of Tamarind gum on Verapamil HCl release

Cumulative percentage drug release for the different concentration of Tamarind gum (20%, 25% and 30%) is given the table 6.6. These formulations were able to extend and control their release pattern to desired period of time. The drug release rate was found to be decreased when concentration of polymers was increased. This may be due to increased swelling of the polymer when concentration is increased which leads to increased viscosity of the medium and thus increases the mean diffusion path length of the drug molecule to get released into the diffusion medium.

Effect of Cassia Roxburghii on Verapamil HCl release

Cumulative percentage drug release for the different concentration of Cassia Roxburghii (20%, 25% and 30%) is given the table 6.6. These formulations were able to extend and control their release pattern to desired period of time. The drug release rate was found to be decreased when concentration of polymers was increased. This may be due to increased swelling of the polymer when concentration is increased which leads to increased viscosity of the medium and thus increases the mean diffusion path length of the drug molecule to get released into the diffusion medium.

Effect of Chitosan on Verapamil HCl release

Cumulative percentage drug release for the different concentration of Chitosan (20%, 25% and 30%) is given the table 6.6. These formulations were able to extend and control their release pattern to desired period of time. The drug release rate was found to be decreased when concentration of polymers was increased. This may be due to increased swelling of the polymer when concentration is increased which leads to increased viscosity of the medium and thus increases the mean diffusion path length of the drug molecule to get released into the diffusion medium.

Effect of combination of polymer on Verapamil HCl release

Cumulative percentage drug release for the combination of different concentration of Tamarind gum, Cassia Roxburghii and Chitosan polymers.These formulations were able to extend and control more as compared to individual polymer and so their release pattern to desired period of time. The drug release rate was found to be decreased when concentration of combination of polymer polymers was increased. This may be due to increased swelling of the polymer when concentration is increased which leads to increased viscosity of the medium and thus increases the mean diffusion path length of the drug molecule to get released into the diffusion medium. So, by using combination of polymer we can retard the drug release up to 12 hrs.

Pre compression parameters of sustained release matrix tablet of Verapamil HCl The blend of powder was prepared using all possible formulation of 3^2 full factorial design and evaluated for evaluation parameters like Angle of Repose, Bulk density,

Tapped density, Carr's index and Hausner's ratio. The method for measurement of angle of repose, bulk density, tapped density; Carr's index and Hausner's ratio are given in method section. Angle of repose of all batches varies from 25° 18' to 34° 12'. Angle of repose less than 40 indicates good flow property. Compressibility index vary from 17.25% to 26.51% which shows good to fair compressibility. Hausner's ratio varies from 1.19 to 1.34. Hausner's ratio between 1.19-1.34 indicates good compressibility. Here all these results showed good flow property and compressibility which is favorable for tablet compression.

Post compression parameters of factorial formulations of sustained release matrix tablet of Verapamil HCl

The average weight of tablet formulations was within the range of 398.93-404.40 mg. So, all tablets passed weight variation test as the % weight variation was within the pharmacopoeia limits of 5% of the weight. The weight of all the tablets was found to be uniform with low standard deviation values. The mean tablet thickness (n=5) were uniform in all batches with values ranging between 3.51-3.65mm. These values thus indicate uniformity within batch and batch to batch. The measured hardness of tablets of each batch ranged between 6.20-7.70 kg/cm^2. This ensures good handling characteristics of all batches. The friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable. The percentage drug content of the all batches was found between 95.64% to 101.80%, which was within acceptable limits and indicating dose uniformity in each batch.

Swelling study

Drug release profiles are dependent upon swelling behaviour of the tablets. Swelling index increased as

the weight gain by the tablets increased proportionally with the rate of hydration. Swelling index of trial batch F1 to F9 was calculated. Results indicate that when the polymer concentration increased, swelling index was proportionally increased. Results also indicate that tablets prepared by Tamarind gum were more swellable then Cassia Roxburghii gum. This result showed due to more hydrophilicity of Tamarind gum gum as compared to Cassia Roxburghii gum.

Here results indicate that Tamarind gum polymer have more swelling properties due to the polyacrylic acid derivatives as compared to Cassia Roxburghii gum.
Factorial batch F7 containing 80 mg of Tamarind Gum and 50 mg of Cassia Roxburghii able to swell 92.65 more after 8 hrs. as compared to other formulations.
In the Invitro study, Tamarind Gum and Cassia Roxburghii gum is hydrophilic in nature. In case of hydrophilic matrix system, drug release involves penetration of solvent into the matrix, hydration and swelling of the polymer and dissolution of the active ingredients and transfer of the dissolved drug and soluble matrix components into the bulk.

From the result it reveals that the rate of drug release was rapid for batches containing Low level of X1 compared with others, due to High quantity of polymer results drug may have entrapped within a polymer matrix causing a decrease in release rate. Therefore, predicted release of drug can be resulted by manipulating the quantities of X1, X2.

The variation in initial rapid release of drug is due to difference in the viscosity of the polymeric mixtures. As we know that viscosity of polymer is inversely proportional to the rate of drug release, variation in the viscosity is due the formation of thicker gel layer in formulation.

Out of 9 formulation of sustained release matrix, only formulation F4-F9 able to sustain release of Verapamil HCl for 12 hrs. Formulation F7 containing 80 mg of Tamarind Gum and 50 mg of Cassia gum able to retard release of Verapamil HCl for 12 hrs. So F7 consider s optimize formulation.

Table 3.5: *In-vitro* drug release study of factorial formulations of sustained release matrix tablet of Verapamil HCl

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9	Market product
0	0	0	0	0	0	0	0	0	0	0
1	26.70	24.10	23.18	22.80	21.78	20.40	20.10	19.56	19.20	20.25

2	35.20	33.20	32.75	30.55	28.56	27.80	26.67	25.50	24.90	25.50
4	53.30	48.10	45.50	44.35	43.33	42.24	41.22	40.80	38.90	38.84
6	71.80	69.35	66.60	64.95	63.65	60.50	59.75	58.76	56.70	56.60
8	84.90	80.48	80.15	79.90	78.65	76.25	75.95	74.66	73.14	75.50
10	99.62	99.10	99.00	94.10	93.50	92.20	91.70	91.76	89.10	89.80
12				98.25	98.05	97.79	99.79	99.20	98.19	99.75

4. DISCUSSION

The purpose of this research was to produce a sustained-release matrix tablet of Verapamil HCl response surface technology that exhibits higher patient compliance, decreases adverse effects, and enhances oral bioavailability. A sustained-release matrix tablet of Verapamil HCl was manufactured by utilizing a granulation process containing 120 mg of Verapamil HCl using natural gum like Tamarind Gum, Cassia roxburgii with Chitosan.

5.CONCLUSION

Full--factorial design 3-level-2-factor factorial design was created as per the conventional technique. The parameters were selected after a preliminary investigation. The amount of tamarind gum (X1) and the amount of Cassia Roxburghii (X2) have been chosen as independent variables. Drug release at 2 hours, 6 hours, and 12 hours were chosen as dependent variables.

The average weight of tablet formulations was within the range of 398.93–404.40 mg. The mean tablet thickness (n = 5) was consistent in all batches, with values ranging between 3.5 and 1.65 mm. The measured hardness of the tablets in each batch varied between 6.20 and 7.70 kg/cm2. The friability was less than 1% in all the formulations, guaranteeing that the tablets were mechanically stable. The percentage drug content of the entire batch was determined to range from 95.64% to 101.80%, which was within acceptable ranges and suggests dosage homogeneity in each batch.

Drug release patterns are dependent on the swelling behavior of the tablets. The swelling index rose as the weight gain from the pills increased proportionately with the rate of hydration. The swelling index of trial batches F1 to F9 was computed. Results suggest that as the polymer content rose, the swelling index correspondingly increased. Results also revealed that tablets made with tamarin gum were more swellable than Cassia Roxburghii gum.

Out of nine formulations of sustained release matrix, only formulations F4–F9 were able to maintain the release of Verapamil HCl for 12 hours. Formulation F7, comprising 80 mg of tamarind gum and 50 mg

of Cassia Roxburghii, is competent to delay the release of Verapamil HCl for 12 hours. Therefore, F7 considers improving formulation. F7 is compared with the marketed product and reveals a similarity factor (f2) of 86.70 and a difference factor (f1) of 1.7024.

Considering the result, it can be stated that the optimized formulations promise a release profile that is quite close to the expected values.

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Trace Level Ion Estimation Method Development for Purified Water by Ion Chromatography

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Abstract: *A simple, accurate, precise and reproducible Ion Chromatography simultaneous estimation method development and validation for estimation of trace level ions in purified water. A specific and sensitive isocratic IC method was developed and validated for analysis of trace level ions in purified water using thermo scientific AS23 (4×250 mm) with flow rate 1.0 ml/min and Temperature 30 °C. The isocratic mode was used for elution and the mobile phase was 30 mM KOH. The samples were analyzed using 70 µl injection volume. The developed method was validated as per ICH Q2R1 for linearity, specificity, accuracy, precision, limit of detection, limit of quantification and robustness. The linearity of the proposed method was investigated in the range of 0.1-2.0 ppm for Fluoride, Chloride, Nitrite, Bromide, Nitrate, and Sulfate (R2 = 0.9991, 0.9974, 0.9997, 0.9982, 0.9979, 0.9968). The % accuracy was found to be in the range of Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate was found to be in range of 98.05 – 99.79%, 98.17 – 101.04%, 99.62 – 101.06%, 98.96 – 102.04%, 99.80 – 101.04%, 99.59 – 102.31%. The RSD for precision and robustness was found less than 2. A rapid and sensitive isocratic elution mode analytical method was developed and validated for the simultaneous analysis for Purified water. Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate been validated in accordance with ICH Q2 (R1) requirements.*

Key Words: Purified water, Analytical Method validation, Trace level Anions, Ion Chromatography

1. INTRODUCTION:

In pharmaceutical processes, water plays a crucial role, acting as a solvent, cleaning agent, etc across manufacturing and quality control[1-3]. Its usage spans as a solvent, a cleaning agent, and a reactant in various chemical processes. However, the presence of impurities such as nitrates, chlorides, and sulfates poses significant challenges, including equipment corrosion, altered chemical reactions, and compromised drug efficacy. Robust analytical techniques are essential to mitigate these issues that ensure the consistent quality of water used in production[4-6].

This paper outlines an advanced ion chromatography method developed to monitor and quantify critical anions. The study focuses on establishing a validated protocol in line with international standards, aiming to enhance the reliability and efficiency of water quality analysis[5-9].

2. METHODOLOGY:

Materials and Instrumentation:

Purified water samples were analyzed using a Dionex IonPac AS23 column paired with a Thermo Scientific ion chromatography system. Milli-Q water served as the diluent to avoid interference from impurities.

Chromatographic Optimization

Isocratic elution was chosen due to its straightforward and reproducible nature. The mobile phase, 30 mM KOH, was optimized for peak resolution, minimal tailing, and theoretical plate counts. Injection volumes of 70 µL ensured adequate sample introduction without overloading the column[10].

Preparation of Standards

A series of standard solutions was prepared to establish calibration curves. Stock solutions were diluted systematically to create working standards spanning 0.1–2.0 ppm for each ion. This range covers typical impurity levels observed in pharmaceutical-grade water.

Validation Parameters

Linearity:

The method exhibited excellent linearity with correlation coefficients (R^2) exceeding 0.996 for all ions. Consistency in response was verified by plotting calibration curves across the specified range.

Accuracy and Precision

Accuracy tests involved spiking water samples at varying concentrations and recovering over 98% of the expected values. Precision was evaluated through repeatability and intermediate precision studies, with relative standard deviations consistently below 2%[11].

Sensitivity (LOD and LOQ)

Limits of detection (LOD) and quantification (LOQ) were calculated using signal-to-noise ratios, highlighting the method's ability to detect trace impurities[12].

Robustness

Robustness testing involved intentional changes in chromatographic settings, including flow rate and column temperature. Results confirmed the method's reliability under slight operational changes[13].

3. RESULT and DISCUSSION:

Preliminary studies were performed using various combinations of mobile phase. From preliminary studies, it was found that 30 mM KOH composition and flow rate of 1.0 mL/min with 30 °C column oven temperature shows good separation with acceptable suitability parameter. In optimized chromatographic condition Retention time of Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate in Fig. 1.

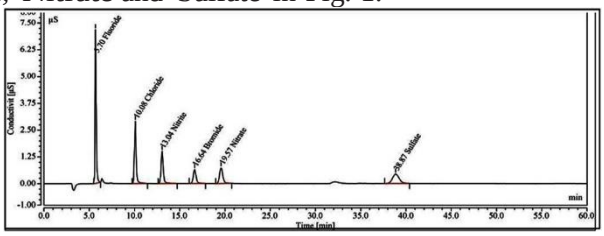

Figure 1: Optimized Chromatogram

System suitability parameter

After calculating the system suitability parameters, it was discovered that all parameters fall within the permissible range. It is mentioned in Table 1. Acceptance criteria for tailing factor is less than 2, for resolution greater than 2 and for theoretical plate it is not less than.

Table 1: System Suitability Parameter of Optimized Condition

Chromatographic Parameter	Optimize Condition
Flow rate	1.0 ml/min
Injection volume	70 µl
Mobile Phase composition	30 Mm KOH
Column	Dionex Ion Pac AS23
Temperature	30˚ C

Method Validation

Linearity

Linear responses were found for Fluoride, Chloride, Nitrite, Bromide, Nitrate, and Sulfate in the concentration range of 0.1-2.0 ppm. Figure 2 represents calibration curves for Fluoride, Chloride, Nitrite, Bromide, Nitrate, and Sulfate respectively.

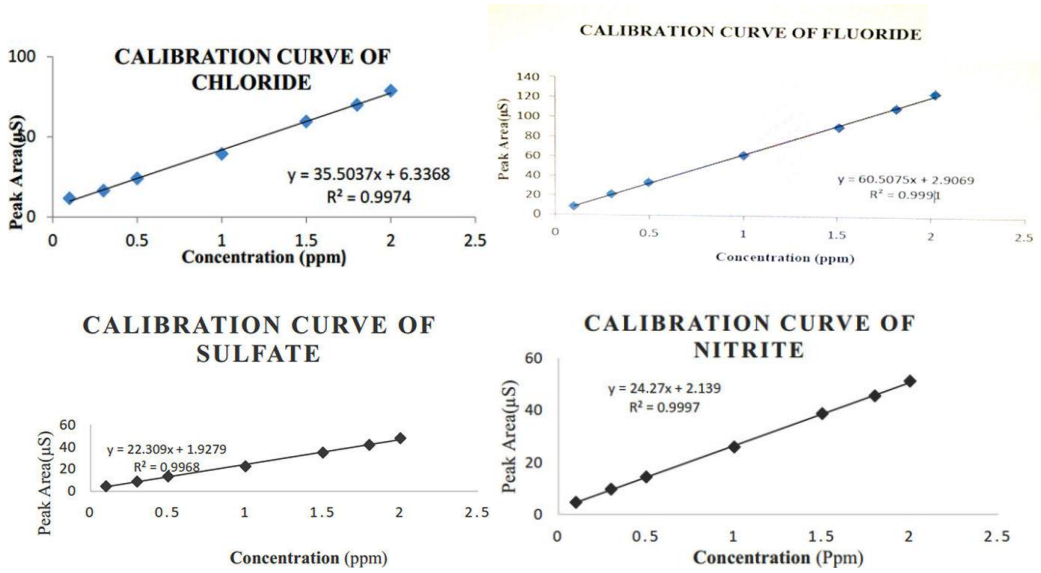

Figure 2: calibration curves

Specificity:

It is proved that there is no any interference of excipient with the peak of Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate by comparing the chromatogram of blank, mobile phase, and standard solution.

Table 2: Specificity data

Level	Conc.(ppm)	Bromide		Nitrate		Sulfate	
		Area (µS)	%Recovery	Area (µS)	%Recovery	Area(µS)	%Recovery
50%	0.5 ppm	10.5	100.05	241.29	100.72	192.36	100.23
		10.41	98.96	241.37	101.44	192.28	99.59
		10.46	99.58	241.2	99.8	192.53	101.54
100%	1.0 ppm	16.41	100.23	249.74	102.79	201.72	102.13
		16.27	99.17	249.68	102.45	201.38	100.61
		16.56	101.25	249.56	101.8	201.25	99.98
200%	2.0 ppm	31.74	99.87	269.95	101.003	227.88	101.55
		31.75	99.9	269.79	100.58	227.42	100.6
		31.77	99.98	269.89	100.84	227.29	100.33

Accuracy:

Percentage recovery for Silodosin was in the range of Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate by IC was found to be in the range of 98.05 – 99.79%, 98.17 – 101.04%, 99.62 – 101.06%, 98.96 – 102.04%, 99.80 – 101.04% and 99.59 – 102.31% data are shown in Table 3.

Table 3: Accuracy Data

Level	Conc. (ppm)	Fluoride		Chloride		Nitrite	
		Area (µS)	%Recovery	Area (µS)	%Recovery	Area (µS)	%Recovery
50%	0.5 ppm	35.77	98.48	2708.85	99.95	14.25	99.62
		35.81	98.61	2708.95	100.41	14.36	100.38
		35.63	98.05	2708.46	98.17	14.34	100.21
		62.84	98.75	2725.46	100.001	25.34	99.9
100%	1.0 ppm	62.94	98.9	2725.86	101.04	25.64	101.06
		63.18	99.31	2725.34	99.69	25.58	100.85
		127.35	99.15	2773.59	100.01	53.35	100.44
200%	2.0 ppm	127.55	99.31	2773.89	100.36	53.55	100.81
		128.16	99.79	2773.54	99.95	53.16	100.07

Precision:

Replicates of Assay concentration for Repeatability and 3 Concentration of 3 Replicates of intermediate precision studies were carried out. The method is precise as RSD and was found to be less than 2. Results are shown in Table 4.

Table 4: Precision Data

Precision		Fluoride	Chloride	Nitrite	Bromide	Nitrate	Sulfate
50%	Mean Area (µS) ± SD	33.19± 0.48	23.29± 0.16	14.58± 0.21	7.35± 0.13	10.79± 0.09	13.86± 0.08
	%RSD	1.46	0.69	1.50	1.81	0.83	0.61
100%	Mean Area (µS) ± SD	61.39± 0.37	38.44± 0.29	25.92± 0.07	14.71± 0.12	19.30± 0.17	23.81± 0.13
	%RSD	0.60	0.77	0.27	0.87	0.917	0.566
200%	Mean Area(µS) ± SD	124.70± 1.49	78.73± 0.09	51.71± 0.27	29.50± 0.21	38.56± 0.27	47.58± 0.17
	%RSD	1.20	0.12	0.53	0.71	0.71	0.36

LOD and LOQ

LOD and LOQ of Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate were determined using average of slope and standard deviation of intercepts. LOD was found to be 0.02, 0.02, 0.03, 0.04, and 0.02 ppm for Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate respectively. LOQ was found to be 0.05, 0.06, 0.09, 0.07, and 0.05 ppm for Fluoride, Chloride, Nitrite, Bromide, Nitrate and Sulfate respectively.

Robustness

The method was found to be robust when different factors such as flow rate and Temperature were deliberately changed. The relative standard deviation of peak area was less than 2 percent when the parameters were deliberately changed.

4. CONCLUSION:

A validated analytical method for detecting trace ions simultaneously is presented in this study. The approach aligns with ICH Q2(R1) guidelines, offering a reliable solution for quality control in the pharmaceutical sector. By adopting this method, manufacturers can enhance their compliance with international standards while optimizing their processes.

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Applications of Artificial Intelligence in Pharmaceuticals: Transforming Drug Discovery, Clinical Trials, and Personalized Medicine

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Abstract:

Artificial Intelligence (AI) has emerged as a transformative technology across various industries, including the pharmaceutical sector, where its impact is reshaping traditional approaches to drug discovery, clinical trials, and personalized medicine. This review explores the diverse applications of AI in addressing critical challenges such as the high costs, lengthy timelines, and inefficiencies associated with drug development. AI-driven tools and algorithms enable the identification and validation of drug targets, virtual screening, and optimization of drug candidates, significantly accelerating the discovery process. In clinical trials, AI enhances patient recruitment, optimizes trial designs, and reduces costs by utilizing predictive modeling and data-driven insights. Furthermore, AI plays a pivotal role in personalized medicine, leveraging genetic, clinical, and socioeconomic data to tailor treatments and improve patient outcomes. Despite its promise, the integration of AI faces challenges, including data privacy concerns, regulatory hurdles, and the need for ethical frameworks. This paper highlights the opportunities and challenges of AI in the pharmaceutical industry, emphasizing its potential to revolutionize healthcare and pave the way for innovative, patient-centered solutions.

Key Words: *Artificial Intelligence, Pharmaceuticals, Drug Discovery, Clinical Trials, Personalized Medicine, AI in Healthcare, Machine Learning, Predictive Modeling, Drug Development, Pharmacogenomics.*

1. INTRODUCTION:

Artificial intelligence (AI) is swiftly becoming a revolutionary discipline of computer science that enables machines to act like people, solving issues, offered by the use of symbolic programming. Artificial intelligence (AI), a term which can be understood as “the capacity of machines to respond strongly to the input like the human perception, contemplation and activity” has grown from imagination to manner of life for a variety of industries, including engineering, corporate and healthcare (Shukla and Jaiswal, 2013). For example, much as AI has rapidly disrupted ‘conventional’ conventions in the pharmaceutical sector, AI has proven particularly advantageous for the pharmaceutical industry, from pharmaceuticals discovery to custom medicine.

Often taken to be the field’s inception: The field dates back to the 1956 conference at Dartmouth. At this key conference, where they were deep-diving into an underlying science of

AI and modeling human thinking and robots that can accomplish these actions, they began. One of the many uses of early AI systems — artificial intelligence programs able to sort out hard issues – was the development of the Logic Theorist, a software to establish mathematical theorems.

The integration into the pharmaceutical sector of AI tackles significant difficulties in the pharmaceutical industry by making drug development delayed and costly. However, it sometimes takes conventional research a decade and costs up to $2.6 billion to get a single medication to market, and many drugs are abandoned during clinical trials. Through Artificial Intelligence (AI), we can help expedite the drug discovery journey and boost the accuracy of target identification and the associated cost (Vyas et al., 2018).

Additionally, the application of AI systems in analyzing massive datasets to the extent never seen before is changing personalized medicine. AI not only improves patient outcomes, but works with treatments tailored to individual genetic and clinical profiles to also optimize healthcare delivery. AI may forecast things as simple as a response to a therapeutic treatment, to as complicated as assistance in a major surgical operation (Shukla and Jaiswal, 2013; Vyas et al., 2018).

In this paper, the diverse uses of AI in the pharmaceutical sector are examined from the standpoint of AI application on drug discovery and personalized medicine, and the problems and opportunities that the AI faces in the fast-evolving industry. With the advent of AI, the necessity of it as a future force in influencing the pharmaceutical landscape develops productively.

2. AI IN DRUG DELIVERY PROCESS:

The emergence of epidemics and pandemics, such as influenza and COVID-19 (Zheng et al., 2020), and the prevalence of severe diseases, such as cancer and heart disease, demonstrate the ongoing need to discover new drugs. A multi-stage procedure (Fig. 1), requiring target selection, validation, high throughput screening, animal investigations, safety and efficacy protocols, clinical trials, and regulatory approval, is routinely followed (Vamathevan et al., 2019). Development of a new medicine takes around 14.6 years and costs about US$ 2.6 billion on average (Wouters et al., 2020). AI-based methods could be utilized at several stages in this process: identifying novel targets (Jeon et al., 2014), evaluating drug-target interactions (Lee et al., 2019; Katsila et al., 2016), examining disease mechanisms (Wouters et al., 2020), and improving small molecule compound design and optimization (Nicolaou and Brown, 2013). These methods can also be used to identify and develop prognostic biomarkers, and study drug efficacy, response, and resistance (Qureshi et al., 2022).

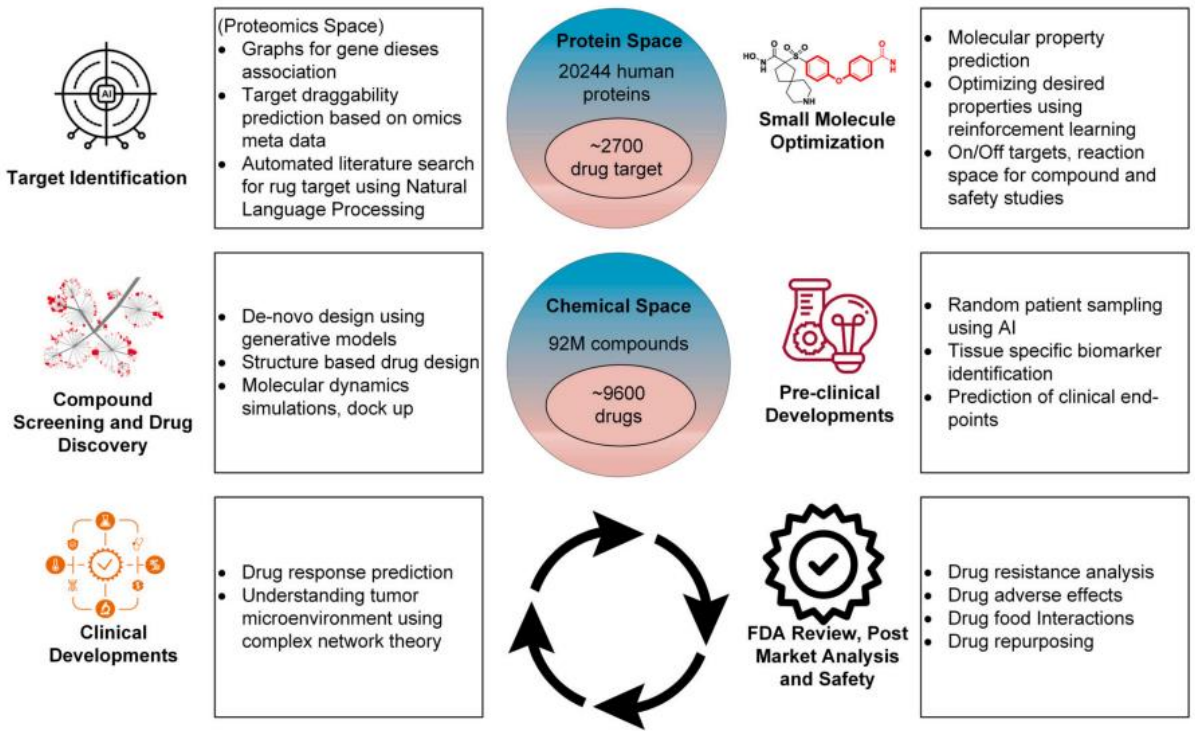

Figure 1: Applications of AI based methods at different stages of a drug discovery pipeline (Qureshi et. al., 2023)

Finding effective new medications is a challenging task and is typically the most challenging aspect of drug development. The reason for this is the enormous extent of what is referred to as chemical space, which is thought to be around 1060 molecules (Segler et al., 2018). Artificial intelligence (AI)-based technologies have evolved into multipurpose instruments that can be used widely in many phases of drug development, including identifying and validating drug targets, creating new drugs, repurposing existing drugs, increasing R&D efficiency, gathering and analyzing biomedical data, and streamlining the selection of patients for clinical trials (Huang et al., 2017; Zhang et al., 2017). These possible applications of AI offer the chance to reduce bias and human interference in the process while addressing the inefficiencies and uncertainties that occur in traditional drug development approaches (Mamoshina et al., 2016).

AI can be used to virtually screen and optimize drugs, evaluate their bio-activities, and anticipate protein-drug interactions **(Seddon et al., 2012**16). One way AI can help in virtual screening is through the development of prediction models, that can discover compounds with a high likelihood of binding to a target protein. These models can be trained using numerous types of data, such as known protein-ligand complexes, structural information, and molecular descriptors. Physico-chemical features of the drug, such as solubility, partition coefficient (logP), degree of ionization, and intrinsic permeability, may have an indirect effect on a medication's interaction with a target receptor family and must be considered while creating a novel medication **(Nicolaou and Brown, 2013)**17. AI can also be used to plan efficient routes for chemical production and create insights into the reaction processes of pharmaceuticals to discover possibly harmful interactions with other compounds.

Candidate structures of medications are refined and adjusted to increase target specificity and selectivity, and their pharmacodynamics, pharmacokinetics, and toxicological aspects. A virtual chemical space combining structure and ligand information may enable profile analysis, faster elimination of non-lead structures, and speed up the drug development process by avoiding costly time-consuming laboratory effort. Multi-objective optimization approaches can tailor molecules in a desired direction (Nicolaou and Brown, 2013). MD simulation and docking methods can be utilized to model the orientation, stability, and dynamics of the molecules.

The approach utilized by Bayer's in silico ADMET platform incorporates artificial intelligence (AI) and machine learning techniques to construct intricate hybrid models for predicting the Absorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET) characteristics of novel drug compounds. This method diverges from the protein-centric model by aggregating secondary data from a variety of chemicals, thereby enabling the generation of predictive models that can simulate the pharmacokinetic and toxicological behavior of these compounds. The integration of AI facilitates the analysis and forecasting of drug properties, offering a more comprehensive and scalable approach to ADMET prediction. However, the efficacy of this method is contingent upon the continual maintenance and updating of data, with manual oversight being required to ensure model accuracy and mitigate the risk of costly errors. (Jimenez et.al., 2013)

Chemoinformatic technologies, which enable the integration and analysis of complicated biological and chemical data, are becoming more and more important in the development of in silico drug design and discovery (Keiser et al., 2009). Among other things, these tools facilitate data mining (Nidhi et al., 2006), predictive analytics, and molecular modeling, and thus speed up the drug discovery process. For instance, ligand-based interaction fingerprints (LIFt) and protein-ligand interaction fingerprints (PLIF) are computational techniques that summarize molecule-to-protein interactions in an effort to suggest therapeutic targets, including p38α MAP kinase and GPR17. It has been demonstrated that these methods are effective in identifying ligand disease target information and possible therapeutic candidates (Wang et al., 2015) (Eberini et.al., 2011)

Network-based drug discovery maps drug protein and protein disease interactions using genomes, proteomics, and metabolomics data. MAGENTA and Ingenuity databases link metabolomic biomarkers to pathways, whereas ReKINect detects cancer kinome mutations. Connectivity Map and other computational frameworks transmit medications, genes, and diseases via gene-expression patterns, enabling drug repurposing and biomarker discovery. These techniques speed drug discovery by uncovering therapeutic targets and pathways, improving pharmaceutical research precision and dependability.

The computational tool ReKINect studies protein mutations (kinase) that influence cell signaling. However, kinases aid cell development, division, and communication. Mutant proteins disrupt cellular signaling, causing illnesses like cancer. ReKINect detects kinase mutations in ovarian cancer tumor cells. It then maps these mutations onto cellular networks to show how mutant kinases affect cell communication. It also helps researchers determine which mutations cause the disease and potential therapeutic targets. (Katsila, 2016)

3. AI IN CLINICAL TRIALS:

The success rate of clinical studies has been historically low. Overall, the probability of success for all medications and vaccinations is 13.8%. This ratio catapults to 20.9% when eliminating oncology medications, which exhibits a paltry 3.4% success rate, whereas vaccinations for infectious disease present a 33.4% success rate (Chi hem wong et. al., 2019). There are various causes which render clinical trials unsuccessful including: premature termination, inability to fulfill accrual targets and enrollment deadlines, and inefficiencies in the recruitment process leading to a mismatch between the patient and the research (Fogel, 2018). Feller observed that a quarter of all cancer studies actually failed to enroll a statistically strong sample size and 18% of trials closed with less than half the aim of enrollees. (Feller, 2015) However, the underlying source of failure remains the inability of a clinical trial to demonstrate efficacy (Fogel, 2018).

Artificial Intelligence (AI) is transforming the way clinical trials are run, making them more efficient, cost-effective, and patient-centered. AI-powered solutions optimize multiple stages of trials, from patient recruitment to data analysis. For instance, machine learning algorithms find prospective participants for trials by evaluating electronic health records and genetic data, dramatically lowering recruiting time. Natural language processing (NLP) accelerates protocol design by collecting significant lessons from past trials. Moreover, AI boosts data monitoring and analysis in real-time, predicting adverse occurrences and boosting patient safety (Ismail et al., 2023).

A program known as HINT (hierarchical interaction network), created in the lab of Jimeng Sun, a computer scientist at the University of Illinois Urbana-Champaign, may forecast the success of a study based on the drug molecule, target disease, and patient eligibility requirements. They then developed a technique known as SPOT (sequential predictive modelling of clinical trial outcome), which also considers the time periods of the trials in its training data and gives greater weight to more recent trials. Pharmaceutical companies may choose to change the design of a trial or try a different medicine entirely based on the expected outcome.

SEETrials, a technique for encouraging OpenAI's massive language model GPT-4 to extract safety and efficacy information from clinical trial abstracts, was created by a firm named Intelligent Medical Objects in Rosemont, Illinois. This makes it possible for trial designers to rapidly view the results and trial design of other researchers. Last year, the lab of geneticist Michael Snyder of Stanford University in California created a tool called CliniDigest that adds references to the unified summary while concurrently summarizing dozens of data from ClinicalTrials.gov, the primary US registry for medical trials. It has been used to provide an overview of how clinical researchers are collecting patient data using wearables including glucose monitors, sleep trackers, and smartwatches.

A team at Stanford led by biomedical data scientist James Zou created a system called Trial Pathfinder that examines a collection of finished clinical trials and evaluates the impact of changing the requirements for enrollment, such as blood pressure and lymphocyte count thresholds, on hazard ratios, or the rates of adverse events, such as patients dying or suffering from severe illness. They used it in medication trials for a particular kind of lung cancer in study. (Liu et. al., 2021) They discovered that, without raising the hazard ratio, doubling the number of eligible patients would have been possible by changing the criteria as recommended

by Trial Pathfinder. The study shown that while the method made sicker people, who stood to benefit more from the medications, eligible for treatment, it also worked for other forms of cancer and also decreased adverse effects.

Researchers must locate eligible patients after deciding on eligibility requirements. Criteria2Query was created in the lab of Chunhua Weng, a biomedical informaticist at Columbia University in New York City who has also worked on enhancing eligibility criteria. The application converts the eligibility criteria into a formal database query to locate matched candidates in patient databases. Users can enter the identification number of a study or type inclusion and exclusion criteria in natural language through a web-based interface.

DQueST is one system that consists of two components. The first extracts criteria from trial descriptions using Criteria2-Query. To assist patients in focusing their search, the second section generates pertinent questions. In order to motivate a big language model to identify suitable trials for a patient, Sun's lab collaborated with the US National Institutes of Health to develop another system called TrialGPT. It initially determines whether a patient meets all trial criteria after receiving a description of the patient and clinical trial, after which it provides an explanation. These evaluations are then combined to provide a trial-level score. It ranks numerous trials in this way for the patient.

Additionally, AI can lower the number of trial participants required. Digital twins of clinical trial participants are produced by a San Francisco, California-based start-up called Unlearn. Researchers can use the twin to compare results and anticipate how the same patient would have developed in the control group based on data from the experimental patient at the beginning of the trial. According to Charles Fisher, the founder and CEO of Unlearn, this approach usually results in a 20%–50% reduction in the number of control patients required. The business collaborates with numerous pharmaceutical firms, both big and small. According to Fisher, patients who participate in studies gain from digital twins as well because they are less likely to receive a placebo. (Hutson et. al., 2024)

4. AI IN PERSONALIZED MEDICINE:

Personalized medicine takes into account each patient's distinct genetic and socioeconomic traits to give them preventive care, customized therapies, and new diagnostics. Personalized medicine is becoming more popular due to the rapid advancement of many modern technologies, such as the fusion of biology and information technology (Jameson et.al., 2015). One of the main factors behind medicine as a representation of contemporary science and technology progress is artificial intelligence (AI). AI is being used to improve workflows in the health system, reduce medical errors, and let patients self-manage their health data (Topol, 2019). It does this by using massive amounts of categorized data, much increased processing capacity, and cloud storage. Furthermore, deep learning models have almost reached the same level of accuracy as physicians in a variety of diagnostic tasks thanks to the advancement of deep learning technologies represented by computer vision, natural language processing, reinforcement learning, and general techniques (Esteva et al., 2019).

Early disease detection and prevention are significantly aided by artificial intelligence. AI, for instance, can assist physicians in cardiology in choosing the most appropriate imaging test and accurately interpreting the images' results. Automated algorithms and artificial intelligence aid

in the analysis of cardiac positron emission tomography (PET) and single-photon emission computed tomography (SPECT) data, the reconstruction of three-dimensional cardiac pictures, the analysis of regional signals, and the provision of information such as innervation (Dilsizian et.al., 2014). These tools help physicians make more accurate and timely treatment decisions. AI may also be utilized to develop tailored intervention strategies and provide precise predictions about the occurrence of diseases. It can detect patterns and trends linked to disease outbreaks through data analysis, greatly slowing the spread of illness and reducing medical costs. AI can be used, for instance, to evaluate data from electronic health records, wearable technology, and various sensors. It is feasible to accurately predict future health outcomes and develop targeted treatments to halt disease epidemics by combining this data with other relevant information, such as social and demographic factors (Badidi, 2023). In order to enable precise diagnosis and treatment, AI systems may swiftly examine a patient's electronic medical record as well as a range of data sources, such as the internet, educational resources, and publications. For instance, IBM's Watson provides screening recommendations and treatment alternatives by utilizing databases, cross-correlating family history data, and synchronizing current research. (Dilsizian et.al., 2014)

The necessity for sophisticated methods to forecast and comprehend individual responses to drugs is further highlighted by the intricacy of gene–drug interactions. Addressing these issues and developing the field of customized medicine can be greatly aided by the use of AI and machine learning in this situation. (Kunal et.al., 2024)

There have been encouraging advancements in the application of deep learning and machine learning to pharmacogenomic research. By combining genomes with pharmacokinetics, these methods allow for the study of vast amounts of data, which makes them ideal for drug discovery. (Manzini et al., 2023) One benefit of deep learning, a subset of machine learning, is representation learning, which does away with the need for feature extraction and has raised the bar for many machine learning applications, such as drug discovery and genomics. (Kalinin et.al., 2018) Beyond traditional single-variable and multivariable statistical approaches, the application of AI methodologies such as machine learning, deep learning, and probabilistic graphs offers pharmacogenomics a timely synergy. (Ravishankar et.al., 2019)

Pharmacogenomics' massive data inflow poses a problem because conventional analytical techniques, including statistical correlation or visual analysis, are insufficient to manage such massive datasets. However, by enabling the effective management of the data as well as the autonomous identification and analysis of patterns within the data, the application of AI and machine learning techniques, particularly big data analytics, mitigates this problem. These methods can be used to enhance patient care and medication development since they offer the capacity to forecast the pharmacological characteristics of therapeutic targets, which is particularly advantageous in clinical settings. (Abdelhalim et al., 2022)

5. CONCLUSION:

Artificial Intelligence (AI) is revolutionizing the pharmaceutical industry by addressing critical challenges in drug discovery, clinical trials, and personalized medicine. Traditional drug development methods, characterized by high costs, lengthy timelines, and significant attrition rates, have long been a barrier to delivering timely and effective treatments. AI has emerged as a powerful tool to mitigate these challenges, offering innovative solutions to accelerate drug

development, enhance clinical trial efficiency, and improve patient-centric healthcare delivery. By integrating advanced technologies such as machine learning, deep learning, and predictive modeling, AI is enabling researchers to explore vast chemical spaces, predict drug-target interactions, and identify lead candidates with remarkable precision and speed.

In clinical trials, AI-driven platforms are optimizing the design, recruitment, and monitoring processes, significantly reducing costs and increasing the likelihood of success. Tools such as predictive models and digital twins not only streamline patient selection but also minimize reliance on placebo groups, thereby improving the overall trial experience for participants. Moreover, AI enhances data analysis capabilities, ensuring real-time monitoring and prediction of adverse events, which is crucial for patient safety and regulatory compliance.

Personalized medicine, another transformative area, benefits immensely from AI's ability to analyze genetic, clinical, and environmental data. By tailoring therapies to individual patients, AI fosters a more precise and effective approach to treatment, improving outcomes and reducing the risk of adverse reactions. The integration of AI into pharmacogenomics further underscores its potential to revolutionize treatment paradigms, enabling the development of customized solutions that address the unique needs of patients.

However, the widespread adoption of AI in the pharmaceutical industry is not without challenges. Data quality and availability, ethical considerations, regulatory compliance, and the risk of algorithmic biases remain key concerns. Ensuring data privacy and security while maintaining transparency in AI-driven decision-making is essential for building trust among stakeholders. Moreover, the industry must invest in interdisciplinary collaboration, integrating expertise from data science, medicine, and regulatory domains to fully harness AI's potential.

Looking forward, the role of AI in the pharmaceutical landscape will continue to expand, driven by advancements in computational power, machine learning algorithms, and access to large-scale datasets. Collaborative efforts between industry leaders, academic researchers, and regulatory bodies will be critical in overcoming existing barriers and fostering innovation. With its capacity to revolutionize drug discovery, optimize clinical trials, and enable personalized medicine, AI is poised to shape the future of healthcare, offering hope for more efficient, affordable, and patient-centric medical solutions. This transformative journey underscores the importance of embracing AI as a cornerstone of modern pharmaceutical research and development.

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Synthesis, characterization and biological evaluation of novel heterocyclic derivatives of DDT

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Abstract: *A number of condensed novel heterocyclic derivatives of Dicloro-diphenyl-tertachloroethan were prepared and characterized by IR spectroscopy, UV–Vis spectroscopy, nuclear magnetic resonance and mass spectrometry. The presence of halo functional groups present in parent molecule provide higher lipophilicity and therein higher toxicity, so this can be optimized by replacement of halo functional group with biological active heterocyclic molecules and it can be predict from the docking study by latest technique Glide Schrodinger a ligand docking program for predicting protein-ligand binding modes and ranking ligands via high-throughput virtual screening. The synthesized molecules may provide more site of attachment with the target and alter the pattern of toxicity shown in DDT and their derivatives.*

Key Words: *DDT, Docking, Heterocyclic,*

1. INTRODUCTION:

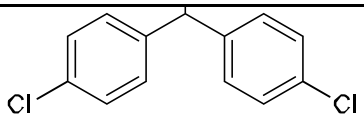
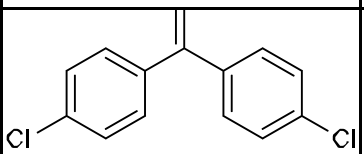
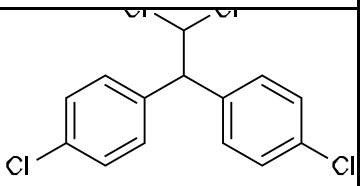
Human health effects from DDT at low environmental doses are unknown. The exposure high dose of DDT, human symptoms can include vomiting, tremors or shakiness, and seizures. Laboratory animal studies showed effects on the liver and reproduction[2]. The molecular mechanism involve activate Na channel firing and acting chiefly on the cerebellum and motor cortex. The liver is the only other organ significantly affected by DDT.[3] It is stable under most environmental condition and also resistance to totally breakdown by the metabolic enzyme present in microorganism present in the soil. Some of its metabolite notably 1,1'-(2,2-dichloro-ethenylidene)-bis [4-chlorobenzene] (DDE), have a stability equal to, or greater than that of parent compound, this is mainly due to fact that they are soluble in most of fat and insoluble in water.

There was a worldwide ban imposed by the UN during the Stockholm convention, with a formalization of its limited use in disease vector control.[4] The ban or continued usage of DDT is still a matter of scientific, economic and environmental controversy.[5] To circumvent the gap created by the ban on an effective and economic pesticide such as DDT, there is an urgent need to discover new pesticide candidates with a

DDT-type mode of action, but with lower non-target toxicity, bioaccumulation and better degradability.[6]

- **Chemical properties of DDT and their derivatives.**

- The structure of DDT permits several different isomeric forms, an example of which is 1-chloro-2[2, 2, 2-trichloro-1-(4-chlorophenyl)ethyl]benzene (*o,p'*-DDT). The term DDT is also applied to commercial products consisting predominantly of *p,p'-DDT together* with some *o,p'*-DDT and smaller amounts of other compounds. A typical example of technical DDT had the following composition: *p,p'*-DDT,77.1%; *o,p'*-DDT, 14.9%; *p,p'*-TDE, 0.3%; *o,p'*-TDE, 0.1%; *p,p'*-DDE, 4.0%; *o,p'*-DDE, 0.1%; and unidentified compounds, 3.5%.[7]

PROPERTIES	• ***p,p'*-DDT**	• ***p,p'*-DDE**	• ***p,p'*-DDD**
Other names	• Dichlorodiphenyltrichloroethane; 1,1'-(2,2,2-trichloroethylidene) bis(4-chlorobenzene); 1,1,1-Trichloro-2,2- bis(4-chlorophenyl)ethane	• Dichlorodiphenyldichloroethylene; 1,1'-(2,2-dichloroethylidene) bis(4-chlorobenzene); 1,1-dichloro-2,2- bis(4-chlorophenyl)ethyl ene	• Dichlorodiphenyldichloroethane; 1,1-bis (4-chlorophenyl)-2,2-dichloroethane; 1,1-dichloro-2,2-bis(4-chlorophenyl)ethane
Chemical structure			
Log K_{oc}	5.18	5.70	5.18
Log K_{OW}	6.19	6.51	6.02
Parachor:	638.9 ± 4.0 cm^3	589.8 ± 4.0 cm^3	602.7 ± 4.0 cm^3

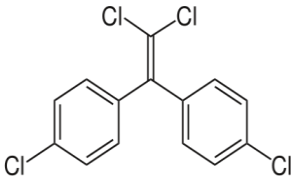
- Several studies have been reported indicating voltage-gated sodium channel (VGSC) as a molecular target of DDT action in insects.[8] While studying the SAR for

organochloride and pyrethroid pesticides, lipophilicity was found to be important for all the groups because it facilitates the delivery of these neurotoxicants to the site of action in the nerve. [9] The lipophilicity and steric factors have been reported important to the activity of all the DDT-type analogues.[10]

2. LITERATURE REVIEW:

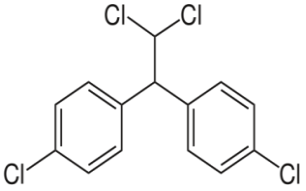
Dichlorodiphenyltrichloroethane, commonly known as DDT, is a colourless, tasteless and almost odourless crystalline chemical compound, an organochloride. Originally developed as an insecticide it became infamous for its environmental impacts. DDT was first synthesized in 1874 by the Austrian chemist Othmar Zeidler. The insecticide properties of "multiple chlorinated aliphatic or fat-aromatic alcohols with at least one trichloromethane group" were described in a patent in 1934 by Wolfgang von Leuthold.[12]

1. *Ke Dong discovered that* In insects, DDT opens voltage-sensitive sodium ion channels in neurons, causing them to fire spontaneously, which leads to spasms and eventual death. Insects with certain mutations in their sodium channel gene are resistant to DDT and similar insecticides.
2. *Kelce, William R.; Stone, Christy R.; Laws et al.* reviewed that DDE an active metabolite of DDT acts as a weak androgen receptor antagonist, but not as an estrogen.



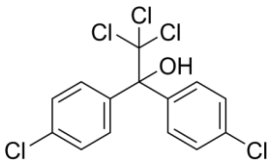
DDE

3. World health organization report number of halogenated derivatives of DDT and all attain high toxicity because of high lipophilicity of synthetic compounds.
4. Handbook of Pollution Prevention and Cleaner Production: Best Practices in the Agrochemical Industry discuss that commercial grade of DDT also contains the compounds dichlorodiphenyldichloroethylene (DDE) and dichlorodiphenyldichloroethane (DDD), both of which are also metabolites of DDT and have similar chemical properties.



DDD

5. *V. Saini and A. Kumar* from computational pesticide design report that the pesticide activity is the result from with a DDT-type mode of action, but with lower non-target toxicity, bioaccumulation and better degradability. By using latest technique 3-D QSAR CoMFA inferred that inferred that a steric contribution of 21% and an electrostatic contribution of about 79% were required for larvicidal activity of DDT analogues.
6. Ruiming Zhang et al. gives report on Computational study on the detoxifying mechanism of DDT metabolized by cytochrome P450 enzymes. This study highlights that DDT can be metabolized by P450 enzymes through the hydrogen abstraction and electrophilic addition mechanism, and the main derivatives are epoxides (2,3-oxide-DDT and 3,4-oxide-DDT), DDE and dicofol.



Dicofol

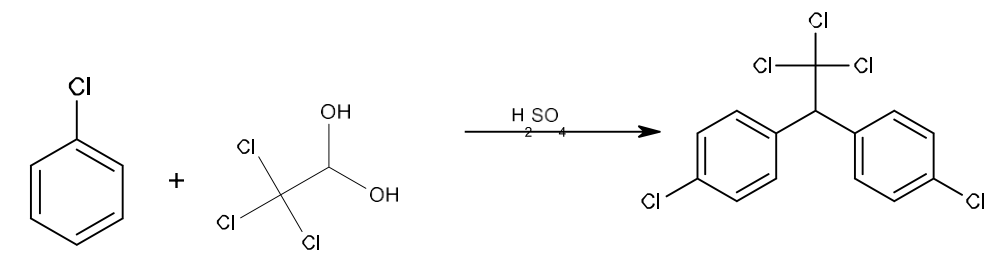
2. OBJECTIVES / AIMS:

- Recent study and article suggest that the high toxicity of and DDT and its analogs it is due to chemical and physicochemical properties of molecule. The goal is to prepare new safe derivatives of DDT and optimise physicochemical properties by structural change with attachment of bioactive heterocyclic moiety with it.

3. RESEARCH METHOD / METHODOLOGY:

1. Target search by Glide Schrodinger.
2. To find structural Similarity from Zinc Database (https://zinc.docking.org/).
3. Characterization by Spectroscopy includes IR Spectroscopy, C-NMR, and Mass Spectroscopy.
4. Biological activity done by cell line assay.

Scheme 1: Preparation of DDT.

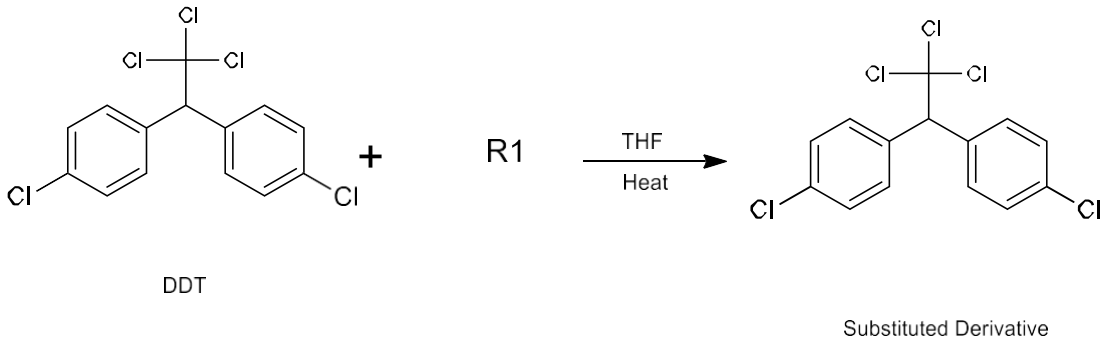


Chlorobenzene Chloral hydrate DDT

Procedure:

Place 17gm of chloral hydrate crystals and 23 ml of chlorobenzene in a glass-stoppered, 500 ml round bottom flask and heat it in water bath at 60-70 C for about 20-30 min with occasional shaking, or until all the crystals have dissolved. Cool to room temperature and slowly add about 180 ml of concentrated H2S04. Stopper and shake vigorously until precipitation starts. This operation usually requires about 1 hr. Let stand for about 15 min with frequent shaking or until precipitation is complete. The upper solid layer contains the crude DDT. Pour the mixture into a glass jar containing about 1 litter of cold tap water and allow to stand for 15 min, or until the solids have settled. Filter through three layers of cheesecloth and wash several times with tap water. Transfer residue from cheesecloth into a wide-mouth bottle or a small glass jar, add about 50 ml of either Na_2CO_3, or 4% $NaHCO_3$, solution, and shake for 5-10 min. This will neutralize the acidity. Recrystalize the crude product with ethanol. % yield is 69 %.

Scheme 2: Preparation of DDT analogs.



DDT

Substituted Derivative

R1 as heterocyclic derivatives.

SR. No	Name of substituents	Docking Score
1	Hydroxymethyl Piperazine	-3.981
2	Amino ethyl Piperazine	-3.877
3	Methyl Piperazine	-2.703
4	Indole	-1.993
5	Pyrrolidine	-1.926
6	Methyl Piperidine	-1.429

Synthesis of 1, 1'-(2, 2, 2-trichloroethane-1,1-diyl)bis(4-piperidine)

Procedure:

2 gm. (0.056 mol) of DDT were taken in 250 with THF (30 mL) followed by the addition of Piperidine (4 ml, 0.046 mol) and the mixture was heated to 120 °Cover 2hs. After complete consumption reaction, the temperature was lowered to 90 °C and the reaction mixture was charged with NaOH (2.6 g, 65 mmol). The reaction mixture was stirred over 1 h, cooled to room temperature, and diluted with 30 mL of water followed by addition of 4 N HCl to adjust the pH to 7. Product is allowed to gradually precipitate. The solid was filtered, washed three times with cold water, and dried to give (0.5 g, 10 % yields) a light brown color compound.

Synthesis of 1, 1'-(2, 2, 2-trichloroethane-1, 1-diyl) bis (4 Morpholine)

Procedure:

To a solution of Methanol (30ml) and DDT (2g) at 25-30°C add Morpholine (3g) drop wise at 25-30°C in more than 1 hour under stirring. Stir the reaction mass at 25-30°C for 1-2 hours. Then add slowly Water (400ml) with stirring the reaction mass at 25-30°C for 1 hour. Filter the solid & wash it with water. The solid is dried at 55-60°C. Percentage 28%.

5. CONCLUSION / SUMMARY:

Work in progress.

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Significance of Benzothiazole Derivatives as Anticancer Molecules

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Abstract: *In Benzothiazole, a combination of benzene and thiazole ring is a versatile moiety. Having Sulphur and nitrogen present in the structure of benzothiazole, it is a heterocyclic compound. Benzothiazole derivatives bear a broad range of biological activities like anticancer, antioxidant, antiviral, antibacterial, anti-tubercular, antimalarial, antifungal, anthelmintic, antidiabetic, anticonvulsant, analgesic, and anti-inflammatory. Cancer, the proliferation of the host cells, is a very dangerous disease and spreading worldwide and human beings are still unable to know the specific reason behind this. Benzothiazole derivatives give a good fight against cancer with different mechanisms depending on the functional group present in the structure of the benzothiazole derivative. This review includes the possible mechanisms through which the cancer can be treated and the various benzothiazole derivatives that can be useful in treating different types of cancer.*

Key Words: *Benzothiazole; Anticancer agent; Drug target receptor, Mechanism of anticancer drug*

1. INTRODUCTION

Heterocycles are significant pharmacophores for drugs in their diverse pharmacological activity. A large number of heterocyclic five-membered ring compounds with different heteroatoms, such as oxygen, nitrogen, or sulphur, are versatile molecules carrying various pharmacological properties[1]. Many of the natural products, with varied medicinal uses, possess the benzothiazole structure where the benzene and thiazole rings are connected[2]. Benzothiazole has a lot of pharmacological activities like anti-diabetic[2], antioxidant[3,4], , anti-inflammatory[5,6], , antiviral[7], analgesic[8,9], antimicrobial[10,11], hepatoprotective[12], antibacterial[13], anticancer[14], antifungal[15], antituberculosis[16]. Human cervical cancer cell line, human liver carcinoma cells, human breast cancer cells, ovarian cancer cells, and many other types of cancer cells are influenced by benzothiazole.

Cancer is the most common, highly complex, and deadliest disease that has emerged as an important concern for modern medical science. One of the biggest challenges that the scientific community in medical research has to face is the task of creating medicines, drugs, and processes for safe treatment and curing of cancer[17]. These neoplasms are heterogeneous, heterogenous, and capable of rapid multiplication tumor cells. These malignant tumors have an invasive or metastatic tendency to invade or spread into other parts of the body through the circulatory and lymphatic systems. Rich research on the anticancer potential of benzothiazole derivatives, which have been highlighted in the

present evaluation of the last decade, will be helpful for the future discovery and development of medications for the treatment of lethal cancer diseases[18].

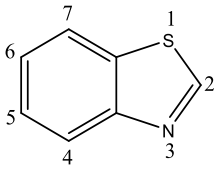


Figure 1. Structure of Benzothiazole

1.1 Structure-Activity Relationship of Benzothiazole derivatives as anticancer moiety

- For the benzothiazole ring system to be anticancer active, the nitrogen atom should be free and structurally unhindered.
- The anticancer activity of the molecule is enhanced when the amine moiety is substituted at position two. Strong anticancer activity will be found when aryl substitution is involved, such as aniline. The placement of 4-thiazolidinone at this position is a viable approach for researching new anti-tumor drugs.
- Anticancer activity is significantly dependent upon the replacement of -Cl, -NH, and -OH at position 7 in the compound.
- Anticancer action is more improved by the substitution of a substituted amine at position six.
- Methylation also increases activity
- The anticancer action increases when the -F atom is substituted at the five position. The compound's anticancer activity increases with the substitution of -F at the five position along with methoxy or methyl at the six position.
- The aryl group attached at the amide or amine bond in the benzothiazole second position has been proved by structure-activity relationship studies to be highly critical for anticancer activity.
- Though the anticancer activity is heavily dependent upon the presence of the fourth-positioned OH of the 4-aryl moieties, higher activity is achieved through the replacement with the more bulky group present there.
- In addition, there have been studies that have proved the anticancer activity of benzothiazole is highly susceptible to the substitution of the F group at position five. This SAR knowledge will be useful in the generation of a more effective molecule that contains a benzothiazole moiety as an anticancer drug.

In order to generate new molecules having promising antitumor activities, molecular hybridization of benzothiazole and other effective antitumor moieties has been carried out depending upon the ligand-based drug design, especially the molecular hybridization approach, which involves coupling two or more groups that have relevant biological properties[19].

2. ANTITUMOR ACTIVITY OF BENZOTHIAZOLE FUSED WITH FURAN

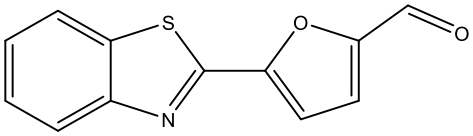
Benzothiazole and furan both contain antitumor activity. When benzothiazole is fused with furan, the antitumor activity of this fusion is synergized. Yu. E. Matiichuk et al. have synthesized 5-(1,3-Benzothiazol-2-yl)furan-2-carbaldehyde which shows antitumor activity against different cell lines

including leukemia, non-small-cell lung cancer, epithelial colon cancer, CNS cancer, ovarian cancer, renal cancer, prostate cancer and breast cancer[20]. 5-(1,3-Benzothiazol-2-yl)furan-2-carbaldehyde is shown as compound 1 in Figure 2.

Livio Racané et al. have synthesized the derivatives of benzothiazole fused with furan heterocycle as anticancer molecules (compound 2). They have anticancer activity in A549, NCI-H358, HCC827, and MRC-5 cell lines[21].

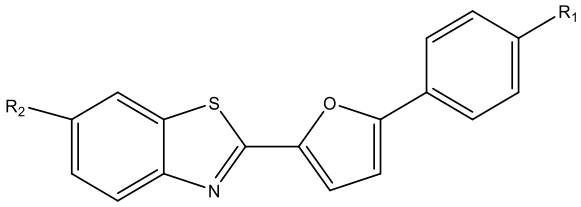
T. I. Chaban et al. have synthesized Novel 2-(1H-Benzoimidazol-2-yland 2-Benzothiazol-2-yl)-3-(5-phenylfuran-2-yl)-acrylonitriles derivatives (Compound 3 and 4) which have antitumor activity for different cancer cell lines[22].

Husain et al. have synthesized Furanone-functionalized benzothiazole derivatives (compound 5) having anticancer activities[23].

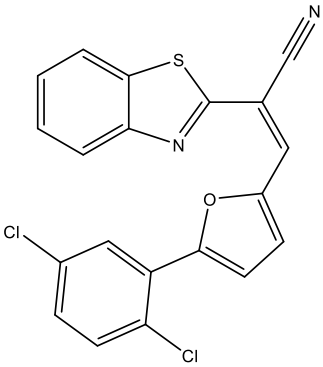


5-(1,3-Benzothiazol-2-yl)furan-2-carbaldehyde

Compound 1

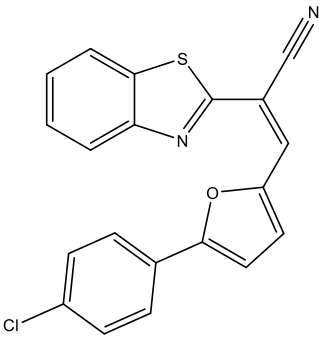


Compound 2 (R_1 = NO_2, R_2 = CN)



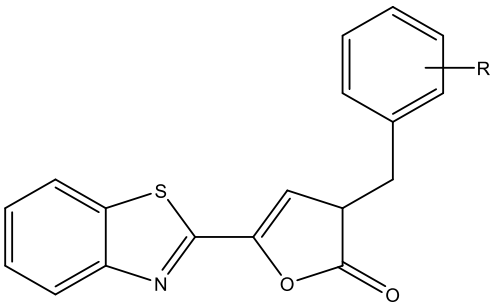
2-Benzothiazol-2-yl-3-[5-(2,5-dichlorophenyl)-furan-2-yl]-acrylonitrile

Compound 3



2-Benzothiazol-2-yl-3-[5-(4-chlorophenyl)furan-2-yl]-acrylonitrile

Compound 4



Compound 5

R	4-OH, 4-N(CH_3)$_2$, 3-NO_2, 2-Cl, 3-Cl, -H, 3-Br, 4-OCH_3, 3-OCH_3, 3,4,5-OCH_3

Figure 2. Benzothiazole derivatives fused with furan

3. ANTITUMOR ACTIVITY OF BENZOTHIAZOLE FUSED WITH PYRROLE

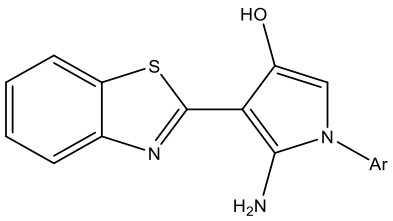
Among N-containing heterocyclic rings, pyrrole is an interesting compound for researchers as it has a broad spectrum of activities like anti-inflammatory activity, HMG CoA reductase inhibition, anticancer activity, inhibition of 5-hydroxytryptamine transporters, antihypertensive activity, DPP inhibition, dopaminergic antagonism, progesterone receptor antagonism, antimalarial activity, etc. Several most widely used drugs in the market are Atorvastatin[24] (hypolipidemic drug),

Tolmetin[25] (drug used for osteoarthritis and rheumatoid arthritis), Indomethacin (analgesic), Remdesivir (antiviral drug), Nargenicin (antibacterial drug), and Prodigiosin (anticancer moiety). Lamellarian alkaloids which contain pyrrole in their structure as a main scaffold are also used as antitumor moieties.

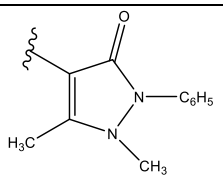
Benzothiazole is also a versatile moiety containing anticancer properties and many other pharmacological activities. Fusion of benzothiazole with pyrrole synergise anticancer activity of the resulting compound. Khaled S. Muhamed et al. have synthesized and evaluated pyrazole and pyrrole derivatives containing benzothiazole moiety. Compounds 6-10 show antitumor activity against liver cancer and breast cancer[26].

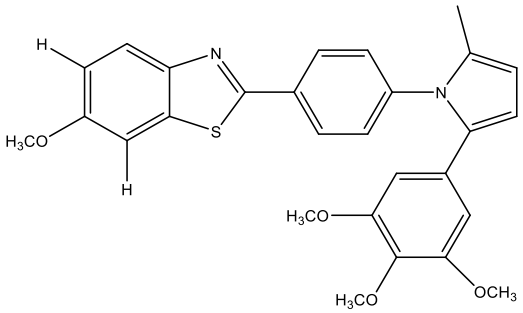
Ahmed Kamal et al. have synthesized benzothiazole conjugates with pyrrole (compound 11) in the control of cell proliferation by modulating Ras/MEK/ERK-dependent pathway in MCF-7 cells[27].

Halyna Kuznetsova et al. have synthesized Pyrrole derivatives as potential anti-cancer therapeutics[28]. 5-amino-4-(benzo[d]thiazol-2-yl)-1-(2-methoxyphenyl)-1,2-dihydro-3H-pyrrol-3-one (compound 12) was evaluated for its anticancer activity.



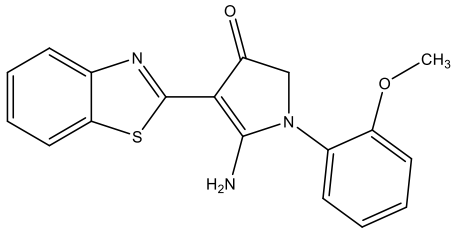
Compound 6 - 10

Compound	-Ar
6	P-Me-C_6H_4
7	P-OH- C_6H_4
8	P-Cl- C_6H_4
9	P-NO_2- C_6H_4
10	



6-methoxy-2-(4-(2-methyl-5-(3,4,5-trimethoxyphenyl)-1*H*-pyrrol-1-yl)phenyl)benzo[*d*]thiazole

Compound 11



5-amino-4-(benzo[*d*]thiazol-2-yl)-1-(2-methoxyphenyl)-1,2-dihydro-3*H*-pyrrol-3-one

Compound 12

Figure 3. Benzothiazole derivatives fused with pyrrole

4. TARGET DRUG RECEPTOR & MECHANISM OF ACTION

Benzothiazole derivatives give antitumor activity through drug-receptor interaction. Literature review reveals that benzothiazole derivatives bind to tyrosine kinase receptors[29] having different families of EGFR[30] (epidermal growth factor receptor), topoisomerase[31] I and II and DHFR[32] (dihydro folate receptor). These receptors are responsible for the induction of cancer by different mechanisms. Benzothiazole derivatives inhibit them to give antiproliferative activity.

5. CONCLUSION

Benzothiazole is a versatile moiety having different pharmacological activities including antitumor activity. When benzothiazole binds with other heterocycles like furan and pyrrole, the antitumor activity gets synergized. The second position of the benzothiazole ring system is active so substitution at this position increases the antitumor activity of the compound. Benzothiazole derivatives give antiproliferative activity through different mechanism of action depending on the moiety with which they are being substituted.

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Junagadh, India, December 27-28, 2024

Formulation and Evaluation of Topical Emulgel Containing *Saraca Asoca* Extract

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Abstract:

Aim and objective: The aim of the study was formulation development and in-vitro evaluation of a *Saraca Asoka* based emulgel formulation for the treatment of wound healing and antibacterial activity. **Materials and Methods:** *Saraca asoca* emulgels aimed to be used topically were created using a 3^2 factorial design and also assessed pharmaceutically. 3^2 factorial design that utilized both quantitative and qualitative approaches. Carbopol 934 and menthol were the two factors/ variables that were investigated and each factor had three levels/ concentrations that were studied. Four responses/ variables were investigated, namely viscosity, spreadability, cumulative drug permeation at 1 h and cumulative drug permeation at 8 h. Total 9 formulation prepared and evaluated for various parameters like pH, viscosity, spreadability, drug content and invitro release. **Result**: Formulation F3 was considered as best formulation out of nine prepared emulgel as it has maximum spreadability, cumulative drug permeation at 1 h and cumulative drug permeation at 8 h. Result confirmed that carbopol concentration was found to increase viscosity which in turn retarded drug release and spreadability, it was preferred that it be minimized and still be kept within the initial range. The best proposed solution which recommended concentrations of 0.5% for carbopol and 9% for menthol. This resembled the composition of formulation F3. **Conclusion**: The plant possess several medicinal value and widely used in Ayurvedic formulation for treat number of disease like to treat painful conditions, to kills all infectious agents, in blood disease, inflammation. *Saraca asoca* emulgels aimed to be used topically, for better patient compliance.

Keywords: *Saraca Asoka*, emulgel, pharmaceutically, factorial, inflammation.

1. INTRODUCTION:

Through the ages, Diseases affect the health of human beings by various types of diseases. The efforts has taken to give newer drug molecules by various administration methods for different routes. The route of administration selected depending upon the severity of the disease, type of disease, emergency of treatment and location of the disease. Each type of drug delivery and route of administration has the merits and demerits. The drug molecule in either cream or gel or lotion or emulsion or suspension or form, when administered through the skin for local actions, called a topical route. [1-2]

The human skin is known as the largest part of the body which contributes around 1015% w/w of the human body. The human skin is made up of four different layers with different cell structure and composition. The drug molecule in formulation, when applied on skin for local action called a topical route. But when the drug molecule in formulations applied on skin for systemic actions then it is called transdermal route. The human skin is easily available for administration of formulation. Once the drug in formulation applied to the skin and depending on its permeability, the drug permeates through the skin. The drug permeates through the skin layers by three routes such as stratum corneum, sweat ducts and sebaceous glands.[3, 4]

Topical Drug Delivery System

TDDS is clearly described as direct application of composition or formulation to the affected area of the skin to get a localized intense effect[5]. Topical drug delivery is categorized into two types: external which easily spread or sprayed on the affected part of the skin whereas internal topical drug delivery is applied on the mucosal surface of different parts of the body like vagina, rectal tissues[6]. This delivery is mainly used to show local effect to the skin infections where other routes of administration fails to show its effect[7]. Drugs are released from the delivery system, into the target area and absorbed by the skin. Percutaneous drug absorption can be increased by increasing the drug release rate in the dosage form. Therefore, physiochemical properties of drugs and carriers are responsible for releasing the drug from topical preparations.[8, 9].

Emulgel[10-13]

Emulgel are emulsions, either oil phase dispersed in water/aqueous as continuous phase or water/aqueous phase dispersed in oil as continuous phase, which is converted to gel by mixing with a suitable polymers. Emulgel is a stable and superior system that incorporates poor water soluble drugs. In brief, emulgel is a combination of emulsion and gel. Despite the numerous advantages of gels, one significant disadvantage is the delivery of hydrophobic medications. As a result, an emulsion-based solution is being used to overcome this limitation, allowing even hydrophobic therapeutic moieties to benefit from the unique properties of the gel. Emulgel can deliver both hydrophilic and lipophilic drugs due to the presence of both aqueous and non-aqueous phases.

In recent years, they have been used as a control release formulation. These are biphasic systems that have better drug loading capacity and better stability[14-16]. Emulgel has several good properties, such as good spreadability, greaseless, thixotropic, good shelf life, odorless, and a pleasant appearance over the conventional topical formulation. Emulgel has both gel and emulsion properties and functions as a dual control release system[17]. Emulgel system = Emulsion + gel

2. LITERATURE REVIEW:

Emulgels possess several advantages, including enhanced drug penetration through the skin due to their dual-phase system, ease of application, and improved drug stability. Studies indicate that emulgels provide superior bioavailability and controlled drug release compared to traditional formulations like creams or ointments[18-19]. Moreover, they are non-greasy, spread easily, and exhibit a pleasant aesthetic feel, contributing to better patient compliance.

Saraca Asoca: Pharmacological Potential

Saraca asoca (Roxb.) De Wilde, commonly known as Ashoka tree, is a well-documented medicinal plant in Ayurveda. Traditionally used for its anti-inflammatory, analgesic, and astringent properties, its bark contains bioactive compounds such as flavonoids, tannins, and glycosides. These constituents exhibit antimicrobial, antioxidant, and wound-healing properties. Recent studies have emphasized its potential in dermatological applications, including the treatment of acne, psoriasis, and wounds. [20-23]

Formulation Strategies for Herbal Emulgels

Developing emulgels incorporating herbal extracts involves selecting appropriate gelling agents, emulsifiers, and penetration enhancers. Carbopol is commonly employed as a gelling agent due to its excellent stability and compatibility with various drugs. The selection of oil and surfactant systems is crucial to ensure the solubilization of lipophilic compounds and stable emulsion formation. Incorporating Saraca asoca extract into an emulgel aims to synergize the therapeutic properties of the extract with the enhanced delivery capabilities of the emulgel base.

Evaluation Parameters for Emulgels[24-25]

- The formulation of topical emulgels requires rigorous evaluation to ensure efficacy and stability. Key parameters include:
- Physical Appearance and Homogeneity: Assessing the consistency, texture, and uniformity of the formulation.
- pH Measurement: Ensuring compatibility with the skin's natural pH.
- Viscosity: Analyzing the rheological properties to predict spreadability and patient acceptability.
- Drug Content Uniformity: Ensuring uniform dispersion of the active ingredient.
- In Vitro Drug Release Studies: Evaluating the release profile to ensure sustained drug delivery.
- Skin Irritation Studies: Confirming the safety of the formulation for topical application.

Applications and Future Prospects

The incorporation of Saraca asoca extract into emulgels opens new avenues for developing herbal dermatological formulations. Preclinical studies suggest promising outcomes in managing skin conditions such as acne and eczema due to the extract's antimicrobial and anti-inflammatory properties. Future research should focus on clinical trials to validate the efficacy and safety of these formulations in human subjects. Additionally, the use of nanotechnology to enhance the bioavailability of Saraca asoca constituents in emulgels presents an exciting area for innovation.

The integration of traditional medicinal plants like Saraca asoca into modern delivery systems such as emulgels represents a promising approach to advancing topical therapeutics. With thorough evaluation and optimization, such formulations have the potential to offer effective, safe, and patient-friendly alternatives for treating various skin ailments.

3. OBJECTIVES :

The primary objective of this study is to formulate and evaluate a topical emulgel containing Saraca asoca extract to harness its pharmacological properties for dermatological applications.

The study aims to: Develop a stable and effective emulgel formulation incorporating Saraca asoca extract. Evaluate the physical, chemical, and therapeutic properties of the formulation. Assess the in vitro drug release profile and in vivo efficacy of the emulgel. Investigate the safety of the formulation through skin irritation studies.

4. RESEARCH METHOD / METHODOLOGY:

Plant material used various plant parts (Bark, Flowers leaves) of Saracaasoca were collected from the Botanical garden, Noble University, Junagadh. The collected plant materials were identified by Dravyaguna Department of Noble Ayurved College, Junagadh.

PHYSICOCHEMICAL EVALUATION OF SARACA ASOCA LEAF

Analysis of Physicochemical constants of the powder leaves has been done to evaluate the quality and purity of the drug. Various Physicochemical parameters like Moisture contents, foreign organic matters. Ash Values and Extract Values were calculated as per WHO Guidelines. The information collected from these test was useful for standardization and obtaining the quality standards. [26-27]

EXTRACTION OF SARACA ASOCA

Preparation of Extracts Plant samples (bark, flowers and leaves) were washed with distilled water and airdried at room temperature for 7-10 days, then oven-dried at 40 °C to remove the residual moisture. The dried plant parts were pulverized and stored in air-tight containers at 4 °C for future use. 50 g of powdered samples of bark, flowers and leaves were extracted with methanol by soxhlation method at

60 to 80 °C. The three filtrates were separately concentrated in water bath at 40 °C and evaporated under reduced pressure.

The design of experiment (DoE) employed in this study was a laboratory based 3^2factorial design that utilized both quantitative and qualitative approaches. A 3-level factorial design is one of the response surface methodologies of experimental design. Carbopol 934 and menthol were the two factors/ variables that were investigated and each factor had three levels/ concentrations that were studied. The API and all other excipients used in the formulation were kept constant. The Design Expert® software was used to randomly generate nine runs as displayed in Table 1, and these formed the basis of this study. Four responses/ variables were investigated, namely viscosity, spreadability, cumulative drug permeation at 1 h and cumulative drug permeation at 8 h.

Table 1: Variables in 3^2 design for saraca asoca emulgel

Serial no	Independent variables	Dependent variables	Goals for dependent variables
1	Quantity of carbopol (X_1)	%Drug permeation after 1 hr	Maximize
		%Drug permeation after 8 hr	Maximize
2	Quantity of menthol(X_2)	Spreadability	Maximize
		Viscosity	Minimize

Table 2: Nine experimental runs generated using Design Expert® software

	Run	1	2	3	4	5	6	7	8	9
Factor1	Carbopol (%w/w)	0.5	0.5	0.5	1	1	1	1.5	1.5	1.5
Factor2	Menthol(%w/w)	1	5	9	1	5	9	1	5	9

PREFORMULATION STUDIES

Physical characteristics, Identification, Solubility studies, Drug excipient compatibility tests
And The drug excipient compatibility (DEC) studies of and all excipients used was done using FTIR spectroscopy.

FORMULATION OF SARACA ASOCA EMULGELS

All the ingredients were weighed and prepared as illustrated Each emulgel was formulated in a three-steps process as explained below.

Table 3: Composition of different saraca asoca emulgel formulations (%w/w)

	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Saraca asoca extract	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Carbopol934	0.5	0.5	0.5	1	1	1	1.5	1.5	1.5	0.5
Menthol	1	5	9	1	5	9	1	5	9	9
Triethanolamine	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Liquidparaffin	15	15	15	15	15	15	15	15	15	15
Propyleneglycol	15	15	15	15	15	15	15	15	15	15
Tween-20	1	1	1	1	1	1	1	1	1	1
Span-20	2	2	2	2	2	2	2	2	2	2
Purifiedwater	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Evaluation Of The Formulations

Evaluation done by Physical examination, pH measurement, Viscosity measurement, Spreadability studies, Content uniformity determination, In vitro drug permeation studies, Optimization of the Saraca asoca semulgel, Assay for drug content and Stability studies were performed.

5. RESULT / FINDINGS:

The four extracts obtained from the powdered flowers of *SaracaAsoca* were subjected to phytochemical tests to determine the presence of active secondary metabolites using standard procedures.

Table 4: Percentage of Losson Drying, Ash and Extractive Value of Saraca Asoca

Loss on drying	5.39±0.19
Total ash	6.04±0.02
Acid isoluble ash	42.06±1.5

Water soluble ash	3.50±0.59
Water soluble extractive	18.45±0.09
Diethyl ether soluble extractive	8.15±0.26

Table 5: Preliminary phytochemical screening of Saraca asoca extract

Sr. No.	Phyto constituents	Plant parts								
		Bark			Flower			Leaf		
		Met-OH	Et-OH	Aqueous	Met-OH	Et-OH	Aqueous	Met-OH	Et-OH	Aqueous
1.	Alkaloids (Dragendroff's test)	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve
2.	Flavonoids (Shinoda test)	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve
3.	Glycosides (Borntrager'stest)	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve
4.	Saponins	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve
5.	Phenols(Ferric Chloride Test)	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve
6.	Steroids	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve
7.	Tannins (Ferric chloride test)	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve
8	Triterpenoids(Salkowaski test)	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve	+ve

Spectroscopic Studies of Selected Extract

On the basis of preliminary physicochemical studies aqueous extract of saraca asoca were selected for U.V. Spectroscopic Studies study. Identification test of Saraca asoca powder by U.V. visible spectroscopy gave a spectrum that was concordant with the reference spectrum of saraca asoca. Figures 6.1 showing maximum absorption at 245nm in phosphate buffer pH7.4

FTIR Spectroscopic Analysis:

The FT-IR spectrophotometer used was Shumatzu atOsmania University. KBr is an important samplematrix for FTIR scanning

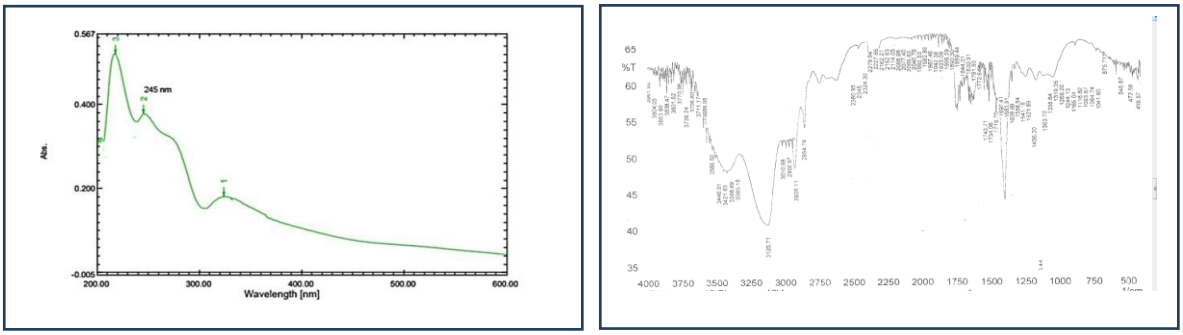

Figure 1: UV spectroscopic study of saraca asoca in 7.4 pH Buffer and FTIR Spectroscopic Analysis of saraca asoca emulgel

Drug excipient compatibility tests

From examination of the FTIR spectra of the binary mixtures obtained, there was no observable variation or chemical group interaction between saraca asocaSaraca asoca and each excipient. All the major peaks observed in Saraca asoca spectrum were present in the spectra of the binary mixtures. A few minor changes observed in the spectra were attributed to overlying of the peaks of Saraca asoca and corresponding excipient. This predicts lack of drug and excipient interaction and can thus be said to be compatible with regards to their physicochemical properties.

EVALUATION OF THE FORMULATIONS

Physical examination

Upon visual examination, all formulations were found to be translucent, homogenous emulgels that looked like creams with no observable grittiness. Their color was a cream to off-white and no phase separation was observed in all the formulations.

pH measurement

The pH of all the formulations was between the desired range of 5-7 as shown in Table 6.6. Formulation F7 had the lowest pH of 5.8 and 6.5 was the highest pH noted in F2. With the pH values obtained, no formulation could be anticipated to cause skin irritation.

Table 6: pH of formulated Saraca asoca emulgels

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
pH	6.4	6.5	6.4	6.2	6.1	6.2	5.8	5.9	6.0

Viscosity measurement

As shown in Table 6.7 and Figure 6.5, viscosity of the formulations ranged between 20759 and 42250 mPa.s, the lowest and highest being exhibited by formulations F1 and F8 respectively. Emulgels having 0.5% w/w carbopol concentration had the lowest viscosity whereas those with 1.5% w/w concentration had the highest viscosity. This observation is in agreement with literature that as polymer concentration is increased in a formulation then viscosity increases, if other factors are held constant.

Table 7: Viscosity of formulated Saraca asoca emulgels

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9

Viscosity(mPa.s)	20759	23250	21910	35251	35467	32857	41510	42250	40115

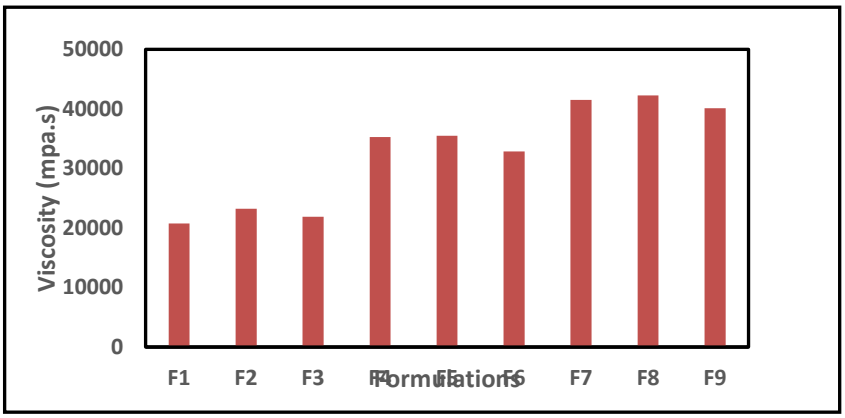

Figure 2: Viscosity of the formulated saraca asoca emulgels.

Spreadability studies

The spreadability of the formulated emulgels was denoted by their increase in diameter following the spreadability test and is illustrated in Table 6.8and Figure 6.6. Formulation F8 had the lowest spreadability of 6.8 cm while F2 had the highest at 8.2 cm. The spreadability of Formulations F1, F2 and F3 was above 8.0 cm and this can be attributed to the lowest polymer concentration of 0.5% w/w. Spreadability was found to be dependent on polymer concentration and viscosity. As polymer concentration increased in the formulations, viscosity increased and consequently spreadability reduced.High spreadability of emulgels allows ease of application and this in turn increases the surface area available for drug permeation. Spreadability values above 7.5 cm imply good spreadability properties as was exhibited by Formulations F1 to F6.

Table 8: Spreadability of the emulgel formulations

Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Diameter(cm)	8.2	8.3	8.1	7.4	7.6	7.7	7.2	6.8	6.9

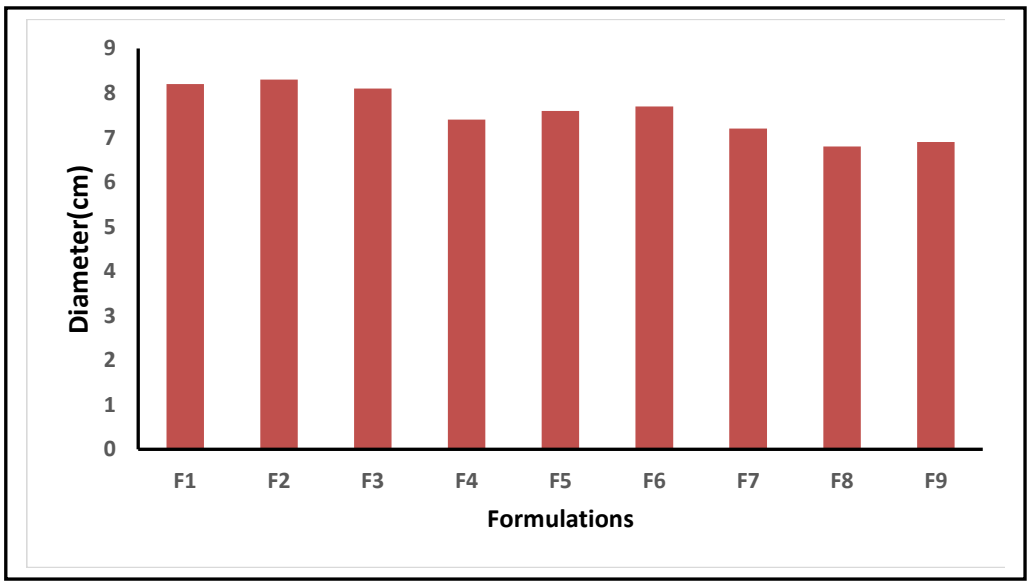

Figure 3: Spreadability of the emulgel formulations.

Content uniformity determination

Saraca asoca drug content of the formulations was determined using UV spectroscopy as shown in Table 6.9. The percentage drug content was between 89.18% (for F7) and 109.1% (for F9). These parameters are an indication that the drug content was uniform.

Table 9: Drug content of saraca asoca emulgel formulations

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug content(mg)	453.6	524.5	482.3	492.5	515.5	479.8	445.9	501.2	545.5
Drug content(%)	90.72	104.4	96.46	98.5	103.1	95.96	89.18	100.24	109.1

In vitro drug permeation studies

The cumulative percentage of saraca asoca drug that permeated following the study is depicted in Table 6.10 and Figure 6.7 Based on cumulative drug permeation after 1 h and after 8 h, the order of permeation from the highest to the lowest was as follows; F3>F2>F1>F9>F6>F5 >F8>F4>F7 and F3>F2>F1>F6>F5>F9>F8>F4>F7, respectively.

The first and the last three in both cases are similar. Formulation F3 which contained 0.5% w/w carbopol and 9% w/w menthol had the highest drug permeation of 37.5% after 8 h. Formulation F7 on the other hand had the lowest drug permeation of 9.9% after 8 h and it contained 1.5% w/w carbopol and 1% w/w menthol. For the formulations containing same amount of carbopol, drug permeation was highest in those with 9% w/w menthol, followed by those with 5% w/w menthol and lowest in those with 1% w/w menthol.

Table 10: Drug permeability study of saraca asoca emulgel formulations

Time(min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
15	4.7	6.2	6.0	2.9	3.5	3.6	1.8	2.4	3.2
30	7.4	10.7	9.2	3.3	3.7	4.1	2.7	3.8	5.3
60	10.7	13.3	14.6	3.5	5.4	7.5	3.2	4.9	8.2
120	12.7	16.8	17.8	5.7	6.1	11.4	4.1	7.5	9.3
180	13.2	18.8	20.9	7.9	8.6	12.3	5.3	7.8	9.9

240	13.9	22.6	25.4	10.0	10.6	12.6	6.4	8.7	11.6
300	16.2	26.0	28.3	10.5	11.7	13.7	7.1	8.9	12.5
360	17.6	29.5	31.4	10.9	12.8	14.3	7.6	11.2	12.6
420	20.3	33.8	34.8	11.9	13.9	14.8	8.4	11.9	13.5
480	23.4	36.6	37.5	12.7	14.9	15.5	9.9	12.8	14.1

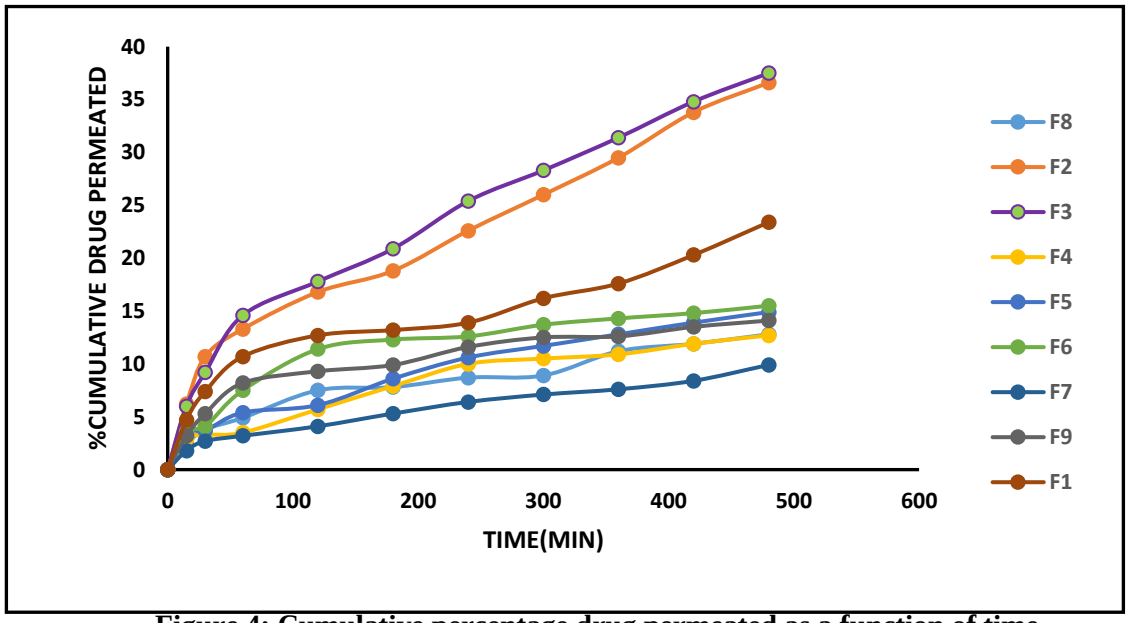

Figure 4: Cumulative percentage drug permeated as a function of time.

Optimization of the saraca asoca emulgel

So final optimized formulation found to be F3 has following response.

Table 11: Characteristic of optimized saraca asoca emulgel

Formulation (F3)	**Value**
Appearance	Translucent, white
Yield (%)	98.2%
pH	6.4
% Drug permeation after 1 hr	14.6%
%Drug permeation after 8 hr	37.5%

Spreadability	8.1cm
Viscosity	21910 mPa.s

Drug release kinetics study

In-vitro release data of formulation F3 of saraca asoca emulgel were fitted to various mathematical models such as Zero order, First order, Higuchi and Korsmeyer- Peppas and Hizson crowell model in order to understand the mechanism of drug release and the release rate from dosage forms.

Table 6.12 illustrated the correlation of dissolution data to different models of release kinetic. F3 that best fit to Korsmeyer-Peppas since it had the highest values of R^2, being 0.9910 for formulations F3, respectively. The mechanism of drug release for both formulations is best described by Fickian diffusion. This is because n values was 0.385 for F3, values that are less than 0.5. When n≤ 0.5, this denotes Fickian diffusion as the leading drug release mechanism where drug is released predominantly through diffusion.

Table 12: Summary of the kinetics modeling data

Formulation Code	Zero Order	First Order	Higuchi Model	Korsemeyer Peppas		Hixson Crowell
	R^2	R^2	R^2	R^2	n	R^2
F3	0.7219	0.7652	0.9623	0.9910	0.385	0.575

Assay for drug content

Optimize formulation F3 show 99.2% of drug estimated by U.V. visible spectrophometer.

Stability studies

Stability study results of the optimized formulations after storage in stability chamber for one month at 40±2°C and 75±5% RH are summarized in Table 6.13. Upon physical examination, optimized formulation F3 had a shade of white colour (cream to off-white) and were found to be translucent and homogenous with no observable grittiness or phase separation. Their appearance initially and after one month in accelerated stability conditions was not different.

Table 13: Stability study results of optimized formulations

Parameter	Expected	Time period	
		Initial	1month
pH	5 – 7	6.5	6.5
Spreadability(cm)	8 – 10	8.1	8.2
Drug content (%)	90 – 110	98.2	98.1

These results imply that the formulated emulgels are stable after one month in accelerated stability chamber conditions.

6. DISCUSSION / ANALYSIS:

Saraca asoca emulgels aimed to be used topically were created using a 3^2 factorial design and also assessed pharmaceutically. 3^2 factorial design that utilized both quantitative and qualitative approaches. Carbopol 934 and menthol were the two factors/ variables that were investigated and each factor had three levels/ concentrations that were studied. Four responses/ variables were investigated, namely viscosity, spreadability, cumulative drug permeation at 1 h and cumulative drug permeation at 8 h. formulation prepared and evaluated for various parameters like pH, viscosity, spreadability, drug content and invitro release. Formulation F3 was considered as best formulation out of nine prepared emulgel as it has maximum spreadability, cumulative drug permeation at 1 h and cumulative drug permeation at 8 h. Result confirmed that carbopol concentration was found to increase viscosity which in turn retarded drug release and spreadability, it was preferred that it be minimized and still be kept within the initial range. Menthol had a linear relationship with drug permeation and preference was set to maximize its concentration and still keep it within the initial range. The best proposed solution which recommended concentrations of 0.5% for carbopol and 9% for menthol. This resembled the composition of formulation F3.

8. CONCLUSION / SUMMARY:

The optimized formulations F3 were translucent, homogeneous, cream-like emulgels with appropriate pH and drug concentration. Their viscosity and spreadability was ideal to allow ease in application and maximise the surface area for medication penetration.

The drug release kinetics of these formulations was best explained by Korsmeyer-Peppas kinetic model and diffusion was the major mechanism of drug release.

This study indicated that synthesising and testing saraca asoca for improved activity is doable. Stability study implies that the formulated emulgels of saraca asoca F3 are stable after one month in accelerated stability chamber conditions.

If developed further, the study findings could possibly provide a safe and efficacious option for symptomatic treatment of pain and inflammation linked with arthritis as well as other muscular aches. A better alternative can in turn lead to increased patients compliance to medicine and consequently enhance their quality of life.

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Abstract: Known for Mount Girnar and Asiatic lions, the Girnar Wildlife Sanctuary in the Junagadh region is home of the tarantula spider Chilobrachys fimbriatus Pocock, 1899, which is the focus of this investigation. Studies of spiders like this one in the Mygalomorphae family are few, and there are very few records of this peculiar tarantula in India. The current study advances knowledge on C. fimbriatus in Junagadh, Gujarat. While walking along paths in the Girnar forest, this species was discovered. It has been sparsely tracked in Goa, Maharashtra, the Western Ghats, and other locations of India.

Key words: Chilobrachys fimbriatus, Girnar Wildlife Sanctuary, Junagadh, Taxonomy, Tarantula

Introduction

Gujarat, one of India's most ecologically diverse states, is characterised by a remarkable bio-geographic heterogeneity that supports an array of floral and faunal communities. The state's geographic variation spanning arid, semi-arid, and coastal ecosystems contributes to its rich biodiversity. Among the significant natural reserves, the Girnar Wildlife Sanctuary (GWS) in Junagadh district stands out as a critical conservation area. The sanctuary is renowned for Mount Girnar, which, at 1,128 meters (Fig. 1.1), is the highest peak in Gujarat, and serves as a prominent geological feature in the region. This mountainous expanse, located between latitudes 21°25' N and 21°35' N and longitudes 70°30' E and 70°40' E, falls within a semi-arid climatic zone, with its dry deciduous forests providing a unique ecological context for numerous endemic and rare species, including the iconic Asiatic lions.

The current study focuses on the enigmatic tarantula *Chilobrachys fimbriatus* Pocock, 1899, a member of the Theraphosidae family, subfamily Selenocosmiinae, and tribe Chilobrachini (West et al., 2012). This species, known for its striking appearance and behavior, remains an understudied element within the diverse arachnid fauna of India. According to the World Spider Catalog 25.5 (2024), the family Theraphosidae includes 1,122 species across 169 genera, making it one of the most prominent families within the Araneae order. Within India, 65 species of Theraphosidae spanning 13 genera have been recorded (Singh and Singh, 2020).

C. fimbriatus Pocock, 1899 has been documented across various regions of India, with significant records from Maharashtra (Pocock, 1899; Tikader, 1977; Bastawade and Khandal, 2006; Pande et al., 2013; Sayyed, 2016), Goa (Pandit and Dharwadkar, 2020), and the Western Ghats (Molur and Siliwal, 2004; Sudhikumar et al., 2010; Sebastian et al., 2012). However, its occurrence in Gujarat has been sparsely reported, and its status within the region remains ambiguous. The first mention of *C.*

fimbriatus in Gujarat, although documented by Parasharya et al. (2011), presents a complex and inconclusive account, pointing to potential underreporting or a lack of focused research on the species in the state.

The sanctuary is a biodiversity rich point for numerous endemic and rare species, with spiders forming an integral part of its ecosystem. Junagadh district, in particular, has witnessed several notable arachnological discoveries in recent years, highlighting the region's rich and underexplored spider diversity. For instance, the endemic *Palpimanus narsinhmehtai* Prajapati, Hun, and Raval 2021, was first identified from Girnar Wildlife Sanctuary (Prajapati et al., 2021). Similarly, the first recorded male of *Piranthus decorus* Thorell, 1895, was discovered from the sanctuary by Hun et al., (2023). These findings underscore the importance of ongoing taxonomic studies in revealing new species and distribution records from this biologically rich region.

Moreover, studies conducted by Mahida et al. (2022) and Hun & Raval (2023) have confirmed a significant diversity of spider species in Junagadh district, establishing it as a critical area for arachnological research. Beyond arachnids, the avifauna of Girnar forests is equally remarkable, with around 276 bird species documented (Zala et al., 2022). This high avian diversity enhances the conservation significance of Girnar forests, further emphasizing the need for habitat preservation and ecological monitoring. Given the ecological importance of the Girnar Wildlife Sanctuary and the gap in comprehensive studies regarding the distribution of *C. fimbriatus* Pocock, 1899 in Gujarat, this study aims to elucidate the occurrence, habitat preferences, and distribution patterns of this species within the sanctuary. By examining the species' ecological niche, its interactions with the local environment, and its potential conservation status, this research seeks to contribute to a deeper understanding of its bio-geographical range in Gujarat. Additionally, this work will address the broader implications for tarantula conservation in semi-arid landscapes.

Methodology

The present study was conducted in the Girnar Wildlife Sanctuary, located in Junagadh district, Gujarat, a region renowned for its biodiversity and unique ecological conditions. The study focused on the occurrence and biology of *C. fimbriatus* Pocock, 1899 within the sanctuary, which serves as a critical habitat for a variety of species in the region. Fieldwork was carried out during the summer months during (2021-2022), a period conducive to observing arachnid activity due to increased visibility of species, during the warmer season. The species was recorded during systematic surveys along designated trails within the sanctuary. These trails (100 m long transect), selected for their accessibility and representation of the region's diverse habitats, were traversed on foot to allow for random, non-biased observations. The search involved traversing various ecosystems, including dry deciduous forests and open scrublands, to capture a comprehensive overview of the species' potential distribution within the sanctuary.

While walking along the trails, natural burrows and holes—characteristic of tarantula species, including *C. fimbriatus* Pocock, 1899 were identified. These burrows, often excavated in soil or under rocks, were indicative of the tarantula's presence. Upon discovering these burrows, careful excavation was performed to uncover the tarantula. This process involved gently removing the surrounding soil to avoid harming the specimen and to accurately document the species. Special attention was given to ensuring minimal disturbance to the local habitat. During the excavation, a large-sized female *C. fimbriatus* Pocock, 1899 was observed. The specimen was photographed for morphological documentation, and key measurements such as body length were taken to aid in the identification process. The identification of the species was confirmed through the comparison of the collected specimen with standard taxonomic references, including those by Pocock (1899), Tikader (1977), and West et al. (2012). These references provided essential diagnostic characteristics for

confirming the species' identity, including its distinctive features such as coloration, leg morphology, and body structure.

Additionally, a comprehensive review was prepared based on a thorough collection of published documents and research papers on *C. fimbriatus* Pocock, 1899 from 1899 to 2024. This review served as a foundation for understanding the historical distribution, taxonomy, and ecological behavior of the species, and helped contextualize the findings from the Girnar Wildlife Sanctuary within broader regional and national studies. This methodology, combining direct field observations with extensive literature review, enabled a holistic understanding of the species' current distribution in Gujarat and its ecological significance within the Girnar Wildlife Sanctuary.

Results and Discussion

The present study marks the current record of *Chilobrachys fimbriatus* Pocock, 1899 in the "Girnar Wildlife Sanctuary (GWS) – *a heart of Junagadh"*, expanding the known distribution of this species within Gujarat. The finding significantly contributes to our understanding of the species' habitat preferences and ecological adaptations. The species (Fig. 1.2) was observed exclusively in shaded environments, suggesting a high sensitivity to temperature and a preference for microhabitats that offer protection from direct sunlight. This behavior aligns with the findings of previous studies on tarantulas, where temperature regulation is crucial for survival and activity patterns (West et al., 2012).

Chilobrachys fimbriatus Pocock, 1899 is known to be one of the more aggressive members of the Theraphosidae family, a characteristic that was observed during fieldwork. While most tarantulas exhibit a relatively passive demeanor, *C. fimbriatus* Pocock, 1899 was notably more defensive when disturbed, exhibiting rapid movement and a readiness to display its characteristic defense posture. This aggression could be an evolutionary adaptation to deter potential predators or competitors, particularly in the harsh conditions of the dry deciduous forest where resources may be limited. The species was found to inhabit burrows, a typical behavior for many Theraphosids, but with distinctive features. The burrows of *C. fimbriatus* Pocock, 1899 were lined with silk threads, a trait common among tarantulas, which serves to reinforce the structure and prevent collapse. These burrows were located in hollow places such as tree trunks, crevices in large stones, and under rocks, indicating that the species occupies a variety of microhabitats. The diversity of these burrows suggests that *C. fimbriatus* Pocock, 1899 is highly adaptable to different substrates within its preferred habitat. Furthermore, the size of the burrow entrance was found to correlate with the size of the individual, a common trait among many burrowing arachnids where the entrance serves as both an entry/exit point and a protective barrier.

As expected, *Chilobrachys fimbriatus* Pocock, 1899 displayed a strong preference for shaded, moist environments. The species was consistently found in locations where the microclimate remained cool and humid, even during the peak of the hot, dry season. These conditions are critical for the tarantula's survival, as they help maintain the necessary hydration levels and mitigate the risks of desiccation. Notably, the species remained predominantly nocturnal, emerging at night to forage and engage in typical behavior, as is common among many tarantulas which are adapted to lower-light conditions to avoid daytime predators.

The most striking revelation of this study is the record of *C. fimbriatus* in a tropical dry deciduous forest, a habitat type that has not been previously associated with this species. Traditionally, *Chilobrachys fimbriatus* Pocock, 1899 has been observed in tropical and subtropical moist deciduous forests, as well as tropical semi-evergreen and evergreen forests (Pocock, 1899; Tikader, 1977). This finding expands the ecological range of the species, suggesting that *C. fimbriatus* is capable of inhabiting a broader spectrum of forest types, even in environments that are subject to more extreme seasonal variations in temperature and moisture. The discovery of this species in a tropical dry

deciduous forest highlights its potential resilience and ability to adapt to varying environmental conditions, a trait that may be vital for its survival amidst changing climatic patterns.

One of the major threats to *Chilobrachys fimbriatus* Pocock, 1899 comes from habitat loss, often driven by deforestation and human encroachment. The destruction of its natural habitat, coupled with the increasing demand for exotic pets, particularly due to its striking coloration, has made this species a target for illegal pet trade. As noted by Molur et al. (2008), such activities put immense pressure on populations in the wild, exacerbating the challenges to their survival. Although *C. fimbriatus* Pocock, 1899 is not currently listed under the Wildlife Protection Act of 1972 in India, it is found within several protected areas, including national parks and sanctuaries, which provide some degree of conservation. Additionally, the species is classified as "Least Concern" (LC) by the International Union for Conservation of Nature (IUCN), reflecting its relatively stable population in some parts of its range. However, this status should not lead to complacency, as habitat degradation and poaching remain significant risks.

Conclusion

In conclusion, this study provides novel insights into the ecological preferences and adaptive behaviors of *Chilobrachys fimbriatus* in the Girnar Wildlife Sanctuary. The findings underscore the importance of continued monitoring and research in lesser-studied ecosystems like the tropical dry deciduous forest, which may harbor previously unrecognized biodiversity. Future research should focus on further elucidating the species' distribution across different forest types and its role within the broader ecosystem, particularly in light of the increasing threats posed by habitat degradation and climate change.

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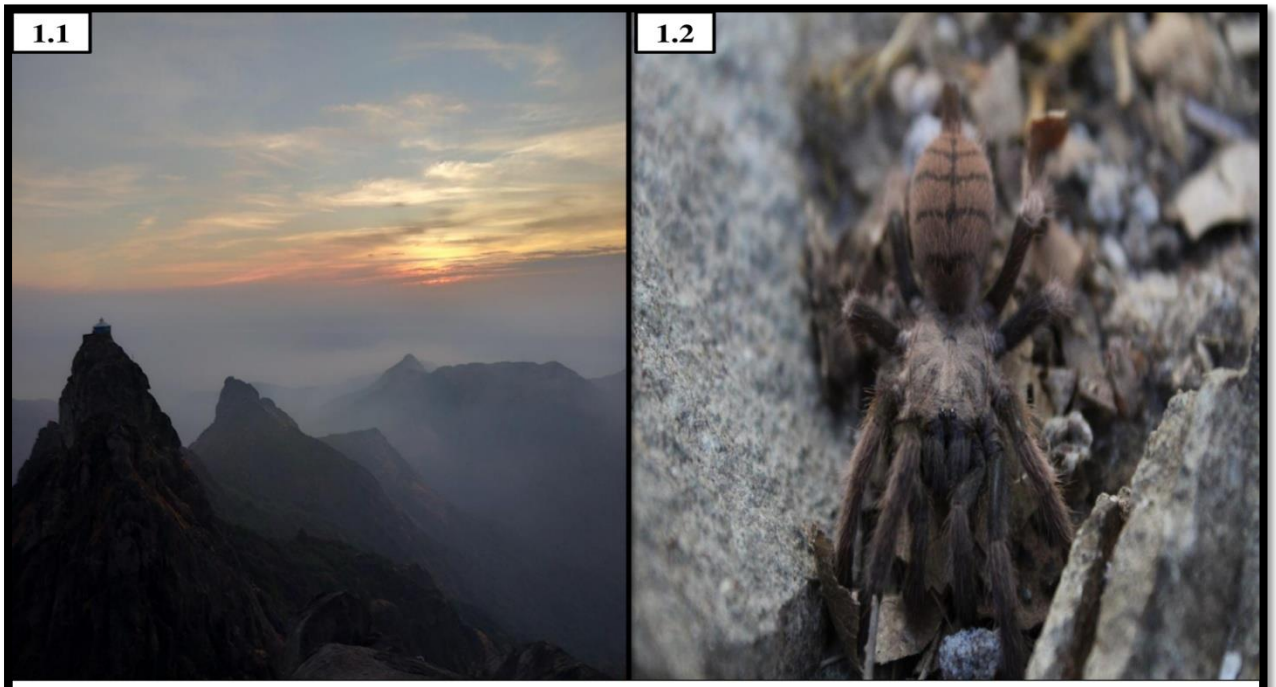

Fig. 1: 1.1 - Mout. Girnar in Girnar Wildlife Sanctuary, Junagadh, 1.2 - *Chilobrachys Fimbriatus* Pocock, 1999 (female) in its natural habitat.

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A Review on Dielectric Properties of AFe2O4 Spinel Ferrites

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Abstract: *In past decades spinel ferrites have made a large impact on application-based research due to their interesting dielectric properties. Two crucial characteristics of these ferrites that aid in determining their suitability for use in the fields of electronics, communications, and other device technologies are their dielectric constant (ε') and dielectric loss (tanδ). It is well-known that frequency and temperature are key factors in modulating dielectric properties as per the need for spinel ferrite specimens. As well as the preparation methods can change the transport properties of various nano and bulk ferrite specimens. This review focuses on the factors affecting the dielectric properties of AFe_2O_4 transition metal-based ferrites for its potential electrical applications. The comparison of dielectric properties of a few ferrites can provide valuable insight to the reader through this literature survey.*

Key Words: *Spinel, Ferrites, Dielectric Properties, applications.*

1. INTRODUCTION:

Spinel ferrites are a class of ferrimagnetic materials with the general chemical formula AB_2O_4, where A and B are typically divalent and trivalent mineral cations respectively, occupying specific sites within a cubic close-packed (CCP) structure of oxygen ions. Their structure is defined by the spinel type, which can be further categorized into three types, as **normal**, **inverse**, or **mixed** spinel based on the sharing of A and B cations between tetrahedral (A) and octahedral (B) site [1-3].

With their distinctive blend of magnetic, electrical, and catalytic characteristics, Spinel ferrites have attracted considerable attention for diverse technological uses, such as in electronics, environmental cleanup, and medical applications [4-6].

Spinel ferrites possess a cubic crystal structure categorised under the *Fd3m* space group. Their structural adaptability enables the customisation of physical properties through the substitution of various cations [7-10]. Commonly studied spinel ferrites include:

- **Nickel Ferrite ($NiFe_2O_4$):** Notable for its excellent electrical resistance and magnetic permeability [3,4].

- **Cobalt Ferrite ($CoFe_2O_4$):** Characterized by its high coercivity, making it ideal for use in permanent magnets and data recording [3,4].
- **Magnesium Ferrite ($MgFe_2O_4$):** A soft magnetic material with significant saturation magnetization [3,4].
- **Zinc Ferrite ($ZnFe_2O_4$):** A weakly magnetic or non-magnetic material, widely applied in gas detection systems [3,4].

The distribution of cations is a critical factor influencing their physical and chemical properties [5,13]. For example:

- **Normal spinel:** Divalent A^{2+} ions are situated in tetrahedral positions, while trivalent B^{3+} ions occupy octahedral positions [3,4].
- **Inverse spinel:** Trivalent ions are distributed across both tetrahedral and octahedral sites, with divalent ions confined to octahedral sites [3,4].
- **Mixed spinel:** A blend of normal and inverse configurations, enabling adjustable magnetic and electrical properties [3,4].

Ferrites' dielectric properties are crucial for their use in high-frequency devices such as microwave systems, inductors, capacitors, and antennas. Parameters such as permittivity, dielectric dissipation, and electrical conductivity are affected by factors such as material composition, microstructural properties, cation arrangement, and the frequency of the external field. Ferrites containing Co, Mn, Zn, Cu, and Ni have been investigated because of their distinct dielectric properties, which are governed by their structural and electronic features [3-4].

2. DIELECTRIC PROPERTIES OF SPINEL FERRITES:

(i) Cobalt Ferrite ($CoFe_2O_4$)

Kalyani Dhabekar, K. Mohan Kant observed that the dielectric permittivity of the compounds was discovered to increase W.R.T temperature. Nanocomposites of $CoFe_2O_4$ were formed by the chemical co-deposition process [11]. According to Jyoti Sharma and Parashar, the cobalt ferrite produced using the sol-gel auto combustion approach was seen at low to high microwave frequencies. The dielectric constant remained nearly constant because of atomic and electronic polarization. [12]. Priyanka Gupta and Dr. Ravi Kumar Vijai have found that CoFe2O4 nanoparticles at room temperature have low dielectric constant with high frequency which have wide range of applications in electrical circuits [13]. At room temperature, the dielectric loss (tanδ) and dielectric constant (ε′) were determined as a function of frequency, according to an analysis by Md. Badiul Alam and Muhammad Sajjad Hossain. The frequency dependence indicates normal dielectric behaviour, governed by Maxwell-Wagner interfacial polarization and electron hopping between Co^{2+}/Co^{3+} and Fe^{2+}/Fe^{3+} ions at octahedral sites [14]. Sathish Boddoll, and D Ravinder studied the dielectric properties of Nd^{3+}-doped cobalt ferrite nanoparticles. $CoFe_{1.98}Nd_{0.02}O_4$ exhibited high grain boundary activation energy, indicating strong dielectric behaviour. These properties make it a promising material for dielectric applications [15].

- **Dielectric constant (ε′):** Because of the electron hopping mechanism between Fe2+ and Fe3+ ions at octahedral locations, cobalt ferrite exhibits a moderate permittivity. As the frequency rises, the permittivity falls, exhibiting normal dispersion behaviour [16-20].

- **Dielectric Loss (tanδ):** Cobalt ferrite has a relatively low dielectric dissipation factor, making it apt for high-frequency applications. However, the loss rises at lower frequencies because of space charge polarization [16-20].
- **Applications:** Owing to its high electrical resistance and durability, cobalt ferrite is extensively utilized in microwave components and as a core material for transformers [13-20]

(ii) Manganese Ferrite ($MnFe_2O_4$)

Othman Hakami (2024) observed that the dielectric constant of manganese ferrite at high frequency is useful for the nanocomposites that can be used in high-frequency devices. The soft magnetic nature of the prepared nanocomposites makes them an excellent choice for a huge range of applications [21]. Chandrashekhar Joshi, R.C. Srivastav (2024) studied that $Co_{0.50}Mn_{0.50}Ce_xFe_{2-x}O_4$ **(**with $x = 0.000$, 0.025, 0.050 and 0.100) nanoparticles were synthesised through the sol-gel method. The composition with x = 0.050 exhibited optimal properties, including maximum dielectric constant, minimum dielectric loss, and high AC conductivity, along with moderate magnetic behaviour. These characteristics suggest its strong potential for electromagnetic interference (EMI) shielding applications [22]. Agami (2022) observed that $MnFe_2O_4$ nanoparticles (8–33 nm) were synthesized via co-precipitation, and their frequency and crystallite size-dependent AC resistivity (ρ_{ac}), dielectric constant (ε'), and dielectric loss (ε'') were studied with and without an applied DC magnetic field (0.1–0.5 T). Results showed that ρ_{ac}, ε', and ε'' decrease with increasing frequency, while ρ_{ac} decreases and ε', ε'' increase with an applied DC magnetic field [23]. Darya Meisak, Jan Macutkevic (2020) investigated epoxy composites with various amounts of manganese ferrite ($MnFe_2O_4$) with two spherical particle sizes (28 and 60 nm) for their broadband dielectric characteristics throughout a broad temperature range of 150 to 500 K. For tiny and big $MnFe_2O_4$ particles, the percolation thresholds in these systems are 30 and 29.3 vol%, respectively. [24].

- **Dielectric Loss (tanδ):** The dissipation factor is considerable at lower frequencies due to interfacial polarization, but it reduces with increasing frequency, enhancing its effectiveness for high-frequency use [25-30].
- **Conductivity:**
  The addition of manganese enhances the dielectric properties by lowering resistance and improving electrical conductivity [25-30].
- **Applications:**
  These fabulous dielectric properties suggests that manganese ferrite can be employed in multilayer ceramic capacitors and electromagnetic wave absorption devices [21-30].

(iii) Zinc Ferrite ($ZnFe_2O_4$)

Mamdouh Omran, Timo Fobritus (2017) The dielectric properties of ZnO and $ZnFe_2O_4$ powders were studied using the coaxial probe method at 2.42 GHz and 1064 MHz. Measurements were conducted at room temperature (23.5°C) and varying temperatures, accounting for electromagnetic dispersion due to particle size. The effect of temperature on real and imaginary permittivity was evaluated with samples sealed in a resonant stainless-steel cavity [31]. Zeljka Cvejic, Srdan Rakic (2009) studied that the dielectric properties of nanosized $ZnFe_2O_4$ and $Y_{0.15}Zn_{0.85}Fe_2O_4$ powders, synthesized by the coprecipitation method, were studied across a

frequency range of 1 Hz to 100 kHz at 300–350 K. The dielectric behaviour, attributed to interface polarization due to structural heterogeneity, shows a decreasing trend in dielectric permittivity (ε) with increasing frequency, consistent with Koops' model. Maximum dielectric loss (tan δ) was observed in the 1–10 kHz range [32].

Jayant K. Jogi, Amarjeet Singh (2023) analysed that Zinc Ferrite nanopowder was synthesized, and its dielectric properties were studied for unirradiated (ZF-1) and laser-irradiated (ZF-2) pellets. The dielectric constants (ε' and ε''), dielectric loss (tan δ), and AC conductivity (σ_{ac}) were analysed as functions of frequency and temperature. The laser irradiation caused an increase in dielectric loss (tan δ), indicating changes in the material's polarization behaviour due to irradiation [33].

Muhammad Salman, Majid Khan (2021) researched that Spinel zinc ferrite nanostructures exhibit unique dielectric properties influenced by zinc non-stoichiometry. Dielectric constant and dielectric tangent loss measurements showed consistent behaviour across all $ZnFe_2O_4$ samples, aligning with Koop's phenomenological theory of dielectric dispersion. Variations in zinc concentration affected dielectric permittivity and loss, with Zn-deficient samples showing improved charge separation efficiencies due to increased surface defects and majority carrier concentration. These findings highlight the role of zinc content in tailoring the dielectric properties of zinc ferrite for energy conversion applications [34].

- **Dielectric constant(ε′):** Zinc ferrite has a lower permittivity than other ferrites because Zn^{2+} ions primarily occupy tetrahedral sites, thereby limiting charge transfer [35-40].
- **Dielectric Loss (tanδ):** Zinc ferrite exhibits minimal dielectric dissipation, making it highly suitable for gas detectors and high-frequency devices [35-40].
- **Applications:** Its low permittivity and minimal losses make it an ideal material for electronic and microwave applications[31-40].

(iv) Copper Ferrite ($CuFe_2O_4$)

The dielectric characteristics of copper-based spinel ferrites with different rare-earth ion concentrations (y = 0.00 to 0.10) were examined as a function of frequency by Hafiz Muhammd, Tahir Farid, and Ishtiaq Ahmad (2018). The contributions of grains and grain boundaries in the frequency range of 1 MHz to 3 GHz were discovered by impedance research. These ferrites have consistent dielectric behaviour and are appropriate for high-frequency applications due to a reduction in dielectric loss caused by rare-earth substitution [41].

Kriti Vaid, Amit Chaurasia (2021) analysed the dielectric properties of $CuFe_2O_4$/LDPE composites, showing a maximum dielectric constant of 4.35, which decreases with increasing frequency. This behaviour reflects typical dielectric dispersion, consistent with the material's structural characteristics. The SEM analysis supports the findings, highlighting the composite's suitability for frequency-dependent applications [42].

Faten Haithum Mulud and Najat A. Dahham studied that the study the frequency-dependent electrical properties of $CuFe_2O_4$, focusing on its real and imaginary dielectric constants, loss factor, and alternating conductivity (σ_{ac}) across a 20 Hz to 3 MHz range. Both the real and imaginary dielectric constants decrease with frequency, typical of ferrites, as dipoles cannot follow the electric

field at higher frequencies. The loss factor and loss tangent are highest at low frequencies and decrease with increasing frequency, consistent with Maxwell-Wagner's polarization theory. Alternating conductivity (σ_ac) initially decreases at low frequencies due to reduced electron transfer between Fe^{2+} and Fe^{3+} ions but improves at higher frequencies as grain boundaries become more active. Overall, the study reveals the intricate relationship between dielectric and conductive behaviours in ferrite materials at varying frequencies [43].

The study investigates the dielectric characteristics of LDPE-based composites with copper ferrite ($CuFe_2O_4$) at 10wt% and 30wt% concentrations, with pH values of 6, 8, and 10, in the frequency range of 1 Hz to 8 MHz, according to Kriti Vaid and Umesh Kumar Dwivedi (2022). The dielectric constant decreases with increasing frequency, a typical behaviour for dielectric materials. Higher ferrite concentrations lead to an increase in the dielectric loss factor, indicating greater energy dissipation. These results suggest that copper ferrite enhances the dielectric properties of LDPE composites, improving their electrical performance and potentially extending their operational life. Further optimization of these composites could offer additional benefits for electrical applications [44].

- **Dielectric Constant (ε′):** Copper ferrite demonstrates a high permittivity due to the significant polarizability of Cu^{2+} ions. However, it shows a strong dependency on frequency, with the permittivity diminishing at higher frequencies [45-50].
- **Dielectric Loss (tanδ)** The dissipation factor is relatively high at low frequencies, primarily due to interfacial polarization and facile charge transfer [45-50].
- **Applications:** Its elevated permittivity and electrical conductivity make copper ferrite suitable for capacitors, sensing devices, and energy storage applications [41-50].

(v) Nickel Ferrite ($NiFe_2O_4$)

Lalita Chanhan, A.K Shukla (2015) investigated that the dielectric properties of $NiFe_2O_4$ ceramics prepared using DL-alanine fuel in the sol–gel auto combustion technique. It finds that the dielectric properties are strongly influenced by the microstructure, which varies with sintering temperature. Sintering at higher temperatures (1200–1300 °C) reduces dielectric losses and dispersion, with 1200 °C being the optimum sintering temperature for minimizing these losses. The complex impedance and electrical modulus spectroscopy reveal that the grain and grain boundary interactions play a significant role in the dielectric response. Overall, the ceramics sintered at 1200 °C exhibit lower losses, reduced dielectric dispersion, and higher resistivity, making them suitable for improved dielectric performance [51].

Sankar S. Menon and Radhu Krishna (2018) studied that Dielectric measurements of nickel ferrite-loaded natural rubber composites show that permittivity decreases with frequency but increases with ferrite loading. The tan delta value also rises with filler concentration, likely due to interfacial polarization between the ferrite particles and rubber. These results suggest that higher ferrite content enhances the dielectric properties of the composite [52].

Venkatraman Manikandan and Ali Mirzaei (2019) studied that the dielectric properties of Ru-doped $NiFe_2O_4$ nanoparticles are influenced by annealing temperature and frequency. The dielectric constant decreases at higher frequencies due to the limited response of dipoles, while interfacial

polarization contributes to higher constants at low frequencies. Ru doping causes lattice distortion, reducing the dielectric constant compared to pure $NiFe_2O_4$, especially at higher annealing temperatures. Dielectric loss shows resonance peaks related to electron hopping between Fe^{2+} and Fe^{3+} ions, which decreases at higher temperatures due to changes in ion valence and lattice structure. Overall, Ru substitution and annealing temperature significantly affect both dielectric constant and loss [53].

Joshi Seema and Kumar Manoj (2014) analysed that Dielectric studies of nickel ferrite nanoparticles synthesized by the wet chemical co-precipitation method reveal strong temperature dependence of dielectric permittivity, loss tangent, and AC conductivity across all frequencies. The temperature-driven variations suggest significant contributions from charge carrier dynamics and polarization effects. The AC conductivity behaviour indicates conduction via polaron hopping between Fe^{3+}/Fe^{2+} ions, highlighting the role of localized charge carriers in the electrical transport properties of $NiFe_2O_4$ nanoparticles. This dielectric behaviour, influenced by temperature and sintering, aligns with the material's mixed spinel structure [54].

- **Dielectric Constant (ε′):** Nickel ferrite exhibits a moderate permittivity that decreases with rising frequency, which is attributed to the dipole dispersion. The interaction between Ni^{2+} and Fe^{3+} ions at octahedral sites governs the dielectric response [55-60].
- **Dielectric Loss (tanδ):** Nickel ferrite has a low dielectric dissipation factor across a wide frequency range, making it suitable for high-frequency uses [55-60].
- **Applications:** Due to its interesting dielectric behaviour Nickel ferrite can be used in inductors, transformers, and electromagnetic shielding materials [51-60].

3. CONCLUSION:

From the above discussions and reviews, we made the following conclusions about the dielectric properties and related applications of Co, Mn, Zn, Co and Ni based Spinel ferrites.

Name of transition metal	**Dielectric constant (ε′)**	**Dielectric loss tangent (tanδ)**	**Application**
Cobalt ferrite	moderate	Low	Microwave devices, transformers
Manganese ferrite	high	Moderate	Capacitors, wave absorbers
Zink ferrite	low	minimum	Sensors, high-frequency devices
Copper ferrite	high	High	Energy storage, capacitors
Nikel ferrite	moderate	Low	Inductors, transformers

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Perovskite ABO_3 ferroelectric materials for their optoelectrical properties: A review

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Abstract: *With the continued growth in population and continued development in industry, the present world is suffering from an energy crisis. To address this issue, researchers have been exploring compounds that possess both electric and optical properties within a single material. Perovskite ABO_3 ferroelectric compounds can be an alternative to serve the energy saving small scale optoelectronic devices. Researchers are focusing on various synthesis processes to minimize the cost of such materials, which can provide required properties in these novel compounds. At present, lead free perovskite ABO_3 type structures have been taken into consideration for their potential ferroelectric properties and simultaneous other applications. By varying doping concentration as well as selecting suitable compounds in the ABO_3 type perovskite structure, one can easily modify the properties as per the required applications. The best thing about perovskite materials is their easy synthesis using either top-down or bottom-up approaches. These materials have versatile applications as per their synthesis process and can be tuned for capacitors, sensors, radio-frequency filters, non-volatile memories, infrared detectors, protection circuits, optical switches and many more.*

Key Words: *ABO_3, perovskite, ferroelectric, optoelectrical properties*

1. INTRODUCTION:

The ideal chemical formula of a perovskite material is ABX_3. It was initially discovered by German geologist Gustav Rose in 1839 in Ural Mountains, and named after Russian mineralogist Lev Perovskite [1, 2]. Here A and B are metal cations having ionic valences combined to +6, e.g., (Li^{+}: Nb^{5+}; Ba^{2+}: Ti^{4+}; Sr^{2+}; Mn^{4+}; La^{3+}; $Fe^{3+;}$ Ca^{+2}) and X is an anion with ionic valence −2 such as O_{2}^{-}, S_{2}^{-} etc. [3–6]. These ABX_3 materials may be oxides, halides, nitrides, sulfides, etc. and they may exist in different forms, such as powders, thin films, etc. [7–10]. The perovskite material has caught our eyes as it can contain a variety of cations at A- and B-sites individually and/or simultaneously, along with anions at X-site [11, 12].

A general perovskite material has simple cubic structure with $Pm^{-}3$ *m* space group. In this space group with perovskite structure, A atoms have *1(a)* site at (0, 0, 0) and B atoms have *1(b)* site at (1/2, 1/2, 1/2) and X atoms have *3(c)* site at (1/2, 1/2, 0). However, the A, B and X atoms can also occupy *1(a)* site at (1/2, 1/2, 1/2), *1(b)* site at (0, 0, 0) and *3(c)* site at (0, 0, 1/2), respectively, as shown in **Figure 1**. In this figure, A, B and X are presented in terms of ionic radii [13, 14]. In the unit cell of ABX_3, the cation 'B' forms an octahedral arrangement with X-anions, i.e., BX_6 and the cation 'A' occupies cuboctahedral site with X-anions, i.e., AX_{12}. The perovskite materials exhibit various oxide forms, including transition metal oxides with the ideal formula ABO_3. The oxide perovskite materials are widely synthesized and are studied for wide applications in various technological fields. In light of these properties, we reviewed oxide perovskites in more detail.

Victor Moritz Goldschmidt gave a relationship among the ionic radii of A, B and O, known as the tolerance factor (t) to estimate the stability of a structure. This relation is valid for the ionic radii at room temperature [15]. The numerical value of the tolerance factor can be found by the following Eq. (1):

$$t = \frac{rA+rO}{\sqrt{2}(rB+rO)} \quad (1)$$

Here r_A is the ionic radius of cation A and r_B is ionic radius of B cation, whereas r_O is the ionic radius of oxygen anion (O_2^-). The ionic radius of A cation is always larger than that of the B cation. The tolerance factor provides an idea about the selection of combination of A and B cations in order to prepare an ideal perovskite material. Eq. (1) can also be expressed in other form, which may be valid for any temperature as given by Eq. (2):

$$t = \frac{d_{A-O}}{\sqrt{2}d_{B-O}} \quad (2)$$

Here d_{A-O} and d_{B-O} are average bond-lengths between A-O and B-O, respectively [16].

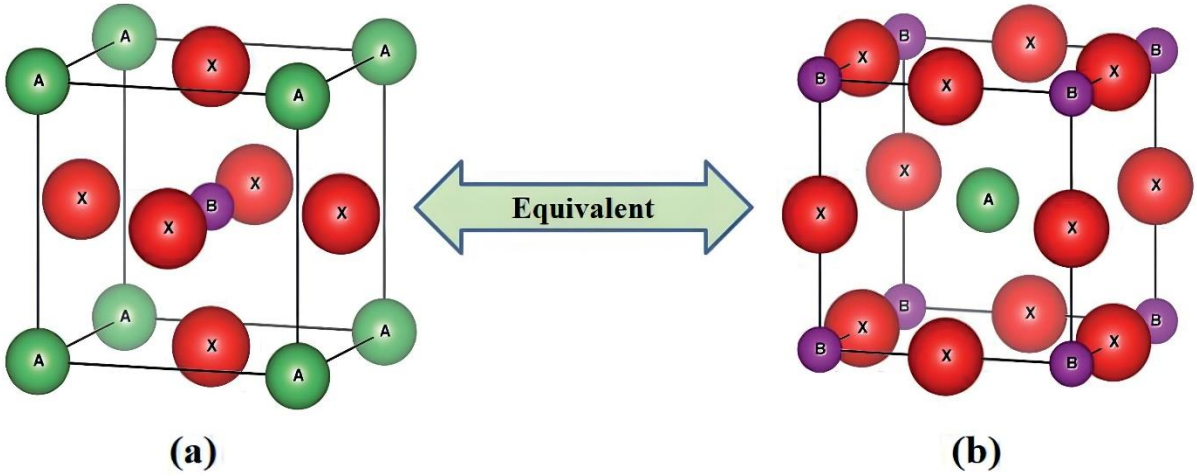

Figure 1. *Molecular structure for ABX_3 perovskite with Pm^{-}* **3** *m space group. The figures (a) and (b) are equivalent structure to each other. In the figure (a), A and B take the positions at the corner and body center of the cubic cell, respectively, and X is at the center of face of the unit cell. However, in the figure (b), A and B occupy at body center and the corner of the cubic cell, respectively, and X lies at the center of edge of the unit cell.*

The distorted perovskite materials are those materials, which crystallize into other than the cubic structures. As we know that the perovskite material can occupies different ions at the A- and B-sites. The variation in the A- and/ or B-sites cations creates a variation in the tolerance factor. The variation in tolerance factor leads to a change in the perovskite structure from cubic to non-cubic distorted perovskite structure. For a stable perovskite, the value of tolerance factor should lie in the range of 0.88–1.09 [17]. An ideal perovskite crystal have tolerance factor equal to unity (i.e., t = 1). For t < 1, the perovskite materials show the rhombohedral or monoclinic structure while in the case of t > 1; it show tetragonal or orthorhombic structure [18]. As distortion in the perovskite system, the BO_6 octahedral change from an ideal situation and causes a change in unit cell volume. **Figure 2** shows unit

cells for some distorted perovskite structures. The perovskite material required two main conditions these are given below.

1. Ionic radii: the average ionic radii of A- and B-sites cations should be greater than 0.90– 0.51 Å, and the value of tolerance factor should be in the range of 0.88–1.09 [19-20].
2. Electro-neutrality: the chemical formula of perovskite material should have neutral charge and the sum of total charges at A- and B-sites cations must be equal to total charges at O-site (oxygen) of anion(s). For example they may have formulas like $A^{3+}B^{3+}O_3$ or $A^{4+}B^{2+}O_3$ or $A^{1+}B^{5+}O_3$ [14, 19].

The prepared perovskite materials (ABO_3) may not always have the useful properties. The doping at A- and/or B-sites may make them useful and change their properties and also generates very interesting phenomena due to change in crystal structure, bond-lengths, ionic states, etc. The general formula after doping in the perovskite materials at A- and/or B-site may be have the form like $A_{1-x}A'_xBO_3$ ($0 < x < 1$) and $AB_{1-y}B'_yO_3$ ($0 < y < 1$), respectively. They can also have simultaneous A- and B-sites doped oxide perovskites have general formula $A_{1-x}A'_xB_{1-y}B'_yO_3$. Here we discuss the synthesis process used for the preparation of perovskite materials [20].

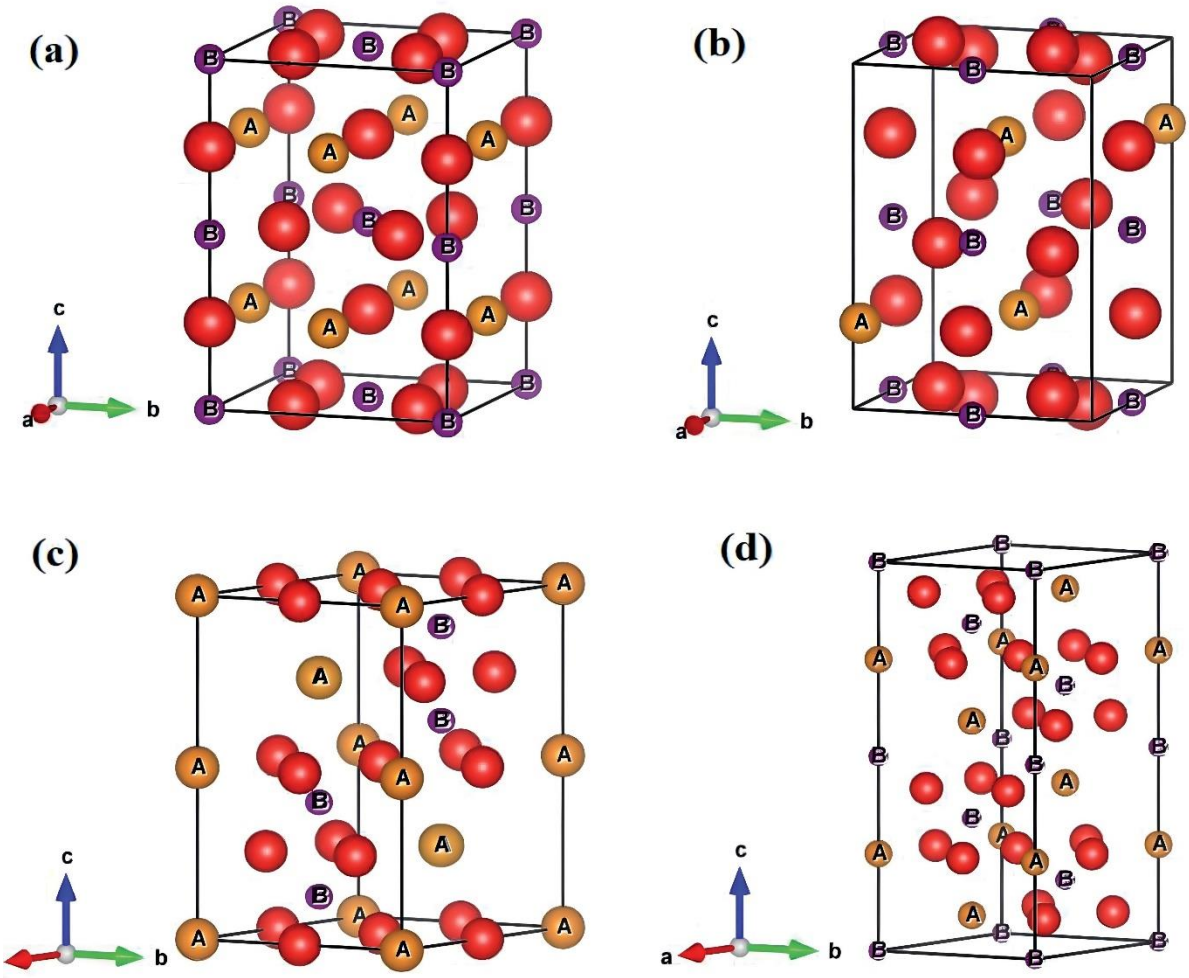

Figure 2. Different distorted perovskite unit cells; (a) tetragonal, (b) orthorhombic, (c) hexagonal, and (d) rhombohedral (Hexa. Setting). Red spheres stand for oxygen anions.

2. SNTHESIS TECHNICS OF PEROVSKITE MATERIALS:

There are many different techniques for the synthesis of the perovskite materials. The properties of the perovskite materials strongly depend on the synthesis routes. Therefore, the synthesis methods are very important factor to get desired properties from the perovskite materials [21]. These synthesis techniques can be divided mainly into three categories:

1. Solid phase synthesis
2. Liquid phase synthesis
3. Gas phase synthesis

2.1 Solid phase synthesis

This synthesis technique is a mostly used for the synthesis of polycrystalline solid perovskite materials from the mixture of solid raw substances. In this method initially the materials do not react to each other at room temperature. But when it calcined at higher temperatures i.e., 900–1500°C, the reaction occurs at a remarkable rate. In this technique raw materials in the oxide form are necessary.

2.1.1 Mechanical ball-milling method

This method is widely used by researchers for the preparation of polycrystalline perovskite oxide materials. This method involves grinding and mixing of raw materials in several times. For the synthesis of any oxide perovskite materials, one has to take stoichiometric amount of metal oxide as starting materials.

Let we take an example of $Ba(Zr_xTi_{1-x})O_3$ [22-24]. They used $BaCO_3$, ZrO_2 and TiO_2 as raw materials. The raw materials were weighted and all-milled for 24 h in ethanol. Then the mixture was calcined at 1100°C, then ball-milled and dried again. After that the powder was mixed with PVA to form pellets. PVA was burned out in the furnace at 650 °C. Finally the samples were sintered at 1400 °C for 4 h.

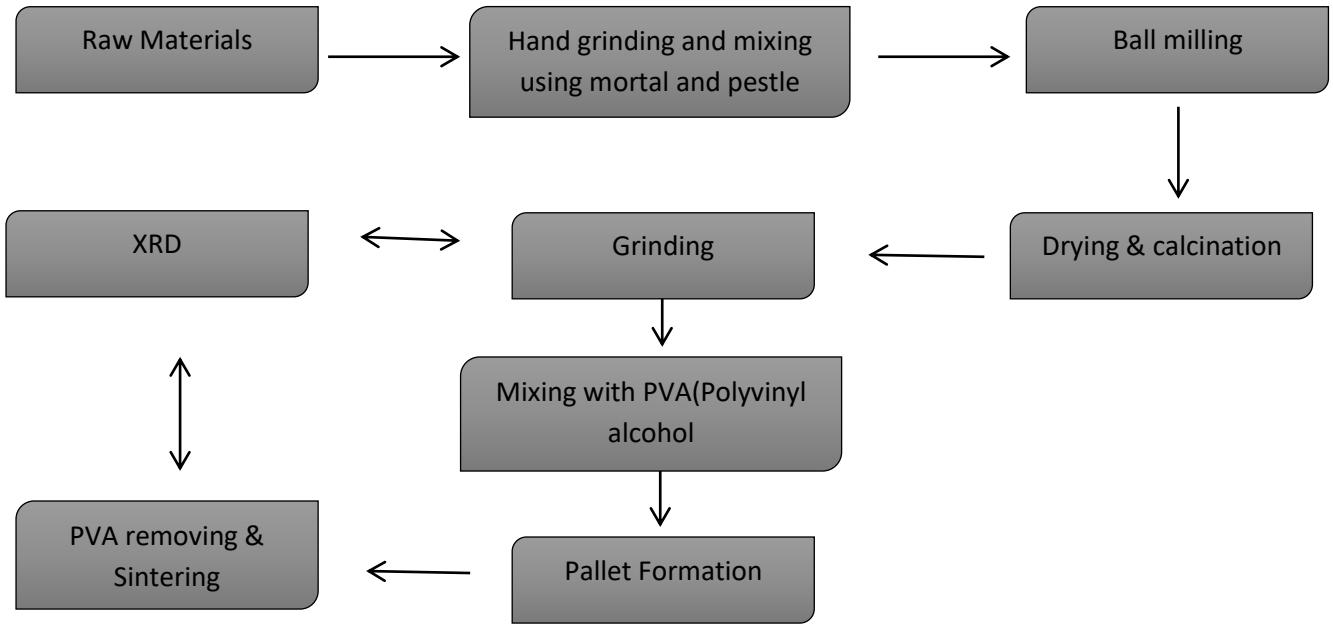

Figure 3. *Flow-chart for the synthesis of oxide materials using ball milling technique.*

2.1.2 High energy ball-milling method

This technique is very similar to that of mechanical ball-milling technique. It is used for the synthesis of nanoparticles of the oxide materials. Like mechanical ball-milling this method also required only metal oxides because there is possibility of chemical reaction during high energy ball-milling, which may generate different toxic and/or unwanted gases. This technique involves large rpm from few hundreds to few thousands. The plus point of this method is that it requires low temperature for the synthesis of materials.

Let we take an example of $Ba_{1-x}Ca_xTiO_3$ [25]. The stoichiometric amounts of highly pure $BaCO_3$, $CaCO_3$ and TiO_2 were taken as raw materials and were hand-milled using mortar and pestle more than 2h with acetone in an agate mortar for homogeneous powder. High energy ball milling was conducted in a planetary ball mill. Milling was done at room temperature for 2 hours with 40 zirconia balls of 10mm diameter at 300 rpm. The ball mixed material was conventionally calcined at 1280°C for 5h in an electric furnace. The XRD patterns were recorded to check the formation of pure phased samples.

2.2 Liquid phase synthesis

The liquid or chemical phase synthesis technique is widely used for the synthesis of nano-sized materials. Due to liquid phase, the starting materials may react to each other at room temperature [19].

2.2.1 Auto-combustion method

This technique is a very simple and inexpensive for the preparation of perovskite nano-materials. This method requires raw materials in nitrate and/or acetate forms, which should be easily soluble in distilled water. It also requires an organic fuel, such as glycine, urea or citric acid to help in the combustion process.

Let us an example of $Bi_{1-x}Nd_xFeO_3$ (BNFO) (x = 0, 0.05, 0.1, 0.15, 0.2) nano particles prepared by H Maleki, S Zare and R Fathi [26]. They used $Bi(NO_3)_3$-$5H_2O$, $Fe(NO_3)_3$,-$9H_2O$, and $Nd(NO_3)_3$-$6H_2O$ as raw materials and evaporated. They used ethylene glycol and 2-methoxyethanol as synthesis fuels. To maintain the pH value acetic acid was added to the solution dropwise. After half an hour of stirring bismuth nitrate and neodymium nitrate were added to the mixture. Again the mixture was stirred for 30 min and then iron nitrate was added. As iron nitrate added a dark red mixture was appeared. Then the mixture was stirred at room temperature for 1 h then temperature was increased to 70 $^{\circ}$C for 3 h to get brownish gel. As they rise the temperature yellow suspension was formed. The suspension was kept at room temperature for 10 h, then it was put at 115°C foe water to evaporate and after combustion they got black colour. After that they calcined the powder at 650°C. They washed the products with dilute nitric acid in order to remove impurity.

2.2.2 Sol-gel method

The sol-gel method involves physical and chemical procedures correlated with hydrolysis, condensation, polymerization, gelation, drying and densification [27]. This method also requires starting materials in the form of metal alkoxides.

Let take the example of $La_{0.875}Ba_{0.125}FeO_3$ [28]. Initially Lanthanum nitrate (La^{+3} = 0.875), barium nitrate (Ba^{+2} = 0.125), ferric nitrate (Fe^{+3} = 0.875:0.125:1) and citric acid (La^{+3} + Ba^{+2} + Fe^{+3}: Cictric =

1:2) were dissolved in water and mixed. After this polyethylene glycol(PEG) was added with continuous stirring to get a sol. Then the gel was dried into pieces, these pieces were hand milled to form fine powder samples, which were heated at 800̊ C for 3 h. The resulted powder was characterized by XRD to determine the phase composition.

The final powders were mixed with PVA solution and ground into paste. This paste was heated at 400°C for 2 hours to improve the stability. Then they measured its properties at different conditions. **Figure 4** shows a schematic flow chart of the processes involved in the synthesis of perovskite materials using this method.

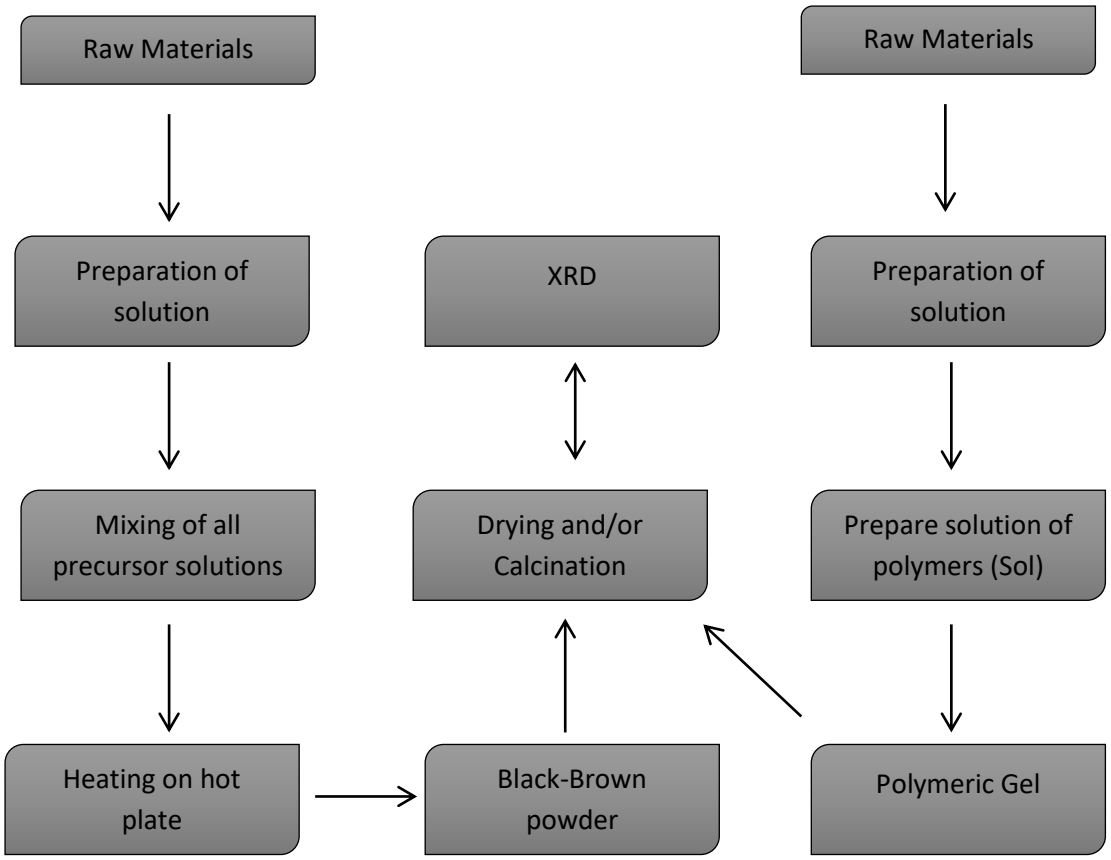

Figure 4. *Flow charts for the synthesis of oxide materials using (a) auto-combustion and (b) sol-gel methods.*

Let take other example of a new sol-gel assisted solid phase method used by lijie and friends in their paper to prepare nano $BaTiO_3$ ceramics. This method can prepare nano $BaTiO_3$ with higher purity at a lower temperature, which has certain significance for the industrial preparation of $BaTiO_3$ ceramics. Barium carbonate ($BaCO_3$, 99%), hydrochloric acid (36%–38%), butyl titanate ($[CH_3(CH_2)_3O]$ Ti, 98%), chloroplatinic acid (H_2PtCl_6, 99.5%), anhydrous ethanol (CH_3CH_2OH, 99.7%) and anhydrous methanol (CH_3OH, 99.5%) were taken as a raw material. 5.6 mL of hydrochloric acid (mass fraction 36%–38%) and 36 mL of deionized water were added to 150 mL of absolute ethanol, followed by constant temperature stirring at 30 °C for 20 min. This solution was called liquid A. To 37.5 mL of absolute ethanol, 13.5 g of butyl titanate was added, followed by stirring at 30 °C for 30 min at a constant temperature, and this solution was called liquid B. 7.8273 g of $BaCO_3$ (molar ratio: tetrabutyl titanate: barium carbonate=1:1) was added to solution B, and stirring was continued at 30 °C for 20min. After that, ultrasonic treatment was performed for 50min and the power was 360 W. Thereafter, the solution A was slowly added to the solution B at a rate of 5s/drop in a constant temperature water bath at 30°C until a sol was formed, and the sol was allowed to stand for 3 h in a dark room to obtain a gel. Then,

the gel was dried by heating at 80 °C for 8 h to obtain a $BaCO_3/TiO_2$ xerogel. After grinding, the $BaTiO_3$ was prepared by sintering in air at different temperatures for 2 h for thermodynamic investigation. [29]

2.2.3 Co-precipitation method

The co-precipitation method requires starting materials of metal cations from a common medium, which precipitates in the form of carbonates, hydroxides, oxalates or citrates [30–36]. The obtained precipitates are consequently calcined at different temperatures to get the single phase of the desired product in powder form. Using this method, we can get highly homogeneous powder sample.

Let take the preparation of $Co_{1-x}Zn_xFe_2O_4$ [37]. For this preparation they used $Fe(NO_3)_3$, $CoCl_2$, $ZnCl_2$ reagents. Initially $CoCl_2$-$6H_2O$, $ZnCl_2$ and $Fe(NO_3)_3$-$9H_2O$ were mixed in co-precipitation agent NaOH. All the mixture was dissolved in distilled water with continuous stirring till a clear solution was obtained. The solution was heated up to 70 ˚C with constant stirring. During all the process they kept the pH of the reaction between 12.5-13. Then the precipitates were washed with distilled water until it was free from sodium and chloride ions. After that the product was dried at 100˚C for 24 h to remove water contents. Then the powder was mixed using mortar and pestle. The powder was palletized and sintered at 600 ˚C for 2 h.

2.3 Gas phase synthesis

Different methods such as flames, furnaces, plasmas and lasers are sub category of gas synthesis methods. In each method, the designed reactor is different. Using gas phase reactors, one can produce highly pure perovskite powder materials.

Various electronic devices of perovskite materials are fabricated in the form of thin films using gas phase synthesis. Many techniques were developed for the preparation of thin films, such as chemical vapor deposition [38], molecular beam epitaxy [39], laser ablation [40], DC sputtering [41], magnetron sputtering [42], thermal evaporation [43] and electron beam evaporation [44]. These gas phase methods can be classified into three categories:

1. Synthesis at the crystallization temperature
2. Synthesis in an intermediate temperature
3. Synthesis at very low substrate temperature

3. STRUCTURAL AND OPTOELECTRICAL PROPERTIES:

3.1 Identification of phase purity: X-ray diffraction studies

It is very necessary to check the phase and purity of the synthesized perovskite materials. Without this information, one cannot conclude about the properties of perovskite materials. The XRD technique is a suitable to identify the phase. From the XRD data, one can find out relative phase fractions of different phases present in the prepared samples. One can also find out lattice constants, unit cell volume, crystallite size, lattice strain and theoretical density from the XRD pattern. By matching the XRD pattern of the synthesized material with the standard XRD pattern of the cubic phase, one can conclude about the phase purity, i.e., whether, the perovskite is pure or has some amount of impure phase(s) or crystallizes into distorted perovskite.

Let discus XRD result of $BaTiO_3$ synthesised by sol-gel assisted solid phase method [29]. In their result before heat treatment, the sample only showed the diffraction peak of $BaCO_3$. This was because the TiO_2 precursor gel has a long-range disordered structure, so it is not reflected in the XRD results. Compared with the standard $BaCO_3$ PDF card, XRD pattern of samples at room temperature is consistent with it but the XRD diffraction peak of the sample prepared at 500 °C moves to high angle, which may be due to the TiO_2 precursor gel entering into $BaCO_3$ and forming a solid solution with BaCO3.The results of TiO_2 gel calcined at 500 °C for 2 h show that TiO_2 was precipitated, but after adding $BaCO_3$, the TiO_2 XRD diffraction peak disappeared, which also proved the formation of solid solution. In XRD spectrum the diffraction peak of $BaTiO_3$ begins to appear at 600 °C, proving that $BaTiO_3$ is initially generated at 600 °C. When the temperature reached 800 °C, pure cubic phase $BaTiO_3$ is obtained, and the space point group is P3m3. When the temperature reached 900 °C,the diffraction peak of (200) split into two peaks of (002) and (200). $BaTiO_3$ began to transform from the cubic phase to the tetragonal phase, and its spatial point group was P4mm [45–47]. A similar conclusion was found in Peigong Wang's study [48].

3.2 Dielectric properties

Dielectric properties of a material can provide information about how the material interacts with an electric field, and how it behaves in various applications. Polarization, Breakdown voltage, Dielectric constant, intermolecular interactions, Energy storage, Semiconductor performance and many more information we can obtained from dielectric properties.

Let us discuss the dielectric result obtain in synthesis of $ErCrO_3$ by microwave synthesised method [49]. They plot the Impedance spectroscopy (IS) data in terms of real (Z') and imaginary (Z'') parts of the impedance. After that they conclude that at 200K 3 distinct semi-circles are displayed, which can be associated with 3 dielectric relaxation processes [50, 51]. The relaxations were assigned to one intrinsic bulk and two extrinsic contributions, grain boundary (GB) and electrode–sample interface. Conventionally, an ideal relaxation process can be modelled with an ideal RC element of parallel resistance and capacitance, and for interface, GB and bulk relaxations 3 RC elements can be simply added in series. They have encountered non-ideal dielectric response though, which was manifested by slightly suppressed semicircles. This can be accounted for by replacing the ideal capacitor with a constant phase element (CPE) [52]. In this case, an almost ideal fit was obtained using 3 R-CPE elements in series. From the plots of $-Z$'' vs. f and the modulus function M'' vs. f, where 3 dielectric relaxation peaks are visible in each plot. For ideal dielectric relaxations as represented by ideal RC elements the height of the peaks in $-Z$''vs. f are proportional to the resistance R: $-Z''(f_{max}) = R/2$ of the respective relaxation, and the height of the peaks in M'' vs. f are inverse proportional to the capacitance C:$M''(f_{max}) = C_0/2C$, where C_0 is a constant factor. Although non-ideal relaxation peaks may be slightly suppressed, the result suggest unequivocally that the interface relaxation exhibits high resistance and high capacitance, the GB relaxation intermediate resistance and capacitance, and the intrinsic bulk relaxation small resistance and capacitance. By using the equivalent circuit model at various temperatures they obtained the temperature dependence of the bulk resistance (R1) and capacitance (CPE1), the GB resistance (R2) and capacitance (CPE2), and the interface resistance (R3) and capacitance (C3). The CPE capacitance values obtained from the fits were corrected to conventional capacitance given in [F/cm] [53]. Such values were then plotted as relative dielectric permittivity ε_r vs. T. The intrinsic bulk ε_r is in the range of 23, which is in remarkable agreement with the value of 22.7 predicted from the Clausius–Mossotti equation for dielectric materials based on the unit cell volume and the sum of the ionic polarizability of each individual atom, both at room temperature [54]. The GB permittivity is in the range of 200 and the interface capacitance in the range of 50 000. All 3 relaxations show capacitance values rather typical for the respective type of contribution [50]. It is worth noting that all 3 capacitance values show no considerable temperature dependence. This is inconsistent with

previous claims that $ErCrO_3$ is ferroelectric, in which case a strong temperature dependence of intrinsic bulk ε_r values, and general ε_r values higher than the Clausius–Mossotti prediction would be expected.

3.3 Optical properties:

Optical properties provide information about the interaction between light and matter, and can be used to learn about the physical properties of materials. One can obtain the information like Electronic and vibrational states, structure, defects and impurities of the materials.

Here we take the reference of $LaFeO_3$ prepared by polymerized complex method [55]. Here all samples prepared at different temperature shows a strong absorption in the ultraviolet and visible light. This absorption is interesting because $LaFeO_3$ could be developed a new visible light photocatalyst. The estimated direct band gaps of all samples were in the range of 2.15-2.23 eV. These small band gaps are interesting for applications in photocatalytic, sensor materials and electrode material in solid oxide fuel cells (SOFCs) [56-58]. The valence states of La and Fe in the prepared samples were investigated by XPS, which is more sensitive to surface. The XPS spectra of La3d, Fe2p and O1 of $LaFeO_3$ showed the peak position at approximately 833.5-833.6 and 850.3-850.6 eV are assigned to $La3d_{5/2}$ and $La3d_{3/2}$ [56,59]. This indicates the La ions are in the La^{3+} ions. The Fe peaks of the samples included two components of Fe^{3+} (709.9-710.0 and 723.2-723.5 eV) and Fe^{4+} (711.6-711.7 and 724.9-725.2 eV) indicated that the Fe ions in this $LaFeO_3$ samples were in a mixed of the Fe^{3+} and Fe^{4+} valence state[56,60]. For O ions in $LaFeO_3$, the samples showed similar peak position of crystal lattice oxygen ($O_{L)}$ at 529.2-529.3 eV and hydroxyl oxygen (O_H) at 531.3-531.6 eV, indicating that it is attributed to the contribution of La-O and Fe-O in $LaFeO_3$ crystal lattice for the O_L signal [59,60] To confirm the valence states of La and Fe in the prepared $LaFeO_3$ samples, they performed experiments by measuring the XANES. The XANES spectra at Fe K-edge were measured in transmission mode at RT. The edge position of Fe_3O_4 (Fe^{2+}, Fe^{3+}) standard was nearby 7124 eV while Fe_2O_3 (Fe^{3+}) standard was nearby 7125 eV and for FeO (Fe^{2+}) standard was nearby 7120 eV. Thus this result showed that most of the Fe ions in these samples are in a mixed valence atate of Fe^{3+} and Fe^{4+}, which agree with the XPS results.

4. APPLICATIONS OF PEROVSKITE MATERIALS:

The perovskite materials are widely studied by researchers due to their attractive properties. The perovskite materials have wide applications in various fields [61-66], which are listed below:

- Photo catalytic activity
- Photovoltaic solar cells
- Phosphor materials in photoluminescence
- Solid oxide fuel cells
- Sensors and actuators
- Magnetic memory devices
- Magnetic field sensors
- Electric field effect devices
- Ferroelectric and piezoelectric devices
- Semiconducting electronic devices
- High dielectric constant
- High temperature superconductor
- Hypothermia
- Supercapacitor

5. CONCLUSION:

Here we review the background and the basic information of the perovskite structure, its stability and distortion. We have also discussed the different formula of the perovskite materials, which accommodate different cations at A- and/or B-sites individually and/or simultaneously. We have also discussed various solid, liquid and gas phase synthesis for the preparation of perovskite materials. We also briefly described the phase identification of the perovskites and their structural analysis using Rietveld refinement of the XRD data by taking an example of $BaTiO_3$ tetragonal perovskite. The dielectrical and optical studies were also incorporated with an example of $ErCrO_3$ and $LaFeO_3$ respectively. We have briefly listed various applications of perovskite materials in different fields.

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"Exploring the Struggle for Survival: A Study of Ernest Hemingway's 'The Old Man and the Sea' in the Context of American Naturalism"

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Abstract: This research paper examines Ernest Hemingway's novella *'The Old Man and the Sea'* through the perspective of American Naturalism. Ernest Hemingway born in 1899; became one of America's most celebrated authors and won the Nobel Prize in Literature in 1954 for his mastery of narrative technique and his influence on modern literature. His experiences as an avid fisherman and his understanding of nature deeply inform *'The Old Man and the Sea'* making it a fitting subject for a study in Naturalism. American Naturalism is a literary movement that focuses on how environment, heredity, and social conditions shape human behavior. The research tries to find out the elements of Naturalism by selecting total six parameters including determinism, pessimism, scientific narration, emphasis on survival, characterization, and naturalistic symbolism. The paper uses a qualitative method to analyze the text, allowing for an in-depth exploration of Santiago, the protagonist. He is an old fisherman who struggles against the forces of nature, representing the Naturalist belief that individuals are often powerless against their environment.

Key Words: The Old Man and the Sea, American Naturalism, Santiago, Survival

1. INTRODUCTION:

"A man said to the universe:
"Sir, I exist!"
"However," replied the universe,
"The fact has not created in me
A sense of obligation."

(Crane)

Social environment plays a crucial role in molding the life of human being. The life of an individual is decided by the environment in which he lives. Sometimes people become slave of the environment in which they are living.

1.1 ABOUT NATURALISM:

Naturalism is a word derived from 'nature'; it is the suggestion that art and literature should present the world and people just as science shows they really are. Naturalism is almost not easy to define and sometimes used as synonym of realism. Naturalism, which emerged in the late 1800s, is a type of writing where authors discuss why characters in their stories act, choose, and believe the way they do. They focus on how family and society impact individuals, leading to complex situations. In Naturalism, the idea is that the environment has the biggest influence on a person's character. According to Oxford Dictionary of Literary Terms,

> *"Naturalism, a more deliberate kind of Realism in novels, stories, and plays, usually involving a view of human beings as passive victims of natural forces and social environment."* (Oxford 167)

In the early 1860s, a French art critic named *Jules Antoine Castagnary* used the term Naturalism to describe a style of painting that looked very realistic. Naturalists were writing about criminals, slums, laborers, strikers and prostitute; they attacked capitalism, but also explained society in Darwinist terms that heredity and environment determine man in world where only the fittest survive. Naturalistic stories focus on how people are guided by their actions and surroundings. The world is ruled by natural forces,

like society and family traits, and only the strongest survive. This means family, social conditions, and the environments have a big role in shaping a person's character in Naturalism. It often talks about fate and how the environment and situations decide what happens, rather than people having free will.

Naturalism serves certain characteristics like; the Naturalists were inspired by scientific storytelling. The storyteller just talks about what's happening without getting too close to the characters. In Naturalist, characters can't really control what happens to them. Even if they try really hard to change their situations or overcome problems, they end up having to accept whatever comes their way. The writers believed that our surroundings and our nature shape us, and we can't get away from that.

In Naturalism, we don't expect cheerful endings instead we come across a lot of sad outcomes and tragic events. The reason for this pessimism is that Naturalist writers think things are pretty much set, or determined. They believe that we can't really change our situations. They thought that where we grow up and the people around us have a big say in whom we become and what happens to us.

Naturalist writers were curious about what we get from our ancestors in terms of our human nature. Naturalist writers were interested in how traits and characteristics are passed down from one generation to the next. Naturalism often talks a lot about poverty. Many of their works focus on characters living in poverty or growing up in poor backgrounds. The reason Naturalists cared about poverty is that it's an extreme situation.

Naturalists were inspired by *Charles Darwin's* ideas, especially the one about 'survival of the fittest' where the strongest animals live longer than the weaker ones and sometimes even eat them. Survival is a significant theme in Naturalist works too. They look at how people manage or struggle to survive. They take Darwin's idea about the strongest surviving and use it to think about human society.

1.2 ABOUT AUTHOR:

Ernest Hemingway (1899-1961), was a poet, novelist, journalist, and short story writer whose name is synonymous with strong characters and even stronger prose; he left an important mark on 20th-century American literature. Instead of going to college, he worked at a newspaper in Kansas City. But when *'World War I'* started, he wanted to be part of it. The writings of Hemingway also contain some autobiographical elements. Hemingway won big awards for his writing, like the Pulitzer Prize and the Nobel Prize in literature.

2. PROBLEM TO BE INVESTIGARED:

This research paper aims to explore how Ernest Hemingway's novella *'The Old Man and the Sea'* contains the elements of American Naturalism. The novella is quite famous for the depiction of Santiago as a protagonist, who fights against the natural forces for his survival. By examining *'The Old Man and the Sea'* from the perspective of American Naturalism the researcher wants to understand Santiago's struggle against natural surroundings.

3. REVIEW OF RELATED LITERATURE:

No.	Title	Author	Genre	Publication Details
1	On the Influence of Naturalism on American Literature	Xiaofen Zhang	Research paper	June - 2010
2	The Old Man and The Sea, The Battle of Life for All Human Kind	Bledar Kurti	Research paper	June - 2023

3	The Theme and Vision of Endurance in Ernest Hemingway's The Old Man and the Sea	Mrs. Susheel Sharma	Research paper	Oct- 2022

The first research paper aims to explore the application of Naturalism in American literature, contributing to a broader understanding of Naturalist literature overall. It also tries to provide a detailed discussion on American Naturalism. The paper also shed light on American Naturalists, such as *Stephen Crane, Frank Norris, Jack London, Henry Adams, Theodore Dreiser,* and *Ernest Hemingway.*

The second research paper examines the novella from the perspective of Hemingway's own life. The paper asks the question is the narrative merely a reflection of Hemingway's personal struggles, or does it transcend into a portrayal of humanity's perpetual struggle through the ages? The paper contends that *'The Old Man and the Sea'* transcends the author's personal voice, becoming a universal work that resonates with the timeless struggle and calling of humanity across centuries.

The third research paper discusses the theme of endurance portrayed in Ernest Hemingway's acclaimed novella. The analysis focuses on the protagonist Santiago's struggle and commitment to overcome challenges, serving as a metaphor for the broader human condition. By examining narrative structure, character development, and symbolic elements, the paper aims to reveal how Hemingway skillfully crafted a timeless masterpiece that captures the indomitable spirit of human perseverance.

4. OBJECTIVES:

- To evaluate the key elements of American Naturalism in *'The Old Man and the Sea.'*
- To assess the significance of the battle between Santiago and the Marlin as an allegory for the naturalistic struggle for survival.

5. HYPOTHESIS:

- In *'The Old Man and the Sea'* Ernest Hemingway illustrates the struggle for survival as a fundamental aspect of the human experience, demonstrating that individual resilience against nature's indifferent forces reflects the central aspects of American Naturalism.

6. RESEARCH DESIGN:

The research design follows a qualitative analysis to examine Naturalism from Ernest Hemingway's *'The Old Man and the Sea'.* The primary data source is the original novella. Secondary data source may include scholarly articles analyzing *'The Old Man and the Sea'* from various perspectives and different articles on American Naturalism.

7. DISCUSSION:

The researcher has selected total six parameters to analyze Naturalism from the original text; the discussion is as follows,

7.1 DETERMINISM:

Determinism, a philosophical concept asserting that all events and actions are predetermined by existing conditions. Determinism in Naturalism also encompasses the role of societal and economic factors in shaping individual experiences. Santiago's status as an aging fisherman living in poverty and struggling to make a living can be viewed through the lens of determinism. His circumstances are largely determined by the socio-economic conditions of his time and place, which he has little control over.

The deterministic aspect of Naturalism suggests that Santiago's actions and struggles are predetermined by the power of nature, particularly the sea. His battle with the Marlin and the subsequent ordeal with the sharks can be interpreted as a manifestation of the deterministic forces in the novella, where human agency is ultimately subordinate to the natural environment.

Let's understand determinism with example,

"He was an Old Man who fished alone in a skiff in the Gulf Stream and he had gone eighty-four days now without taking a fish. In the first forty days a boy had been with him. But after forty days without a fish the boy's parents had told him that The Old Man was now definitely and finally salao, which is the worst form of unlucky, and the boy had gone at their orders in another boat which caught three good fish the first week."

(Hemingway 1)

The fact that he has gone eighty-four days without catching a fish establishes a pattern of adversity, suggesting an inherent lack of control over the outcomes. The mention of the boy's departure after forty days without success discusses the societal perception of Santiago as *'salao'* or deeply unlucky, reflecting the deterministic forces at play in shaping his fate.

7.2 PESSIMISM:

Pessimism is a philosophical outlook characterized by a general idea to see and emphasize the negative aspects of situations, events, or life in general. Pessimism contrasts with optimism, which leans towards a more positive and hopeful interpretation of events. The novella, set against the backdrop of the struggle between man and nature, captures the essence of pessimism through its portrayal of the old fisherman Santiago's arduous journey in the Gulf Stream. Santiago's eighty-four days of futile fishing, marked by relentless adversity, symbolize the inherent pessimism in the Naturalist philosophy, where individuals are subject to external forces beyond their control. Let's understand it with one instance,

"I wish it had been a dream now and that I had never hooked the fish and was alone in bed on the newspapers. 'But man is not made for defeat,' he said. 'A man can be destroyed but not defeated.' I am sorry that I killed the fish though, he thought. Now the bad time is coming and I do not even have the harpoon. The dentuso is cruel and able and strong and intelligent. But I was more intelligent than he was. Perhaps not, he thought. Perhaps I was only better armed."

(Hemingway 79-80)

The passage reflects Santiago's complex emotions after catching the fish, presenting the elements of regret, resilience, and a looming sense of pessimism. The statement, 'I wish it had been a dream now,' suggests a desire to escape the harsh reality of the situation, indicating a certain level of regret for having hooked the fish. The Old Man seems to entertain the notion that avoiding the struggle altogether would have been preferable. The expression, 'But man is not made for defeat. A man can be destroyed but not defeated,' conveys his resilient spirit. The Old Man, despite his initial excitement over the catch, experiences feel bad for taking the life of the magnificent fish.

7.3 SCIENTIFIC NARRATION:

Scientific narration in literature is a style that combines storytelling with scientific ideas. It often features characters who are scientists or explores themes related to science, such as ethics and discovery. This approach helps readers understand complex scientific concepts through engaging narratives. Scientific narration also plays a crucial role in depicting the protagonist's understanding of the marine environment. Scientific Narration, in this context, becomes a tool for conveying the harsh realities of the natural world, emphasizing the struggle for survival.

The novella's portrayal of the protagonist Santiago's struggle with the Marlin and the challenges he faces at sea reflects an understanding of the natural world, akin to a scientific exploration. The narrative discusses with a keen awareness of the ecological cycle of the Gulf Stream, showing Hemingway's commitment to portraying nature realistically. This approach mingles with the Naturalist movement, where literature is seen as a reflection of the deterministic forces of nature on human existence. Hemingway's descriptions of various fish species, the behavior of sharks, and the anatomy of the Marlin demonstrate a commitment to accuracy and detail. This scientific narration contributes to the overall authenticity of the narrative and provides readers with an immersive experience that goes beyond mere storytelling. For more understanding let's delve in the text,

"The Old Man was thin and gaunt with deep wrinkles in the back of his neck. The brown blotches of the benevolent skin cancer the sun brings from its reflection on the tropic sea were on his cheeks. The blotches ran well down the sides of his face and his hands had the deep-creased scars from handling heavy fish on the cords. But none of these scars were fresh. They were as old as erosions in a fishless desert. Everything about him was old except his eyes and they were the same colour as the sea and were cheerful and undefeated."

(Hemingway 1)

This quote from vividly describes the physical attributes of Santiago, emphasizing the effects of the harsh natural environment on his body. The deep wrinkles, brown blotches from the sun's reflection,

and deep-creased scars on his hands reflect the physical toll of a life spent battling the elements and handling heavy fish. The scars are described as old as erosions in a fishless desert, suggesting a sense of inevitability and determinism in Santiago's life. The reference to the sea as the same color as his eyes, which are described as cheerful and undefeated, adds a contrasting element. Despite the physical toll and the harshness of the environment, Santiago's eyes remain resilient, perhaps symbolizing an undefeated spirit and a determination to face the challenges given by nature.

7.4 EMPHASIS ON SURVIVAL:

Survival, both physical and existential, is a recurrent motif, portraying the struggle of Santiago, against the forces of nature. The Old Man's eighty-four-days without catching a fish discuss the harsh and unpredictable nature of the sea, where success in fishing is not guaranteed but subject to the fate. Santiago's solitude on his skiff expresses the isolation inherent in the struggle for survival. The vastness of the sea and the absence of companionship magnify the individual's vulnerability in the face of nature's forces.

Santiago's struggle with the Marlin is a duel not only with an individual fish but with the primal forces that govern life and death in the sea. Let's see one interesting example regarding survival,

"I could not fail myself and die on a fish like this," he said. "Now that I have him coming so beautifully, God help me endure. I'll say a hundred Our Fathers and a hundred Hail Marys. But I cannot say them now.

(Hemingway 67)

The quoted passage discusses Santiago's internal struggle and underscores the profound emphasis on survival that permeates Ernest Hemingway's novella. Hemingway presents survival as a multifaceted endeavor that requires not only physical strength but also a profound mental and spiritual resilience. If we see another example of pain,

"Now they have beaten me, he thought. I am too old to club sharks to death. But I will try it as long as I have the oars and the short club and the tiller."

(Hemingway 87)

The quoted passage reflects the protagonist Santiago's determination to survive despite the challenges given by the sharks, emphasizing the element of survival within the Naturalistic framework of Ernest Hemingway's novella. The pragmatic approach to using the available resources mingles with the Naturalistic belief that survival necessitates adaptability and resourcefulness. The use of the word 'try' implies recognition of the uncertainty in the struggle for survival.

7.5 CHARACTERIZATION:

Santiago, the aging Cuban fisherman, stands as the central character embodying the Naturalistic element of struggle, endurance, and the impact of the environment on an individual's life. His appearance, deep wrinkles, and scars from handling heavy fish exemplify the harsh conditions of his profession. Santiago's resilience, despite going eighty-four days without a catch, reflects his spirit of feeling undefeated against natural forces. Let's see one example regarding Santiago's character,

"Every day is a new day. It is better to be lucky. But I would rather be exact. Then when luck comes you are ready."

(Hemingway 22)

The quote provides the essence of Santiago's characterization and serves as a reflection of the Naturalistic element presented in the novella. The pragmatic philosophy expressed in the quote reflects the Naturalistic belief that survival depends not only on luck but on an individual's ability to adapt, learns, and applies acquired knowledge.

Manolin, the young boy and Santiago's companion, serves as a contrast to the old fisherman. His character represents the intergenerational continuity of the fishing tradition. Manolin's admiration for Santiago, despite the latter of bad luck, illustrates the profound impact of the elder's experiences on the younger generation. The environment of the fishing village mould Manolin's values and aspirations, fostering a sense of respect for the sea and the enduring spirit required to navigate its uncertainties. When Manolin again asks Santiago about fishing together, but Santiago denied, through Manolin's reply present his character as dedicated towards Santiago.

The Marlin, Santiago's opponent in the struggle for survival, is a manifestation of the sea's formidable influence. Its size, strength, and majestic appearance make it a symbol of the powerful and unpredictable forces in the natural world. The Marlin's role extends beyond a mere fish; it becomes a representation of the primordial struggle between man and nature. Hemingway's detailed descriptions of the Marlin's physical attributes and the challenges it poses underscore the idea that the environment shapes the creatures that inhabit it. Santiago describes about Marlin's size and his nature,

> *"He is a great fish and I must convince him, he thought. I must never let him learn his strength nor what he could do if he made his run. If I were him I would put in everything now and go until something broke. But, thank God, they are not as intelligent as we who kill them; although they are more noble and more able."*

(Hemingway 47)

Santiago acknowledges the Marlin as a formidable adversary, recognizing its greatness and strength.

7.6 NATURALISTIC SYMBOLISM:

The Sea stands as a potent Naturalistic symbol, embodying both the life-sustaining and challenging aspects of existence. The vastness and unpredictability of the sea mirror the enormity of life itself. Santiago, the aging fisherman, engages in a struggle with the sea, representing humanity's battle against the forces of nature. The sea's nature mirrors the dichotomy of life's blessings and hardships. Santiago's journey on the open sea becomes a metaphor for the human condition, highlighting the relentless cycles of endurance, survival, and inevitable confrontations with external challenges.

The Marlin symbolizing the abundance and challenges inherent in the sea. Santiago's pursuit of the Marlin becomes a metaphor for the inherent human desire to conquer and harness nature's resources. The Marlin's massive size and strength underscore the forces that individuals must contend with in their quest for survival. Furthermore, as Santiago battles the Marlin for an extended period, the struggle expresses the perseverance required to overcome life's adversities. The Marlin, highlighting the dualities of beauty and harshness woven into the fabric of existence.

The Sharks serve as powerful Naturalistic symbols representing the harsh and unforgiving forces of nature. As The Old Man, Santiago, battles to bring the giant Marlin back to shore, the sharks become a threat to his hard-earned prize. The sharks symbolize the inevitable challenges of life, emphasizing the struggle for survival in the natural world. Their attacks on Santiago's prized catch underscore the harsh realities of the sea, presenting the Naturalistic element that life is a constant struggle against forces beyond one's control. Hemingway uses the sharks as a metaphor for the persistent and often destructive elements that individuals face in their quest for survival and success.

The Skiff serves as a significant Naturalistic symbol, embodying Santiago's, connection to the challenging environment of the sea. The small, boat becomes a metaphor for Santiago's isolation in the vast expanse of the ocean. As he navigates in the water, the skiff becomes a representation of the

struggle for survival in the face of powerful natural forces. The resilience and craftsmanship of the skiff, like Santiago himself, are put to the test against the sea, reflecting the Naturalistic element that individuals are at the mercy of their environment, and survival demands resilience and adaptability. The skiff becomes both a practical vessel and a symbolic element, illustrating the struggles and triumphs within the natural world depicted in the novella.

The Lions on the beach represent a Naturalistic symbol; embodying Santiago's nostalgic yearning for his youthful and past achievements. The lions, once majestic and powerful, are now reduced to a distant memory, much like Santiago's own strength and glory in his later years. As Santiago dreams of the lions on the African beach, they become a symbolic reminder of the inevitable passage of time and the inescapable cycle of life. The presence of the lions serves as a Naturalistic reflection on the transient nature of strength and success, expressing the broader element of man's struggle against the relentless forces of time and nature in the novella.

9. FINDINGS:

The researcher came across the following findings;

Hemingway's novella *'The Old Man and the Sea'* contains many elements that align with the literary movement of Naturalism. The Old Man Santiago is constantly at the mercy of the powerful natural forces around him in his journey to catch the great Marlin fish. The novella vividly portrays the struggle between man and nature, with Santiago having all his skills, strength and resilience; he has to survive on the open sea.

The sea itself is depicted as an immense, uncontrollable force far stronger than any man. The descriptions of the waves, currents, winds and movements of the water make it feel like a living, breathing entity that Santiago must do battle with. When the great fish finally strikes his line, it tows his skiff for two days and nights across the sea, with Santiago unable to pull it in or break free. All he can do is hold on for as long as his feeble human strength allows until the fish's inexhaustible power finally wears him down.

Even when he finally kills the fish, sharks begin arrives to attack and slowly takes his hard-won prize. Santiago is almost killed himself as he desperately tries to fight with just a tiny harpoon and some rope. But he is ultimately helpless against these superior powers of nature and can only watch as they strip the Marlin's flesh down to the skeleton. This depiction of nature's supremacy over man's efforts reflects a key tenet of naturalistic literature.

Human society is also shown to be indifferent and uncaring toward The Old Man's plight when he returns, exhausted and defeated, to the village. Despite his great struggle, Santiago receives little compassion from the people around him who are concerned only with self-interest and wealth, presenting the Naturalistic view of society as a hostile environment. Only the young boy Manolin seems to fully appreciate Santiago's skill, effort and sacrifice out on the sea.

Santiago's characterization aligns with the Naturalist depiction of humans as beings tightly bound to their nature and instinct for survival. Though he has wisdom and degree of human dignity, he is fundamentally driven by the animalistic needs to feed himself, defend against threats, and exercise his inherited abilities as a fisherman.

His actions out on the open sea are often narrated with Naturalistic description, such as he is going as a 'man-against-fish' with the Marlin or feeling 'humble and obscure' toward the inescapable power of nature. The language used to portray Santiago enhances the Naturalistic element of depicting him as more of a natural organism than a character with free will, controlled by natural forces and bodily impulses more than personal motivations.

In many ways, Santiago displays more in common with the animals of nature than the people of his small village. Just like a lion struggling to make a kill on the animals, Santiago's story is a portrayal of one creature among many desperately striving to persevere against a hostile environment by any means necessary for survival. This Naturalistic depiction was a hallmark of Hemingway's unique writing style.

10. TESTING OBJECTIVES:

The first objective is *'To evaluate the key elements of American Naturalism in 'The Old Man and the Sea.'* Key elements such as determinism, nature's indifference, and realism can be analyzed through Santiago's relentless battle against the marlin and the sea. This evaluation highlights the broader themes of human vulnerability and resilience in an indifferent universe. By examining these Naturalistic elements, the study can reveal deeper insights into the human condition as portrayed in Hemingway's work.

The second objective is *'To assess the significance of the battle between Santiago and the Marlin as an allegory for the naturalistic struggle for survival.'* This battle serves as a microcosm of the broader themes of human endurance and existential struggle inherent in American Naturalism. By analyzing this allegory, the study can explore how Santiago's fight reflects not only personal resilience but also the deterministic forces of nature. This assessment can deepen the understanding of survival as a central theme in Hemingway's work.

11. TESTING HYPOTHESIS:

The hypothesis of the research is *'In 'The Old Man and the Sea' Ernest Hemingway illustrates the struggle for survival as a fundamental aspect of the human experience, demonstrating that individual resilience against nature's indifferent forces reflects the central aspects of American Naturalism.'* The research hypothesis is well-founded within the context of the paper topic. Hemingway's portrayal of Santiago's relentless battle with the Marlin exemplifies the Naturalistic themes of survival and resilience against overwhelming odds. This struggle highlights the indifference of nature, emphasizing how individual perseverance is essential in confronting life's challenges. By framing Santiago's experience as an allegory for human resilience, the hypothesis effectively connects to key elements of American Naturalism.

12. CONCLUSION:

Ernest Hemingway's *'The Old Man and the Sea'* shows the struggle for survival in a way that fits well with American Naturalism. The main character, Santiago, fights hard against nature and faces many challenges that are part of being human. The story paints a clear picture of the sea, highlighting how unpredictable life can be. Santiago's journey represents not just the physical fight against outside forces but also his inner search for respect and meaning in a world that often seems indifferent.

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સારાશ : શિક્ષણ આર્થિક અને સામાજિક પ્રગતિ તરફ દોરી જાય છે તે કારણોસર શાળા અને કોલેજ સ્તરે દેશ માટે સારી રીતે વ્યાખ્યાયિત અને ભવિષ્યવાદી શિક્ષણ નીતિ આવશ્યક છે. વિવિધ દેશો પરંપરા અને સંસ્કૃતિને ધ્યાનમાં લઈને અલગ-અલગ શિક્ષણ પ્રણાલી અપનાવે છે અને શાળા અને કૉલેજ શિક્ષણ સ્તરે તેમના જીવન ચક્ર દરમિયાન વિવિધ તબક્કાઓ અપનાવે છે. તેને અસરકારક બનાવા માટેતાજેતરમાં ભારત સરકારે તેની નવી શિક્ષણ નીતિ જાહેર કરી છે જે ડૉ.કસ્તુરીંગનની આગેવાની હેઠળની નિષ્ણાત સમિતિની ભલામણો પર આધારિત છે,ઇડિયન સ્પેસ રિસર્ચ ઓર્ગેનાઇઝેશન (ISRO)ના ભૂતપૂર્વચેરમેન છે. આ પેપર ઉચ્ચ શિક્ષણ પ્રણાલીમાં જાહેર કરવામાં આવેલી વિવિધ નીતિઓ પર પ્રકાશ પાડે છે અને હાલમાં અપનાવવામાં આવેલી સિસ્ટમ સાથે તેની તુલના કરે છે. ભારતીય ઉચ્ચ શિક્ષણ પ્રણાલી પર NEP2020 ની વિવિધ નવીનતાઓ અને આગાહીઓ અને તેના ગુણોની ચર્ચા કરવામાં આવી છે. અંતે, તેના હેતુઓને હાંસલ કરવા માટે તેના અસરકારક અમલીકરણ માટે કેટલાક સૂચનો પ્રસ્તાવિત કરવામાં આવ્યા છે. **ચાવીરૂપ બાબતો** : ઉચ્ચ શિક્ષણનેટિનલ એજ્યુકેશન પોલિસી 2020વિહંગાવલોકનવિશ્લેષણઅમલીકરણવ્યૂહરચના

પરિચય : ભારતીય, શૈક્ષણિક સુધારાઓ માટે વિકસતો ઉદાર દેશ હોવાને કારણે, હાલમાં લગભગ 845 યુનિવર્સિટીઓ અને આશરે 40,000ઉચ્ચ શિક્ષણ સંસ્થાનો (HIEs) છે, જે આ યુનિવર્સિટીઓ સાથે સંકળાયેલા દેશમાં એકંદર ઉચ્ચ વિભાજન અને ઘણા નાના કદના હેલ્સને પ્રતિબિંબિત કરે છે (1). એવું જાણવા મળ્યું છે કે આ નાના કદની 40% થી વધુ સંસ્થાઓ ઉચ્ચ શિક્ષણની બહુ-શાખાકીય શૈલીમાં અપેક્ષિત સુધારાની વિરુદ્ધ એક જ કાર્યક્રમ ચલાવી રહી છે જે 21મી સદી માટે દેશમાં શૈક્ષણિક સુધારાઓ માટે આવશ્યક જરૂરિયાત છે(2) એ પણ નોંધવામાં આવ્યું છે કે 20% થી વધુ કોલેજોમાં વાર્ષિક નોંધણી 100 કરતા ઓછા વિદ્યાર્થીઓ છે જે તેમને શિક્ષણની ગુણવત્તા સુધારવા માટે અયોગ્ય બનાવે છે અને માત્ર 4% કોલેજો પ્રાદેશિક અસંતુલનને કારણે વાર્ષિક ધોરણે 3000 થી વધુ વિદ્યાર્થીઓની નોંધણી કરે છે. તેઓ જે શિક્ષણ આપે છે તેની ગુણવત્તા. ભારતીયમાં ઉચ્ચ શિક્ષણ (HE) સિસ્ટમના વિભાજન માટેના કેટલાક કારણો છે (3)વિદ્યાર્થીઓનો વિવિધ વિદ્યાશાખાઓમાં પ્રારંભિક પ્રવાહ,તેનો પ્રવેશનો અભાવ, ખાસ કરીને સામાજિક-આર્થિક રીતે વંચિત વિસ્તારોમાં જેના પરિણામે વર્તમાન કુલ નોંધણીરેસયો (GER) માત્ર 25% છે,ઘણા વિદ્યાર્થીઓને આકર્ષવા માટે શિક્ષક અને સંસ્થાકીય સ્વાયત્તતાનો અભાવ,કારકિર્દી વ્યવસ્થાપન અને ફેકલ્ટી અને સંસ્થાકીય નેતાઓની પ્રગતિ માટે અપૂરતી પદ્ધતિઓ,મોટાભાગની યુનિવર્સિટીઓ અને કોલેજોમાં

સંશોધન અને નવીનતાઓનો અભાવ,ઉચ્ચ શિક્ષણ સંસ્થાઓમાં શાસન અને નેતૃત્વનો સૂચારૂ આયોજનનો અભાવ,એક ભ્રષ્ટ નિયમનકારી પ્રણાલી જે નકલી કોલેજને ખીલવા દે છે જ્યારે ઉત્કૃષ્ટ, નવીન સંસ્થાઓને અવરોધે છે.

અભ્યાસના ઉદ્દેશ્યો: રાષ્ટ્રીય શિક્ષણ નીતિ 2020 ભારતમાં શિક્ષણ પ્રણાલીની ગુણવત્તા અને વ્યાપકતાને સુધારવા માટે ઘણી પહેલ કરે છે. રાષ્ટ્રીય શિક્ષણ નીતિ 2020 પરના આ અભ્યાસના ઉદ્દેશ્યો છે:(1) નવી સ્વીકૃત ઉચ્ચ શિક્ષણ પ્રણાલી (NEP2020) ની નીતિઓને હાઇલાઇટ્સ અને વિહંગાવલોકન કરવા માટે(2) ભારતમાં હાલમાં અપનાવાયેલી નીતિ સાથે રાષ્ટ્રીય શિક્ષણ નીતિ (NEP2020)ની તુલના કરવી(3) નવી રાષ્ટ્રીય ઉચ્ચ શિક્ષણ નીતિ (NEP2020) માં નવીનતાઓને ઓળખવા.(4) ભારતીય ઉચ્ચ શિક્ષણ પ્રણાલી પર (NEP2020) ની અસરોની આગાહી કરવા.(5) NEP2020ની ઉચ્ચ શિક્ષણ નીતિઓના ગુણોની ચર્ચા કરવા.(6) NEP2020નીઅસરકારક અમલીકરણ માટે તેના ધ્યેયને સાકાર કરવા માટે વધુ સુધારાઓ માટે સૂચનો.

પદ્ધતિ:રાષ્ટ્રીય શૈક્ષણિક નીતિ માળખાના ભાવાર્થને પ્રકાશિત કરવા, NEP2020 ની નીતિના વિવિધ વિભાગોને પ્રકાશિત કરવા અને વર્તમાનમાં અપનાવવામાં આવેલી શિક્ષણ નીતિ સાથે તેની તુલના કરવા માટેની વૈચારિક ચર્ચાનો સમાવેશ થાય છે. ફોકસ જૂથ ચર્ચા પદ્ધતિનો ઉપયોગ કરીને કરવામાં આવેલી નવીનતાઓને ઓળખવી. નીતિની અસરોનું અનુમાનિત વિશ્લેષણ તકનીકનો ઉપયોગ કરીને વિશ્લેષણ કરવામાં આવે છે. ફોકસ જૂથ વિશ્લેષણના આધારે ઘણા સૂચનો આપવામાં આવે છે.

રાષ્ટ્રીય શિક્ષણ નીતિ 1986 અને રાષ્ટ્રીય શિક્ષણનીતિ NEP2020 ની સરખામણી

	NEP1986	NEP2020
1	શિક્ષણની ભૂમિકા વિદ્યાર્થીઓના સર્વાંગી વિકાસની છે.	વસ્તુનિષ્ઠ અને ભરણ પોષણ થઈસકે તેવું સરળ શિક્ષણ પૂરું પાડવાનો ઉદ્દેશછે.
2	10 (5+3+2)+2+3+2નું સામાન્ય શિક્ષણ માળખું અનુસરવામાં આવે છે.	સામાન્ય શિક્ષણ માળખું 5+3+3+4+4+1 સૂચવવામાં આવ્યું છે.
3	પ્રથમ પ્રાથમિક શિક્ષણ બાળકના 6વર્ષે પ્રાથમિક શાળા સ્તર તરીકે શરૂ થાય છે.	પ્રથમ પ્રાથમિક શિક્ષણ બાળકના 7 વર્ષે પ્રાથમિક શાળા સ્તર તરીકે શરૂ થાય છે.
4	બે વર્ષમાધ્યમિક સ્તર અને બે વર્ષ ઉચ્ચ માધ્યમિકસ્તરોને અલગથી	ચાર વર્ષનું માધ્યમિક શિક્ષણનું સ્તર,બે વર્ષમાધ્યમિક સ્તર અને બે વર્ષઉચ્ચ માધ્યમિકસ્તરનો સમન્વય કરવામાં આવ્યો છે,10

	ધ્યાનમાં લેવામાં આવ્યા હતા અને બંનેની બોર્ડ પરીક્ષાઓ હતી.	અને 12માં બોર્ડ લેવલની પરીક્ષાઓ સિવાય શાળા કક્ષાએ પરીક્ષાઓ સૂચવવામાં આવે છે
5	ઉચ્ચ માધ્યમિક સ્તરના બે વર્ષ, વિદ્યાર્થીઓ વિશેષતાના ક્ષેત્રો પસંદ કરે છે અને કલાના વિષયોમાં વિજ્ઞાન વિષય અથવા વાણિજ્ય વિષય જેવા વિષયો પસંદ કરે છે	ઉચ્ચ માધ્યમિક સ્તરના બે વર્ષ, વિદ્યાર્થીઓ વિશેષતાના ક્ષેત્રો પસંદ કરે છે અને કલા વિષયોમાં વિજ્ઞાન વિષય અથવા વાણિજ્ય વિષય જેવા વિષય પસંદ કરે છે
6	તમામ મેડિકલ કોલેજો અંડરગ્રેજ્યુએટ અને અનુસ્નાતક પ્રવેશ NITsદ્વારા પ્રવેશ અને મેડિકલ કોલેજો સિવાય કોલેજ સ્તરે અથવા રાજ્ય સ્તરે લેવામાં આવતી પ્રવેશ પરીક્ષા પર આધારિત છે.	પબ્લિક હેલ્સના તમામ અંડરગ્રેજ્યુએટ અને અનુસ્નાતક પ્રવેશો રાષ્ટ્રીય સ્તરે હાથ ધરવામાં આવેલા રાષ્ટ્રીય પરીક્ષણ એજન્સી (NTA) સ્કોર્સ દ્વારા સંચાલિત એજન્સી (NTA) સ્કોર્સ પર આધારિત છે.
7	પબ્લિક હેલ્સના તમામ અંડરગ્રેજ્યુએટ અને અનુસ્નાતક પ્રવેશો રાષ્ટ્રીય સ્તરે હાથ ધરાયેલા રાષ્ટ્રીય પરીક્ષણ એજન્સી (NTA) સ્કોર્સ પર આધારિત છે.	અંડરગ્રેજ્યુએટ પ્રોગ્રામ્સ ડિપ્લોમા સાથે એક વર્ષ પછી, એડવાન્સ્ડ ડિપ્લોમા સાથે બે વર્ષ પછી, પાસ ડિગ્રી સાથે ત્રણ વર્ષ પછી અને પ્રોજેક્ટ આધારિત ડિગ્રી સાથે ચાર વર્ષ પછી બહાર નીકળવાની જોગવાઈ સાથે ચાર વર્ષનો હોય છે.
8	અનુસ્નાતક શિક્ષણ વિશેષતા ફોકસ સાથે બે વર્ષનું છે.	અનુસ્નાતક શિક્ષણ વધુ વિશેષતા અને સંશોધન ફોકસ સાથે એક થી બે વર્ષનું છે
9	હેલ્સની મોટાભાગની કોલેજો રાજ્યની યુનિવર્સિટીઓ સાથે સંલગ્ન છે અને અભ્યાસક્રમ અને મૂલ્યાંકનમાં તેમને કોઈ સ્વાયત્તતા નથી.	કોલેજો સહિતની તમામ સંસ્થા સ્વાયત્ત છે અને અભ્યાસક્રમ અને મૂલ્યાંકન નક્કી કરવામાં રાજ્યની યુનિવર્સિટીઓ અને સ્વાયત્તતા સાથે કોઈ સંલગ્ન કોલેજો રહેશે નહીં
10	પરીક્ષા શિક્ષણથી સ્વતંત્ર છે. તમામ પરીક્ષા અને મૂલ્યાંકન સંલગ્ન યુનિવર્સિટી દ્વારા નિયંત્રિત છે.	પરીક્ષાએ સતત મૂલ્યાંકન પ્રણાલીનો એક ભાગ છે. ફેકલ્ટી સભ્યો કે જેઓ વિષય ભણાવી રહ્યા છે તેઓ

	વિદ્યાર્થીઓનું સીધું મૂલ્યાંકન કરવામાં ફેકલ્ટી સભ્યોનેથોડી ભૂમિકા છે	મૂલ્યાંકન માટે જવાબદાર છે અને પરીક્ષાઓ વિભાગીય બાબતો છે.
11	અધ્યાપન-શિક્ષણ પદ્ધતિ મુખ્યત્વે વર્ગખંડની તાલીમ અને ક્ષેત્રીય કાર્ય પર ધ્યાન કેન્દ્રિત કરે છે	અધ્યાપન-શિક્ષણ પદ્ધતિ મુખ્યત્વે વર્ગખંડમાં તાલીમ ફીડવર્ક અને સંશોધન પ્રોજેક્ટ પર ધ્યાન કેન્દ્રિત કરે છે
12	ઉચ્ચ શિક્ષણ પ્રણાલીમાં, અપેક્ષિત વિદ્યાર્થી-ફેકલ્ટી રેશિયો 20:1 છે,	ઉચ્ચ શિક્ષણ પ્રણાલીમાં, અપેક્ષિત વિદ્યાર્થી ફેકલ્ટી રેશિયો 30:1 છે
13	HEIsમાં ફેકલ્ટી સભ્યોને વિદ્યાર્થીઓને સક્ષમ બનાવવા માટે શિક્ષિત કરવા માટે સુવિધા આપનાર તરીકે ગણવામાં આવે છે.	HEIs માં ફેકલ્ટી સભ્યોને સહયોગી તરીકે ગણવામાં આવે છે અને વિદ્યાર્થીઓને ઇનોવેટર અને સર્જનાત્મક વિચારકો તરીકે શિક્ષિત કરવા માટે માર્ગદર્શન આપવામાં આવે છે.
14	વિદ્યાર્થીઓને તેમના અભ્યાસના સમગ્ર ક્ષેત્રમાં વિષયો પસંદ કરવાની સ્વતંત્રતા હોય છે	વિદ્યાર્થીઓને તેમના અભ્યાસના ક્ષેત્રની બહાર અને સમગ્ર વિષયો પસંદ કરવાની સ્વતંત્રતા છે.
15	એક વર્ષની સંશોધન ડિગ્રી જે એમ. ફિલ કોઈપણ વિષયમાં સંશોધન કરવા માટે પ્રારંભિક અનુભવ પ્રદાન કરવા માટે ઓફર કરવામાં આવે છે.	એક વર્ષની સંશોધન ડિગ્રી જે એમ. ફિલ કોઈપણ વિષયમાં વિદ્યાર્થીઓ તેમના અંડરગ્રેજ્યુએટ અને પોસ્ટ-ગ્રેજ્યુએટ અભ્યાસક્રમોમાં પ્રારંભિક સંશોધનનો સંપર્ક કરે છે તે કારણોસર બંધ કરવામાં આવે છે.
16	કોઈપણ પ્રકારનીHEIs માં આસિસ્ટન્ટ પ્રોફેસર બનવા માટે જરૂરી લાયકાત તરીકે સંબંધિત માસ્ટર્સ સાથે નેટ/સ્લેટમાં પાસહોવા જોઈએ.	પીએચ.ડી. કોઈપણ ત્રણ પ્રકારની HEIs માં આસિસ્ટન્ટ પ્રોફેસર બનવા માટે આવશ્યક લાયકાત તરીકે નેટ/સ્લેટ પાસ સાથે ડિગ્રી ફરજિયાત છે
17	યુજીસી અથવા અન્ય કોઈપણ એજન્સીઓ દ્વારા સંશોધન ભંડોળનો ટેકો મુખ્યત્વે કોલેજો કરતાં યુનિવર્સિટીઓ માટે છે.	નેશનલ રિસર્ચ ફાઉન્ડેશન અને અન્ય કોઈપણ એજન્સીઓ દ્વારા સંશોધન ભંડોળનો ટેકો સંશોધન દરખાસ્તના યોગ્ય મૂલ્યાંકનના આધારે ત્રણેય

		પ્રકારની HEIs માં સમાનરૂપે વિતરિત કરવામાં આવશે.
18	HEIs માન્યતા માત્ર ભંડોળ અને સરકારી સુવિધાઓ મેળવવા માટે ફરજિયાત છે.	કામગીરી અને ડિગ્રી ઓફર કરવા માટે HEIs માન્યતા ફરજિયાત છે. સતત કામગીરી માટે દર પાંચ વર્ષમાં એકવાર ફરજિયાત માન્યતા જરૂરી છે.
19	ક્રમાંકિત માન્યતા મોડેલને અનુસરવામાં આવે છે.	સંસ્થા માટે વિવિધ ગ્રેડને બદલે દ્વિસંગી માન્યતા મોડેલને અનુસરવામાં આવશે જે હા કે ના સિસ્ટમ છે
20	પસંદગી આધારિત ક્રેડિટ સિસ્ટમ.	STEAM પર આધારિત ઉદાર શિક્ષણ અને ક્રેડિટ સિસ્ટમ પર આધારિત યોગ્યતા.
21	માત્ર અધિકૃત અને માન્ય યુનિવર્સિટીઓને જ ઓનલાઈન ડિસ્ટન્સ લર્નિંગ (ODL) શિક્ષણ પ્રદાન કરવાની મંજૂરી છે.	ODLઓફર કરવા માટે માન્યતા પ્રાપ્ત તમામ 3 પ્રકારની HEIs ને ODLઓફર કરવાની પરવાનગી છે
22	પ્રોગ્રામ અભ્યાસક્રમના ભાગરૂપે દરેક વિદ્યાર્થી માટે સામાજિક જોડાણ વૈકલ્પિક છે	દરેક વિદ્યાર્થી માટે સામાજિક જોડાણ ફરજિયાત છે અને પ્રોગ્રામના સમગ્ર સમયગાળા દરમિયાન ઓછામાં ઓછા એક સંપૂર્ણ સેમેસ્ટર જેટલું હોવું જોઈએ
23	ત્રણ વર્ષના સ્નાતક ડિગ્રી ધારકો પીએચ.ડી. માં સીધા પ્રવેશ માટે પાત્ર નથી.જ્યાં સુધી તેઓ માસ્ટર ડિગ્રીફરજ્યાત જ્યાત છે.	ચાર વર્ષના સ્નાતક ડિગ્રી ધારકો ચોથા વર્ષ દરમિયાન સારું સંશોધન પ્રદર્શન સાથે સીધા જ પીએચ. ડી. માં પ્રવેશ મેળવી શકે છે. બંને પ્રકારનીHEIsમાંમાસ્ટર્સ ડિગ્રીસાથેની સગવતા છે.
24	પ્રોગ્રામના પ્રકાર પર આધાર રાખીને 3 વર્ષથી 4 વર્ષ સુધીના અંડરગ્રેજ્યુએટ પ્રોગ્રામ્સ	બધા અંડરગ્રેજ્યુએટ પ્રોગ્રામ્સ 4 વર્ષના છે, કેટલાક કિસ્સાઓમાં, ડિગ્રી પ્રમાણપત્ર સાથે 3 વર્ષમાં બહાર નીકળવું શક્ય છે

25	કોઈપણ વિદેશી યુનિવર્સિટીઓને ભારતમાં સીધી રીતે કામ કરવાની મંજૂરી નથી	લગભગ 100ટોચની નામાંકિત વિદેશી યુનિવર્સિટીઓને ભારતીય યુનિવર્સિટીઓ સાથે સ્પર્ધા કરવાઅને ભારતમાં કામ કરવાની મંજૂરી આપવામાં આવશે.

NEP 2020 માં નવીનતાઓ:

(1) 100 ટોચની ભારતીય યુનિવર્સિટીઓને વિદેશમાં કામ કરવા માટે પ્રોત્સાહિત કરવામાં આવશે.
(2) 100 ટોચની વિદેશી યુનિવર્સિટીઓને ભારતમાં સંચાલન કરવાની મંજૂરી અને સુવિધા આપવામાં આવશે
(3) દરેક વર્ગખંડમાં અદ્યતન શૈક્ષણિક ટેક્નોલોજીની ઍક્સેસ હશે જે બહેતર શીખવાના અનુભવોને સક્ષમ કરે છે.
(4) નિયુક્ત સંસ્થામાં ફેકલ્ટી સ્થિરતા પ્રદાન કરવામાં આવશે જેમાં સામાન્ય રીતે અન્ય સંસ્થાઓમાં કોઈ ટ્રાન્સફર કરવામાં આવશે નહીં.
(5) ફેકલ્ટી સભ્યોને માન્ય માળખામાં અભ્યાસક્રમ અને શિક્ષણશાસ્ત્રની સ્વતંત્રતા મળે છે.
(6) શૈક્ષણિક અને સંશોધન કામગીરીના આધારે ફેકલ્ટી પ્રોત્સાહનો અને જવાબદારી નિશ્ચિત કરવામાં આવશે.
(7) ઉચ્ચ પ્રભાવ સંશોધન યોગદાન માટે ફેકલ્ટી ફાસ્ટ-ટ્રેક પ્રમોશન સિસ્ટમ ઓફર કરવામાં આવશે.
(8) સાથીદારો અને વિદ્યાર્થીઓના પ્રતિસાદ, શિક્ષણ અને શિક્ષણશાસ્ત્રમાં નવીનતાઓ, વ્યાવસાયિક વિકાસ, ગુણવત્તા અને અસર સંશોધન, પ્રવેશની દ્રષ્ટિએ સંસ્થામાં યોગદાન અને સામાજિક સમુદાયના યોગદાન સાથે બહુવિધ પરિમાણ-આધારિત APIનીતિ હશે.
(9) API નીતિ સંસ્થાકીય વિકાસ યોજનામાં સ્પષ્ટપણે વ્યાખ્યાયિત કરવામાં આવશે.
(10) 2035 સુધીમાં ટકાઉ શિક્ષણ વિકાસ ધ્યેય (SEDG) અને 50% હાંસલ કરવા પર ધ્યાન કેન્દ્રિત કરે.
(11) તમામ પીએચ.ડી. નોંધાયેલા વિદ્યાર્થીઓએ અધ્યાપનઅને અભ્યાસક્રમ વિકાસને લગતો એક વિષય લેવો જોઈએ અને શિક્ષણ કૌશલ્ય વધારવા માટે શિક્ષણ સહાયકતા સ્વીકારવી જોઈએ.
(12) દરેક વિદ્યાર્થીઓને દરેક સેમેસ્ટરમાં ઓછામાં ઓછા બે અભ્યાસક્રમો સ્વયં ઓનલાઈન અભ્યાસક્રમો લેવા માટે પ્રોત્સાહિત કરવા જોઈએ.
(13) વિદ્યાર્થીની વસ્તીના ઓછામાં ઓછા 50% સુધી પહોંચવા માટે વ્યાવસાયિક શિક્ષણ (VE) ને મજબૂત બનાવવું. HEIs બધા વિદ્યાર્થીઓને કેવી રીતે ઓફર કરી શકાય તેની યોજના બનાવવી જોઈએ
(14) B.Voc. આપવાની યોજના.ODL(ઓનલાઈન ડિસ્ટન્સ લર્નિંગ) મોડમાં ડ્યુઅલ ડિગ્રી પ્રોગ્રામ તરીકે અથવા કૌશલ્ય પ્રયોગશાળાઓ દ્વારા અને ઉદ્યોગ અનેNGOs સાથે ભાગીદારી દ્વારા 2 કલાકના સાંજના કાર્યક્રમ તરીકે.
(15) HEIsમાં, ભારતમાં સંશોધન અને નવીનતા રોકાણ GDPના 0.69% છે જે વૈશ્વિક સરેરાશGDP3% છે.
(16) અન્ડરગ્રેજ્યુએટ અભ્યાસક્રમમાં સંશોધન અને ઇન્ટર્નશિપનો અત્યંત આવશ્યક ઘટક તરીકે સમાવેશ.

(17) (1) નિયમન (NHERC), (2) માન્યતા (NAC), (3) ભંડોળ/ગ્રાન્ટ્સ (HEGC), અને (4) શૈક્ષણિક ધોરણ સેટિંગ (GES) ના ચાર કાર્યો એક છત્ર સંસ્થા દ્વારા નિયંત્રિત થાય છે, ભારતનું ઉચ્ચ શિક્ષણ આયોગ (HECL).

નિષ્કર્ષ :ઉચ્ચ શિક્ષણ એ દરેક દેશમાં અર્થતંત્ર, સામાજિક દરજ્જો, ટેકનોલોજી અપનાવવા અને સ્વસ્થ માનવ વર્તનને શિક્ષિત કરવા માટે એક મહત્વપૂર્ણ પાસું છે. દેશના દરેક નાગરિકને ઉચ્ચ શિક્ષણની ઓફરમાં સામેલ કરવા માટે સુધારો કરવો એ દેશ સરકારના શિક્ષણ વિભાગની જવાબદારી છે. ભારતની રાષ્ટ્રીય શિક્ષણ નીતિ 2020 ખાનગી ક્ષેત્ર માટે ઉચ્ચ શિક્ષણ ખોલીને ગુણવત્તા, આકર્ષણ, પોષણક્ષમતા અને પુરવઠામાં વધારો કરવા માટે નવીન નીતિઓ બનાવીને અને તે જ સમયે જાળવણી ગુણવત્તા પર કડક નિયંત્રણો સાથે આવા ઉદ્દેશ્યને હાંસલ કરવા તરફ કૂચ કરી રહી છે. દરેક ઉચ્ચ શિક્ષણ સંસ્થામાં. મફતશીપ કાર્ડ અને શિષ્યવૃત્તિઓ સાથે મેરિટ-આધારિત પ્રવેશને પ્રોત્સાહિત કરીને, ફેકલ્ટી સભ્યો તરીકે સતત મેરિટ અને સંશોધન આધારિતઅને નિયમનકારી સંસ્થાઓમાં મેરિટ આધારિતપ્રવેશ અને તકનીકી-આધારિત દેખરેખ દ્વારા પ્રગતિની સ્વ-ઘોષણા પર આધારિત દ્વિવાર્ષિક માન્યતા દ્વારા ગુણવત્તાનું સખત નિરીક્ષણ કરીને NEP-2020નું 2030 સુધીમાં તેના ઉદ્દેશ્યો પૂરા કરે તેવી અપેક્ષા છે. વર્તમાન નામકરણ સાથે તમામ ઉચ્ચ શિક્ષણ સંસ્થાઓ આનુષંગિક કોલેજોનું વિસ્તરણ બહુ-શિસ્તની સ્વાયત્ત કોલેજો તરીકે થશે અને તેમના નામસાથેની ડિગ્રી આપશે અથવા તેમની સંલગ્ન યુનિવર્સિટીઓની ઘટક કોલેજો બનશે.

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Modern Received Pronunciation: The Benchmark of Excellence in Global Communication, Professional Domains and Academia"

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Abstract:

Globally, Modern Received Pronunciation (R.P.) remains the gold standard for spoken English and is often linked to clarity, neutrality, and prestige. Entrenched in its historical association with the British elite, Modern R.P. has evolved into a more comprehensive and adaptable accent, making it highly relevant in today's interconnected world. This paper explores the reasons behind Modern R.P.'s sustained prominence in critical fields such as international diplomacy, academia, broadcasting, and corporate communication. Through a combination of phonetic analysis, case studies, and sociolinguistic research, the study examines how R.P.'s distinct lack of strong regional features allows it to transcend cultural and geographic boundaries, making it the preferred choice for clear and influential communication. The research highlights the role of R.P. in English Language Teaching (ELT), where it is often promoted as the aspirational model for non-native speakers aiming for global eloquence and professional success. Additionally, the paper investigates the psychological and cultural perceptions of Modern R.P., focusing on how it commands respect, conveys professionalism, and fosters trust in high-stakes environments. Despite its traditional ties to privilege, Modern R.P.'s evolution 2 has made it more accessible, reflecting subtle influences from other accents while maintaining its core identity. The findings underscore Modern R.P.'s unique balance between tradition and adaptability, affirming its status as the premier accent for excellence and effectiveness in global English communication. This paper also discusses potential challenges and the future of R.P. in an increasingly diverse linguistic landscape.

Introduction

With over 2 billion English speakers worldwide, the diversity of accents within this language is astounding. English has approximately over 160 recognised accents worldwide, ranging from the various tones of the United Kingdom to the complex rhythms of Africa, Asia, North America, and beyond.

Amongst all the English accents, the posh English accent, aka "Modern Received Pronunciation" or Queen's English has been regarded as the hallmark of clarity, a symbol of sophistication, and authority in spoken English.

Modern Received Pronunciation is an accent that has become synonymous with prestige and refined mannerisms. It has achieved unparalleled status in the realms of Global communication and professionalism. Historically associated with the British elite, R.P. has evolved over time, shedding its exclusive ties to privilege and adapting to the needs of an interconnected world. Its clarity, neutrality,

and status have made it the most preferred accent across critical fields such as International Diplomacy, Academia, Broadcasting, and Corporate Communication.

This paper explores the historical evolution of Modern R.P., analyses its continued dominance in professional domains, particularly in fields such as academia, diplomacy, media, and corporate environments and discusses the sociolinguistic perceptions that contribute to its enduring appeal. While acknowledging criticisms of its elitist origins, the study highlights how Modern R.P. has become an icon of excellence, authority, and adaptability in a linguistically diverse world.

Methodology:

This study employs a **mixed-methods approach**, combining **phonetic analysis**, **case studies**, and **sociolinguistic surveys**. The following methods were used:

1. **Phonetic Analysis**: A close examination of the phonetic features of Modern R.P., including vowel and consonant articulation, stress patterns, and intonation, was conducted using existing phonetic databases and recordings of R.P. speakers.
2. **Analysis**: Detailed analysis of style of speaking of prominent figures in diplomacy, academia, and business who utilize Modern R.P. in their communication were done. These include individuals like, Sir Michael Atiyah, **David Attenboddrough**, Dr. Shashi Tharoor whose use of R.P. in public speeches and media engagements is exemplary and quite eloquent.

Analysis:

1. The Evolution of Modern Received Pronunciation:

1.1 Historical Foundations-

Traditional R.P. emerged as the accent of the British upper class in the late 19th and early 20th centuries. Codified through education at prestigious institutions like Eton and Oxford, it became synonymous with privilege and authority. Early R.P. was marked by its rigid pronunciation rules, a deliberate lack of regional influence, and an association with social superiority.

1.2 Transition to Modern R.P.-

In recent decades, R.P. has undergone significant transformation. Influences from other British accents, such as Estuary English, have softened its rigid features, making it more inclusive and less formal. This modernized version, often termed "Modern R.P.," retains its clarity and neutrality while being more approachable and relatable. Its evolution reflects broader social changes, including the democratization of English accents and increased acceptance of linguistic diversity.

1.3 Accessibility and Media Influence-

The accessibility of R.P. has been facilitated by its widespread use in British media, particularly through the British Broadcasting Corporation (BBC). The "BBC English" standard has exposed global audiences to R.P., fostering its perception as the ideal model for clear and authoritative English communication. R.P. is associated with prestige and was considered a necessity for social and educational advancement.

2. Dominance in International Diplomacy:

2.1 Clarity and Neutrality in Negotiations-

R.P. has been favoured in international diplomacy due to its perceived neutrality and clarity. In high-stakes negotiations, where misunderstandings can have significant consequences, R.P. provides a reliable medium for precise communication. Its lack of strong regional features ensures that it is easily understood by non-native English speakers, making it a preferred choice for diplomats and international mediators.

2.2 Case studies in Diplomatic Contexts-

Prominent figures such as Sir Winston Churchill and Queen Elizabeth II exemplified the use of R.P. in diplomatic contexts, leveraging its prestige to command respect and authority. In contemporary times, R.P. continues to feature prominently in speeches by prodigious leaders and United Nations representatives, reinforcing its role as a standard for professionalism.

3. Leadership in Academia:

3.1 Establishing a Standard for English Pronunciation:

English has a variety of accents spoken all over the world and every accent differs from each and other in several ways. So, to have uniformity and standardisation especially for Non-Native English speakers R.P. has been the basis for most of the English Language Teaching (ELT) materials, dictionaries, and pronunciation guides. For example, the **Oxford English Dictionary**, **Cambridge English Dictionary** and renowned language courses like the often use R.P. as their reference.

Phonetic Studies: Linguists and phonologists, such as Daniel Jones in his *English Pronouncing Dictionary*, used R.P. as a model for phonetic transcription, establishing it as a standard for academic study.

3.2 Facilitating International Collaboration:

Neutral Accent for Global Discourse: In international academic collaborations, R.P.'s neutrality makes it an effective medium of communication across diverse linguistic backgrounds.

Influence on Global Academia: Many scholars from former British colonies and other countries trained in British institutions adopted R.P., disseminating it in their own academic systems.

3.3 Bridging Multicultural Classrooms:

In academia, Modern R.P. plays a vital role in fostering comprehension among diverse student populations. Its phonetic precision and standardized pronunciation help minimize linguistic barriers, ensuring that lectures and presentations are accessible to international audiences.

3.4 Prevalence in Conferences:

Modern R.P. is often the accent of choice for keynote speakers at global academic conferences. Scholars and researchers use it to present their findings with clarity, allowing their work to reach a broader audience. For instance, the influence of Modern R.P. is evident in TED Talks and other educational platforms where global intelligibility is a priority.

Examples in Action:

- **Sir David Attenborough (Natural Historian):** His R.P.-influenced narration of documentaries underscores his expertise and enhances comprehension.
- Sir Michael Atiyah (Mathematician): He was a key figure at the University of Edinburgh and a recipient of numerous awards.

4. Prestige in Broadcasting and Media:

4.1 The BBC Effect-

The British Broadcasting Corporation (BBC) played a pivotal role in establishing R.P. as the "voice of authority" in broadcasting. From its early days, the BBC required its announcers to speak in R.P., associating the accent with reliability and professionalism. It reached to the audience to the remotest areas through radio as the mediums like Televisions and the Internet were not available for everyone. This practice cemented R.P.'s dominance in global media.

4.2 Modern Broadcasting Practices-

Even as media landscapes diversify, R.P. remains a standard for news anchors and presenters on international platforms. Figures like Sir David Attenborough and BBC anchors continue to embody the professionalism associated with R.P., making it synonymous with trustworthiness and credibility.

5. The Corporate Sector and Executive Communication:

5.1 Professional Credibility:

In corporate settings, R.P. is frequently adopted by executives and public speakers to project authority and competence. Its precise enunciation and neutral tone help build trust and establish a sense of professionalism during presentations and negotiations.

5.2 R.P. in Multinational Business

In multinational corporations, R.P. serves as a lingua franca for English-speaking professionals. Its clarity ensures effective communication among employees and clients from diverse linguistic backgrounds. For instance, R.P. is often the accent of choice for executives addressing global audiences during conferences and shareholder meetings.

6. Sociolinguistic Perceptions of R.P.-

6.1 Prestige and Authority-

Sociolinguistic studies reveal that R.P. is widely perceived as a marker of acumen, expertise, and professionalism. Its historical association with the elite continues to influence these perceptions, making it a desirable accent for individuals seeking to advance in professional settings.

6.2 Criticisms and challenges:

While R.P. enjoys widespread respect, it is not without criticism. Its traditional ties to privilege and social exclusivity have led to perceptions of elitism, particularly in contexts that value linguistic diversity. Nevertheless, Modern R.P.'s evolution has mitigated some of these concerns, making it more inclusive and adaptable.

7. Challenges and the Future of R.P.:

7.1 Competition from other Accents:

The rise of other accents, such as General American and Estuary English, presents challenges to R.P.'s dominance. These accents, often perceived as more relatable, are gaining traction in global communication.

7.2 Adaptability in a Diverse World:

The future of R.P. depends on its ability to adapt to an increasingly inclusive linguistic landscape. As English continues to evolve as a global language, R.P. must balance its traditional prestige with the need for diversity and accessibility.

Conclusion:

Modern Received Pronunciation remains the benchmark of excellence in global communication and professional domains. Its evolution from a symbol of exclusivity to an accessible and adaptable standard underscores its relevance in today's interconnected world. Dominating fields such as diplomacy, academia, media, and corporate communication, R.P. continues to command respect and trust. However, as the linguistic landscape diversifies, its ability to embrace inclusivity will determine its long-term significance.

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Wordsworth's "I Wandered Lonely as a Cloud" and Keats' "Bright Star": A Comparative Study

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Abstract: *If we look back in the history of English language and literature, we can find various artists especially of English literary canon who have contributed by their writings. William Wordsworth and John Keats are the personalities who belong to that category. When we talk about nature and imagination in the context of English literature, we surely get the idea of 'Romanticism' in our mind. Through this paper, the researcher has tried to throw light on the poetic style of two major poets of the romantic age: William Wordsworth and John Keats. The present paper aims to analyse the various aspects of both the poets by selecting their pieces of poetry: Wordsworth's I Wandered Lonely as a Cloud and Keats' Bright Star.*

Key Words: *William Wordsworth, John Keats, Romantic age, Romanticism, English literature, English romantic poets, Bright Star, Daffodils, I Wandered Lonely as a Cloud*

1. INTRODUCTION:

William Wordsworth and John Keats along with Coleridge and Shelley are considered and will always be considered as the true pioneers of the romantic age of English history. Among these writers, Wordsworth and Coleridge are the most influential poets of the age. The contribution in the domain of English literature – especially in the form of poetry; we can find Wordsworth and Coleridge in depth. The commencement of romanticism brought another colour in English literature. Along with Wordsworth, Keats has also contributed a lot in the romantic age. All such pioneers have dedicated their lives in the field with writing of poetry. Whether we talk about Keats, Coleridge or Wordsworth - all were indeed the worshipers of nature. Throughout their poetries we can find out "Nature Mother".

2. LITERATURE REVIEW:

The researcher has reviewed following research papers for the present research:

1. ***Comparison Between Biography of William Wordsworth and Samuel Coleridge*** **- Dr. Rajesh Yadav**

   Dr. Rajesh Yadav highlights the contribution of two pioneers of the romantic age – William Wordsworth and Samuel Taylor Coleridge in his paper. He has taken the reference of "Lyrical Ballads" for the research. He argues that in "Lyrical Ballads" Ballads and lyrical are two words that suggest that a new interpretation of an ancient heritage is accepted. Through the lyrical ballads we can find the introduction of a number of concepts that are completely new to contemporary poetry, including sympathy for human suffering—particularly that experienced by women—repressions of children, the goodness of nature, nature as a source of moral guidance, and how it aids human beings in maintaining their innocence. "The poetic language used in Lyrical Ballads had changed from the contemporary poets' works during the end of 18th century." (Yadav 34)

2. ***Exploring Nature's Reality: A Study through the Poetry of Wordsworth and Keats*** **- Radha Ahluwalia & Dr. Shukla Chatterjee**

Radha Ahluwalia & Dr. Shukla Chatterjee have analysed the representation of nature in the literary works of two Romantic poets, William Wordsworth and John Keats – two 19th century poets especially of the romantic age of English literature. The literature has been composed by taking reference of nature or natural elements. Radha Ahluwalia & Dr. Shukla Chatterjee argue in their research that the research reveals the presentation of Wordsworth's realistic nature, characterized by its femininity and beauty, Keats' works take a more scenic approach, capturing the essence of nature in its grandeur and physical beauty. Overall, this paper aims to contribute to the discussions surrounding the depiction of nature in Romantic literature. (Ahluwalia & Chatterjee 15)

3. ***Importance of Romantic Period in Modern Day English*** **- Dr. Sofia Sadique Qureshi**
Dr. Sofia analyzed the importance of the romantic age in English Literature. She argues that this era brought a vast change in English writing and transformed English Literature remarkably. The romantic age literature stressed upon human emotions and individual feelings instead of stressing upon cultural artificiality. Through this study, Dr. Sofia has provided a constructive overview on ways this era influenced area of English Literature. Through this research paper, we can find the significance of the romantic age that led change in literature writing. (Dr. Sofia 81)

3. OBJECTIVES:

- To compare the selected poems of William Wordsworth and John Keats.
- To find out the similarities and dissimilarities from the selected poems of William Wordsworth and John Keats.
- To explore the writing techniques of William Wordsworth and John Keats.
- To analyze the imagination and observation of natural things of William Wordsworth and John Keats through their selected poems.

4. RESEARCH METHOD / METHODOLOGY:

- The researcher has used primary source (the original poems from web) as well as secondary sources for this research.
- For the present research, the researcher has used 'Qualitative method'.

5. William Wordsworth's Poem "Daffodils" (1807)

5.1 Background of The Poem:

The poem "Daffodils" also known as "I Wandered Lonely as A Cloud". As far as the background of the poem is concerned, it is believed that this poem has been written by taking reference of a true-life event. When William Wordsworth and his sister Dorothy Wordsworth were walking in a forest in 1802, they saw a bulk of flowers on their way and that were daffodils; the flowers were eye-catching. Wordsworth was wondered and got spark in his mind while seeing that natural beauty and in tranquillity he composed the poem on those flowers. Here we can analyse that how William Wordsworth is concerned about minute natural object that is the creation of God. In a general sense, we often go to nature for refreshment or for enjoyment, but have we ever observed the nature and its elements? And if we have, we are not conscious enough to write a piece of literature.

5.2 Imagery Used in the Poem "Daffodils":

Almost all the poets of the romantic age have used natural imagery for their poetry. From the romantic age, we can find major shift or transition in writing style of literature. Poets started writing by referring nature in their poems. Same in the case of Wordsworth we can find that he has taken natural elements as a reference in his poems. Wordsworth begins the poem "Daffodils" as:

I wandered lonely as a cloud

That floats on high o'er vales and hills, (Wordsworth)

Here, in the very first line 'cloud' has been taken and Wordsworth has compared himself with the cloud.

Further Wordsworth discusses that how he saw the golden daffodils in his way:

When all at once I saw a crowd,

A host, of golden daffodils;

Beside the lake, beneath the trees,

Fluttering and dancing in the breeze. (Wordsworth)

The imagery that has been used by William Wordsworth is very significant for the poem itself. As he used various natural elements: lake, trees, breeze etc. Though this images, he wants to create or specify his personal experience to his readers. Wordsworth has tried to frame a visual, the full picture of nature that has been observed by him.

Continuous as the stars that shine

And twinkle on the milky way,

They stretched in never-ending line

Along the margin of a bay:

Ten thousand saw I at a glance,

Tossing their heads in sprightly dance. (Wordsworth)

From above lines from the poem, we can find that how he imagines nature. Wordsworth is not only a lover of nature he is the worshiper of nature. He has a positive vibration for nature and whatever he felt, he served in his poetry. How flowers are tossing their heads and dancing – this is the only poet who could imagine flowers like this!

5.3 Structural Analysis of The Poem: "Daffodils"

William Wordsworth is remembered for his writing style as well. In the poem Daffodils, we can analyse the structure that has been employed by him.

1. **Figures of Speech used in the Poem:**

   Wordsworth has used various figures of speech such as Simile, Personification, Hyperbole etc. the evidence of **Smilie** is there in the beginning line of the poem:

   I wandered lonely as a cloud…
   Continuous as the stars that shine (Wordsworth)

   Wordsworth compares himself with a cloud and says, he was wandering as cloud wonders in the sky.

   Another figure of speech that has been used in this poem is **Personification**. Wordsworth has personified the flowers in this poem as:

A host, of golden daffodils;

Beside the lake, beneath the trees,
Fluttering and dancing in the breeze. (Wordsworth)

The flowers are shown as they (daffodils) are fluttering and dancing in the breeze. Furthermore, Wordsworth says that they are tossing their heads.

Tossing their heads in sprightly dance. (Wordsworth)

Thus, these are the evidence of personification.

Wordsworth has also used **Hyperbole** in this poem as:

Ten thousand saw I at a glance… (Wordsworth)

2. **Rhyme Scheme of The Poem: "Daffodils"**

The role of rhymes in the poem is to add musical quality. Any lyrical poem only becomes lyrical when a poet adds rhymes into it. William Wordsworth has used rhymes for his poems to add linguistic charm.

In "Daffodils", we can find the rhyme scheme: **ABABCC**. The poem has been composed with 4 stanzas of 6 lines each.

5.3 Major Themes of The Poem: "Daffodils"

Throughout the poem, we can find the following themes:

- Purity
- Beauty of Nature
- Bliss of Solitude

5.4 Wordsworth's Definition of 'Poetry' – Reference in the Poem "Daffodils":

In the final stanza of the poem "Daffodils", we can observe the concept of poetry that has been given by Wordsworth in the preface to the second edition of *Lyrical Ballads* (1800). (Qtd. in Edward Albert, pp. 313-323)

He defines poetry as:

"The spontaneous overflow of powerful feelings: it takes its origin from emotion recollected in tranquillity." (Wordsworth)
By analysing this definition, Wordsworth mentions poetry as the spontaneous overflow of our inner feelings, he also mentions that how is a poem composed – human emotion/ feeling that has been experienced by a poet that is recollected in the deep stat of peace. And after this process, a poem is come out. In the poem "Daffodils", we can observe Wordsworth's intention that is indirect indication for composition and its process:

For oft, when on my couch I lie

In vacant or in pensive mood,

They flash upon that inward eye

Which is the bliss of solitude;

And then my heart with pleasure fills,

And dances with the daffodils. (Wordsworth)

In above last stanza, we can find that how he becomes peaceful and comfortable and after that he sees through his inward eyes, all the images that he has seen from the nature he remembers again and again and finds the higher stat of happiness that is the 'Bliss of Solitude'. He furthermore mentions that how he feels pleasure in his heart and dances with those daffodils. Thus, here in the last stanza we can connect the definition of poetry and the concept given by Wordsworth.

6. John Keats' poem – "Bright Star" (1838)

6.1 Background of the Poem:

John Keats, another poet that has been remembered for his poetic style of literary writings in English literature of the romantic age. If we go through the information available of his life, we can find that He had a love affair with a girl named Fanny. It is believed that John Keats the poem has written the poem "Bright Star" for his girlfriend. In the last part of the poem, we can find the evidence for the same that has been discussed in this research. The poem is also known as "Bright star, would I were stedfast as thou art".

6.2 Imagery Used in the Poem "Bright Star":

Similar to William Wordsworth and other romantic poets, John Keats has taken natural elements for his poem. Here, in *Bright Star* as the poem's title itself suggests - it is the reference of a star shines in the sky that is bright as John Keats.

As far as the imagination and the power of observation is concerned, Unlike William Wordsworth, John Keats had a different eye to observe the nature.

Bright star, would I were stedfast as thou art—

Not in lone splendour hung aloft the night…

No—yet still stedfast, still unchangeable, … (Keats)

Keats has introduced nature in different way that has not been done in the case of Wordsworth, the reason behind is that Keats has mentioned demerits of a bright star. No doubt, it shines it is bright, it is eye catching, charming for all creature, part of the milky way but it also has a demerit that is Keats says it is steady – and he does not want to be steady like that star.

6.3 Structural Analysis of The Poem: "Bright Star"

1. **Form of the Poem: "Bright Star"**

   The poem Bright Star has been composed in the Shakespearean sonnet by John Keats. The poem has total 14 lines - 3 quatrains (4 lines of each) and 1 couplet as it is the pattern of the Shakespearean sonnet.

2. **Figures of Speech used in the Poem "Bright Star"**

   John Keats has used various figures of speech as:

Simile: Here, in the poem Keats compares himself with the bright star:

Bright star, would I were steadfast as thou art. (Keats)

Personification: Keats has used personification to personified natural object as human being's action:

The moving waters at their priestlike task

Of pure ablution round earth's human shores, …

And watching, with eternal lids apart. (Keats)

3. **Rhyme Scheme of The Poem: "Bright Star"**
   From the poem "Bright Star", we can find the rhymes: **ABAB CDCD EFEF GG**.

6.4 Reflection of Keats' Personal Life in The Poem: "Bright Star"

The last part of the poem gives evidence of John Keats' personal life and his love towards Fanny:

Pillow'd upon my fair love's ripening breast,

To feel for ever its soft fall and swell,

Awake for ever in a sweet unrest,

Still, still to hear her tender-taken breath,

And so live ever—or else swoon to death. (Keats)

From the above lines, we can observe and analyse that how Keats wants his love for ever. He wants to feel comfort on the soft breast of his lover. In addition, he wants to be awake for ever with her and wants to feel her breath. And if this would not be possible, he wants to die!

7. CONCLUSION:

Thus, from the above analysis and comparison, we can find that there are various similarities as well as dissimilarities in various ways in these two distinct poets. However, both – Wordsworth and Keats belong to the same area of English literature. Both have taken the reference or we can say base of their poems from nature itself as Wordsworth has written on daffodils and Keats on the other hand has written on a star but we can find the difference in the imagination and observation. William Wordsworth's imagines nature as in very positive and fresh mood while John Keats not in a negative intension, he observes the nature with some kind of demerits of it. Wordsworth as always used to be the worshiper of nature as he mentions in his poem *Daffodils* – how he imagines the purity and beauty is very fantastic, on the other hand John Keats expresses his love and wish that provides comfort to him, is by choosing the element with the same nature but in different manner. Imagination comes from the real and observed things. Ultimately, literature is the medium of expression where every artist expresses his/her own feelings through particular language. Wordsworth and Keats are two personalities that are and will always be remembered for their remarkable contribution to the history of literature.

8. RECOMMENDATIONS:

- Further research can be done by selecting other poets of the romantic age.

- One can do research by comparing different ages' poems. i.e. Poems written in Romantic age and Modern age.

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Building Tomorrow: Empowering Students to Design the Sustainable Smart City of the Future

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Abstract: *The design of the Smart City involved extensive student collaboration through MS Teams (Khan, & Magd, 2023). Sub-groups focused on sustainable energy, transport and smart housing, each making a significant contribution to the overall project. Using OneNote, they maintained a common project notebook for research, brainstorming and meeting minutes, ensuring transparency and collective ownership. This collaborative effort promoted equal contribution and fostered teamwork and collective problem-solving skills among the students. Students constructed knowledge by synthesizing and interpreting information. Students researched urban planning, environmental science and technology, using OneNote for research and Excel for data analysis on renewable energy and sustainability (Guggenberger, 2022). They proposed solutions such as solar panels, wind turbines and green roofs for neighbourhood design. Using Minecraft: Education Edition to visualise and refine their ideas in 3D, enhancing the practical application of their theoretical knowledge. This interdisciplinary approach gave them a deep understanding of futuristic urban planning and showcased their creative problem-solving skills. Students planned and controlled their own work (Crespo, 2021; Kuhn, 2018). Pupils set goals and tracked progress without teacher prompting. They initiated the project by setting goals and milestones in OneNote. They delegated tasks, used Excel for Gantt charts, and held regular team check-ins to stay on track, adapt based on feedback, and ensure timely completion. This self-regulation fostered critical skills for meeting deadlines and achieving goals, preparing them for future challenges in academia and beyond. By integrating Microsoft technologies and focusing on key 21CLD skills - collaboration, knowledge construction and self-regulation - students not only enhanced their understanding of modern urban planning and sustainable living, but also developed critical skills for their future endeavours. The Smart City of the Future project demonstrated how technology can facilitate high-level learning and skill development, preparing students for the complexities of the 21st century. All our projects are based on and inspired by the 11th goal of the United Nations Sustainable Development Goals (SDG 11), which aims to make cities and human settlements inclusive, safe, resilient and sustainable, ensuring access to affordable housing, sustainable transport and green spaces for all (Yamasaki & Yamada, 2022; Beccarello & Di Foggia, 2022).*

Key Words: *smart city, sustainability, 21CLD skills*

1. INTRODUCTION: (11BOLD)

The *Smart City of the Future* project exemplifies the integration of innovative educational practices and cutting-edge technology to address real-world challenges. Grounded in the principles of the United Nations Sustainable Development Goal 11 (SDG 11), this initiative focused on fostering inclusive, safe, resilient, and sustainable urban environments. Leveraging Microsoft technologies such as MS Teams,

OneNote, Excel, and Minecraft: Education Edition, students engaged in interdisciplinary collaboration to design a visionary urban landscape. By exploring areas such as sustainable energy, transportation, and smart housing, the project cultivated teamwork, knowledge construction, and self-regulation. Students applied theoretical insights from urban planning, environmental science, and technology to propose practical solutions, including renewable energy systems and eco-friendly architectural designs. The use of digital tools facilitated project management, research synthesis, and interactive visualization, empowering students to develop critical skills for academic and professional success. This project not only advanced students' understanding of sustainable urban development but also highlighted the transformative potential of technology in education. By encouraging creativity, collaboration, and self-directed learning, the initiative prepared participants to tackle the complexities of the 21st century with confidence and innovation.

2. LITERATURE REVIEW:

The *Smart City of the Future* project draws from diverse scholarly insights into education, sustainability, and technology, emphasizing the integration of interdisciplinary learning frameworks and 21st-century skills. A key focus is aligning educational initiatives with global objectives, particularly the United Nations Sustainable Development Goal 11 (SDG 11). This goal emphasizes creating inclusive, safe, resilient, and sustainable urban spaces (Yamasaki & Yamada, 2022; Beccarello & Di Foggia, 2022). These principles guided the project's development, which sought to merge sustainable urban planning with advanced student-centered learning methodologies.

Collaborative Learning and Technology Integration

Research underscores the transformative potential of collaborative learning in equipping students with problem-solving and teamwork skills. Khan and Magd (2023) emphasize the value of digital tools like MS Teams in facilitating real-time collaboration and effective communication among diverse student groups. By forming sub-groups to address specific challenges, such as energy sustainability, transportation, and smart housing, the project mirrors best practices in collaborative problem-solving. These sub-groups encouraged students to contribute equally and collectively build knowledge, reflecting the pedagogical frameworks proposed by Crespo (2021) and Kuhn (2018), which advocate for autonomy and shared responsibility in learning.

The use of OneNote in maintaining a central repository for research, brainstorming, and meeting minutes aligns with Guggenberger's (2022) findings on digital tools fostering transparency and collective ownership. This approach ensured that students synthesized and interpreted data collaboratively, a process critical to knowledge construction.

Interdisciplinary Knowledge Construction

The project's interdisciplinary nature reflects the principles of integrated learning highlighted in urban planning, environmental science, and technology literature. Guggenberger (2022) identifies the importance of using practical tools like Excel for data analysis to engage students

in real-world applications. This was evident in the students' exploration of renewable energy sources, such as solar panels, wind turbines, and green roofs, which served as tangible solutions for sustainable neighborhood design.

The incorporation of Minecraft: Education Edition to visualize ideas in 3D resonates with the growing body of literature advocating for gamification and simulation in education. Visualization tools not only bridge theoretical knowledge with practical applications but also enhance student engagement and creativity. This approach aligns with Yamasaki and Yamada's (2022) perspective on experiential learning, where students refine their understanding through immersive environments.

Self-Regulation and Goal Setting

The project also highlights the role of self-regulation in modern pedagogy, consistent with the work of Crespo (2021) and Kuhn (2018). Students independently set goals, monitored progress through Gantt charts in Excel, and conducted regular team check-ins, fostering essential project management skills. This process of goal setting and adaptation demonstrates the alignment of the project with frameworks promoting autonomy and accountability in education.

Contribution to 21st-Century Skills Development

By integrating technology and emphasizing collaboration, knowledge construction, and self-regulation, the project reflects a strong alignment with the 21st Century Learning Design (21CLD) framework. Research from Guggenberger (2022) and Khan and Magd (2023) highlights the importance of these skills in preparing students for future academic and professional challenges. The ability to collaboratively tackle complex, real-world problems ensures that learners are equipped to navigate the multifaceted demands of the 21st century**.**

6. DISCUSSION / ANALYSIS:

The *Smart City of the Future* project demonstrates how technology-driven, student-led initiatives can effectively cultivate critical 21st-century skills while addressing real-world sustainability challenges. By integrating tools like MS Teams, OneNote, Excel, and Minecraft: Education Edition, students engaged in meaningful collaboration, knowledge construction, and self-regulation. These activities not only enhanced their academic and technical skills but also prepared them to navigate complex problem-solving scenarios relevant to modern urban planning.

The interdisciplinary approach, which combined urban planning, environmental science, and technology, reflects best practices in integrated learning. Students synthesized diverse data to propose practical solutions, such as renewable energy systems and sustainable housing designs. This aligns with research highlighting the importance of experiential and gamified learning environments in bridging theory and application.

Self-regulation was a key strength of the project, as students independently managed their tasks, monitored progress, and adapted strategies to achieve their goals. This autonomy mirrors

real-world professional expectations and demonstrates the effectiveness of structured goal-setting and project management in education.

However, the success of such initiatives relies heavily on equitable participation and access to technology. Future implementations could focus on addressing potential barriers to ensure inclusivity and maximize the project's impact. Overall, this project showcases the potential of interdisciplinary, technology-integrated learning to prepare students for the demands of a sustainable future.

8. CONCLUSION / SUMMARY:

This literature review situates the *Smart City of the Future* project within a rich theoretical and empirical context. By leveraging insights from sustainability education, digital tools, and collaborative frameworks, the project demonstrates how interdisciplinary, technology-driven learning initiatives can foster critical skills and align with global sustainability goals. These findings underscore the value of such projects in preparing students for the complexities of contemporary and future challenges.

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AI in Early Education: Curriculum Design Strategies and Implementation Methods

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Abstract: *As more and more educators and policymakers see AI's ability to enhance learning experiences and equip children for a technologically advanced future, its incorporation into early education is rapidly gaining momentum. This paper explores the strategies for designing and implementing AI curricula tailored for young learners. It starts with a comprehensive review of the literature on AI education, drawing attention to key challenges and theoretical frameworks. The study then outlines specific objectives and research questions guiding the investigation. Using a mixed-strategies approach that includes surveys, interviews, and classroom observations, this suggests excellent curriculum design concepts and practical implementation methods. Key components of an AI curriculum are identified, emphasiz in gage-appropriate content and pedagogical strategies. This also addresses the importance of teacher training and the utilization of educational tools and resources. Evaluation and assessment methods are discussed to measure the effectiveness of AI education, with insights drawnfrom case studies and feedback from various stakeholders. It suggests that early exposure to AI concepts canconsiderably improve cognitive and computation thinking skills in young children. The paper closes with recommendations for educators, policymakers, and curriculum creators, emphasizing the need for more research to address current problems and optimize the advantages of AI instruction in early life.*

Key Words: *rtificial intelligence (AI), Curriculum design, Early education, Teacher training in AI, Assessment in AI education*

1. INTRODUCTION:

1.1 Context about the significance of AI education

Artificial intelligence (AI) is quickly revolutionizing a variety of industries, including education, healthcare, and manufacturing, making it critical for individuals to understand and take advantage of these technologies. As AI continues to evolve, equipping the next generation with foundational knowledge and skills related to AI becomes increasingly critical. According to Yim (2024), teaching children about artificial intelligence (AI) from a young age helps them develop computational thinking, problem-solving skills, and an understanding of the societal impacts of AI. This, in turn, prepares them for their future academic and professional endeavors.

1.2 Relevance of introducing AI in early education

Early childhood is a critical phase for cognitive development, hence it is an appropriate time to introduce key principles of AI. Integrating AI into early education not only demystifies complex technologies but also aligns with developmental milestones by encouraging curiosity, creativity, and critical thinking. By embedding AI education within the existing curriculum, educators can provide children with hands-on, experiential learning opportunities that promote engagement and comprehension (Su J. Ng D. T. et al., 2023). Furthermore, early AI education can assist to close the digital gap, making sure all children, no matter their background, have access to critical technology information.

1.3 Objectives of the study

The aim of this initiative intends to investigate successful ways for building and implementing AI courses for young learners. The primary objectives are:

- To identify key components and principles of an AI curriculum suitable for early education.
- The goal is to look at some real ways that teachers of young children might incorporate AI ideas into their lessons.
- Assess the influence of AI education on children's learning and development.
- Provide guidance on effective methods of teaching artificial intelligence to young children to educators, curriculum developers, and lawmakers.

2. LITERATURE REVIEW:

2.1 An investigation of the literature on artificial intelligence (AI) in early childhood

The literature on artificial intelligence (AI) education for young students is growing, with studies describing the pros and cons of exposing kids to AI at a young age (Wang S. et al., 2024). Existing research emphasizes the potential of AI to enhance cognitive development, foster problem-solving skills, and promote an understanding of technology's role in society (Su. J. et al., 2024) (Su J. & Yang W., 2022). Various pilot programs and experimental studies have demonstrated that young children can grasp basic AI concepts through age-appropriate activities and interactive learning tools (Su J. &Zhong Y., 2022). This section summarizes the findings of various research, offering a thorough summary of the present level of AI education in early childhood.

2.2 Current trends and obstacles to incorporating AI into primary and secondary schools

There are a number of current tendencies toward using AI in preschools and kindergartens. Among them, we can see the rise of AI-driven learning resources, the integration of AI-related subjects into STEM courses, and the push to instill digital literacy in children at a young age (Yang W., 2022) (Vansdadiya R. P. et al., 2023). Despite these advancements, challenges remain. Key issues include the lack of standardized curricula, insufficient teacher training, and worried about the moral consequences of teaching kids about artificial intelligence (Nayek M. B., &BiswajitNayek M., 2023). The effects of early AI instruction on children's development and its long-term consequences need more research.

2.3 Theoretical frameworks and pedagogical approaches in early AI education

Many pedagogical and theoretical frameworks advocate for the use of AI in early childhood education. Constructivist theories, which emphasize hands-on, experiential learning, align well with AI

education, encouraging children to explore and experiment with AI concepts. Socio-cultural theories also support AI education by emphasizing the value of collaborative learning and how social interactions impact the development of cognitive abilities (Rufai A. A. et al., 2024.) (Zajda J., 2021). This section reviews these and other relevant theories, discussing how they inform the design and implementation of AI curricula for young learners.

2.4 Gaps in the current literature

Despite increased interest in AI education for young children, there are still considerable gaps in the research. More detailed research is desirable to assess the effectiveness of various AI training techniques and curricula. Longitudinal research is particularly lacking, It is difficult to quantify the long-term influence of early AI education on children's academic and career trajectories (Gibson D. et al., 2023)(Agerfalk P. J. &Karlsson F., 2020). Additionally, there is a lack of research about the most effective methods for educating AI education teachers and meeting the varied demands of their students. Identifying and bridging these gaps is critical for progressing the field and ensuring that AI education is accessible and useful for all young learners (Song Y. et al., 2024).

Successful curriculum design methodologies and practical implementation approaches for AI training in early childhood are provided in the subsequent sections of the study, which build on the results of this research review.

3. OBJECTIVES AND RESEARCH QUESTIONS:

3.1 Objectives

The major objective of this study is to investigate and create successful ways for building and implementing AI curriculum specifically for young learners in early education settings. By outlining essential elements of an age-appropriate AI curriculum and practical ways to include them, this research hopes to contribute to the growing amount of information in AI education. Specific objectives include:

- To identify and outline the key components and concepts of an AI program of study appropriate for ECCE.
- To investigate the best practices and problems involved with incorporating AI principles into early childhood schools.
- Assess the influence of AI education on young children's learning results, cognitive development, and engagement.
- Make practical recommendations for educators, curriculum creators, and policymakers to effectively incorporate AI education in early childhood.

3.2 Research questions

In order to accomplish these aims, the initiative investigates the following research inquiries:

Curriculum design:

- What are the key mechanism of an effective AI curriculum for young children?
- How can AI concepts be made age-appropriate and engaging for early learners?

Implementation methods:

- What are the most effective methods for integrating AI education into early childhood classrooms?
- When it comes to implementing AI curriculum, what role does professional development and training for teachers play?

Impact assessment:

- How does early AI education affect children's cognitive development, problem-solving skills, and understanding of technology?
- How can we quantify the impact of introducing AI ideas in preschool on students' learning?

Challenges and solutions: What are the biggest problems educators and institutions encounter when adopting AI education for young learners?

- What strategies can be employed to overcome these challenges and ensure equitable access to AI education for all children?

4. METHODOLOGY:

4.1 Methodology and framework of the study

The integration of AI into preschool curricula is assessed in this study via the use of a mixed-methods research strategy. The mixed-methodologies approach enables a full investigation of both quantitative and qualitative elements of AI curriculum design and implementation methods (Roy et al., 2024).

4.2 Selection of the study's population and sample

The study population includes early childhood educators, curriculum developers, and stakeholders involved in AI education initiatives. A purposive sampling method will be used to select participants who have experience and expertise in AI education or are actively involved in implementing AI curricula in early education settings (Campbell S. et al., 2020).

4.3 Data collection methods

Surveys: A structured survey will be distributed to gather quantitative data on educators' perceptions, practices, and challenges related to AI education.

Interviews: In-depth interviews will be conducted with key stakeholders, including educators, curriculum developers, and policymakers, to explore their experiences, insights, and recommendations regarding AI curriculum design and implementation.

Classroom observations: Direct observations in early childhood classrooms will provide qualitative insights into how AI concepts are integrated into teaching practices and children's engagement with AI-related activities (Su J. & Yang W., 2022).

4.4 Data analysis techniques

Quantitative analysis: Educators' responses will be summarized and patterns in AI teaching approaches will be discovered by analyzing the survey findings using descriptive statistics.

Qualitative analysis: In order to find commonalities, difficulties, and solutions with AI education for young children, thematic analysis will be used to interview transcripts and field notes.

4.5 Ethical considerations

Consent after full disclosure: Prior to data collection, participants will be given a thorough explanation of the study's purpose, methodology, and any risks involved. Their free consent will then be sought after.

Confidentiality: Confidentiality of participants' identities and responses will be strictly maintained throughout the study, with data anonymized during analysis and reporting.

Ethical approval: To guarantee the research abides by ethical standards and protects the rights and welfare of participants, we shall seek ethical approval from relevant institutional review boards or ethics committees.

The study's overarching goal is to draw useful conclusions about the efficacy of AI teaching in preschools and kindergartens from the data collected using this rigorous technique. Educational approaches and policies that seek to encourage computational thinking abilities and digital literacy in children from an early age may be informed by these results, which will also contribute to the advancement of AI education.

5. CURRICULUM DESIGN STRATEGIES:

5.1 Principles of curriculum design for early AI education

Effective curriculum design for early AI education should be grounded in several key principles to ensure relevance, engagement, and developmental appropriateness:

Developmental appropriateness: Align AI concepts with children's cognitive abilities, ensuring activities and content are suitable for their age and stage of development.

Interdisciplinary approach:Integrate AI instruction with other courses like math, physics, and language arts to promote holistic learning.

Hands-on learning: Highlight the importance of hands-on learning by facilitating children's exploration of AI ideas via interactive activities and projects. (Vansdadiya, R. P. et al., 2023).

Inquiry-Based learning: Encourage curiosity and critical thinking by posing open-ended questions and challenges related to AI.

Ethical considerations: Encourage responsible usage and decision-making by include conversations on the ethical implications of AI technology.

Table 1. Outline and summarize the essential components that should be included when designing an AI curriculum tailored for young children. Discuss each component in the text before or after presenting the table to provide context and explanation.

Table 1: Key components of an AI curriculum for young children

Component	Description
Introduction to AI	Basic concepts such as algorithms, patterns, and problem-solving using age-appropriate examples.
Robotics and Coding	Hands-on activities with robotics kits and introduction to coding principles (e.g., block coding).
Machine Learning	Understanding how machines learn from data and make predictions, demonstrated through interactive simulations.
Ethical Discussions	Discussions on privacy, fairness, and ethical considerations in AI technologies.

5.2 Key components of an AI curriculum for young children

An effective AI curriculum for young children should include the following essential components:

Introduction to AI: Basic concepts such as algorithms, patterns, and problem-solving using examples familiar to children (e.g., puzzles, stories).

Robotics and coding: Introduction to simple coding concepts and hands-on activities with age-appropriate robotics kits.

Machine learning: Understanding how machines learn from data and make predictions, illustrated through interactive games and simulations.

Ethical discussions: Discussions on privacy, fairness, and bias in AI systems, emphasizing ethical decision-making in technology use (Akgun S., & Greenhow C., 2022).

5.3 Age-Appropriate content and skills to be taught

Tailoring content and skills to children's developmental stages ensures engagement and comprehension:

Preschool (3-5 years): Focus on foundational concepts like cause-and-effect relationships, basic coding sequences using tangible objects, and storytelling with AI-related themes.

Early elementary (6-8 years): Introduce more complex AI concepts such as logic and decision-making processes, basic programming languages like block coding, and collaborative projects involving simple AI applications.

Late elementary (9-11 years): Explore advanced topics such as data analysis, supervised learning with structured activities, and discussions on societal impacts of AI technologies.

5.4 Strategies for integrating AI concepts into existing curricula

To seamlessly integrate AI concepts into existing curricula, educators can employ the strategies as per shown in the table 2 below.

Table 2: Strategies for integrating AI concepts into existing curricula

Strategy	Description
Cross-Curricular Connections	Identifying opportunities to embed AI themes into subjects like math, science, and language arts.
Project-Based Learning	Designing multidisciplinary projects in which youngsters use AI principles to tackle real-world challenges.
Teacher Professional Development	Providing ongoing training and resources for educators on AI concepts and teaching methods.
Collaboration with Experts	Partnering with AI professionals to enrich classroom activities and provide real-world insights.
Parental Engagement	Involving parents in children's AI learning through workshops and resources for support at home.

Cross-curricular connections: Identify opportunities to incorporate AI themes into subjects like math, science, and social studies.

Project-based learning: Design interdisciplinary projects that involve problem-solving with AI tools and technologies.

Teacher professional development: Provide ongoing training and resources to educators on AI concepts and teaching methods.

Collaboration with experts: Partner with AI professionals or researchers to enrich classroom activities and provide real-world insights.

Parental engagement: Involve parents in children's AI learning by sharing resources and hosting workshops to promote understanding and support at home.

Educators may effectively incorporate AI education in early childhood settings by using these curriculum design principles, which foster children's curiosity, critical thinking, and digital literacy abilities, all of which are necessary for their future success in a technologically driven environment.

6. IMPLEMENTATION METHODS:

6.1 Practical approaches for introducing AI in early education settings

Introducing AI in early education requires thoughtful planning and implementation strategies:

Start with basics: Begin with simple, age-appropriate AI concepts such as cause and effect, pattern recognition, and basic problem-solving activities.

Hands-on activities: Incorporate hands-on activities using tangible materials and interactive games to engage children in learning about AI.

Integration with daily activities: Embed AI concepts into daily routines and existing subjects to demonstrate real-world applications.

Collaborative learning: Foster collaborative projects where children work together to solve problems using AI tools and technologies.

Adaptability: Adapt activities and lessons based on children's interests, abilities, and developmental stages to ensure meaningful engagement.

6.2 Teacher training and professional development

Effective teacher education and ongoing professional growth are required for successful AI application:

Workshops and seminars: Offer workshops and seminars to familiarize educators with AI concepts, teaching strategies, and curriculum integration.

Hands-on training: Provide hands-on training sessions where teachers can practice using AI kits, software, and tools themselves.

Peer collaboration: Encourage collaboration among teachers to share best practices, resources, and lesson plans for integrating AI into their classrooms.

Ongoing support: Provide ongoing support and mentorship to help teachers implement AI education effectively and address challenges as they arise.

6.3 Use of educational tools and resources

Utilize a variety of educational tools and resources to enhance AI learning experiences:

AI kits: Utilize age-appropriate robotics kits and AI platforms that allow children to build and program simple robots, fostering hands-on learning experiences.

Software and apps: Integrate educational software and apps that teach basic coding skills, AI concepts, and problem-solving through interactive games and simulations.

Online resources: Access online resources such as tutorials, videos, and virtual labs that explain AI concepts and provide additional learning opportunities.

Games and simulations: Make use of simulations and games centered on artificial intelligence to teach kids about the technology as they have fun.

6.4 Classroom Activities and Instructional Methods

Implement diverse classroom activities and instructional methods to promote AI learning:

Project-based learning: Design project-based activities where children solve real-world problems using AI technologies, encouraging creativity and critical thinking.

Role-playing: Engage children in role-playing scenarios where they act as AI programmers, robots, or users to understand different perspectives and applications of AI.

Debate and discussion: Facilitate debates and discussions on ethical issues related to AI, encouraging children to consider diverse viewpoints and make informed decisions (Adams C. et al., 2023).

Demonstrations and experiments:Conduct demos and exercises to show how AI topics like machine learning algorithms and natural language processing work.

6.5 Case Studies or Examples of Successful Implementation

Highlighting case studies or examples can provide insights into successful AI implementation in early education:

Example 1: A kindergarten class uses a robotics kit to build and program a simple robot that follows basic commands, teaching children about sequencing and logic.

Example 2: A third-grade teacher integrates AI-themed math problems into daily lessons, challenging students to apply AI concepts to solve mathematical problems collaboratively.

Example 3: A school partners with local AI professionals to host a coding workshop where students learn to create their own AI-based games, enhancing their coding and problem-solving skills.

7. EVALUATION AND ASSESSMENT:

7.1 Methods for evaluating the effectiveness of AI curricula

To evaluate the effectiveness of AI curricula inside early education, the following methods can be employed:

Pre and post assessments:Conduct pre-post assessments to monitor changes in children's knowledge, abilities, and attitudes concerning AI concepts (Bower M. et al., 2024).

Performance tasks: Design performance-based tasks that require children to apply AI principles and problem-solving skills in real-world scenarios.

Observations: Observe children's engagement and interactions during AI-related activities to gauge their understanding and level of participation.

Surveys and interviews: Conduct surveys and interviews with instructors, students, and parents to accumulate qualitative participation on the apparent benefits and obstacles of AI education.

7.2 Assessment tools and techniques for measuring learning outcomes

Apply a diversity of evaluation tools and techniques to measure learning outcomes related to AI education:

Rubrics: Make some evaluation criteria for kids' coding, troubleshooting, and analytical thinking skills as they pertain to artificial intelligence.

Checklists: Use checklists to track children's progress in mastering specific AI skills and competencies over time.

Performance assessments: Evaluate children's ability to apply AI knowledge through performance assessments, such as coding challenges or project presentations.

Portfolio reviews: Review children's portfolios to examine their AI-related projects, reflections, and growth throughout the learning process.

7.3 Feedback from Teachers, Students, and Parents

Collect feedback from various stakeholders to understand their perspectives on AI education:

Teachers: Gather feedback from teachers on the effectiveness of AI curricula, challenges encountered during implementation, and recommendations for improvement.

Students: Solicit feedback from students on their interests in AI, enjoyment of AI activities, and perceived learning outcomes.

Parents: Seek input from parents on their perceptions of AI education, concerns about technology use, and support for integrating AI into their children's learning experiences.

7.4 Examining how teaching AI affects kids' growth and learning

Examine how teaching AI affects kids' growth and learning using:

Quantitative analysis: Analyze assessment data to measure changes in children's academic performance and skill development related to AI concepts (Martínez-Comesaña M. et al., 2023).

Qualitative analysis: Analyze qualitative data using thematic framework (e.g., assessments, open-ended survey responses) to discover themes about children's attitudes, interests, and comprehension of AI. (Naeem M. et al., 2023).

Longitudinal studies: Find out how teaching kids about AI affects their brain growth, problem-solving skills, and aspirations for the future by following them over time. (Polyportis A., 2024).

Comparative studies: Compare outcomes between classrooms or schools implementing different AI curricula or instructional methods to identify effective practices and areas for improvement (Lee S. J. & Kwon K., 2024).

You may find a variety of tools and approaches for evaluating the success of AI-based early childhood education in Table 3.

Table 3: Assessment tools and techniques for AI education

Assessment Method	Purpose

Pre and Post Assessments	Measuring changes in children's knowledge and skills before and after AI education.
Performance Tasks	Evaluating children's capacity to use AI concepts in real-world situations.
Rubrics	Assessing proficiency in coding, problem-solving, and critical thinking related to AI concepts.
Checklists	Tracking progress in mastering specific AI skills and competencies.
Portfolio Reviews	Reviewing children's AI-related projects, reflections, and growth over time.

8. DISCUSSIONS:

The conclusions of this study reveal important insights into how AI education in early childhood can impact young learners' development, providing a foundation for the field's growth. Analysis shows that well-designed AI curricula can significantly enhance cognitive skills, problem-solving abilities, and digital literacy, as evidenced by assessment data and qualitative feedback from both educators and students (Hooda et al., 2022). Additionally, the hands-on nature of AI activities promotes children's curiosity and engagement, creating interactive learning environments that foster a positive attitude toward technology from a young age. The key to a successful AI education program is making sure teachers are well-prepared to teach the subject. Educators need to undergo thorough training and participate in continuing professional development if they want to feel confident in their ability to teach AI. (Ayanwale et al., 2022).

These findings have several implications for educators, policymakers, and curriculum developers. Educators are encouraged to pursue professional development focused on AI teaching methodologies suitable for young learners. Policymakers can support AI education by promoting policies that integrate AI into early childhood curricula, ensuring that resources and access are equitably distributed (Ifenthaler D. et al., 2024). Curriculum developers, meanwhile, can enhance AI learning outcomes by designing developmentally appropriate, interdisciplinary programs that align with educational standards. By addressing these roles, stakeholders can work collaboratively to build a robust framework for AI education in early childhood, making it accessible and beneficial for a diverse range of learners (Kim J.et al., 2022).

Despite these hopeful results, the study had certain obstacles and limitations. The subject of AI education for young children is still developing, with little research and few defined curriculum to assist implementation. Resource restrictions, such as uneven availability to AI kits and qualified educators, presented hurdles to the uniformity and quality of AI training across diverse educational contexts.(Cheng E. C. K. & Wang T., 2023). Ethical considerations, such as data privacy and the possibility of bias in AI technology, must be continuously addressed in order to permit responsible usage of AI in educational contexts. Potential research is supposed to concentrate on performing longitudinal studies to examine the long-term impacts of AI education, creating inclusive curriculum for varied learners, setting ethical guidelines, and investigating sophisticated AI techniques such as machine learning for early childhood applications.

9. CONCLUSION:

This study has revealed that incorporating AI education into early childhood settings offers substantial benefits, enhancing young learners' cognitive development, problem-solving skills, and digital literacy. Engaging, hands-on activities significantly boost children's curiosity and motivation, while the success of these programs hinges on well-prepared educators equipped with relevant knowledge and skills through dedicated training. By providing empirical support for the effectiveness of AI curricula, identifying best practices, and addressing literature gaps, this research makes a valuable contribution to early AI education. Looking ahead, AI education in early childhood promises growth through technological advancements and interactive tools, though ethical considerations and equitable access remain crucial. The field must continue to address these challenges to ensure all children can benefit from AI's educational potential.

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વિદ્યાર્થીઓની જરૂરિયાતનો અભ્યાસ

Study of Students' Needs

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સારાંશ

પ્રસ્તુત અભ્યાસમાં વિદ્યાર્થીઓની જરૂરિયાતના સંદર્ભે બે અલગ અલગ શાળાઓના મળીને કુલ 30 વિદ્યાર્થી ઉપર આ પ્રયોગ હાથ ધરવામાં આવેલ હતો.જેમાં અબ્રાહમ મેસલોના જરૂરિયાતના સિદ્ધાંતને ધ્યાને રાખીને વિદ્યાર્થીઓની જરૂરિયાતોની ઓળખ કરવામાં આવેલી હતી. ત્યારબાદ ક્લાર્ક હલના પ્રેરણા સિદ્ધાંતને ધ્યાનમાં લઇ તેમની જરૂરિયાતોની પૂર્તિ કરવા આંતરિક પ્રેરણા ઉદભવે તેવી રીતે માવજત આપવામાં આવેલી હતી. જેથી વિદ્યાર્થીઓ જરૂરિયાતોની પૂર્તિ કરવા માટે પ્રયત્ન કરે. અભ્યાસમાં વિગોટ્સ્કીની ZONE OF POXIMAL DEVELOPMENT સિદ્ધાંતને આધારે શિક્ષકની સહાયક ભૂમિકાઓ નક્કી કરી તે મુજબ વિદ્યાર્થીઓને શિક્ષક સહાય પૂરી પાડવામાં આવેલ હતી. આમ, માવજત આપ્યા પહેલા પૂર્વ કસોટી તરીકે HOLISTIC PROGRESS CARD દ્વારા માહિતી એકત્રિત કરવામાં આવી હતી. ત્યારબાદ માવજત આપ્યા પછી ઉત્તર કસોટી લેવામાં આવી અને HOLISTIC PROGRESS CARD દ્વારા ફરીથી માહિતી એકત્ર કરવામાં આવી હતી. આપેલ માવજતની અસરકારકતા તપાસવા માટે પૂર્વ કસોટી અને ઉત્તર કસોટીના પ્રાપ્તાંકોના આધારે મળેલ તફાવતને પ્રયોગની અસરકારકતા તરીકે સ્વીકારેલ હતી. તેના આધારે પ્રયોગના તારણો, શૈક્ષણિક ફલિતાર્થો તેમજ શિક્ષક, વાલી અને સમાજ માટે અમુક ભલામણો રજૂ કરવામાં આવી હતી.

કી વર્ડ- વિદ્યાર્થીઓની જરૂરિયાત , પ્રેરણા, શિક્ષકની ભૂમિકા

૧.૧ પ્રસ્તાવના

માણસ એક સામાજિક પ્રાણી છે. દરેક પ્રાણીની પોતાની જરૂરિયાત હોય એવી રીતે માણસની પણ જરૂરિયાતો હોય તે બાબત સર્વ-સ્વીકૃત છે. માણસની જરૂરીયાતો સંદર્ભે અમેરિકન મનોવૈજ્ઞાનિક 'અબ્રાહમ મેસલો' દ્વારા "જરૂરિયાતનો સિદ્ધાંત" આપવામાં આવ્યો હતો. જેમાં તેમણે સાત ક્રમિક જરૂરીયાતો તરીકે **"શારીરિક, સલામતી, પ્રેમ, પ્રભુત્વ, આત્મ સાર્થક્ય, જ્ઞાન અને સમજ અને સૌંદર્યાત્મક રજૂ કરી છે."** આ સિદ્ધાંત મુજબ શાળા સમય દરમ્યાન વિદ્યાર્થીઓની શારીરિક જરૂરરીયાત માટે સરકારશ્રી દ્વારા મધ્યાહન ભોજન, મફત ગણવેશ, સાધન સહાય, શિષ્યવૃતિ

વગેરે સહાય આપવામાં આવે છે. સલામતીની જરૂરિયાત પૂર્ણ કરવા માટે પણ સરકારશ્રી દ્વારા અલગ-અલગ કાયદા અને વ્યવસ્થા પૂરી પાડવામાં આવે છે.

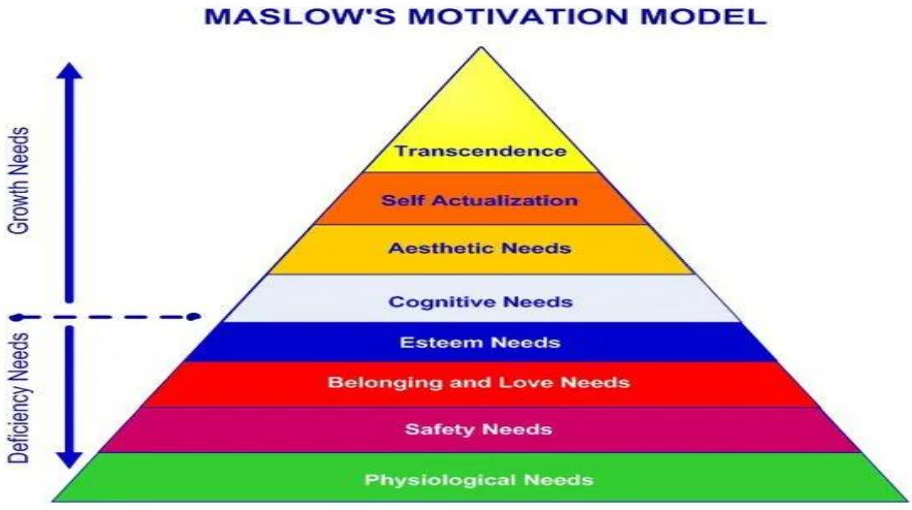
જ્યારે વિદ્યાર્થીઓની સાંવેગીક જરૂરીયાતો તે જાતે પૂરી કરી શકતો નથી કેમકે, કિશોરાવસ્થા અને તરુણાવસ્થા દરમ્યાન તેમનામાં EMOTIIONAL INTELLIGENCE(EQ)/ સાંવેગીક પરિપક્વતા ન હોય આથી તે વિદ્યાર્થીઓ પોતાની જરૂરિયાત પૂર્ણ કરવા માટે સહપાઠી, મિત્ર વર્તુળ, વાલી ,સમાજ તેમજ શિક્ષકો પાસેથી મળતા અનુભવો પર આધારિત હોય છે.

વિદ્યાર્થીઓના સંવેગોની ઓળખ કરી તેમની જરૂરીયાતો સંતોષાય તેવા પ્રયત્ન કરવામાં આવે તો તેની આગળની જરૂરિયાત સંતોષવા વિદ્યાર્થી માનસમાં આંતરિક પ્રેરણા ઉદ્દભવશે . આ સિદ્ધાંત વિદ્યાર્થીઓ માટે અને શિક્ષક માટે કઈ રીતે ઉપયોગી બની શકે તેની સમજ મેળવીએ.

૨.૧ સંદર્ભ સાહિત્યની સૈદ્ધાંતિક સમીક્ષા :

અબ્રાહમ મેસલો

કેટલે જરૂરિયાતના સ્વરૂપમાં બે પ્રકારના પ્રેરણો અવયવ પૃથકરણ વડે શોધ્યા છે: (૧)મૂળગત પ્રેરણો અને (૨)પ્રાપ્ત પ્રેરણો. મૂળગત પ્રેરણોમાં ભય, આત્મરતિ, આક્રમકતા, સંવનન વગેરેનો સમાવેશ થાય છે. પ્રાપ્ત પ્રેરણોમાં સ્વમૂલ્યાંકન, કારકિર્દી, માતૃ-પિતૃ ભાવ વગેરેનો સમાવેશ થાય છે.



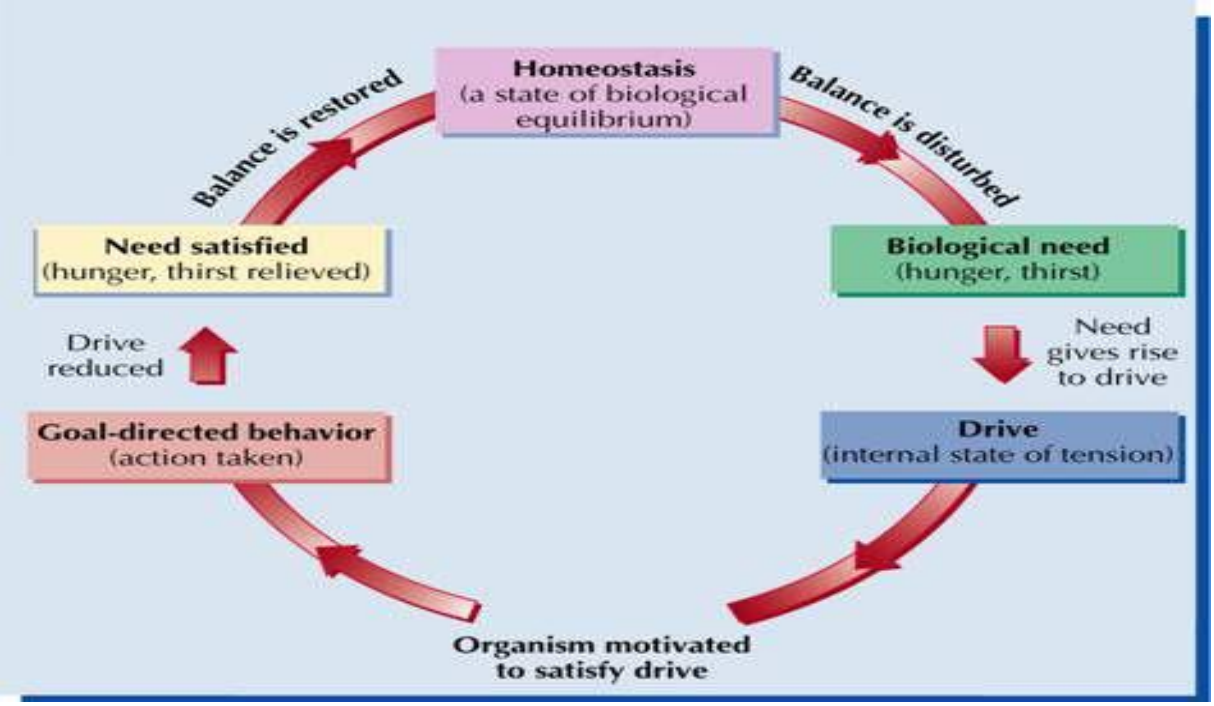
આકૃતિ ૨.૧ મેસલોની જરૂરિયાતનો સિદ્ધાંત

આકૃતિ ૨.૧માં જણાવેલ મુજબ મેસલોએ જરૂરિયાતના સંતોષ પર આધારિત જરૂરિયાત સંતોષવા માટે પ્રેરણાનો સિદ્ધાંત રજૂ કર્યો છે. તે જણાવે છે કે જ્યારે નીચલી કક્ષાની જરૂરિયાતો સંતોષાય છે, ત્યારે ઉચ્ચ કક્ષાની જરૂરિયાતો ઉદ્ભવે છે. તેણે સાત જરૂરિયાતો -શારીરિક, સલામતી, પ્રેમ, પ્રભુત્વ, આત્મ સાર્થક્ય, જ્ઞાન અને

સમજ અને સૌંદર્યાત્મક રજૂ કરી છે. પ્રથમ ચાર જરૂરિયાતો ઉણપ જરૂરિયાતો છે, કારણ કે માણસતે દરેકને પરિપૂર્ણ કરવા વર્તન કરે છે. છેલ્લી ત્રણ જરૂરિયાતો પાયાની ઈચ્છાઓ છે, જે માણસને 'કંઈક' બનવા માટેના પ્રેરકો છે.

મેસલોની દ્રષ્ટિએ દરેક જરૂરિયાત સ્વ વિકાસની દિશામાં પ્રગતિ નું સોપાન છે, અર્થાત જરૂરિયાતોની શ્રેણી છે. બીજી જરૂરિયાત પ્રેરક ત્યારે જ બને જ્યારે પ્રથમ જરૂરિયાત સંતોષાય. જયાં સુધી વ્યક્તિની શારીરિક જરૂરિયાત ન સંતોષાય ત્યાં સુધી તે સલામતી માટે પ્રયત્ન કરશે નહીં. આથી શિક્ષકે વિદ્યાર્થીને પ્રથમ તેની ઉણપ જરૂરિયાતો સંતોષવામાં મદદ કરવી જોઈએ. તો જ તેનામાં જ્ઞાન અને સૌંદર્યાત્મક જરૂરિયાતોનો વિકાસ થશે.

ક્લાર્ક હલ



આકૃતિ ૨.૨ ક્લાર્ક હલનો સિદ્ધાંત

આકૃતિ ૨.૨માં જણાવેલ મુજબ ઈરણ એટલે પ્રાણીની ઉત્તેજિત ક્ષુબ્ધા અવસ્થા. પ્રાણીની જરૂરિયાત અસંતુષ્ટ રહેવાના કારણે ઉત્પન્ન થાય છે ઈરણના કારણે પ્રાણીમાં પ્રતિચાર કરવાની શક્તિ જન્મે છે અને ટકી રહી છે. ઉપરોક્ત બાબત એ સ્પષ્ટ કરે છે કે જ્યારે પ્રાણીની જરૂરિયાત અસંતુષ્ટ હોય અર્થાત સંતોષાયેલ ન હોય ત્યારે પ્રેરણા ઉત્પન્ન થાય છે અને તેની જરૂરિયાતને પૂર્ણ કરવા પ્રેરક બળ આપે છે અને પ્રક્રિયાથી પ્રાણીમાં જરૂરિયાત સંતોષવાની ક્ષમતા જન્માવે છે અને પ્રાણી તેના આધારે પોતાની જરૂરિયાત પૂર્ણ કરવા પ્રેરાય છે અને પ્રતિચાર રૂપે તેને પૂર્ણ

કરે છે . આમ, એક પછી એક જરૂરિયાત પૂર્ણ કરવા પ્રેરણા સહાયરૂપ બને છે અને પ્રાણી સમાજમાં ટકી રહે છે.

એલ. વિગોટ્સ્કી

એલ. વિગોટ્સ્કી જેઓ રશિયન મનોવૈજ્ઞાનિક હતા. જેમના દ્વારા સામાજિક વિકાસ સિદ્ધાંત રજૂ કરવામાં આવ્યો છે . તે અંતર્ગત The zone of poximal development નો ખ્યાલ રજૂ થયોછે. એટલે કે જ્ઞાનાત્મક વિકાસનો એવો તબક્કો કે જ્યાં વિદ્યાર્થીને યોગ્ય મદદ મળે તો તે કાર્ય પર પ્રભુત્વ મેળવી શકે. તેઓ ZPD ને આ રીતે વ્યાખ્યાયિત કરે છે: "બાળકની વ્યક્તિગત રીતે સમસ્યા ઉકેલવાની શક્તિ વડે નિયત થયેલી વિકાસ -કક્ષા અને વડીલના માર્ગદર્શન નીચે કે વધુ જ્ઞાન ધરાવતા સમવયસ્કોના સહકારથી સમસ્યા ઉકેલવાની શક્તિ વડે નિયત થયેલી વિકાસ-કક્ષા વચ્ચેનો તફાવત છે.

વિગોટ્સ્કીના સિદ્ધાંતના શૈક્ષણિક ફલિતાર્થોનો શિક્ષક નીચેની રીતે ઉપયોગ કરી શકે :

- Zone of poximal developmentનો ઉપયોગ કરો. ઝોનની ઉપલી કક્ષાએ બાળકને લઈ જવાના ધ્યેયથી શિક્ષણકાર્યનો પ્રારંભ કરો.
- વિદ્યાર્થીઓના ઈરાદાઓ અને પ્રયત્નોનું અવલોકન કરો, જરૂર જણાય ત્યાં મદદ પૂરી પાડો અને જયાં મૂંઝવણ અનુભવે ત્યાં પ્રોત્સાહન આપો.
- વિદ્યાર્થીઓને વધુ કૌશલ્ય વાળા સમવયસ્કો સાથે કામ કરવાની તક આપો.
- સહકારયુક્ત અધ્યયનને પ્રોત્સાહન આપો.
- અધ્યયન માટે સાંસ્કૃતિક સંદર્ભ પૂરો પાડો.
- બાળકોને અંગત બોલીનો ઉપયોગ કરવાની તક આપો અને તેનો ઉપયોગ કરવા પ્રોત્સાહિત કરો.
- બાળકોના બુદ્ધિ આંક નું માપન કરવાને બદલે તેના ZPD નું માપન કરો.

૨.૨ પૂર્વે થયેલા સંશોધનની સમીક્ષા :

ભરત ત્રિવેદી (2019)ના મત મુજબ “There is no significant difference in Educational Aspiration between male and female students.There is no significant difference in Educational Aspiration between General Stream male and female students”

સુજાતા બારોટ (૨૦૨૧) “There is a significant difference in achievement motivation between ST and SC students, SC and OBC students, OBC male and female students,

SC and OBC male students, SC and ST female students, OBC and ST male students.There is a significant difference in self concept between ST male and female students. Study of self-efficscy, quality of life, psychological well-being, frustration, mental health, anxiety and depression also can be done as a part form achievement motivation and stress."

૩.૧ અભ્યાસના હેતુઓ

૧. શાળા સમય દરમ્યાન વિદ્યાર્થીઓને સહાયરૂપ થવા તેમની જરૂરીયાતોની ઓળખ કરવી.

૨. આ જરૂરિયાતની પૂર્તિ કરવા માટે શિક્ષકની સહાયક તરીકે ભૂમિકા નક્કી કરવી.

૩. અગાઉ નક્કી કરેલ ભૂમિકા મુજબ વિદ્યાર્થીઓને યોગ્ય માવજત આપવી.

૪. પ્રાપ્ત માવજાતથી જરૂરિયાતો પૂર્તિ થતા વિદ્યાર્થી આગળની જરૂરિયાત પૂર્ણ કરવા પ્રયત્ન કરે છે કે કેમ તેનું અવલોકન કરવું. (આગળની જરૂરિયાત પૂર્ણ કરવા માટે પ્રેરક બળ અસરકારક છે કે નહીં?)

૪.૧ અભ્યાસની પદ્ધતિ :

પ્રસ્તુત અભ્યાસમાં વિદ્યાર્થીઓની જરૂરિયાતના સંદર્ભે અસરકારકતા ચકાસવાની હોવાથી હેતુની દ્રષ્ટિએ પ્રાયોગિક પદ્ધતિ ગણાય. પૂર્વ પ્રાયોગિક પદ્ધતિના વિભાગોમાંથી આ સંશોધન એક જૂથ પૂર્વ કસોટી ઉત્તર કસોટી યોજના પ્રકારનું દર્શાવી શકાય.

સારણી ૪.૧

પ્રયોગ યોજનાની સાંકેતિક રજૂઆત

જુથ	પૂર્વ કસોટી	સ્વતંત્ર ચલ (માવજત)	ઉત્તર કસોટી
પ્રાયોગિક જુથ (E)	T_1	X	T_2

E = પ્રયોગમાં સમાવિષ્ટ ૩૦ વિદ્યાર્થીઓનું જુથ

T_1 = HOLISTIC PROGRESS CARD / સર્વગ્રાહી પ્રગતિ પત્રક(HPC)

X = વિવિધ સિદ્ધાંતો મુજબ આપવામાં આવેલ માવજત

T_2 = HOLISTIC PROGRESS CARD / સર્વગ્રાહી પ્રગતિ પ્રત્રક(HPC)

૫.૧ માહિતીની રજૂઆત

અબ્રાહમ મેસલોની જરૂરિયાતના સિદ્ધાંતના સંદર્ભમાં વિદ્યાર્થીઓની જરૂરિયાતોને આ મુજબ દર્શાવી શકાય.

સારણી ૫.૧

વિદ્યાર્થીઓની પ્રાથમિક જરૂરીયાતો

શારીરિક જરૂરિયાતો	સલામતી ની જરૂરિયાતો	સંવેગો ની જરૂરિયાતો	સ્વ-સન્માનની જરૂરિયાતો
ખોરાક પાણી વર્ગખંડ ઉર્જા /આરામ વાતાવરણીય સંરક્ષણ સ્વાસ્થ્ય	શારીરિક સલામતીની સુરક્ષા આર્થિક સલામતીની સુરક્ષા માનસિક સલામતીની સુરક્ષા	પારસ્પરિક સમર્થન સંતુલિત પ્રેમના સંબંધો પરિવર્તન માટે સમય આત્મવિશ્વાસની ભૂમિકા વિચારોનું આદાન-પ્રદાન વિપરીત સ્થિતિમાં સ્થિરતા	સ્વ -સન્માન અન્ય તરફથી પ્રોત્સાહન સકારાત્મક પ્રતિસાદ

- શારીરિક જરૂરિયાતો

ખોરાક: મધ્યાહન ભોજનની યોજના.

પાણી: શાળામાં પીવાના પાણીની વ્યવસ્થા તથા તાસ દરમિયાન તરસ છીપાવવા માટે શિક્ષકની પરવાનગી વગર વ્યક્તિગત રીતે પોતાની બોટલ માંથી પાણી પી શકે છે. વર્ગખંડ

:વર્ગખંડની ભૌતિક સુવિધા ખુરશી,પાટીયુ અને શાળામાંથી પુરા પાડવામાં આવતા પુસ્તકો. ઉર્જા અથવા આરામ: સમાન અંતરે રિસેસ તથા વ્યક્તિગત જરૂરિયાત મુજબ શૌચ ક્રિયા માટે વિશેષ પરવાનગી આપવી. વાતાવરણીય સંરક્ષણ: ગણવેશ/ શિષ્યવૃત્તિ ,વર્ગખંડમાં ઉપલબ્ધ સંસાધનોનો યોગ્ય અને પૂરતો ઉપયોગ. સ્વાસ્થ્ય: શાળાનું ભૌગોલિક વાતાવરણ તથા શાળા દરમિયાન યોજવામાં આવતા વિવિધ આરોગ્ય કેમ્પનું આયોજન.

- સલામતીની જરૂરિયાત

શારીરિક સુરક્ષા: દૂર રહેતા બાળકો માટે વાલી સંપર્ક કરી પરીવહનની વ્યવસ્થા.

આરોગ્ય અને તબીબી સલામતીની સુરક્ષા માટે સમગ્ર શાળાની સફાઈ, રોગચાળથી બચવા માટે યોગ્ય સારવારની ઉપલબ્ધિ.

આર્થિક સલામતીની સુરક્ષા: વિવિધ સરકારી યોજના નો લાભ વિદ્યાર્થી સુધી પહોંચાડવો જેવા કે વિદ્યાલક્ષ્મી બોન્ડ, વિદ્યાદીપ યોજના, શિષ્યવૃત્તિ યોજના.

માનસિક સલામતી સુરક્ષા: વિદ્યાર્થી સાથે ગેરવર્તન તથા શોષણ સામે કાનૂની કાર્યવાહી કરવી. પછાત વર્ગના બાળકો અને દીકરીઓના સંદર્ભમાં સૌપ્રથમ દરેક વિદ્યાર્થીને પ્રાર્થના સભા દરમિયાન વિસંગતતા દૂર કરવાના કાયદા વિશે અવગત કર્યા તેથી વિદ્યાર્થી શોષણ સામે રક્ષણ મેળવી શકે. પરિવાર તરફથી સુરક્ષા: નકારાત્મક વર્તન સામે વાલીઓને જાગૃત કરી આવા વર્તનો અટકાવી શકાય.

- સંવેગોની જરૂરિયાત

પારસ્પરિક સમર્થન અને તાકાત: શાળામાં એકબીજા વિદ્યાર્થી પ્રત્યે ધ્રુણા રાખનાર વિદ્યાર્થીઓને ઓળખી તેમને એકબીજાની નબળાઈ અને ખુબીઓથી અવગત કરી તેમને એક જૂથમાં કાર્યની સોપણી કરાય.

સંતુલિત પ્રેમના સંબંધો: શિક્ષકો, વડીલો અને માતા પિતાએ પોતાના દરેક બાળક માટે સરખું વર્તન રાખવું. બાળકની વ્યક્તિગત ભિન્નતાને અને ક્ષમતાને ધ્યાને રાખી એમની જરૂરિયાત મુજબ યોગ્ય વ્યવહાર કરવો. બાળકની ક્ષમતા અને લાગણીઓની જરૂરિયાતને ઓળખી તેમના માતા પિતાને તેનાથી અવગત કરી તેની સમજ આપવી. માતા પિતાએ વારંવાર પોતાના બાળકની અન્યની સાથે તુલના કરતા અટકાવવા જેથી તેમની લઘુતાગ્રંથી દ્રઢ ન બને.

પરિવર્તન માટે સમય: બાળકની કક્ષા અને ક્ષમતા મુજબ તેમને પોતાની જરૂરિયાતનું ચક્ર પૂરું કરવા માટે યોગ્ય સમય ઉપલબ્ધ કરાવવો, અને જરૂર જણાતાં ZPD સિદ્ધાંત મુજબ તેમને આ માટે સહાય કરવી.

આત્મવિશ્વાસની ભૂમિકા: વિદ્યાર્થીમાં આત્મવિશ્વાસ વધે તે માટે તેમની ક્ષમતાઓ ઓળખી તે મુજબ નાના નાના કાર્ય સોંપવા. અભ્યાસિક અને સહ અભ્યાસિક પ્રવૃત્તિમાં ભાગ લેતા કરવા તથા સફળતાના પ્રત્યેક તબક્કે તેમને હકારાત્મક સુદ્રઢકો પૂરા પાડવા.

વિચારોનું આદાન-પ્રદાન: વિદ્યાર્થીઓમાં વિચારોનું આદાન-પ્રદાન વધે તે માટે જરૂરી ચર્ચાઓ ગોઠવી અને આ પ્રક્રિયા માટે તેને યોગ્ય તક અને સ્વતંત્રતા આપવી. આ સમગ્ર ઘટના શિક્ષકના નિરીક્ષણ અંતર્ગત ઉપલબ્ધ કરાવવી.

વિપરીત પરિસ્થિતિમાં સ્થિરતા : પોતાની વિપરીત પરિસ્થિતિ સામે જાતે રક્ષણ મેળવી પોતાના જ પ્રયત્ન દ્વારા પરિસ્થિતિને અનુકૂળ થવા અથવા અનુકૂળ પરિસ્થિતિ ઉભી કરવા અભી પ્રેરિત થાય તેવી સમજ વિકસાવવા શિક્ષક દ્વારા પ્રયત્ન કરાયા.

- સ્વ-સન્માનની જરૂરિયાત

સ્વ-સન્માન: વિદ્યાર્થીનો શાળા, કુટુંબ, મિત્ર વર્તુળ અને સમાજમાં સ્વીકાર થાય તેમની ક્ષમતાઓનો સ્વીકાર થાય તેમના કાર્ય અને ક્ષમતાઓની પ્રશંસા થાય જેથી કરી તેનામાં સ્વ સન્માનનો વિકાસ કરી શકાય.

અન્ય તરફથી પ્રોત્સાહન: વિદ્યાર્થીની શૈક્ષણિક અને સહ શૈક્ષણિક સિદ્ધિ અને યોગ્યતાને જાહેરમાં બિરદાવી અને માતા પિતાને પણ પ્રોત્સાહિત કરવા.

સકારાત્મક પ્રતિસાદ: વિદ્યાર્થીની ભૂલ થતાં ભૂલ શા કારણે થઈ છે તે જાણીને થયેલ ભૂલનું પુનરાવર્તન ન થાય તેના માટે અન્ય સકારાત્મક વિકલ્પ પૂરા પાડી તેને નિરાશ કરવાને બદલે આત્મવિશ્વાસ વધારવો.

૬.૧ માહિતીનું અર્થઘટન અને પૃથ્થક્કરણ :

પ્રસ્તુત અભ્યાસની શૂન્ય ઉત્કલ્પના આ મુજબ હતી.

H_{01} HPC પર વિધાર્થીઓએ પૂર્વ કસોટી અને ઉત્તર કસોટી દરમ્યાન મેળવેલા પ્રાપ્તાંકોના સરેરાશ અંકો વચ્ચે સાર્થક તફાવત નહીં હોય.

સારણી ૬.૧

પ્રયોગમાં સમાવિષ્ટ પાત્રોએ HPC પરના સરેરાશાંકોના તફાવતની સાર્થકતા

ક્રમ	જૂથ	પાત્રોની સંખ્યા	સરાસરી સંખ્યા	પ્રમાણ વિચલન	સરાસરી તફાવત	ટી-ગુણોત્તર	સાર્થકતા ની કક્ષા
૧.	પૂર્વ કસોટી	૩૦	૩૧.૪૦	૪.૭૭૫	૩.૫	૨.૯૧૩	૦.૧ કક્ષાએ સાર્થક થયેલ છે.
૨.	ઉત્તર કસોટી	૩૦	૨૭.૯૦	૪.૫૨૮			

સારણી ૬.૧ના આધારે જાણી શકાય કે પ્રસ્તુત અભ્યાસમાં સમાવિષ્ટ પાત્રોની સંખ્યા ૩૦ હતી. જેમને HPC પર પૂર્વ-ઉત્તર કસોટી દરમ્યાન પ્રાપ્ત કરેલ સરાસરી ક્રમશઃ ૩૧.૪૦ અને ૨૭.૯૦ હતી. આ સરસરીનું પ્રમાણ વિચલન ક્રમશઃ ૪.૭૭૫ અને ૪.૫૨૮ હતું. જેમનો સરાસરી તફાવત ૩.૫ અને ટી-ગુણોત્તર મૂલ્ય ૨.૯૧૩ મળેલ હતું. આ આધારે કહી શકાય કે પૂર્વ કસોટી અને ઉત્તર કસોટી દરમ્યાન મેળવેલા પ્રાપ્તાંકોના સરેરાશ અંકો વચ્ચે સાર્થક તફાવત છે. આથી ચકાસણીના અંતે ઉપરોક્ત શૂન્ય ઉત્કલ્પના ખોટી સાબિત થાય છે. પ્રયોગના ભાગ સ્વરૂપે વિદ્યાર્થીઓને મળેલ માવજત અસરકારક સાબિત થાય છે.

૭.૧ અભ્યાસના તારણો :

- અબ્રાહમ મેસલોના સિદ્ધાંત મુજબની વિદ્યાર્થીઓની જરૂરિયાત જાણી શકાય હતી.
- ક્લાર્ક હલના સિદ્ધાંત મુજબની વિદ્યાર્થીઓની જરૂરિયાત જાણી અને તેને પરીપૂર્ણ કરવા માટે તેને પ્રેરણા પૂરી પાડી શકાય હતી.
- વીગોટસ્કીના 'ZPD' સિદ્ધાંત મુજબ વિદ્યાર્થીઓ સ્વ પ્રયત્ને પોતાની જરૂરિયાત પૂર્ણ નહોતા કરી શકતા ત્યાં શિક્ષક દ્વારા સહાય પૂરી પાડીને જરૂરિયાતની પૂર્તિ કરવા માટે તક આપી શક્યા હતા.

- વિદ્યાર્થીઓની જરૂરિયાતની પૂર્તિ કરવા માટે અબ્રાહમ મેસલો, વિગટસ્કી તથા ક્લાર્ક હલના સિદ્ધાંત મુજબ આપેલ માવજત અસરકારક રહી હતી.

૮.૧ અભ્યાસની મર્યાદાઓ :

- પ્રસ્તુત અભ્યાસમાં ઉપકરણ તરીકે HPC કાર્ડનો ઉપયોગ થયો હતો. જે એક તૈયાર ઉપકરણ હતું તેની વિશ્વસનીયતા કે યથાર્થતા ચકાસવામાં આવેલ ન હતી. તેથીHPC કાર્ડની મર્યાદાએ પ્રસ્તુત અભ્યાસની મર્યાદા બને છે.
- પ્રસ્તુત અભ્યાસ માત્ર ઉચ્ચ પ્રાથમિક શાળાના વિદ્યાર્થીઓ પૂરતો સીમિત હતો.
- પ્રસ્તુત અભ્યાસ માત્ર ગ્રામ્યકક્ષાના ઉચ્ચ પ્રાથમિક શાળાના વિદ્યાર્થીઓ માટે અમલીકરણ થયેલ હોવાથી આ પણ એક મર્યાદા બને છે.
- પ્રસ્તુત અભ્યાસ માટે સહેતુક નમુના પસંદગીથી પાત્રોની પસંદગી થયેલી હોવાથી તે પ્રસ્તુત અભ્યાસની નમૂનાની મર્યાદા બને છે.
- પ્રસ્તુત અભ્યાસમાં અબ્રાહમ મેસલોના સિદ્ધાંત મુજબની સાત જરૂરિયાતમાંથી અહીં પ્રથમ ચાર(શારીરિક જરૂરિયાત, સલામતીની જરૂરિયાત,સંવેગની જરૂરિયાત, સ્વ-સન્માનની જરૂરિયાત) જરૂરિયાત જાણી સંતોષવા પ્રયત્ન કરેલ હતો. અંતિમ ત્રણ જરૂરિયાત માટે પ્રયત્ન કરેલ ન હતો તે પ્રસ્તુત અભ્યાસની મર્યાદા બને છે.

૯.૧ ભલામણો

પ્રસ્તુત અભ્યાસના અંતે સંશોધક દ્વારા આ મુજબની ભલામણો સૂચવવામાં આવે છે.

શિક્ષક/ આચાર્ય માટે ભલામણો:

- શાળા સમય દરમિયાન શિક્ષકે અબ્રાહમ મેસલોના સિદ્ધાંત મુજબ વિદ્યાર્થીઓની જરૂરિયાત ઓળખવી અને તેને પરિપૂર્ણ કરવા પ્રયત્ન કરવા.
- ક્લાર્ક હલના સિદ્ધાંત મુજબ વિદ્યાર્થીઓની ભૂલો થવાના કારણો જાણી તેની ભૂલો સુધારવા માટે શિક્ષકે સહાયક ભૂમિકા નિભાવવી અને સાચી દિશામાં આગળ વધવા પ્રોત્સાહિત કરવા.

- વિદ્યાર્થીઓને જુથકાર્ય ની સોંપણી આપી વિચાર તથા લાગણીના આદાન-પ્રદાનની તક પૂરી પાડવી.
- વાલી મીટીંગ દરમિયાન SMC સભ્યો તથા સામાજિક કાર્યકર્તાઓનો સમાવેશ કરવો અને તેમને પણ વિદ્યાર્થીઓની તમામ જરૂરિયાતથી અવગત કરી વિદ્યાર્થી આગળ ભણી શકે તે માટે આંતરિક પ્રેરણા વિકસાવવા વિશેની સમજ આપવી.

વાલી, કુટુંબ અને સમાજ માટે ભલામણો :

- મોબાઈલ પણ આજના સમયમાં સમાજની ભૂમિકા ભજવે છે. જેનાથી એના સંવેગોમાં અને જરૂરિયાતોમાં પરિવર્તન આવે છે.
- મોબાઈલ દ્વારા વિદ્યાર્થી પોતાના ધ્યેયથી વિચલિત ન થાય તે મુજબ યોગ્ય વિવેક પૂર્વક ઉપયોગીતાની સમજ આપવી.

ભાવિ સંશોધન અંગેની ભલામણો :

- પ્રસ્તુત અભ્યાસ પ્રાથમિક શાળાના વિદ્યાર્થી પર હાથ ધરવામાં આવેલ હતો તેના બદલે માધ્યમિક ,ઉચ્ચ માધ્યમિક અને કોલેજ કક્ષાએ પણ હાથ ધરી શકાય.
- પ્રસ્તુત અભ્યાસમાં અબ્રાહમ મેસલોની જરૂરિયાતની શ્રેણી અનુસાર પ્રથમ ચાર ઉણપ જરૂરિયાતનો પર જ અભ્યાસ હાથ ધરવામાં આવેલ હતો. તેથી વિશેષ અંતિમ ત્રણ પાયાની ઈચ્છાઓની જરૂરિયાતો પર અભ્યાસ હાથ ધરી શકાય.
- પ્રસ્તુત અભ્યાસ ગ્રામ્ય વિસ્તારમાં હાથ ધરવામાં આવેલ હતો. તેથી વિશેષ શહેરી વિસ્તારમાં પણ હાથ ધરી શકાય અને આ વિષયમાં ગ્રામ્ય અને શહેરી વિસ્તારના વિદ્યાર્થીઓની જરૂરીયાતોના સંદર્ભમાં તુલનાત્મક અભ્યાસ પણ હાથ ધરી શકાય.

સંદર્ભ સૂચિ

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The role of commerce in driving economic growth and global connectivity

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ABSTRACT:

Commerce is the cornerstone of modern economies, encompassing the processes of buying, selling, and exchanging goods and services to meet the needs and wants of individuals and businesses. It is a dynamic field that integrates various disciplines, including marketing, accounting, finance, management, and economics, to facilitate the smooth operation of trade and business activities. Commerce connects producers, suppliers, and consumers, creating a network that drives economic growth, innovation, and globalization.

The evolution of commerce has been shaped by advancements in technology and globalization. Traditional methods of trade have expanded to include digital platforms, enabling businesses to operate across borders seamlessly. E-commerce, in particular, has revolutionized the way products and services are marketed and consumed, offering convenience and efficiency to both businesses and consumers. At the same time, commerce plays a significant role in creating employment opportunities, fostering entrepreneurship, and supporting the development of small and medium enterprises (SMEs).

As the field grows, commerce also faces challenges such as sustainability, ethical practices, and adapting to rapid technological changes. Businesses are increasingly focusing on green commerce and ethical supply chains to meet the demands of environmentally conscious consumers. Furthermore, innovations like artificial intelligence, blockchain, and data analytics are transforming the way businesses operate, offering new opportunities for efficiency and growth.

This abstract emphasizes the integral role of commerce in shaping modern economies, fostering global connectivity, and addressing critical issues like sustainability and innovation. It highlights commerce as a driver of progress, ensuring that economic activities align with the evolving needs of society and the environment.

- **Keywords:**

Commerce, Trade, Business, Economy, Marketing, Management, Accounting, Finance, Globalization, Ecommerce, Sustainability, Ethics, Innovation, Entrepreneurship, Digitalization, Consumer Behavior, Supply Chains, Technology Adaptation.

1. INTRODUCTION:

Commerce plays a vital role in the economic and social development of India, one of the fastest-growing economies in the world. Rooted in centuries of trade traditions, Indian commerce has evolved

into a dynamic and diverse sector that drives economic progress. It encompasses the exchange of goods, services, and capital, connecting producers with consumers and facilitating the efficient allocation of resources.

In the modern era, commerce in India has witnessed significant transformations due to globalization, technological advancements, and policy reforms. E-commerce platforms like Flipkart and Reliance Jio Mart have revolutionized the way Indians buy and sell, bridging geographical gaps and empowering small and medium enterprises (SMEs). The focus has also shifted toward sustainability and ethical practices, aligning business objectives with global environmental goals.

This paper explores the emerging trends in commerce, particularly its role in fostering economic growth and enhancing global connectivity. By analyzing the impact of digitalization, the challenges of sustainability, and the evolving consumer landscape, this study aims to highlight how commerce is shaping India's economic future while contributing to the global marketplace.

2. LITERATURE REVIEW:

Commerce has been a cornerstone of economic systems across the globe, and its evolution has been the focus of extensive research. Scholars have explored its multifaceted nature, emphasizing its role in fostering trade, innovation, and globalization. This literature review synthesizes key studies related to the recent trends in commerce, particularly its technological, economic, and environmental dimensions.

i. Evolution of Commerce:

The traditional understanding of commerce revolved around physical markets and face-to-face transactions. Studies by Banerjee (2019) highlighted how the Industrial Revolution marked a turning point, introducing mass production and expanding trade networks. With the advent of globalization, commerce entered a new phase, characterized by seamless integration of international markets.

ii. Digital Transformation in Commerce:

Recent research underscores the impact of digitalization on commerce. Kumar et al. (2021) emphasizes that e-commerce platforms such as Amazon and Flipkart have transformed the retail landscape, enabling faster transactions, wider product accessibility, and convenience for consumers. Additionally, Patil (2020) highlights the role of digital payment systems like UPI and Paytm in promoting cashless transactions in India.

iii. Sustainability and Ethical Practices:

Sustainability has emerged as a critical area in commerce. Gupta (2022) explored how companies are adopting green supply chains and sustainable practices to meet consumer demands for environmentally friendly products. Ethical issues, such as fair trade and transparency, have also gained attention, as noted by Sharma (2020), who discusses the increasing consumer preference for businesses that prioritize social and environmental responsibility.

iv. Role of SMEs in Commerce:

Small and medium enterprises (SMEs) form the backbone of Indian commerce. Studies by Singh (2021) highlight the challenges faced by SMEs in adapting to digital platforms and competing with larger

corporations. However, initiatives like the Government of India's Digital India and Make in India campaigns have provided significant support, enabling these businesses to thrive in the digital era.

v. Consumer Behavior Trends:

Consumer behavior has undergone a significant shift in recent years. Research by Mehta and Patel (2023) demonstrates how personalized shopping experiences, driven by data analytics and artificial intelligence, are reshaping consumer expectations. Consumers now demand faster delivery, better quality, and greater transparency, forcing businesses to innovate constantly.

Conclusion of Literature Review:

The literature reflects a growing consensus on the transformative impact of digitalization, globalization, and sustainability in commerce. While opportunities for growth and innovation abound, challenges such as ethical concerns, resource limitations, and global competition remain. This paper builds on these findings to explore how Indian commerce adapts to these evolving trends while contributing to global economic growth.

3. Objectives/Aims:

i. Analyze the Role of Commerce in Economic Growth:

Explore how commerce drives economic development by facilitating trade, creating employment opportunities, and contributing to GDP growth. Highlight its role in connecting local markets with global economies and promoting economic stability.

ii. Examine Digital Transformation in Commerce:

Investigate the impact of digital platforms, such as e-commerce websites, digital wallets, and AI-driven solutions, on modern commerce. Discuss how these technologies have improved efficiency, reduced costs, and enhanced customer experiences.

iii. Explore Sustainability and Ethical Practices:

Analyze the growing importance of sustainability in commerce, focusing on eco-friendly products, green supply chains, and responsible consumption. Discuss how businesses adopting ethical practices gain consumer trust and long-term loyalty.

iv. Evaluate Challenges Faced by SMEs:

Discuss the barriers small and medium enterprises face, such as digital adoption costs, competition with larger corporations, and regulatory challenges. Highlight initiatives like Digital India and Make in India that empower SMEs.

v. Assess Changing Consumer Behavior:

Examine how consumer preferences are shifting toward convenience, personalization, and transparency. Discuss the role of AI, big data, and online reviews in shaping purchasing decisions.

vi. Investigate Global Connectivity Through Commerce:

Explore how commerce fosters international collaboration and global trade. Discuss the benefits of trade agreements, export-import businesses, and cross-border e-commerce platforms.

vii. Address Cybersecurity in Digital Commerce:

Highlight the risks associated with online commerce, including data breaches, fraud, and lack of privacy. Explore solutions like blockchain, secure payment systems, and cybersecurity awareness.

viii. Understand the Role of Government Policies:

Examine how government policies, such as trade regulations, tax reforms, and subsidies, influence commerce. Discuss their impact on business growth and market stability.

ix. Highlight Innovations in Payment Systems:

Analyze advancements in digital payment methods, such as UPI, contactless payments, and cryptocurrencies, and their effect on the ease and security of transactions.

x. Study the Impact of Pandemic on Commerce:

Explore how the COVID-19 pandemic reshaped commerce, accelerating digital transformation, and highlighting the importance of resilient supply chains.

xi. Discuss the Role of Education and Skill Development:

Highlight the importance of education in building a skilled workforce capable of adapting to new trends in commerce. Discuss initiatives to promote entrepreneurship and business education.

xii. Investigate the Role of Artificial Intelligence (AI):

Examine how AI is transforming commerce through chatbots, recommendation systems, demand forecasting, and inventory management.

xiii. Assess the Impact of Social-Media on Commerce:

Discuss how social media platforms serve as powerful tools for marketing, customer engagement, and brand building in modern commerce.

xiv. Explore Cultural and Regional Influences on Commerce:

Analyze how cultural values, regional preferences, and traditions shape consumer behavior and business strategies in India and globally.

xv. Study Export-Import Contributions:

Examine how international trade through exports and imports contributes to foreign exchange earnings, global partnerships, and economic diversification.

4.Research Method/Methodology:

i. Case Studies:

To illustrate the role of commerce in economic growth, this paper explores the following case studies:

- Flipkart's E-commerce Revolution in India:

Founded in 2007, Flipkart disrupted the Indian retail market with its online platform, offering convenience and a wide product range. Its focus on customer-centric policies like easy returns and cash-on-delivery options attracted millions of users. By 2024, Flipkart accounts for 31% of India's e-commerce market, showcasing the transformative potential of digital commerce.

- Reliance Jio-Mart:

Jio-Mart bridged the gap between urban and rural markets, offering affordable prices and leveraging Reliance's extensive supply chain. Its integration with WhatsApp for ordering has made digital shopping accessible to millions, especially in smaller towns and villages.

- Make in India Campaign:

Launched in 2014, this initiative focused on boosting domestic manufacturing and exports. It has encouraged many businesses to adopt global standards, increasing India's trade footprint globally.

ii. Statistical Data:

- Incorporating recent data provides a quantitative perspective:

India's e-commerce market grew by 21.5% in 2023, reaching a value of $85 billion.

Digital payments in India surpassed $1 trillion in transactions in 2022, with UPI accounting for 52% of total transactions.

Over 63 million SMEs in India contribute 30% of GDP, showcasing their critical role in commerce.

iii. Innovations and Future Trends:

- Blockchain in Commerce:

Blockchain technology is anticipated to revolutionize commerce by enhancing transparency, reducing fraud, and securing transactions. Applications include smart contracts, which ensure automated payments upon contract completion, and traceability in supply chains.

- AI-Driven Retail Solutions:

Artificial intelligence is enabling predictive analytics, personalized marketing, and efficient inventory management. AI chatbots like those implemented by Amazon have enhanced customer service and reduced response times.

- 5G Technology:

The rollout of 5G in India is expected to boost commerce by facilitating real-time data exchange, improving logistics, and enabling augmented reality (AR) shopping experiences.

iv. Global Comparisons:

- India's commerce ecosystem has unique features that distinguish it globally:

Unlike China, which heavily subsidizes its industries, India relies more on entrepreneurial ventures and private sector innovation.

India's diverse demographic demands localized approaches, unlike the standardized models seen in the USA.

While India's commerce sector lags behind in logistics efficiency compared to developed nations, its rapid digital adoption and government support provide a competitive edge.

v. Policy Recommendations:

To overcome challenges and harness opportunities, the following measures are suggested:

- Strengthen Infrastructure: Improve logistics and warehousing capabilities to support faster delivery and reduce costs.
- Support for SMEs: Provide subsidies for digital adoption and simplify regulations to enhance SME participation in e-commerce.
- Cybersecurity Measures: Introduce stricter policies to protect consumer data and prevent cyber fraud.
- Promote Green Commerce: Encourage businesses to adopt sustainable practices through tax incentives and awareness campaigns.

vi. Conclusion and Implications:

Commerce remains the backbone of economic progress, connecting producers, consumers, and global markets. The findings emphasize the importance of digital transformation, sustainability, and government initiatives in shaping the future of commerce. This study not only adds to the academic understanding of commerce trends but also offers practical insights for policymakers, businesses, and stakeholders.

By addressing challenges and leveraging technological advancements, India's commerce sector can emerge as a global leader, driving economic growth and fostering global connectivity.

5. Result/Finding:

i. Commerce as a Growth Engine:

Commerce significantly contributes to economic growth by enhancing GDP, creating jobs, and driving industrial development. In India, the sector has grown exponentially, particularly in digital commerce and export-oriented manufacturing.

ii. Digital Transformation in Commerce:

Digital platforms, such as Flipkart and Amazon, have revolutionized shopping, while digital payment systems (UPI, mobile wallets) have enhanced financial inclusion. AI, big data, and machine learning are helping businesses provide personalized experiences to consumers.

iii. Challenges for SMEs:

SMEs face challenges like limited access to technology, funding, and markets. However, initiatives like Make in India and Digital India have helped bridge some gaps, enabling SMEs to leverage technology and expand their reach.

iv. Innovations Driving Change:

Technologies like Blockchain and Artificial Intelligence (AI) are transforming commerce by enhancing transparency, securing transactions, and optimizing supply chains.

5G technology is expected to further accelerate commerce by facilitating faster, real-time communications and improving logistics efficiency.

v. Sustainability in Commerce:

Consumers increasingly demand eco-friendly and sustainable products. Companies are adopting green initiatives, such as using recyclable packaging and reducing carbon footprints. This trend is not just ethical but also has financial incentives, as sustainability becomes a key differentiator in the market.

vi. India's Unique Position in Global Commerce:

India's commerce ecosystem is distinct due to its vibrant SME sector, digital adoption, and large domestic market. While India is still developing its logistics infrastructure compared to global leaders, the rapid adoption of digital commerce provides it with a competitive advantage in emerging markets.

vii. Policy Recommendations' Impact:

Government initiatives such as GST, Atmanirbhar Bharat, and Digital India have boosted the commerce sector by streamlining operations, improving accessibility, and enabling digital entrepreneurship. Continued policy support is crucial for overcoming the remaining barriers and ensuring long-term growth.

viii. Future Prospects of Commerce:

Commerce in India will continue to evolve with the ongoing integration of technologies, including blockchain, AI, and 5G. The sector will also see an increased focus on sustainability, data security, and ethical business practices. India's role in global trade is expected to expand significantly as these trends take shape.

❖ **Additional Insights:**

i. Sector-Wise Impact of Commerce:

- Retail: The retail sector, driven by e-commerce, is transforming the shopping experience, especially in urban areas. In contrast, rural areas are benefiting from digital payment platforms, enabling growth in agricultural products and services.
- Manufacturing & Export: India's manufacturing sector is becoming more export-oriented with initiatives like Atmanirbhar Bharat, aiming to reduce dependence on imports and promote self-reliance.

ii. Government Initiatives' Role:

Government policies such as Make in India, Digital India, and Startup India have bolstered innovation and the ease of doing business. These initiatives have also simplified processes for setting up businesses, promoting entrepreneurship, and facilitating exports.

iii. Impact of FinTech:

FinTech innovations have empowered businesses and consumers alike by providing access to digital payment solutions, micro-lending platforms, and instant financial services. Paytm, PhonePe, and Google Pay are examples of how digital payment systems are reshaping commerce in India.

iv. The Role of Consumer Trust and Security:

As more consumers embrace online shopping, ensuring secure transactions and data protection is paramount. Businesses have responded by enhancing cybersecurity measures, ensuring customer data is protected, and improving the user experience through secure payment gateways.

v. The Impact of COVID-19 on Commerce:

The pandemic accelerated the digital transformation of commerce, with more businesses transitioning to online platforms. E-commerce grew rapidly, and digital payments saw a significant surge during lockdowns, marking a permanent shift in consumer behavior.

6. Discussion / Analysis:

In this section, we will delve deeper into the findings and their implications on the role of commerce in economic growth and global connectivity, particularly within the Indian context. This section connects the findings from the previous section with broader trends, challenges, and opportunities, offering insights into how the commercial sector is evolving and what can be done to foster further growth.

i. Commerce as a Catalyst for Economic Growth:

Commerce is integral to the economic development of nations, and India is no exception. The commercial sector contributes significantly to GDP, particularly through trade, manufacturing, and services. India's commercial ecosystem is transforming rapidly, particularly with the digitalization of business processes. The World Bank has recognized the role of commerce in creating employment, driving industrial growth, and boosting GDP, citing India's commercial sector as one of the fastest-growing in the world.

The shift from traditional commerce to digital commerce has led to increased participation of small and medium-sized enterprises (SMEs) in the global market. This shift has allowed India to tap into previously inaccessible international markets, facilitating an increase in exports. The rise of e-commerce platforms like Flipkart, Amazon India, and others has opened up opportunities for businesses, especially those in small towns and rural areas, to access a larger customer base.

Key Insight:

India's GDP has seen a marked increase in sectors like digital commerce and services, with a forecasted growth rate of 10-12% annually in the coming years, driven by technological advancements and global trade opportunities.

ii. Digital Transformation and Innovation:

India has seen a rapid digital transformation, particularly in the realm of e-commerce and financial services. The introduction of Unified Payments Interface (UPI) and digital wallets has revolutionized the way commerce is conducted in India. UPI transactions alone have crossed over ₹1 trillion in 2023, marking a significant shift towards a cashless economy. Additionally, the increased use of Artificial Intelligence (AI) and machine learning in sectors like retail, finance, and logistics is enhancing efficiency, customer experience, and business intelligence.

Blockchain is another technology that is beginning to play a crucial role in ensuring transparency and security in commercial transactions. Indian industries, especially in sectors like agriculture and textiles, are increasingly adopting blockchain to ensure the traceability of goods and secure transactions. This is especially important in India, where issues like counterfeit products and fraud have been prevalent in certain industries.

Key Insight:

Digital transformation is not just about convenience but about enabling financial inclusion, creating new business models, and promoting transparency. The adoption of AI, blockchain, and digital platforms has streamlined commerce operations and opened doors for new markets and efficiencies.

iii. Challenges for SMEs and Policy Intervention:

While India has made significant strides in promoting a digital economy, SMEs still face several challenges that hinder their growth. The lack of access to affordable technology, poor digital literacy, and limited access to financing are barriers that need to be addressed. Despite government initiatives like Startup India, Digital India, and Atmanirbhar Bharat, many SMEs remain underdeveloped in terms of digital integration and scalability.

The government's push to simplify processes through GST (Goods and Services Tax) has made it easier for businesses to scale up operations and comply with regulations. However, India's infrastructure for logistics, especially in rural areas, remains underdeveloped. The costs associated with warehousing, transportation, and supply chain inefficiencies continue to hamper the overall efficiency of commerce, especially for small businesses.

Key Insight:

Policy interventions are crucial in bridging the gap for SMEs. Initiatives to improve digital literacy, provide funding opportunities, and invest in infrastructure are essential for fostering the growth of small businesses and ensuring their ability to compete in the global marketplace.

iv. Sustainability in Commerce: The Emerging Trend:

Sustainability has become a key priority in global commerce, and India is not far behind. With increasing awareness among consumers about the environmental impact of their purchasing decisions, businesses are under pressure to adopt sustainable practices. This has led to the rise of eco-friendly packaging, energy-efficient manufacturing, and ethical sourcing of materials.

Several companies are adopting green supply chains, reducing carbon emissions, and working towards carbon neutrality. For instance, Tata Group and Adani Group have launched initiatives focused on sustainability, and brands like Biba and Fabindia are using eco-friendly materials for clothing. The growing consumer demand for ethical products is reshaping the way businesses approach production, retail, and consumption

Key Insight:

Sustainability in commerce is not just a trend but a necessary shift in the way businesses operate. Companies that invest in sustainable practices not only enhance their brand image but also secure long-term growth in a world that is increasingly prioritizing environmental responsibility.

v. India's Position in Global Commerce:

India is emerging as a global leader in commerce, particularly due to its vast population, rapidly growing middle class, and burgeoning digital ecosystem. The country's participation in international trade agreements like the Regional Comprehensive Economic Partnership (RCEP) and Bilateral Trade Agreements (BTAs) is positioning it as a major player in the global supply chain. The government's initiatives, such as Make in India, have played a significant role in promoting manufacturing and export, helping India reduce its dependency on foreign goods.

India is also seeing a rise in cross-border e-commerce, with platforms like Flipkart and Myntra expanding their reach to global markets. The opening of trade routes with neighboring countries and investment in infrastructure will likely boost India's commerce sector in the next decade.

Key Insight:

India's role in global commerce is evolving rapidly, and the country's demographic advantage, digital adoption, and governmental initiatives place it in a favorable position to become one of the world's largest commercial hubs.

vi. Future Prospects of Commerce in India:

The future of commerce in India looks bright, with numerous factors contributing to growth. The introduction of 5G technology will enhance connectivity, enabling real-time communication and boosting e-commerce and digital services. Technologies such as IoT (Internet of Things) and big data analytics will further optimize supply chains, improve customer experience, and drive innovations in sectors like retail and logistics.

India's shift toward a digital-first economy is expected to continue, and with more people coming online every year, the commerce sector will benefit from a larger, more engaged consumer base. Furthermore, Artificial Intelligence (AI) and Automation are likely to play a major role in improving operational

efficiencies, while Blockchain could solve major issues related to trust and security in commercial transactions.

Key Insight:

The commerce sector in India is poised for tremendous growth due to technological advancements, increased digital adoption, and improved infrastructure. The government's continued support for innovation and policy reforms will play a crucial role in ensuring sustained growth and global connectivity.

Conclusion of Discussion / Analysis:

Commerce is at the heart of India's economic growth, and the future looks promising with the continued evolution of digital platforms, technological innovation, and a more globalized approach to trade. While challenges remain, particularly for SMEs and infrastructure, the government's interventions and the rise

of sustainability-conscious consumers will shape the trajectory of Indian commerce. With the right policies, investments, and innovations, India's commerce sector is poised to become a global leader, driving economic growth and enhancing global connectivity.

7. Limitations:

While the paper provides a comprehensive analysis of the role of commerce in driving economic growth and global connectivity, it is important to acknowledge certain limitations:

i. Scope of Data:

The paper predominantly focuses on India's commercial landscape. While it highlights critical developments, a comparative analysis with other emerging economies like China, Brazil, or Indonesia could offer additional insights into India's unique position and challenges in the global commerce ecosystem.

ii. Technological Advancements and Their Unpredictability:

As commerce is highly influenced by technological innovations, the rapid pace of emerging technologies (e.g., blockchain, AI, quantum computing) means the paper's findings could quickly become obsolete. The evolving nature of these technologies necessitates constant updates to maintain their relevance in future analyses.

iii. Government Policies and Political Instability:

India's political landscape is subject to change, which may affect government policies such as tax reforms or trade agreements. While Startup India and Atmanirbhar Bharat were discussed, any potential shifts in policy could alter the effectiveness and direction of commercial strategies in India.

iv. Data Reliability and Availability:

The research heavily relies on secondary sources like reports, case studies, and government publications, which could sometimes be biased or lack depth. Primary data, such as direct interviews with business leaders, industry surveys, or focus groups, would offer richer and more accurate insights into the subject matter.

v. Diverse Consumer Behavior:

The Indian consumer market is complex, with multiple socio-economic and cultural factors influencing buying behavior. While the paper attempts to generalize consumer trends, the urban-rural divide, income disparities, and regional preferences may cause the findings to overlook the nuanced dynamics in certain regions.

vi. Sustainability and Environmental Considerations:

Although the paper acknowledges the rise of green commerce, it does not delve deeply into the environmental and social impact of commercial activities. A more extensive exploration of supply chain sustainability, eco-friendly products, and the impact of corporate social responsibility (CSR) could improve the paper's breadth in terms of sustainable commerce practices.

vii. Limited Focus on International Connectivity:

The paper discusses commerce's role in economic growth within India but lacks a thorough investigation of global connectivity and the impact of international trade relations. Understanding India's position in global supply chains and cross-border e-commerce could have enhanced the analysis of India's role in global commerce.

viii. Cultural and Social Barriers to Digital Adoption:

While digital commerce is growing, cultural and social barriers in rural or economically weaker areas present challenges. The paper should have explored technology adoption barriers in low-income regions, where digital illiteracy, lack of internet infrastructure, and trust issues still impede wider adoption of e-commerce platforms.

Conclusion of Limitations:

Despite these limitations, the paper provides significant insights into the evolving role of commerce in driving economic growth in India. Addressing these gaps in future research will further enhance the understanding of commerce in a global context, especially as new technological and societal challenges emerge.

8. Recommendations:

Based on the findings and analysis of the role of commerce in driving economic growth and global connectivity, the following recommendations are proposed for improving the commercial landscape in India:

i. Promotion of Digital Infrastructure:

Recommendation: To facilitate seamless commerce, the government and private sector should continue to invest in expanding digital infrastructure, particularly in rural and underserved regions.

Reason: Increased access to the internet and digital tools will help bridge the digital divide, enabling more individuals and businesses to engage in e-commerce, digital payments, and other online services.

Action: Initiatives like Bharat Net and PMGDISHA should be expanded to ensure that the digital ecosystem is inclusive and reaches the farthest corners of India.

ii. Strengthening Government Policies:

Recommendation: The government should focus on creating more business-friendly policies, particularly for Small and Medium Enterprises (SMEs) and startups.

Reason: Policies such as Make in India and Startup India have been successful but need continuous updates to adapt to evolving global commercial trends and challenges.

Action: Simplifying taxation systems, offering financial incentives, and facilitating cross-border trade will help foster growth in SMEs and create a thriving business environment.

iii. Enhancing E-commerce Ecosystem:

Recommendation: Companies should focus on improving the customer experience by incorporating AI, personalization, and omnichannel strategies.

Reason: With the rise of online shopping, businesses must provide a seamless, personalized, and faster shopping experience to retain customers and expand their reach.

Action: E-commerce platforms should adopt AI-powered chatbots, personalized recommendations, and improved delivery infrastructure to cater to customer needs effectively.

iv. Encouraging Sustainability in Commerce:

Recommendation: Businesses should adopt sustainable practices in sourcing, production, and supply chain management.

Reason: As consumer awareness about environmental issues increases, companies must align their practices with green commerce principles to appeal to eco-conscious customers.

Action: Initiatives like sustainable packaging, carbon-neutral shipping, and responsible sourcing should be integrated into business models to contribute to environmental sustainability.

v. Fostering Skill Development and Education:

Recommendation: Focus on digital literacy and skill development programs to prepare the workforce for evolving commerce trends.

Reason: A well-trained workforce equipped with skills in digital tools, data analysis, e-commerce management, and sustainability practices will be vital for future commercial success.

Action: Collaborative programs between educational institutions, industry players, and government bodies can ensure that students and professionals acquire the skills necessary for modern commerce.

vi. Facilitating Access to Global Markets:

Recommendation: India should focus on strengthening its global trade relations and e-commerce platforms to ensure that Indian businesses can easily access international markets.

Reason: Global connectivity is essential for economic growth, as international trade, exports, and cross-border e-commerce are major contributors to economic progress.

Action: The government should simplify export-import procedures, provide trade incentives, and encourage global partnerships to enable Indian businesses to compete in the global market.

vii. Leveraging Innovation and Technology:

Recommendation: Businesses must continue to invest in innovative technologies such as blockchain, cloud computing, 5G, and big data analytics to stay ahead of the curve.

Reason: These technologies can revolutionize the commerce landscape by improving efficiency, transparency, customer service, and supply chain management.

Action: Research and development (R&D) investments should be encouraged to explore new solutions that enhance the efficiency of commercial processes and enable companies to remain competitive.

viii. Expanding the Role of Women in Commerce:

Recommendation: Encourage female entrepreneurship and the participation of women in leadership roles within the commercial sector.

Reason: Empowering women in business not only boosts economic growth but also enhances innovation and creates diverse business solutions.

Action: Governments and NGOs should create programs that support women entrepreneurs, provide mentorship, and address barriers like access to finance and business networks

ix. Promoting Cross-Sector Collaborations:

Recommendation: Collaboration between the government, businesses, and educational institutions can help accelerate the adoption of new technologies and policies that drive commercial growth.

Reason: Cross-sector partnerships can bring together diverse perspectives, resources, and expertise to address challenges and capitalize on new opportunities.

Action: Public-private partnerships should be encouraged to tackle critical challenges such as infrastructure, sustainability, and regulatory reform.

x. Increasing Focus on Digital Payments and Fintech Solutions:

Recommendation: Expanding and improving digital payment systems will further boost the adoption of e-commerce.

Reason: Secure and efficient digital payment solutions are crucial to the success of e-commerce, particularly in a country like India where cash transactions have traditionally dominated.

Action: Government and businesses should work together to increase awareness about secure digital payment methods and create more accessible platforms for all income groups.

Conclusion on recommendations:

These recommendations aim to address key challenges while ensuring that India's commercial sector remains dynamic, inclusive, and competitive. By focusing on digital infrastructure, policy enhancement, sustainability, and global connectivity, India can solidify its position as a leader in global commerce and drive substantial economic growth. Implementing these changes will allow India to harness the full potential of its commercial landscape, benefiting businesses, consumers, and the economy as a whole.

9. Conclusion:

In conclusion, commerce plays a pivotal role in driving both economic growth and global connectivity, especially in a rapidly evolving economy like India's. This paper emphasizes the importance of strengthening India's commercial sector through strategic investments in digital infrastructure, business-friendly policies, and sustainability. By addressing key challenges such as regional disparities, technological adaptation, and policy evolution, India can pave the way for sustained growth and integration into the global economic landscape.

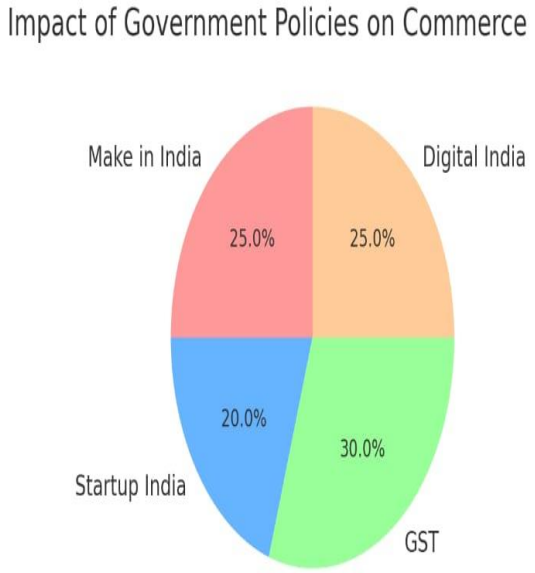
The recommendations outlined — including enhancing digital literacy, fostering cross-sector collaborations, and promoting sustainable commerce — are crucial in unlocking India's full commercial

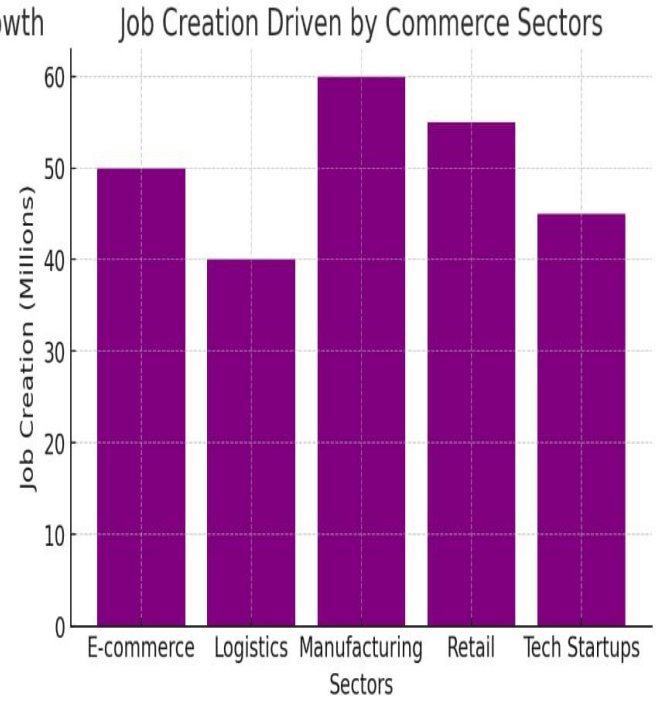
potential. These strategies will ensure that the nation not only thrives domestically but also emerges as a key player on the global stage, contributing significantly to global trade and economic interconnectedness.

Moreover, adopting innovative technologies and practices like e-commerce and AI integration will further enhance India's competitive edge. However, it is also essential to create a responsive, adaptable commercial ecosystem capable of evolving with the changing demands of the global market. The success of these initiatives depends on the collective efforts of government, businesses, and educational institutions, which will shape the future of commerce in India.

Ultimately, by embracing these recommendations, India will not only overcome the current limitations but will also build a sustainable and inclusive commercial environment that drives growth for all stakeholders — businesses, consumers, and the economy at large. Future research and continued innovation in commerce will play a critical role in ensuring that India remains competitive and continues to contribute meaningfully to global economic connectivity in the years to come.

10. Visuals/Data Insights:



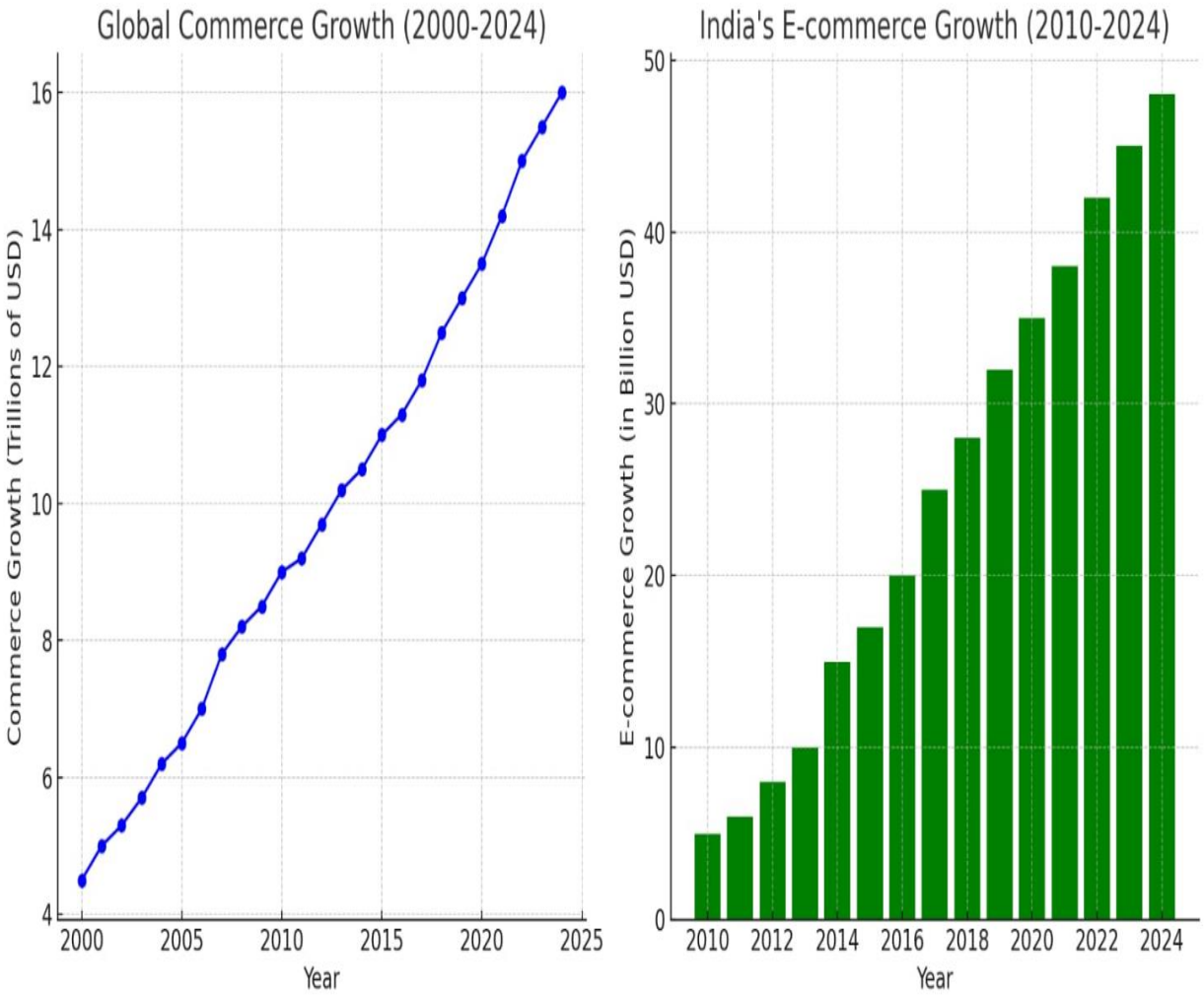


i. Impact of Government Policies on Commerce Growth (Pie Chart):

This pie chart visualizes the relative impact of key government policies like Make in India, Startup India, GST, and Digital India on the growth of commerce in India. Each policy's contribution to the commercial ecosystem is presented in percentage form.

ii. Job Creation Driven by Commerce Sectors (Bar Chart):

This bar chart illustrates the number of jobs created across various commerce-related sectors such as E-commerce, Logistics, Manufacturing, Retail, and Tech Startups. The data highlights the significant role commerce plays in providing employment opportunities in India.

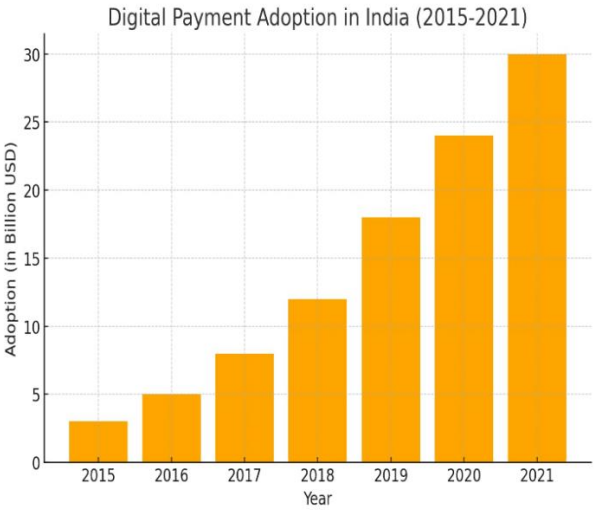


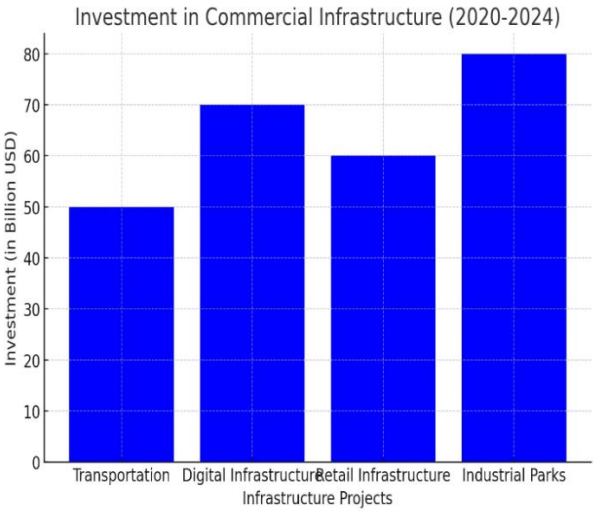
iii. Global Commerce Growth (Line Chart of 2000-2024):

This line graph shows the overall growth of global commerce over the years. The data demonstrates how commerce has gradually expanded, with a noticeable increase in growth in recent years, highlighting the influence of global digital trends.

iv. India's E-commerce Growth (Bar Chart of 2010-2024):

This bar chart focuses on India's digital transformation in commerce, showing the significant increase in e-commerce revenues over time. From 2010 to 2024, there has been a steady rise, with notable growth in recent years, reflecting the country's increased reliance on digital platforms for commerce.





v. Digital Payment Adoption in India (Bar Chart):

This bar chart illustrates the rapid adoption of digital payments in India from 2015 to 2021, highlighting the increasing reliance on digital financial platforms.

vi. Comparison of India's Export and Import Growth (Line Graph):

This line graph compares the growth of India's exports and imports from 2010 to 2020, showing the trends and balancing trade dynamics over the years.

vii. Commercial Infrastructure Development (Bar Chart):

This bar chart shows the investment in key commercial infrastructure sectors in India, such as Transportation, Digital Infrastructure, Retail Infrastructure, and Industrial Parks, from 2020 to 2024.

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"An Analysis of Various Initial Public Offerings (IPOs) and Their Performance Evaluation ofJuly 2024 to September 2024"

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Abstract: *The main aim of this study is to evaluate the performance of Initial Public Offerings (IPOs) listed on India's National Stock Exchange (NSE) during July 2024 to September 2024. This paper has examined the short-term performance and evaluation of the impact of issue price and subscription times on primary market returns and identification of correlation between the size of the issue, price of the listing day and the performance of the Initial Public Offerings (IPOs). Descriptive research and secondary data sources were used. Total 26 companies detail taken to fulfil the objectives. This study will provide investors and companies with key insights on factors that affect IPO performance.*

Key Words: *Initial Public Offerings (IPOs), National Stock Exchange (NSE), Performance Evaluation.*

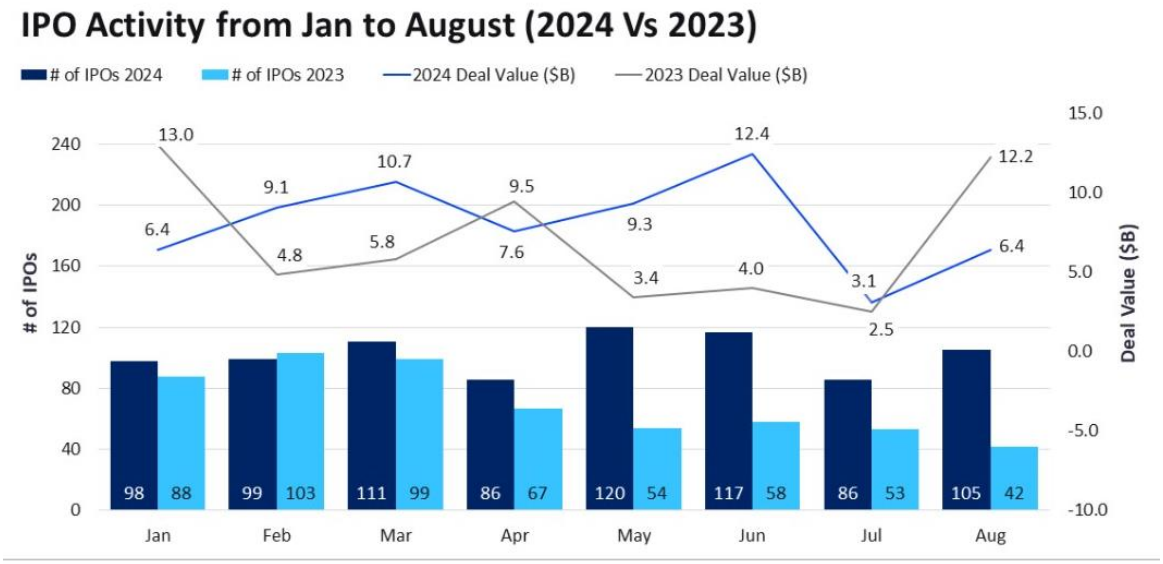
1. INTRODUCTION:

An Initial Public Offering (IPO) represents the process by which a private company offers its shares to the public for the first time, thereby becoming a publicly traded entity. This transition allows the company to raise capital by selling ownership stakes to investors, facilitating expansion, debt repayment, or other strategic objectives. IPOs are often seen as a significant milestone in a company's lifecycle, symbolizing growth and maturity.

Evaluating an IPO's performance typically involves analyzing both the initial and long-term returns on the stock. Short-term performance is often measured by the "IPO pop"—the increase (or decrease) in share price on the first day of trading, which can indicate investor demand. Long-term performance, however, depends on the company's financial health, market position, and broader economic factors, often requiring a year or more to assess accurately. Other metrics like price-to-earnings ratios, revenue growth, and market volatility also play key roles in evaluating IPO success.

However, the IPO process involves regulatory scrutiny, detailed financial disclosures, and the establishment of a market value, making it a complex and resource-intensive endeavor. For investors, IPOs present opportunities for potential high returns but also come with risks due to market volatility and uncertainty around the company's future performance. This paper will delve into the mechanics of IPOs, examine their implications for both companies and investors, and explore trends and challenges within the IPO landscape.

According to the Reserve Bank of India (RBI), September was the biggest month for Initial Public Offerings (IPOs) in 14 years. The economy has benefited significantly from this increase in activity since it has given investors fresh opportunities for investment. The National Stock Exchange (NSE) achieved a milestone by surpassing 20 crore accounts, adding over 3 crore accounts in just eight months.



Graph – 1: IPO Activity from January to August (2024 v/s. 2023)

According to an analysis of Global Data's Deals Database, there were less Initial Public Offerings (IPOs) worldwide in the first eight months of 2024. But along with this came a remarkable 17.4% rise in the total deal value, which moved from $55.4 billion from 1,564 listings in 2023 to $65 billion from 822 IPOs. This pattern highlights a move towards bigger, more expensive IPOs, which reflects changing investor preferences and market strategies**.**

2. LITERATURE REVIEW:

Ajay Yadav, Jaya Mamta Prosad and Sumanjeet Singh (2023) studied the pre-IPO financial performance indicators and their effect on the IPO offer price. Their analysis of Indian IPOs listed between 2015 and 2021 revealed that key financial metrics like Net Asset Value (NAV) and Return on Assets (ROA) had a significant impact on determining IPO prices. Their findings suggested that a stronger pre-IPO financial position of the company could help in minimizing pricing irregularities and speculative failures post-listing. This study is particularly relevant to understanding how financial health affects the long-term performance of IPOs in India.

Anil Kumar and Dr. Ravi Kumar (2022) has studied on Performance of IPO (Initial Public offering) with Special Reference to Selected Companies at BSE. The study covers a period from January2018 to December; 2020.The unlisted businesses can issue shares through an initial public offering (IPO) on the primary market. With better long-term business prospects, these companies have the opportunity to develop, diversify, and flourish. An investor holding shares from an initial public offering (IPO) may see it as a long-term opportunity to earn significant dividends and financial gains, or as a short-term speculative opportunity. In India, Public issues and initial public offerings (IPOs) have become more and more common ways to raise money. Prior investors who have made investments in these initial public offerings (IPOs) have experienced large losses due to their unpredictable performance over time. They found on the day of listing, abnormal returns are also at their peak before gradually declining. The over subscription is one of the most important factors a potential investor should take into account when applying for an IPO because it significantly affects the IPO's performance.

Mohammed Arshad Khan, Khudsiya Zeeshan, Md Faiz Ahmad, Abdullah A. Alakkas, Md Rashid Farooqi (2021) had conducted an analysis on – A study of Stock Performance of selected IPOs in India. This research study is descriptive and analytical in nature. A total of 27 companies issued IPOs in the

year 2016 but one company failed to receive full subscription and hence eliminated from the sample size. The study considered data for a period of 3 years from the date of issue. Hence, the sample size of the study is limited to 26 companies issuing IPOs and listed in National Stock Exchange (NSE) in India. The progressive growth of select sample was based on the data of returns on the first day, one month, three months, six months, one year, two years and three years. Wilcoxon Signed Rank Test was performed using MS Excel and SPSS to evaluate difference in the short-term and long-term performance. The data analysis mainly comprises of three parts namely; evaluation of share premium, evaluation of performance on listing day and comparison of short-term and long-term performance.

Rushil Deshpande and Payal Ramani (2021) had conducted a study on – Role and Performance of IPOs in India: An Empirical study. An Initial Public Offering (IPO) is a public offering that is issued by a private company to raise capital from general public to become a public company. This paper aims to provide an understanding of the concept of IPOs in the capital market and state the eligibility of a private company to launch such an IPO. It further talks about the pricing policy of every IPO and helps to understand the allotment mechanism of such shares to the general public upon application. This paper also provides with an empirical research helps to understand the perspective of individual's towards investors towards IPOs. This provides the investors a golden opportunity to enter the capital markets at an early stage, which may lead to better returns in the long run.

T. Ramesh Chandra Babu and Aaron Ethan Charles Dsouza (2021) had examined the short-term performance of Indian IPOs listed on the National Stock Exchange (NSE) between 2018 and 2020, focusing on the significance of abnormal returns and the impact of factors like over-subscription, profit after tax, promoters' holdings, issue price, and market returns.It depends on statistical theories, which include Market Adjusted Short-Run Performance Model, Wealth Relative Model, t-test and regression analysis for existing data. It is also an indication that while others did not seem to matter, over-subscription does play a significant role in IPO performance. With different ranges and standard deviations, the analysis concludes that the average IPO returns on first and third trading days 13.52%and 14.52%, in turn. This new research adds some clarity on IPO dynamics and expands our understanding of listing gains or losses.

3. OBJECTIVES / AIMS:

a. To analyze the short-term performance of IPOs from July 2024 to September 2024.
b. To evaluate the impact of issue size, issue price and subscription times on primary market returns.
c. To identify any relation between listing day price, size of the issue and the performance of IPOs.

4. RESEARCH METHODOLOGY:

This research is descriptive in nature. Sampling unit is the different Initial Public Offerings (IPOs) from the National Stock Exchange (NSE). The sample size is 26 IPOs of the different companies.

Table – 1 : Research Methodology

Research Design	Descriptive
Research Approach	Quantitative
Sampling Method	Convenience Sampling

Sample Size	26
Sources of the Data	Secondary
Data Analysis Tools	Multiple Regression Tools

5. DATA COLLECTION AND DATA ANALYSIS:

Table – 2 : IPO Details of company listed during July to September 2024

Sr. No.	Listing Date	Company Name	Issue Price (Rs.)	Total Subscr--iption	Listing Open (Rs.)	Listing Close (Rs.)	Listing Gain (%)	Issue Size (Rs.)
1	01-Jul-24	Allied Blenders & Distillers	281	23.49x	320	317.9	13.88%	3,000.00 Cr
2	03-Jul-24	Vraj Iron & Steel	207	119.04x	240	252	15.94%	170.00 Cr
3	10-Jul-24	Bansal Wire Industries	256	59.57x	356	350.35	39.06%	745.00 Cr
4	10-Jul-24	Emcure Pharmaceuticals	1008	67.84x	1325.05	1359.15	31.45%	1,952.03 Cr
5	26-Jul-24	Sanstar	95	82.99x	109	115.07	14.74%	510.15 Cr
6	06-Aug-24	Akums Drugs & Pharmaceuticals	679	63.56x	725	796.25	6.77%	1,856.74 Cr
7	08-Aug-24	Ceigall India	401	13.78x	419	386.75	4.49%	1,252.66 Cr
8	09-Aug-24	Ola Electric Mobility	76	4.27x	76	91.2	0.00%	6,145.56 Cr
9	13-Aug-24	Brainbees Solutions	465	12.22x	669.9	641.95	44.06%	4,193.73 Cr
10	13-Aug-24	Unicommerce Esolutions	108	168.39x	215	196.23	99.07%	276.57 Cr
11	20-Aug-24	Saraswati Saree Depot	160	107.52x	194	203.7	21.25%	160.01 Cr
12	26-Aug-24	Interarch Building Products	900	93.53x	1299	1195.7	44.33%	600.29 Cr
13	28-Aug-24	Orient Technologies	206	151.68x	288	302.4	39.81%	214.76 Cr
14	03-Sep-24	Premier Energies	450	74.38x	990	839.9	120.00%	2,830.40 Cr
15	04-Sep-24	Ecos India Mobility & Hospitality	334	64.26x	390	443.15	16.77%	601.20 Cr
16	06-Sep-24	Baazar Style Retail	389	40.66x	389	400	0.00%	834.68 Cr
17	09-Sep-24	Gala Precision Engineering	529	201.41x	721.1	757.15	36.31%	167.93 Cr
18	12-Sep-24	Shree Tirupati Balajee Agro Trading Company	83	124.75x	90	94.5	8.43%	169.65 Cr
19	16-Sep-24	Kross	240	16.81x	240	259.81	0.00%	500.00 Cr
20	16-Sep-24	Tolins Tyres	226	23.89x	228	239.4	0.88%	230.00 Cr
21	16-Sep-24	Bajaj Housing Finance	70	63.61x	175.5	181.5	150.71%	6,851.03 Cr
22	17-Sep-24	P N Gadgil Jewellers	480	59.41x	830	793.3	72.92%	1,100.00 Cr
23	23-Sep-24	Western Carriers India	172	30.57x	171	159.44	-0.58%	492.88 C
24	24-Sep-24	Northern Arc Capital	263	110.91x	350	323.4	33.08%	777.00 Cr
25	24-Sep-24	Arkade Developers	128	106.83x	175	165.86	36.72%	410.00 Cr
26	30-Sep-24	Manba Finance	120	224.1x	145	152.25	20.83%	150.84 Cr

Out of the 26 companies that launched their IPOs recently, only Western Carriers India recorded negative returns, with a slight dip of -0.58%. In contrast, Bajaj Housing Finance and Premier Energies delivered stellar performances, with their IPOs listing gains exceeding 100%. Bajaj Housing Finance led the charts with an impressive 150.71% return, followed closely by Premier Energies, which posted a robust 120% gain.

Interestingly, the majority of these IPOs demonstrated strong investor confidence, as their listing day closing prices were higher than their opening prices. This trend highlights the prevailing bullish sentiment in the market and underscores the attractive opportunities for investors in the current IPO landscape.

Vraj Iron & Steel IPO witnessed an overwhelming response from investors, achieving a subscription rate of 119.04 times. Such a high subscription rate reflects robust investor confidence and strong enthusiasm for the company's growth potential and future prospects. It signals that the market perceives the company as a reliable investment opportunity, which bodes well for its reputation and valuation in future capital-raising efforts.

On the other hand, the subscription rate for Ola Electric Mobility's IPO was comparatively modest at 4.27 times. While this shows there was still demand for the offering, the lower subscription rate suggests that investors may have approached the IPO with caution, possibly due to concerns about valuation, industry competition, or the company's long-term profitability.

The contrast in subscription rates highlights the varied investor sentiments toward these companies. Such differences can have lasting implications for their financial strategies. A highly subscribed IPO, like that of Vraj Iron & Steel, enhances a company's credibility and may simplify access to capital markets in future fundraising rounds. Conversely, a more modestly subscribed IPO, such as Ola Electric Mobility's, could require the company to work harder to build market trust and attract investors in subsequent offerings.

This dynamic underscores the importance of market perception and investor sentiment in determining the success of an IPO and its impact on a company's financial trajectory.

The largest issue size among recent IPOs, Bajaj Housing Finance's offering of ₹6,851.03 crore, stands as a testament to the company's maturity and market presence. Such large issue sizes typically indicate a well-established business with robust revenue streams, scalable operations, and promising opportunities for continued growth. Companies with sizable IPOs often exude confidence, signalling their readiness to take on substantial expansion plans or strengthen their market leadership.

Conversely, smaller IPOs like Gala Precision Engineering, with an issue size of ₹167.93 crore, often represent companies that are still in the early or intermediate stages of development. These businesses may be focused on carving out their niche, growing operations, or scaling their market share. While their smaller issue sizes may imply a lesser degree of maturity, they also offer investors a chance to get in early on potential growth stories.

The interplay between issue size and subscription rates is equally significant. Larger IPOs, such as Bajaj Housing Finance, often draw more attention from institutional and retail investors alike, due to their perceived stability and the scale of their operations. Such "banger" issues tend to dominate media coverage, fostering greater investor confidence and heightened participation. Smaller IPOs, while offering opportunities for significant returns, may struggle to achieve similar levels of visibility or enthusiasm, depending on market sentiment and the company's perceived potential.

This dynamic underscores how both issue size and subscription rates serve as vital indicators of a company's current market standing and future outlook. Large IPOs often anchor the market, providing benchmarks of success, while smaller issues bring diversity and new growth prospects to the table, enriching the investment landscape.

❖ MULTIPLE REGRESSION TEST:

Multiple regression tests are a statistical tool that allows you to examine how multiple independent variables are related to a dependent variable. Once you have identified how these multiple variables relate to your dependent variable, you can take information about all of the independent variables and use it to make much more powerful and accurate predictions about why things are the way they are. This latter process is called "Multiple Regression".

Formula of Simple linear Regression: $\mathbf{Y = a + b_x}$

Where,

Y = Dependent Variable
X = Independent Variable

Here multiple regression is applied which means more than one independent variable's effect on a dependent variable, So here one dependent variable and four independent variables are,

Table – 2 : Regression Line

Independent variable	Issue size : X_1 Issue price : X_2 No. of time subscribed : X_3
Dependent variable	Primary Market Return : Y

Therefore,

$$\mathbf{Y = a + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3}$$

Where,

A = Constant
B_1 = beta 1 of regression line is issue size
B_2 = beta 2 of regression line is issue price
B_3 = beta 3 of regression line is subscription time

Table - 3 : Regression Analysis

	Coefficients	*Standard Error*	*t Stat*	*P-value*
Intercept	-101.37	41.71	-2.43	0.02
Issue Size	0.02	0.01	2.31	0.03
Issue Price	1.37	0.06	22.62	0.00

Total Subs	0.70	0.29	2.44	0.02

$$Y = - 101.37 + (0.02 \times X_1) + (1.37 \times X_2) + (0.70 \times X_3)$$

The regression analysis reveals that the issue price is the most influential factor affecting IPO returns, showcasing a substantial positive impact. Specifically, a 1-unit increase in the issue price leads to a 1.37-unit increase in IPO returns, highlighting a direct and robust relationship. This relationship is statistically significant, as evidenced by the t-value of 22.62, which denotes a strong association between the issue price and IPO returns. Furthermore, the corresponding p-value of 0.00 reinforces the high level of significance, indicating that the observed impact is not due to chance.

In addition to the issue price, two other variables were found to have a significant effect on IPO performance. These variables, though not as dominant as the issue price, still play a crucial role in influencing investor returns and the overall success of the IPO. Their statistical significance underscores their importance in explaining variations in IPO performance.

Such findings highlight the need for investors to adopt a comprehensive analytical approach when evaluating IPOs. While the issue price emerges as a key determinant, assessing other significant variables provides a more nuanced understanding of the factors driving returns. This enables investors to make informed decisions, balancing potential risks and rewards effectively.

For issuers, these insights emphasize the importance of strategic pricing during the IPO process. Setting an appropriate issue price not only impacts immediate market performance but also shapes investor perception and confidence in the long term. Combined with other key performance indicators, this strategy can help issuers maximize subscription rates and foster a favorable market reception.

Thus, the regression analysis underscores the critical role of issue price, alongside other factors, in determining IPO success. For both investors and issuers, understanding these dynamics is essential for optimizing returns and achieving strategic objectives in the capital market.

6. RESULTS / FINDINGS:

Out of 26 companies only Western Carriers India IPO (-0.58%) generated negative returns. Bajaj Housing Finance (150.71%) & Premier Energies IPO (120%) have listed more than 100 per cent returns. The Listing day close is higher than listing day open.

Vraj Iron & Steel IPO was subscribed 119.04 times. A higher subscription rate indicates healthy investor confidence and enthusiasm in the company's future prospects, while the subscription rate for Ola Electric Mobility was only 4.27 times, suggesting lower enthusiasm than other issuances. The difference in subscription rates will also play an important role in the company's future fundraising initiatives; with successful subscription of an IPO potentially making it easier to access the capital markets in future rounds.

Largest issue size, Bajaj Housing Finance's IPO of Rs. 6,851.03 Cr., widely serve as indicators of a mature business, one with established revenue-sea channels and opportunities for growth. Conversely, the smaller issue sizes Gala Precision Engineering, for example, has an issue size of Rs. 167.93 Crmay come across as companies that are newer to the field and working their way up, rather than as fully fledged players in the market. The dynamic between issue size and total subscription can be telling, too: well-received bangers often get more media attention and general investor confidence than smaller IPOs.

The regression analysis shows that Issue price has largest impact on IPO return. For 1 unit increase in the issue price cause 1.37 unit increases in IPO return, here t value is 22.62 shows strong association result into p value 0.00 indicate it is highly significant. Other 2 variables also have significance effect on IPO performance.

7. CONCLUSION:

In conclusion, it can be said that an Initial Public Offering (IPO) presents an attractive opportunity for investors to earn significant profits, especially in the short term. Many investors view IPOs as a chance to capitalize on market enthusiasm and speculative opportunities, often exiting their positions on the listing day to lock in gains. This behaviour is fuelled by the "abnormal returns" phenomenon, where the initial spike in stock prices on the listing day typically represents the peak, with gains tapering off in the days or weeks that follow.

The performance of an IPO is influenced by various factors, among which the issue price plays a critical role. A well-priced IPO can strike a balance between investor demand and company valuation, maximizing subscription rates and fostering positive sentiment in the market. Conversely, an overvalued issue price may deter investors or lead to underperformance post-listing. Hence, investors are advised to carefully analyze the issue price in conjunction with other factors, such as the company's financial health, growth potential, industry position, and market conditions, before deciding to apply for an IPO.

Additionally, the broader market environment can also impact IPO performance. In bullish markets, investor sentiment tends to be more optimistic, often resulting in higher subscriptions and stronger post-listing performance. On the other hand, in bearish or uncertain markets, even fundamentally strong companies may face tepid responses.

For long-term investors, it's crucial to look beyond the short-term speculative gains and assess whether the company aligns with their investment strategy. Factors like consistent revenue growth, sound management, and innovative market positioning can be key indicators of a company's potential to deliver sustained value.

In summary, IPOs offer a mix of speculative and strategic opportunities. While they can be a profitable venture in the short term, informed decision-making and thorough analysis are essential for maximizing returns and minimizing risks.

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Understanding Customer Satisfaction in E-Banking: A Systematic Literature Review

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Abstract :*The main objective of this research is to show how e-banking impacts consumer's assessments of their experiences with service and to create a framework for determining the key elements of electronic banking that affect banks' bottom lines. Design, methodology, and strategy Using a digital banking perspective, this systematic review of the literature identifies articles published between 2014 to 2024 that examine different aspects of digital banking and their effects on financial performance. It is guided by the preferred reporting items for systematic reviews and meta-analyses framework. Results Functional clues (functional quality, trust, and convenience), mechanic clues (website qualities, design, and perceived usability), and humanic clues (managing customer complaints) all contribute to the customer experience (CE). CE is being combined with the service profit chain model in order to further the investigation. Additionally, this study closes the knowledge gap on the application of "gamification" to technology-driven financial services in order to improve CE. Lastly, an integrative framework is suggested to connect aspects linked to technology (gamification and digital banking hints), customers (CE, customer satisfaction, and customer loyalty), and performance (financial performance). Implications for practice A "total" CE framework is conceptualized in the paper, which banks can utilize to improve their online visibility. Value and originality The goal of this study is to make a substantial contribution to the body of knowledge on digital marketing and CE in banks.*

Key Words: *E-Banking, Customer Satisfaction, Customer Loyalty, Systematic Review, Customer Experience (CE)*

1. INTRODUCTION:

The banking business has undergone tremendous transformations in recent years, with digitalization becoming a prominent trend. Digital banking has grown in popularity, allowing users to conduct financial transactions from any location in the world. However, the impact of digital banking on client satisfaction and loyalty to commercial banks is unknown. The purpose of this systematic literature analysis was to look into how digital banking affects consumer satisfaction and loyalty to commercial banks. The review looked at existing literature on the topic, including empirical investigations, theoretical frameworks, and case studies. The review investigated the important aspects that influenced customers' satisfaction and loyalty to digital banking, such as usability, trust, convenience, and customer service.

The evaluation also looked at the challenges that commercial banks face when adopting digital banking, such as regulatory compliance, technological limits, security concerns, illiteracy, internet disruption, and opposition to change.
Overall, this study shed light on the benefits and problems of digital banking, as well as its impact on client perceptions and attitudes toward commercial banks. This review's conclusions will be valuable for commercial banks aiming to improve their digital banking services and increase consumer happiness, as well as researchers who want to learn more about the subject. The primary goal of this research was to investigate the influence of digital banking on customer satisfaction and loyalty in commercial banks using a systematic literature review.

Specific objectives:

1. Identify the important elements that impact customer satisfaction and loyalty to digital banking, including usability, security, trust, convenience, and customer service.

2. To examine the relationship between digital banking and customer satisfaction and loyalty in commercial banks.

3. Examine problems in implementing digital banking in commercial banks, such as regulatory compliance, technological limits, and opposition to change.

4. Based on the findings of this evaluation, recommendations will be made for commercial banks looking to improve their digital banking services and increase customer satisfaction and loyalty.

2. LITERATURE REVIEW:

Pareek (2020) targeted on educated and employed women aged 25 to 45 living in the Bhilwara area. According to the report, 86% of employees in the study area use online banking services. The popularity of online banking services was due to its ease of use, dynamism, efficient emergency assistance, and low cost. Customers believe that internet banking services prevent discrimination against bank customers. However, there are also limitations to using e-banking services, such as high volume and client faith in relevant services, such as checks.

Hadid et al. (2020) discovered that reliability, managers' responsiveness, and security have a significant impact on customer satisfaction (P-value=0.05).To guarantee that banks' digital banking services fulfill the essential standards, Malaysia's regulatory agency provides broad guidelines and suggestions to banks. This study provides useful insights into the aspects that drive consumer satisfaction and can help banks enhance their digital banking offerings.

Goi (2014) emphasized the importance of social media for banks, notably in terms of communication, promotion, publishing, and interaction. Malaysian commercial banks communicate with their consumers through social media platforms.

Nguyen (2021) conducted a case study of a commercial bank in the Mekong Delta, Vietnam, to identify the elements that influence employee engagement and organizational loyalty. The study discovered the following factors, in descending order of significance, that influence existing customers' personnel retention rates: pay, work characteristics, work environment, colleagues, and management.

A bank's location, service quality, and financial performance have a substantial impact on its clients' perceptions in all areas. Customers tend to transfer banks when profits or interest rates do not outperform those of competitors. Customers react similarly to poor service quality, as well as banks with only one branch or branches located distant from the city center (Pirzada et al. 2014).

According to the assessment, online control specifically with the help of the financial institution may be acceptable. In any event, ethnic groups believe that personal interaction is more important for the relationship between clients and banks. However, people use web-based finance managers to save money, avoid cash storage, withdrawal waits, and easily evaluate criteria on financial institution websites. Most individuals choose to exchange cash using Google Pay. Satisfied clients are an important component of the trustworthy performance at the heart of internet banking (Thilagaraj, Manohar, and Karthik, 2021).

According to George (2015), consumer pleasure on snapdeal.com in India and lazada.com in Thailand is directly proportional to accessibility, privacy, customer value, trust, and attitude. Trust was critical to both Thai consumers' perception of value and Indian customers' pleasure. Satisfaction is linked to each variable. Thai and Indian contentment is based on the majority of traits. While trust and India are highly associated, privacy is not notably positively correlated with India.

Relationship marketing, which was previously thought to be a major predictor of client loyalty, was discovered to have just a slightly positive link with customer loyalty. This is because product personalization is uncommon in the industry, and different banks follow the same forgetting-to-know-customer method. As a result, relationship marketing looks to be comparable among banks, and customers may be unable to switch service providers solely on this basis. However, customer relationship management is critical for satisfying customers in industries with similar products and prices (Kaguri, 2016).

According to Alsaggaf (2017), excitement and emotional response have a substantial impact on service quality. Customers' intents and feelings are also strongly influenced by subjective norms. Furthermore, both directly and indirectly, emotional responses have a substantial impact on customer intent. Overall, the study's findings show that consumer attitudes and emotional responses to happiness and excitement acted as mediators between quality-of-service affects on e-WOM and switching intent.

According to Akintaro and Shonubi (2019), a bank's corporate governance characteristics have a positive impact on its financial success. As a result, improving these traits will boost a bank's

return on capital. The makeup of the Board of Directors and the Audit Committee are important aspects in corporate governance and, as a result, influence a bank's financial performance.

3. RESEARCH METHOD / METHODOLOGY :

3.1.RESEARCH PROTOCOL.

The researcher did a thorough search of electronic databases to find relevant publications for the study. The following phase entailed using inclusion and exclusion criteria to discriminate between different types of published articles. Following a thorough examination, the findings were presented, and relevant works were chosen based on the research questions.

3.2. RESEARCH QUESTIONS

Q1. What effective strategies have commercial banks employed to promote client satisfaction and loyalty?
Q2. Does there exist a link between service quality, customer happiness, and customer loyalty in commercial banks?
Q3. How has the advancement of digital banking technology affected client satisfaction and loyalty in commercial banks?
Q4. At what frequency should commercial banks update digital banking to increase consumer happiness and loyalty?

3.3. Data Sources

The researcher conducted the systematic literature review by searching for relevant research articles in numerous electronic databases, including Google Scholar (https://scholar.google.com.pk), shodhganga.inflibnet.ac.in, and Research Gate. The following step entailed selecting the most appropriate articles based on inclusion and exclusion criteria.

3.4. Eligibility criteria

3.4.1. Inclusion Criteria

The eligibility criteria for the review approach included the following: (1) Studies published between 2006 and 2022 in Shodhganga, Research Gate, and Google Scholar (2) Focused on digital banking, service quality, customer satisfaction, and customer loyalty (3) Considered authors of both genders and employed qualitative, quantitative, and mixed-methods research conducted in any country worldwide (4) Investigated a range of factors in commercial banks, including service level, customer happiness, and customer loyalty.

3.4.2. Exclusion criteria

To assure the study's relevance, the following exclusion criteria were used: (1) papers that were comprehensive literature reviews, theoretical analyses, conceptual papers, or rely solely on secondary data sources such as government reports and online sources; (2) studies published before 2006; (3) papers published in languages other than English; and (4) non-peer-reviewed studies. Additionally, research studies conducted by the same authors and focusing on the same research topic were omitted to avoid duplication of findings.

3.5 Data analysis.

In this systematic literature review research, data analysis entailed examining statistical findings from individual investigations. The statistical data was examined using Microsoft Excel. To visually illustrate the statistical study results, flow charts and graphs were created using the Excel spreadsheet tool.

4. CONCLUSION / SUMMARY:

The review identified that while digital banking offers substantial benefits like ease of access, cost efficiency, and convenience, there are challenges that commercial banks must address. These include regulatory compliance, technological limitations, security concerns, and issues such as internet disruptions and consumer resistance to change. Overcoming these barriers is crucial for banks to fully capitalize on the potential of digital banking to enhance customer satisfaction.

The evaluation determined that, while digital banking provides significant benefits such as ease of access, cost efficiency, and convenience, commercial banks must address some difficulties. These include regulatory compliance, technology limits, security problems, internet outages, and customer opposition to change. Overcoming these constraints is critical for banks to fully realize digital banking's potential to improve consumer happiness. Furthermore, the study proposes that commercial banks should prioritize service quality, invest in user-friendly digital interfaces, implement strong security measures, and promote trust through open communication and customer assistance. This allows banks to create long-term customer loyalty, which is critical for continued corporate success in a competitive financial sector.

Furthermore, the report emphasizes the significance of regular changes to digital banking platforms in order to satisfy changing client expectations. As technology advances, it is critical to maintain a dynamic and responsive digital banking system to keep clients delighted and loyal.

Finally, this study adds to our understanding of the relationship between digital banking, consumer happiness, and loyalty. The findings provide useful tips for commercial banks looking to improve their digital banking services and enhance the client experience. These findings will also aid future study in the subject, directing greater investigation into the interaction of technology, customer service, and banking satisfaction.

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A descriptive study on impact of Ind AS on disclosure of financial performance of maruti suzuki limited

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Abstract: *Recent product introductions, particularly in the automotive sector, are more suited to consumer needs. After the restrictions were lifted, the industry is flourishing. The major user of rubber, plastic, steel, aluminium, and zinc alloys is the automotive sector. The automobile industry, which employs 13 million people, becomes the backbone of the economy. Best performer among this industry at national and international level is Maruti Suzuki. Which is one of the multinational company who are performance oriented. Honesty revels from every aspects by this company so for the study of impact measurement due to changing reporting requirement this is best company for research as compare to other automobile company. 2016 was the year when company need to change the reporting format so here in this study we had cover total ten years of period. Five year before the implementation of Ind AS and five years after the implementation of Ind AS considers for this study. Requirement of Ind AS is arouse for standardization and Harmonization of Accounting policies. All country need to have a one common language for reporting of business transaction which known as financial reporting. Almost country required convert their own local level reporting language to international level so there are common reporting language for business. The Ind AS Framework is a relevant, honest, and faithful representation of financial statements, and its qualitative features are expected to increase the value of financial statements. Time will prove that Ind AS is the qualitative way of accounting, and that implementing it is the best way to reach a global level in this competitive era as it converges toward IFRS. Value of financial statement will lead to enhance through the qualitative characteristics. Changes in reporting requirement from the AS to Ind AS will show the impact on profitability in this scenario other thing might not show much impact due to changes in reporting requirement.*

Key Words: *Automobile Industry, Maruti Suzuki, IFRS, Ind AS, AS, Financial Performance.*

1. INTRODUCTION: (11BOLD)

The corporate offices of the Indian carmaker Maruti Suzuki India Limited, often known as Maruti, are located in New Delhi. It was established in 1981 and is a part of the Japanese automaker Suzuki Motor Corporation. Maruti is one of the largest automobile manufacturers in India, holding a 42% market share as of September 2022. The company runs three manufacturing facilities: one in Uttar Pradesh, two in Haryana (Gurugram and Manesar), and one in Gujarat. Its vast network of more than 3,060 sales outlets and 4,600 service centers makes it one of the most accessible brands in India.

In order to provide Indian consumers with cost effective automobiles, the Government of India and Suzuki launched a joint venture that resulted in Maruti. It all began with the creation of the Maruti 800, one of the first automobiles made in India, which later became a household brand. Since then, Maruti has released a variety of vehicles in a variety of classes, such as hatchbacks, sedans, small SUVs, and MPVs. The business has progressively increased its footprint in various nations with assistance from parent firm Suzuki Motor Corporation. Currently, Maruti Suzuki exports to almost 100 nations. The company's key export markets include Asia, the Middle East, Africa, and Latin America. Due to availability in multinational country reporting requirement also need to take care. As per requirement of statue Maruti Suzuki Motors limited already follows Ind AS as per reporting requirement of MCA since 2016. Before the new requirement emergence financial statement are prepared according to AS. Than initially company need to prepare in both reporting language as per AS as well as Ind AS for fulfilling the required guideline. In this research briefing also provided with regard to reporting requirement changing from time to time. Whether the changes impacted to any manner in the company's reporting is most important question. So here we try to clarify through some of the measure that how much impacted in the reporting requirement.

Meaning of certain terminology:

GAAP:

GAAP Stand to generally accepted accounting principles which is common set of accepted accounting principles, standards and procedures that business reporting must follow in the preparation and presentation of financial statement.

Accounting Principles:

Accounting principles are a body of doctrines commonly associated with the theory and procedures of accounting. Accounting principles should be based on real assumptions, followed consistently, Reflect future predictions, Informational to users.

Accounting Standard:

Accounting standards are written documents, policy documents issued by expert accounting body or by government or other regulatory body covering the aspects of recognition, measurement, treatment, presentation and disclosure of accounting transactions in the financial statements.

IFRS:

International Financial Reporting Standards is a set of accounting standards developed by an Independent, not for profit organization called the International Accounting Standards Board.

Ind AS:

Ind AS stand to INDIAN ACCOUNTING STANDARDS are IFRS converged standard issued by the central government of India under the supervision of accounting standard Board (ASB) of ICAI and in consultation of NFRA.

2. LITERATURE REVIEW:

(Dr. Ramesha V; 2016) has attained study on convergence of Ind AS with IFRS, in that particular study found that changes from the one accounting system to another accounting system is not easy task. It require lot of time to use through of that system which are newly introduce. Other resources also need

to consume from that part. Research broadly categorise toward IFRS implementation and challenges and systematic steps to implement IND AS.

(Sharma & Gupta; 2018) conducted research for conference research paper on challenges in implementation of Ind AS in India and identified challenges in implementation of Ind AS in India also has put some solution to face the same challenges. Broadly, author has given some basic solution to face such challenges on reporting issue. There are major challenges like fair value measurement, conversion cost, and complexity in understanding various term etc. for such challenges researcher come with the solution training programme and seminar and various conference or one can go for expert talk. Author has also site the reference of MCA and ICAI specially.

(Kaur, Balwindar & Madhavbhattacharya; 2019), has conducted research on "Comparative analysis of GAAP, IFRS and Ind AS" in that study provided comparison of Indian GAAP, IFRS and Ind AS also mention that there is no big challenges in adoption of IFRS and provide detail about IFRS that IFRS is nothing but a accounting language which common for globally for all corporate giant. Author has also concluded that Ind AS is converged form of IFRS and most of provision of IFRS is adopted in Ind AS. There is major difference between Indian GAAP and IFRS.

(N.Sharadha, V.Manickavasagam; 2018); in the study of "Ind AS – India's accounting standards converged with the IFRS (Ind AS adoption and applicability)" try to intended to identify the need of Ind AS and challenges for the same. Also describe that Ind AS has more disclosure requirement and other new concept in financial reporting. End of study author has concluded that there is set of financial statement for the purpose of reporting as per Ind AS which is describe in the paper. Accounting activity cannot be work in isolation it is integrated, coordinated activity with primary activity in the business.

(MinoutiJani and SonalGogri; 2018) has done the study on "Impact of Ind AS on corporate governance" and has try to find out growth of Indian capital market due to having convergence with international financial reporting standard to Accounting standard which ultimately known as Ind AS. Due to growth in international capital market and cross border transaction like merger and acquisition standardization and harmonization is become very essential in that respect to take in confidence to global investor. They also describe various benefit due to implementation of Ind AS in this paper. They also mention the successful implementation of Ind AS lead to true and fair view of accounting. Which is more relevant in today's financial reporting practice and more focus of this study is on corporate governance.

3. OBJECTIVES / AIMS :

Following are the main objective of the study:

- To understand the impact of Ind AS on financial performance of Maruti Suzuki Ltd.
- To compare the financial performance of Maruti Suzuki Ltd through implication of AS and Ind AS.

To achieve the objective of the study following hypotheses has been considered;

Null hypothesis (H_0)

1. There is no significance difference in profitability of Maruti Suzuki Ltd before and after implementation of Ind AS.
2. There is no significance difference in Financial Leverage of Maruti Suzuki Ltd before and after implementation of Ind AS
3. There is no significance difference in Efficiency of Maruti Suzuki Ltd before and after implementation of Ind AS
4. There is no significance difference in Liquidity of Maruti Suzuki Ltd before and after implementation of Ind AS

Alternative Hypothesis (H_1)

1. There is significance difference in profitability of Maruti Suzuki Ltd before and after implementation of Ind AS
2. There is significance difference in Financial Leverage of Maruti Suzuki Ltd before and after implementation of Ind AS
3. There is significance difference in Efficiency of Maruti Suzuki Ltd before and after implementation of Ind AS
4. There is significance difference in Liquidity of Maruti Suzuki Ltd before and after implementation of Ind AS

4. RESEARCH METHOD / METHODOLOGY:

Type of Research

This research is empirical in nature because we need to get conclusion based on available evidence which can be direct or indirect.

Period of study:

To conduct this study, I have consider Ten financial years, viz.2011-12, 2012-13, 2013-14, 2014-15, 2015-16,2016-17, 2017-18, 2018-19, 2019-20 and 2020-21.

Collection of data:

Data has been be collected from the annual report of the selected companies.

Other formal source for data collection has been used in the study are Money control.

Sampling Method:

Non-probability convenient sampling.

Data analysis and statistical tools:

The data collected from the above stated methods, has been analysed by using various statistical tools like percentage, Average, Standard Deviation, T-test etc.

5. COLLECTION OF DATA AND KEY PERAMETER:

Data collection for this study was carried out using a secondary approach. Wherein every ratio has been taken into account, and the following data has been averaged as a statistical tool. This chapter contains the reference collection details for a number of ratios:

For the purpose of financial performance measurement we have taken following parameters:

- ✓ Profitability,
- ✓ Financial leverage,
- ✓ Efficiency
- ✓ Liquidity

Profitability Ratio													
		AS						***Ind AS***					
Ratios		**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**	**2015-2016**	**Avg. of AS**	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**Avg. of IND AS**
MARUTI SUZUKI	**PBDIT Margin**	9.38	11.56	13.54	15.09	17.98	**13.51**	18.59	17.68	15.76	14.18	11.78	**15.598**
	PBIT Margin	6.18	7.29	8.77	10.15	13.07	**9.092**	14.77	14.22	12.25	9.51	7.47	**11.644**
	PBT Margin	6.03	6.86	8.37	9.74	12.93	**8.786**	14.64	13.79	12.16	9.34	7.33	**11.452**
	Net Profit Margin	4.59	5.48	6.36	7.42	9.32	**6.634**	10.8	9.68	8.71	7.47	6.01	**8.534**
	Return on Networth / Equity	10.76	12.87	13.26	15.65	17.95	**14.098**	20.17	18.49	16.25	11.66	8.23	**14.96**
	Return on Capital Employed	10.37	11.95	12.39	15	17.35	**13.412**	26.42	25.83	21.6	14.04	9.74	**19.526**
	Return on Assets	7.33	8.94	9.11	11.06	12.79	**9.846**	14.34	13	11.91	9.03	6.03	**10.862**

Financial Leverage Ratio		
	AS	***Ind AS***

Ratios		2011-2012	2012-2013	2013-2014	2014-2015	2015-2016	Avg. of AS	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Avg. of IND AS
MARUTI SUZUKI	Interest Coverage ratio	1.93	1.6	21.8	24.63	92.33	**28.458**	112.41	32.82	139.07	54.15	52.18	**78.126**
	Proprietary ratio	68.09	69.49	68.69	70.65	71.25	**69.634**	71.08	70.33	73.31	77.43	73.31	**73.092**
	Total Debt/Equity	0.07	1.8	0.08	0.01	0	**0.392**	0.01	0	0	0	0.01	**0.004**
	Capital Gearing Ratio	0	13.34	45.56	163.7	0	**44.52**	0	0	0	0	0	**0**

Efficiency Ratio													
		AS						*Ind AS*					
Ratios		2011-2012	2012-2013	2013-2014	2014-2015	2015-2016	Avg. of AS	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Avg. of IND AS
MARUTI SUZUKI	Inventory Turnover Ratio	19.81	23.68	25.62	19.11	18.37	**21.318**	20.86	25.23	25.87	23.52	23.06	**23.708**
	Account receivable ratio	0.027	0.034	0.033	0.022	0.023	**0.0278**	0.01	0.018	0.027	0.029	0.019	**0.0206**
	Account Payable ratio	0.096	0.097	0.11	0.11	0.131	**0.1088**	0.125	0.134	0.116	0.104	0.152	**0.1262**
	Asset Turnover Ratio	159.56	163.04	143.11	148.93	137.19	**150.37**	132.74	134.34	136.68	120.87	100.37	**125**

Liquidity Ratio		
	AS	**Ind AS**

Ratios		2011-2012	2012-2013	2013-2014	2014-2015	2015-2016	Avg. of AS	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Avg. of IND AS
MARUTI SUZUKI	**Current Ratio**	1.69	1.63	1.76	0.93	0.71	**1.344**	0.66	0.51	0.87	0.75	1.15	**0.788**
	Quick Ratio	1.42	1.35	1.54	0.63	0.43	**1.074**	0.42	0.31	0.64	0.46	0.96	**0.558**
	Dividend Pay-out Ratio	13.25	10.1	13.02	20.34	14.07	**14.156**	14.38	29.34	32.21	42.76	42.85	**32.308**
	Dividend Pay-out Ratio	7.81	5.68	7.44	12.21	9.22	**8.472**	10.62	21.61	22.97	26.33	24.96	**21.298**
	Earnings Retention Ratio	86.75	89.9	86.98	79.66	85.93	**85.844**	85.62	70.66	67.79	57.24	57.15	**67.692**
	Cash Earnings Retention Ratio	92.19	94.32	92.56	87.79	90.78	**91.528**	89.38	78.39	77.03	73.67	75.04	**78.702**

6. DISCUSSION / ANALYSIS:

Profitability Ratio

Maruti Suzuki:

H_O: There is no significance difference in profitability of Maruti Suzuki before and after implementation of Ind AS during the study period.

H_a: There is significance difference in profitability of Maruti Suzuki before and after implementation of Ind AS during the study period.

t-Test: Paired Two Sample for Means		
	Average of AS	*Average of Ind AS*
Mean	10.76829	13.22514
Variance	8.379257	13.59605
Observations	7	7
Pearson Correlation	0.885042	
Hypothesized Mean Difference	0	

Df	6	
t Stat	-3.70252	
P(T<=t) one-tail	0.005029	
t Critical one-tail	1.94318	
P(T<=t) two-tail	0.010058	
t Critical two-tail	2.446912	

Interpretation:

The above table shows that the P value is 0.001, which is less than the 0.05 significance level. As a result, the null hypothesis will not be accepted in this case, indicating that Maruti Suzuki's profitability before and after the implementation of Ind AS during the study period differed significantly.

Financial Leverage

Maruti Suzuki:

H_O: There is no significance difference in Financial Leverage of Maruti Suzuki before and after implementation of Ind AS during the study period.

H_a: There is significance difference in Financial Leverage of Maruti Suzuki before and after implementation of Ind AS during the study period.

t-Test: Paired Two Sample for Means		
	Average of AS	*Average of Ind AS*
Mean	35.751	37.8055
Variance	842.7999	1909.696
Observations	4	4
Pearson Correlation	0.500966	
Hypothesized Mean Difference	0	
df	3	
t Stat	-0.10676	
P(T<=t) one-tail	0.46086	
t Critical one-tail	2.353363	

P(T<=t) two-tail	0.92172	
t Critical two-tail	3.182446	

Interpretation:

The P value in the above table is 0.921, which is greater than the 0.05 significance level. As a result, the null hypothesis will be accepted in this case, indicating that there was no discernible difference in Maruti Suzuki's financial leverage before and after the introduction of Ind AS during the study period.

Efficiency Ratio

Maruti Suzuki:

H_O: There is no significance difference in Efficiency of Maruti Suzuki before and after implementation of Ind AS during the study period.

H_a: There is significance difference in Efficiency of Maruti Suzuki before and after implementation of Ind AS during the study period.

t-Test: Paired Two Sample for Means		
	Average of AS	*Average of Ind AS*
Mean	42.95515	37.2137
Variance	5227.941	3549.216
Observations	4	4
Pearson Correlation	0.998793	
Hypothesized Mean Difference	0	
Df	3	
t Stat	0.874471	
P(T<=t) one-tail	0.223113	
t Critical one-tail	2.353363	
P(T<=t) two-tail	0.446227	
t Critical two-tail	3.182446	

Interpretation:

The P value in the above table is 0.446, which is greater than the 0.05 significance level. As a result, the null hypothesis will be accepted, indicating that Maruti Suzuki's efficiency was not significantly different before and after the implementation of Ind AS during the study period.

Liquidity Ratio

Maruti Suzuki:

H_O: There is no significance difference in Liquidity of Maruti Suzuki before and after implementation of Ind AS during the study period.

H_a: There is significance difference in Liquidity of Maruti Suzuki before and after implementation of Ind AS during the study period.

t-Test: Paired Two Sample for Means		
	Average of AS	*Average of Ind AS*
Mean	25.4865	25.35675
Variance	1546.621	1018.859
Observations	8	8
Pearson Correlation	0.965612	
Hypothesized Mean Difference	0	
Df	7	
t Stat	0.030883	
P(T<=t) one-tail	0.488112	
t Critical one-tail	1.894579	
P(T<=t) two-tail	0.976225	
t Critical two-tail	2.364624	

Interpretation:

The P value in the above table is 0.976, which is greater than the 0.05 significance level. As a result, the null hypothesis will be accepted, indicating that there was no discernible difference in Maruti Suzuki's liquidity before and after the introduction of Ind AS during the study period.

8. CONCLUSION / SUMMARY:

Company	Ratio	P Value	Null Hypo.(H0)	Alt. Hypo (H1)
MARUTI SUZUKI	Profitability	0.001	**Rejected**	Accepted
	Financial Leverage	0.921	Accepted	-

	Efficiency	0.446	Accepted	-
	Liquidity	0.976	Accepted	-

From the above table we can conclude that due to implementation of Ind AS in financial disclosure only profitability ratio has been affected. Other ratio remain the unaffected as per the data collection and analysis after performance of t-test. This might due to the various accounting standards having different impact in the reporting. Reporting framework which has been changed that only affect in the financial reporting.

9. LIMITATIONS:

- ✓ The study covers only 10 years.
- ✓ Results of this research are confined and limited to selected companies.
- ✓ The statistical techniques used by researcher have their own limitations.
- ✓ Owing to the limited knowledge of the researcher, the results of the research might need further refining.
- ✓ Only particular company is selected for the study.

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Determinants Influencing the Adoptions of Mobile Payment Services: An Analysis of Literature Review

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Abstract: *In the World of Finance, Mobile Payment Services are a technology that facilitates the conversion of manual payments into digital ones through the use of smartphone devices. Primarily to the advantages of mobile payments, which meet the demands of financial and commercial operations, the usage of mobile payments has grown throughout the past five years. The factors influencing the adoption of mobile payments must be taken into consideration in order to investigate new research prospects in this area. This literature study's objective is to conduct a systematic review of the literature while considering the results of previous research. This research compiles publications about the use of mobile payments. It examines them using theory, context, and elements that affect mobile payments from Web of Science, ABDC, and Scopus-indexed Journals. According to the results of the comprehensive literature review, the primary determinants of the desire to adopt mobile payments services include technological factors, merchant adoptions, social influence, financial literacy and incentives, security and trust, and external variables. The paper aims to An Analysis of literature Review on the adoption of mobile payment services and usage of various kinds of Mobile Payment at present.*

Key Words: *Fintech, Mobile Payment Service, Adoption, Determinants, Digital Payment*

1. INTRODUCTION:

The rapid growth of mobile technologies has transformed the worldwide financial system, providing new and improved ways to make transactions easier and more efficient. In the last ten years, there has been a considerable increase in the popularity of mobile payment services, allowing users to conduct financial transactions using smartphones and other mobile devices. These services remove the necessity for physical cash or card payments, offering a quick, safe, and adaptable option to traditional methods. Nevertheless, even though they have many benefits and are readily accessible, the use of mobile payment services varies among regions, demographic groups, and socio-economic situations (Dahlberg et al., 2015). Recognizing and comprehending the factors that impact the acceptance and long-term success of mobile payment services is essential for promoting their adoption.

The use of mobile payment services is impacted by a combination of technological, personal, and environmental factors. Factors like how easy it is to use, security guarantees, and compatibility are crucial in influencing how users view and are willing to embrace technology (Kim et al., 2010). Additionally, user acceptance is influenced by factors such as trust in service providers, perceived risks, and the perceived usefulness of the services (Zhou, 2011). Factors related to income, technological literacy, and societal norms contribute additional complexity to the adoption process. Researchers have turned to theoretical frameworks like the Technology Acceptance Model (TAM), Unified Theory of Acceptance and Use of Technology (UTAUT), and Diffusion of Innovations Theory to study and clarify

user behavior in mobile payments (Venkatesh et al., 2003; Rogers, 2003) due to the diverse determinants involved.

Variations in adoption rates are significant between developed and developing economies, as emphasized in current literature. In advanced economies, the use of technology is commonly influenced by superior infrastructure, widespread smartphone usage, and a desire for digital convenience (Thakur & Srivastava, 2014). On the other hand, in emerging economies, mobile payment services are often seen as ways to promote financial inclusion by catering to the unbanked and underbanked individuals (Donner & Tellez, 2008). The importance of conducting a thorough analysis that combines the factors influencing mobile payment adoption in various environments is highlighted by these contextual variations.

This study seeks to perform a methodical review of existing literature in order to pinpoint the primary factors that affect the uptake of mobile payment services. The paper aims to gain a comprehensive understanding of the factors influencing adoption behaviors by studying research in different geographic, cultural, and technological settings. The review also seeks to pinpoint areas where research is lacking and new trends are developing, providing valuable information for academics, practitioners, and policymakers. The results will help in creating plans that increase user confidence, reduce perceived dangers, and encourage more people to use mobile payment options.

In doing so, this study not only enriches theoretical discussions on technology adoption but also provides practical guidance for stakeholders seeking to foster a user-centric approach in the development and deployment of mobile payment services.

2. LITERATURE REVIEW:

Mobile Payment Services: An Overview

Mobile payment services have become a groundbreaking development in the financial technology industry, allowing users to conduct financial transactions easily on their mobile devices. These services utilize different technologies like Near Field Communication (NFC), Quick Response (QR) codes, and mobile banking apps to facilitate secure, quick, and convenient transactions. The use of mobile payment services is changing how people and businesses interact with financial systems, moving away from conventional cash and card transactions to digital options.

Categories of Mobile Payment Services

1. Proximity Payments:

Proximity payments require the user's mobile device to directly interact with a payment terminal, usually using NFC technology or QR code scanning. NFC, a technology for short-range communication, enables devices to share data by being near each other physically. Apple Pay, Samsung Pay, and Google Pay use NFC technology to enable smooth transactions at brick-and-mortar stores. QR code systems allow for payments to be made by scanning a code provided by a merchant, which is advantageous in areas where NFC technology is not widely used or where infrastructure is limited.

The increasing popularity of proximity payments is driven by their quickness, convenience, and expanding merchant acceptance. An example is a research conducted by Pham and Ho (2020) which showed that NFC payments improve customer happiness because of their ease of use and protection, whereas QR code technology offers inexpensive options for SMEs with limited infrastructure.

2. Remote Payments:

Remote payments involve non-physical interactions, enabling users to conduct transactions via mobile banking apps, online shopping platforms, or digital wallets. These transactions are frequently utilized for making purchases online, paying bills, and subscribing to services. Frequently cited instances include PayPal, Amazon Pay, and in-app payment systems embedded in services like Uber or Spotify. Remote payment services depend on internet connection and secure verification methods, like two factor authentication (2FA) or biometrics, to guarantee transaction security.

A study conducted by **Dahlberg et al. (2015)**, suggests that remote payment systems have greatly changed how consumers behave by allowing cross-border transactions and decreasing reliance on cash. Younger, tech-savvy demographics are attracted to the convenience and flexibility of remote payments, as they prioritize digital solutions for their financial requirements.

3. Peer-to-Peer (P2P) Payments:

P2P payment services enable individuals to directly conduct financial transactions without involving banks or other traditional middlemen. Apps like Venmo, Zelle, and WeChat Pay have become popular for their convenience in facilitating fast and easy transactions. Frequently, these systems incorporate social aspects like transaction notes or sharing payments within social media platforms, improving user interaction and efficiency.

The simplicity of P2P payments and the growth of mobile-centered ecosystems in developed and emerging markets are driving the adoption of these services. A recent research by **Chen et al. (2021)** emphasizes the importance of P2P payments in promoting financial inclusion by allowing individuals without access to traditional banking services to engage in the digital economy.

Dynamic Ecosystem Influencing Mobile Payment Adoption

The use of mobile payment services is influenced by how users perceive them, the capabilities of the technology, and external environmental factors.

User Perceptions:

Users' perceptions of mobile payments are significantly impacted by how easy they find it to use, how beneficial they believe it is, and how much they trust it. The Technology Acceptance Model (TAM) suggests that individuals are more inclined to use technologies that they perceive as useful and easy to use (Davis, 1989). Additionally, confidence in the safety of mobile payment platforms is essential, given consumers' concerns about fraudulent activities, data leaks, and privacy infringements.

Technological Features:

Advancements in technology supporting mobile payments, such as biometric authentication (e.g., fingerprint or facial recognition), tokenization, and real-time processing, have greatly improved the user experience. Research conducted by Zhou (2011) emphasizes that characteristics such as secure encryption protocols and user-friendly interfaces play a crucial role in promoting adoption.

External Factors:

Factors outside of the company's control, such as regulations, economic climate, and societal beliefs, also influence the acceptance of mobile payment services. For instance, efforts by governments such as India's demonetization move in 2016 and China's promotion of a society without cash, have sped up the embrace of mobile payment platforms. Likewise, the availability of smartphones and cost-effective data plans in developing markets has increased the accessibility of these technologies.

Global Trends and Regional Variations

The adoption of mobile payments differs greatly among regions because of variations in infrastructure, cultural preferences, and market maturity.

- *In countries like China and India in Asia, mobile payment usage is primarily led by platforms like Alipay, WeChat Pay, and Paytm, which combine payments with e-commerce, messaging, and utility services.*
- *NFC-based proximity payments are widely adopted in Europe, with countries like Sweden progressing towards a society that uses very little cash.*
- *In Africa, mobile payment systems such as M-Pesa have significantly impacted financial inclusion by offering essential financial services to those without access to traditional banking.*

A research conducted by Schierz et al. (2010) showed that varying adoption rates in different regions are affected by factors like smartphone usage, literacy rates, and confidence in online platforms.

Theoretical Frameworks for Mobile Payment Adoption

Understanding mobile payment adoption requires delving into established theoretical models that offer diverse perspectives on user behavior. Each framework provides insights into the factors influencing users' decisions and the dynamics shaping technology adoption.

1. Technology Acceptance Model (TAM):

The Technology Acceptance Model (TAM), established by Davis in 1989, highlights two main factors: perceived usefulness (PU) and perceived ease of use (PEOU).

- **Perceived usefulness** is the level of belief that mobile payments enhance the efficiency and convenience of transactions for users. For instance, if users view mobile payments as quicker and more dependable than traditional methods, they are more inclined to use them.

- **Perceived ease of use** evaluates the ease with which users can navigate and operate the system. This factor is especially important for individuals who are not very skilled with technology, as shown in research such as Zhou (2011), where the ease of use was found to greatly influence adoption among older or less technologically savvy groups.

TAM's popularity stems from its simplicity and emphasis on user perceptions, making it a widely utilized framework for comprehending mobile payment behaviors. Nevertheless, it fails to consider external social or contextual factors.

2. Unified Theory of Acceptance and Use of Technology (UTAUT):

The UTAUT model, developed by Venkatesh et al. (2003), expands upon TAM by incorporating new factors such as performance expectancy, effort expectancy, social influence, and facilitating conditions.

- **Performance expectancy** and **perceived usefulness** are similar, as they both show users' confidence in the speed and security improvement of financial transactions through mobile payments.
- **Effort expectancy**, similar to user-friendliness, evaluates how easy it is to interact with mobile payment services.
- **Social influence** focuses on the influence of societal trends, peer suggestions, and endorsements on adoption. For example, promoting cashless systems in society on a large scale can motivate people to start using mobile payment platforms.
- **Facilitating conditions** encompass the essential infrastructure and technical assistance required for seamless utilization. Having access to strong internet connections, compatibility with smartphones, and responsive customer support are essential resources.

The comprehensive nature of UTAUT enables it to understand wider socio-technical factors affecting the adoption of mobile payments, as proven by its use in research on digital payment systems in various cultural settings.

3. Diffusion of Innovation (DOI):

Rogers (2003) developed the **Diffusion of Innovation (DOI)** theory, which points out five factors that affect how quickly technology is adopted: relative advantage, compatibility, complexity, trialability, and observability.

- **Relative advantage** is the perceived benefits of mobile payments compared to traditional transaction methods, including quicker processing and less reliance on cash.
- **Compatibility** evaluates the degree to which mobile payments match with current user behaviors, cultural standards, and beliefs. In societies where smartphones are widely used, compatibility is probably greater.
- **Complexity** refers to how hard it is to utilize mobile payments. Complex technologies discourage use, particularly among older individuals or those with low literacy levels.
- **Trialability** enables users to test mobile payments through promotions or temporary trials before making a full commitment.
- **Observability** measures how visible benefits, like rewards programs or payment notifications, are to users, thus increasing adoption.

DOI helps us understand how new technologies spread through populations as time goes on.

4. Theory of Planned Behavior (TPB):

According to Ajzen's (1991) Theory of Planned Behavior (TPB), attitudes, subjective norms, and perceived behavioral control are the factors that determine behavior.

- Attitudes towards mobile payments are influenced by beliefs regarding their effectiveness, safety, and ease of use. Having a positive attitude is promoted when it comes to adopting.

- Subjective norms are the encouragement and impact from social groups and friends that prompt individuals to adopt mobile payment technologies. In societies where digital payments are commonly used, individuals are more likely to embrace this approach.
- The level of confidence that users have in being able to use mobile payment systems effectively is shown in their perceived behavioral control. This pertains to the capability of using mobile devices, online resources, and being skilled in utilizing applications.

TPB effectively predicts behavioral intentions by linking personal attitudes with external social and technical factors.

Determinants Influencing Mobile Payment Adoption

(Source: Google Images)

The integration of mobile payment systems is influenced by a combination of technological, social, financial, and external factors. Here is an in-depth investigation of these factors backed by research evidence.

Challenges in Adoption

Despite the numerous benefits, several barriers hinder mobile payment adoption:

1. **Security Concerns**: Users often fear data breaches, phishing scams, and unauthorized transactions, which discourage participation.

2. **Access Limitations**: In developing regions, limited access to smartphones, internet connectivity, and digital literacy restrict adoption.
3. **Resistance to Change**: Certain demographics, particularly older adults or those in rural areas, may prefer traditional payment methods due to familiarity and mistrust of digital systems.

Addressing Challenges: Tailored solutions, such as simplified apps for less tech-savvy users, improved security protocols, and government-led awareness campaigns, are needed to overcome these barriers.

3. OBJECTIVES / AIMS:

- Determine important elements that impact the adoption of mobile payments, such as technological, financial, and social factors.
- Analyze how technological advancements, like biometric authentication and AI, can improve adoption rates.
- Examine the impact of socio-cultural and external influences on adoption in various regions and demographic groups.
- Evaluate obstacles to implementation, such as security issues, lack of digital skills, and reluctance to accept new methods.
- Examine how financial literacy and incentives influence both the initial uptake and ongoing utilization.

4. RESEARCH METHODOLOGY:

This study employs a **systematic literature review (SLR)** approach to analyze determinants influencing mobile payment adoption. The methodology ensures a structured and comprehensive synthesis of research.

1. **Research Design:**

- Qualitative and exploratory, focusing on synthesizing peer-reviewed literature from databases and journals.

2. **Data Collection and Analysis:**

- Articles were screened based on titles, abstracts, and full-text relevance.
- Thematic analysis categorized factors into themes like technological, social, and external influences.
- Theoretical frameworks (e.g., TAM, UTAUT) were applied to interpret findings.

5. RESULT / FINDINGS:

Key Determinants:

- **Technological Factors:** Adoption is increased by user-friendly design, reliability, and advancements such as NFC and biometric security.
- **Security & Trust:** The perceived security and trustworthiness of service providers are essential.
- **Financial Literacy & Incentives:** Educated users and incentives like cashback promote usage.

- **Social Influence:** Recommendations from friends and current trends in society motivate people to try something new.
- **Merchant Integration:** Increased merchant participation improves functionality.
- **External Factors:** Government policies and infrastructure have a major impact on the level of adoption.

Challenges:

- *Security issues, lack of access in developing areas, and reluctance to embrace change are obstacles to adoption.*

6. RESEARCH GAPS AND FUTURE DIRECTIONS:

1. Cross-Cultural Analysis**: More research is needed to explore how cultural factors influence adoption behavior across regions.**
2. Emerging Technologies**: Investigating the role of blockchain, artificial intelligence, and IoT in enhancing mobile payment systems.**
3. Longitudinal Studies**: Understanding how user behavior evolves over time as technologies and societal attitudes change.**
4. Inclusive Design**: Developing mobile payment solutions that cater to underserved populations, such as the elderly or those with limited financial literacy.**

7. CONCLUSION:

The adoption of mobile payment services is a multifaceted phenomenon influenced by a combination of technological, psychological, and contextual factors. While frameworks like TAM, UTAUT, and DOI provide valuable insights, the dynamic nature of technology and user expectations necessitate ongoing research. Addressing challenges such as security concerns and access disparities can further accelerate adoption, contributing to a more inclusive and cashless global economy.

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A study on Financial Literacy among the Farmers of Junagadh District of Gujarat.

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Abstract: *Financial literacy is the ability to manage money. Broadly, it refers to the knowledge and understanding of financial concepts; the ability to apply it confidently and behaving in a responsible manner to make informed decisions for the financial well-being of the individual. It includes financial awareness, attitude, behavior, and knowledge. This study aims to analyses the financial literacy among the farmers of Junagadh district. A descriptive research design will be used to conduct research and a convenient sampling method will be used to select a sample from the Junagadh District of Gujarat, India. Possible outcomes will be used to identify level of financial literacy and the factors affecting financial literacy among the farmers in Junagadh District.*

Key Words: *Farmers, Financial Attitude, Financial Behaviour, Financial Knowledge, Financial Literacy*

1. INTRODUCTION:

Since financial literacy has become more significant in recent years, it is crucial that middle-class and lower-class individuals who take part in these markets as investors or borrowers understand the range of products available in these financial markets. It has been noted that people who are unaware of financial items either reserve money or make safe investments rather than putting it into other markets. They are uncertain to make investments in financial items with negligible or no risk. Understanding and rising awareness of financial products and how they operate in markets so that customers may apply them to financial choices in order to make well-informed selections and can practically.

In the last couple of years, financial literacy received special attention from researchers, financial institutions and policy makers (Kumari, 2017; Lusardi, 2019). The capability to manage personal finances has become increasingly important in today's world. Financial literacy is a basic concept in understanding money and its use in daily life. This includes the way income and expenditure are managed and the ability to use the common methods of exchanging and managing money.

- **Financial Literacy**

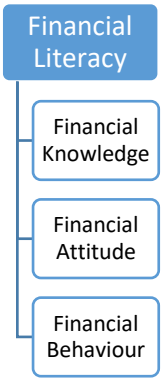
In simple terms, financial literacy refers to the ability to manage money effectively. It generally involves having knowledge and understanding of financial concepts, being able to apply them with confidence, and behaving responsibly to make informed decisions that promote personal financial well-being (Samriti Kamboj, 2017).

Remund (2010) broadly defined financial literacy as the extent to which individuals understand essential financial concepts and have the ability and confidence to manage their personal finances through wise short-term decisions and solid long-term financial planning, while considering life changes and economic fluctuations.

Huston (2010) described financial literacy as the ability to comprehend and use personal finance-related information effectively.

The OECD (Organization for Economic Co-Operation and Development) INFE (International Network on Financial Education) defined financial literacy as a combination of awareness, knowledge, skills, attitudes, and behaviors needed to make sound financial decisions and, ultimately, achieve personal financial well-being.

- **Components:**



2. LITERATURE REVIEW:

Kamboj S. (2017) revealed that certain subgroups, such as women, people living in rural areas, those who are not working, and individuals with low educational qualifications, are more vulnerable, suggesting the need to improve financial literacy. Specifically, low income levels, income instability, and younger age are associated with lower levels of financial literacy.

Jayamary P. (2019) concluded that the level of financial literacy among males is higher than that among female respondents. The key determinants of financial literacy include time orientation, impulsivity, social status, self-control, locus of control, and attitudes towards savings, spending, and borrowing. Among these, self-control and locus of control significantly influence the level of financial literacy. The demographic profile of individuals plays an important role in their financial literacy levels.

Popat D. (2019) concluded that urban respondents exhibit higher financial literacy compared to rural respondents, primarily due to their higher education levels. The study also found that the overall financial literacy among respondents was moderate, with private sector employees in rural areas showing higher financial literacy. A majority of respondents expressed a preference for planning and saving for unexpected circumstances and a secure future.

Chowdhary T. (2019) concluded that financial literacy empowers investors to make informed decisions and wise investments. The study found that demographic factors such as gender, age, educational

qualification, nature of occupation, and annual income have a statistical influence on financial literacy and investment decisions.

Manchanda P. (2019) concluded that age, education, and occupation significantly impact the barriers affecting financial literacy among working women. Additionally, the study found that working women in the private sector are more concerned about their finances and more proactive in choosing investment avenues compared to their counterparts in the public sector.

Yadav N. (2020) concluded that demographic factors influence financial literacy and should be considered when designing financial literacy courses and programs. The study also found that respondents with formal financial education possess significantly more financial knowledge than others. High financial literacy empowers investors to make informed decisions.

Balani S. (2016), in her research on demographic variables, concluded that gender and academic qualification do not have a significant association with the financial literacy level of salaried individuals. The study also found that more postgraduate respondents were in the high financial literacy group compared to undergraduates, and more private sector employees were in the high financial literacy group compared to those in the government sector.

Bhushan P. and Medury Y.(2014) concluded that financial literacy levels are affected by gender, education, income, nature of employment, and place of work, but not by age or geographic region.

Kaur R. (2021) concluded that financial literacy levels were significantly influenced by age, family life stage, academic qualification, occupational sector, work profile, monthly income, total work experience, and tax payment status, but not by residential house status. The financial behavior of respondents and the factors affecting their investment decisions were found to be significantly related to these same factors, except for work profile. Additionally, the study found that financial literacy levels significantly impacted financial behavior and investment decision-making.

Singh C. (2019) concluded that financial knowledge, financial behavior, and financial attitude are the three main components determining financial literacy. The study also found a positive association between all three components. Working women who had knowledge of numeracy, inflation, interest, risk and diversification, and the time value of money were more likely to have a risk-taking attitude, feel confident in their investment decisions, and be satisfied with their current financial status.

3. OBJECTIVES :

The main objective of this study is to assess the level of financial literacy among farmers in Junagadh District, Gujarat.

- Specific objectives include:

1. To Identify the factors that influence financial literacy among farmers in Junagadh District.
2. To Understand the preferences of farmers in collecting financial information.
3. To Evaluate the financial knowledge of farmers.

4. RESEARCH METHODOLOGY :

Research Design : It is based on descriptive design

Sampling Frame :

Sample size : 115 Farmers

Sample unit : Farmers

Sampling Methodology : Convenient Sampling

Data Collection : Primary : Structured Questionnaire

Secondary : Websites, Articles, Reports, etc.

Data Analysis Techniques : SPSS, Frequency, Mean and Percentage

5. DATA ANALYSIS :

- **RESPONDENCE PROFILE**
  1. **Demographic Details**
  a. **Frequency Analysis**

Variable		Frequency	Percent	Remarks
Gender	Male	84	73.0	The majority of the respondents are Male
	Female	31	27.0	
	Total	115	100.0	
Age	18-30	23	20.0	The majority of the respondents belong to the age group of 41 years to 50 years
	31-40	23	20.0	
	41-50	48	41.7	
	51-60	15	13.0	
	Above 60	6	5.2	
	Total	115	100.0	
Education level	illiterate	17	14.8	The majority of the respondents had education up to 10th
	Upto 10th	54	47.0	
	12th pass	21	18.3	
	Graduate	14	12.2	
	Post graduate	9	7.8	
	Total	115	100.0	

Occupation	Agri Holder only	23	20.0	Most of the respondents are cultivators who own the land and are engaged in farming activities
	Cultivators	88	76.5	
	Tenants / Sharecropper	3	2.6	
	other	1	.9	
	Total	115	100.0	

2. **Socio Economic Information**

a. Frequency Analysis

Variable		**s**	**Percent**	**Remarks**
Marital Status	Married	95	82.6	Most of the respondents are married.
	Divorced	2	1.7	
	Unmarried	18	15.7	
	Total	115	100.0	
How many persons are there in your family?	2	9	7.8	Most of the respondents said that they have more than 2 members in a family.
	2-4	53	46.1	
	more than 4	53	46.1	
	Total	115	100.0	
How many earning persons are there in your family?	1	52	45.2	Most of the respondents said that they are the only bread earners of the family
	2	42	36.5	
	3-4	21	18.3	
	Total	115	100.0	
Religion	Hindu	114	99.1	Most of the respondents are Hindu
	Muslim	1	.9	
	Total	115	100.0	
Social group	General	23	20.0	Most of the respondents belong to the OBC category
	SC	1	.9	

	ST	1	.9	
	OBC	90	78.3	
	Total	115	100.0	
How do you make Financial Decisions in the house?	Individual	13	11.3	Most of the respondents make joint decisions with all family members
	Joint decision with life partner	24	20.9	
	Joint decision of all family members	77	67.0	
	After consulting financial advisor	1	.9	
	Total	115	100.0	
Farming land	Owned	108	93.9	Most of the respondents owned the farming land.
	On rent	7	6.1	
	Total	115	100.0	
Land for Farming (in Vigha)	0-5	14	12.2	Most of the respondents have 10 to 20 vidha land for farming.
	5 to 10	33	28.7	
	10 to 20	51	44.3	
	20 to 30	11	9.6	
	Above 30	6	5.2	
	Total	115	100.0	
House	Owned	108	93.9	Most of the respondents owned a house
	Leased/Rented	6	5.2	
	12	1	.9	
	Total	115	100.0	
House Condition	Kacha	8	7.0	Most of the respondents have a "Pakka" house
	Pakka	107	93.0	

	Total	115	100.0	

Assets Own:	Assets	Owned	Do not Own	Remarks
	Fridge	101	14	Most of the respondents owned the fridge as a basic household Asset
	Gas Stove	106	9	Most of the respondents owned the gas stove as a basic household Asset
	TV	95	20	Most of the respondents owned the TV as a basic household Asset
	Toilet	107	8	Most of the respondents owned the toilet as a basic household need
	Cycle	18	97	Most of the respondents do not own the cycle
	Bike	109	6	Most of the respondents owned the bike
	Car	21	94	Most of the respondents do not own the car
	Mobile Phone	93	22	Most of the respondents owned the phones
	Bullock Cart	58	57	Most of the respondents owned the bullock cart
	Tractor	45	70	Most of the respondents do not own the tractor
	Thresher	15	100	Most of the respondents do not own the thresher
	Trolly	18	97	Most of the respondents do not own the trolly

3. Sources of Information

a. Frequency Analysis

	Not preferred	Least preferred	Neutral	Somewhat Preferred	Most preferred	Remarks
Newspaper	25	33	19	24	14	Most of the respondents agreed that

						they least preferred newspapers
TV channels	16	35	18	39	7	Most of the respondents agreed that they somewhat preferred TV channels
Internet	31	13	28	26	17	Most of the respondents agreed that they not preferred the internet
Financial Advisor	12	18	33	35	17	Most of the respondents agreed that somewhat preferred
Friends and relatives	9	11	24	51	20	Most of the respondents agreed that they somewhat preferred friends and relatives
Books and magazines	28	29	22	28	8	Most of the respondents least preferred Books and Magazines
Social media	26	28	34	16	11	Most of the respondents they were neutral

b. Mean

	N	**Mean**	**Rank**
Sources of Financial Information_Friends and relatives	115	3.54	1
Sources of Financial Information_Financial advisor	115	3.23	2
Sources of Financial Information_TV channels	115	2.88	3
Sources of Financial Information_Internet	115	2.87	4
Sources of Financial Information_Newspaper	115	2.73	5
Sources of Financial Information_Books and magazines	115	2.64	6
Sources of Financial Information_Social Media	115	2.63	7

- **FINANCIAL LITERACY**

1. Awareness of financial avenue

a. Mean

	N	Mean	Rank
From the given terms, which of the different investment avenues are known to you? _Gold and Silver	115	4.12	1
From the given terms, which of the different investment avenues are known to you? _Real Estate	115	3.97	2
From the given terms, which of the different investment avenues are known to you?_Bank Deposits	115	3.56	3
From the given terms, which of the different investment avenues are known to you?_Post Office Deposits	115	3.5	4
From the given terms, which of the different investment avenues are known to you? _Insurance	115	3.29	5
From the given terms, which of the different investment avenues are known to you? _Commodity Market	115	2.88	6
From the given terms, which of the different investment avenues are known to you?_Mutual Fund	115	2.6	7
From the given terms, which of the different investment avenues are known to you? _Givernment Securities	115	2.55	8
From the given terms, which of the different investment avenues are known to you? _Shares	115	2.53	9
From the given terms, which of the different investment avenues are known to you?_Govt. Pension Scheme	115	2.47	10
From the given terms, which of the different investment avenues are known to you? _Senoir citizen Saving Scheme	115	2.37	11
From the given terms, which of the different investment avenues are known to you? _Debenture and Bond	115	2.2	12

2.Awareness about financial terms:

a. Mean

	N	Mean	Rank
From the given terms, which of the financial terms are known to you? _Banking Terms_ATM	115	1.09	1
From the given terms, which of the financial terms are known to you? _Basic terms_Return	115	1.12	2
From the given terms, which of the financial terms are known to you? _Basic terms_Risk	115	1.23	3
From the given terms, which of the financial terms are known to you? _Basic terms_Simple interest and compound Interest	115	1.23	4
From the given terms, which of the financial terms are known to you? _Banking Terms_Bank Cheque	115	1.3	5
From the given terms, which of the financial terms are known to you? _Banking Terms_Premium	115	1.38	6

From the given terms, which of the financial terms are known to you? _Banking Terms_Sum Assured	115	1.41	7
From the given terms, which of the financial terms are known to you? _Basic terms_Inflation	115	1.45	8
From the given terms, which of the financial terms are known to you? _Banking Terms_Bullish and Berish	115	1.54	9
From the given terms, which of the financial terms are known to you? _Banking Terms_Debit Card	115	1.67	10
From the given terms, which of the financial terms are known to you? _Basic terms_Holding Period	115	1.69	11
From the given terms, which of the financial terms are known to you? _Banking Terms_Mobile Banking	113	1.7	12
From the given terms, which of the financial terms are known to you? _Banking Terms_Claim	115	1.7	13
From the given terms, which of the financial terms are known to you? _Banking Terms_Internet Banking	115	1.73	14
From the given terms, which of the financial terms are known to you? _Banking Terms_SIP	115	1.73	15
From the given terms, which of the financial terms are known to you? _Banking Terms_Credit Card	115	1.74	16
From the given terms, which of the financial terms are known to you? _Banking Terms_Digital Payment	113	1.75	17
From the given terms, which of the financial terms are known to you? _Basic terms_KYC	115	1.8	18
From the given terms, which of the financial terms are known to you? _Banking Terms_SEBI	115	1.8	19
From the given terms, which of the financial terms are known to you? _Banking Terms_RBI	115	1.82	20
From the given terms, which of the financial terms are known to you? _Banking Terms_Demand Draft	115	1.84	21
From the given terms, which of the financial terms are known to you? _Banking Terms_Dividend	115	1.84	22

From the given terms, which of the financial terms are known to you? _Banking Terms_Bank Overdraft	115	1.86	23
From the given terms, which of the financial terms are known to you? _Banking Terms_Sensex and Nifty	115	1.86	24
From the given terms, which of the financial terms are known to you? _Banking Terms_SWP	115	1.87	25
From the given terms, which of the financial terms are known to you? _Banking Terms_RTGS	115	1.88	26
From the given terms, which of the financial terms are known to you? _Banking Terms_BSE and NSE	115	1.88	27
From the given terms, which of the financial terms are known to you? _Banking Terms_NEFT	115	1.9	28
From the given terms, which of the financial terms are known to you? _Banking Terms_IRDA	115	1.9	29
From the given terms, which of the financial terms are known to you? _Banking Terms_DeMAT	115	1.91	30
From the given terms, which of the financial terms are known to you? _Basic terms_Annuity	115	1.95	31
From the given terms, which of the financial terms are known to you? _Banking Terms_NAV	115	1.95	32
From the given terms, which of the financial terms are known to you? _Banking Terms_Market Capitalization	115	2.06	33

6. DISCUSSION / ANALYSIS:

Demographic detail

- Majority of the respondents are from Porbandar District
- The majority of the respondents are Male
- The majority of the respondents belong to the age group of 41 years to 50 years
- The majority of the respondents had education up to 10th
- Most of the respondents are cultivators who own the land and are engaged in farming activities

Socio-economic details

- Most of the respondents are married.
- Most of the respondents said that they have 2-4 members in a family
- Most of the respondents said that they are the only bread earners of the family
- Most of the respondents are Hindu
- Most of the respondents belong to the OBC category
- Most of the respondents make joint decisions with all family members

- Most of the respondents owned the farming land.
- Most of the respondents have 10 to 20 vidha land for farming.
- Most of the respondents owned a house
- Most of the respondents have a "Pakka" house
- Most of the respondents owned fridge, gas stove, TV, toilet, bike, and bullock cart
- Most of the respondents do not own a cycle, car tractor thresher trolly
- Most of the respondents have annual income between 1 lakh to 5 lakh
- Most of the respondents do not have any other source of income

Information related factors

- Most of the respondents agreed that they least preferred newspapers, the internet, Books and Magazines, and, they somewhat preferred TV channels and friends & relatives and they are neutral about social media for getting financial advice
- As per mean analysis, farmers preferred to collect information and advice from friends and relatives compared to other sources of financial information and advice

Financial Literacy: Financial Knowledge

- Most of the farmers are aware of post office deposits, bank deposits, insurance, gold & silver, and real estate.
- Most of the respondents can't say about mutual funds, senior citizen saving schemes, govt. Pension schemes, commodity markets, and government securities
- Most of the respondents have never heard about shares and debentures.
- As per the mean analysis, most of the respondents are highly aware of gold & Silver compared to other investment avenues.
- As per mean analysis, most of the respondents are aware of the ATM and return term compared to other terms related to the financial market.

8. CONCLUSION :

In conclusion, the majority of the respondents in this study are male, aged between 41 to 50 years, with education up to 10th grade. They primarily belong to the OBC category and are married, with 2-4 members in their families. Most are cultivators who own land and are engaged in farming activities, with a significant portion being the sole breadwinners. Their annual income ranges from 1 lakh to 5 lakh, and they rely mostly on farming for their livelihood, with limited access to additional income sources. The respondents tend to gather financial information from friends and relatives rather than media or financial advisors, and exhibit a strong awareness of traditional investment avenues such as post office deposits, bank deposits, gold & silver, and real estate. However, their knowledge of more complex financial instruments like mutual funds, shares, and government securities is limited. Despite this, they show familiarity with key financial terms and concepts such as inflation, interest, risk, and return, with particular awareness of investment returns.

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Machine Learning Techniques to Predict Heart Disease: A Comparative Performance Analysis

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Abstract: *The heart is the central organ of the cardiovascular system in the human body. The heart disease is still among the top causes of death and undeniably poses a life-threatening risk. It's crucial for both individuals and healthcare systems to prioritize early diagnosis and proactive management to mitigate the impact of heart disease on public health. Heart Disease is also called Cardiovascular Disease. Machine Learning & Artificial Intelligence indeed makes some great strides in revolutionizing health care, especially within sectors related to heart diseases prediction. Through analyzing huge data and recognizing patterns, AI and ML models can help in early detection and better management of heart. The different machine learning (ML) algorithms vary in performance based on the nature of the problem, the data used, and the characteristics of the model. The main objective of this research is a Comparative Performance Analysis of the (SVM) Support Vector Machine and K- Nearest Neighbors (KNN) algorithms to determine which one provides better prediction accuracy for heart disease using the UCI datasets.*

Key Words: *Machine Learning, Support Vector Machine, K-Nearest Neighbour, Supervised Learning, Heart Disease,*

1. INTRODUCTION: The heart, being the most essential organ in the human. Early detection of heart diseases can be a significant challenge in countries or regions where healthcare infrastructure is limited or not easily accessible. Machine Learning brings tremendous possibility for better healthcare outcomes, about early heart diseases detection. Machine Learning is a branch of Artificial Intelligence that equips systems to learn from data, uncover patterns, and make decisions without specific programming. In healthcare, ML techniques can be incredibly powerful in solving problems related to diagnostics, predictive analytics, personalized treatment, and more. Over the years, numerous efforts have been made by researchers to apply Machine Learning techniques to predict heart diseases, and this area has become a vibrant field of study due to its potential to improve diagnostic accuracy, aid in early detection, this is an additional effort to compare two popular Machine Learning Techniques on benchmarking UCI Machine learning Repository datasets et al [7]. When comparing two popular machine learning techniques to determine which one is more efficient model.

2. LITERATURE REVIEW:

Baban U. Rindhe,Nikita Ahire, Rupali Patil,Shweta Gagare, & Manisha Darade et al [1] applied data classification techniques like support vector machine, artificial neural network(ANN), random forest. The project centers on analyzing a dataset of heart disease patients, with a particular focus on ensuring proper data processing techniques. The UCI dataset used, which contains 14 input features in 303 samples & 1 output feature. They analyze the loan applicant data, with its features describing the social, personal, and financial characteristics of the applicants. It offers detailed insight into the machine learning algorithms that are used within the heart disease classification. Predicting cardiovascular risk using machine learning (ML) models is emphasizing the comparison of already existing techniques to identify most accurate and efficient systems for the early detection of heart diseases. They achieved 84.0% accuracy using support vector machine, 83.5% accuracy using neural network & 80.0% accuracy using Random forest classifier.

Archana Singh, Rakesh Kumar, et al [2] have computed the accuracy of machine learning algorithms in predicting heart disease from the UCI Heart Disease dataset using the four algorithms: Decision Tree, Support Vector Machine, K-Nearest Neighbours and Linear Regression. The dataset used is that from the UCI Machine Learning Repository to predict heart disease. The UCI repository is well-verified and has been used by researchers in different domains. They used train & test ratio as 73% - 27% of the data for the model. K-Nearest Neighbours outperforms other algorithms in this analysis of heart disease prediction. The confusion matrix is a great way to evaluate the performance of machine learning algorithms, so decision tree provides 79%, support vector machine provides 83% and linear regression 78%, k-nn 87%.They concluded that k-nearest neighbours is best among them.

Vijeta Sharma, Shrinkhala Yadav, Manjari Gupta, et al[3] have used the UCI Heart Disease Dataset, for predictive modeling tasks related to heart disease prediction. The dataset related to heart disease with 14 attributes. Naive Bayes, Random Forest, Decision Tree and Support Vector Machine used to predict the ML model. The Cleveland Heart Disease Dataset that is easily accessed from the UCI Repository was used in the experiments performed with 1025 instances, where handling of missing values was part of the pre-processing process itself. Data is split & allocating 80% for training & 20% for testing. The model has been created using the Weka Data Mining Tool. Finally, result of experiment shows that Random Forest achieves the highest accuracy of 99% and SVM achieves accuracy of 98% as compared to Decision Tree and Gaussian Naive Bayes. Their result can vary greatly with the chosen set of data, its characteristics, but in the case of their experimentation they have found this one out.

Abhijeet Jagtap, Priya Malewadkar, Omkar Baswat, & Harshali Rambade,et al [4] have developed a web application which makes use of machine learning to predict the risk for heart disease, based on a model trained on UCI dataset. A heart disease prediction web application that utilizes datasets from Kaggle and the Cleveland Heart Disease dataset. They intend to identify a machine learning technique that efficiently predicts the heart disease. Predicting heart disease based on user inputs and displaying the result on a webpage is an excellent way to make healthcare more accessible, faster, and efficient using machine learning. The format of the data has played a crucial role in the effectiveness of the system. System has used a set of algorithms like Logistic Regression, Support Vector Machine & Naive Bayes. The machine learning algorithms were trained with 75% of the training set of data and 25% of the testing set of data. Besides, several strategies and techniques applied to optimize the algorithms for heart disease prediction. The server will interact with the MySQL database to process user data. In the project, classifying patients into different groups based on heart disease predictions is useful, especially in healthcare applications depending on their medical details. They found that SVM achieved an

accuracy of 64.4%, Logistic Regression had 61.45%, and Naive Bayes reached 60%. As a result, SVM was chosen as the most effective algorithm for their web application.

Srinivas Kanakala, Vempaty Prashanthi et al [6] have made prediction and comparison using various algorithms for research in heart failure: using, decision tree, logistic regression, random forest, Support Vector Machine, Naive Bayes & K-nearest neighbor, etc. A heart failure prediction project entirely depends on data quality; the more relevant it will be for the task or problem being solved and enhances the effectiveness of a given predictive model. The given dataset to train models from a CSV file:. The main objective of data cleaning is to enhance the quality of the dataset, handling issues of missing values, duplicates, inconsistencies, and outliers. Understanding the significance of data in each column and its relationship with heart health is significant for feature processing as well as model interpretation. It is among the key steps in the machine learning workflow that splits the data into training and test datasets. After thorough analysis, it was observed that the random forest and decision trees performed better than other algorithms in predicting heart failure. The highest area under the ROC curve and the highest accuracy was shown by random forest, which means it is effective in distinguishing the positive and negative cases of heart failure. Through the use of Random Forest, heart failure prediction can be made much more accurate, and earlier intervention is possible, thus improving the outcome for the patient.

RELATED WORK USING ML TECHNIQUES

Authors	Algorithms	Dataset	~Approx. Accuracy
Baban. U. Rindhe, Nikita Ahire,Rupali Patil, Shweta Gagare,& Manisha Darade[1]	ANN,RF,SVM	UCI dataset ~303	Neural Network -83.5% SVM - 84.0 % RF Classifier– 80.0%
Archana Singh, Rakesh Kumar,[2]	KNN,DT,LR, SVM	UCI dataset	SVM -83% DT -79%, LR -78% , KNN -87%
Vijeta Sharma, Shrinkhala Yadav, Manjari Gupta.[3]	RF,SVM, Naive Bayes, DT	UCI dataset ~1025	SVM 98%,RF-99% Naive Bayes- 90% DT – 85%
Abhijeet Jagtap, Priya Malewadkar,Omkar Baswat,& Harshali Rambade [4]	SVM,LR, Naive Bayes	Kaggle and Cleveland Foundation medical Research	SVM-64.4% Naive Bayes – 60% LR – 61.45%
D. Hemalatha, S. Poorani, [5]	DT,MLP, Naive Bayes, RF,SVM	Cleveland Dataset from UCI ~303	MLP– 77.54 % J48 -96.04% SVM- 73.44 % Bayesnet- 90.33 % RF- 80.22 %
Nikhil Bora, Sreedevi Gutta, Ahmad Hadaegh [8]	Naïve Bayes, LR,SVM, KNN,RF, XGBoost	UCI dataset ~ 303	Naïve Bayes–86.89% LR – 90.16% SVM – 91.80% KNN – 90.16% RF – 90% XGBoost – 88.52%

Table 1 Related work using ML Techniques

3. RESEARCH METHOD:

Data Collection: The process begins with data collection, where the UCI Repository et al [7] dataset used, which has been thoroughly validated and widely used by researchers.

Pre-Processing: It is an important phase in machine learning workflow. It generally includes cleaning, transforming and getting data in the right shape to let the machine learn algorithm effectively learn from the data. This process can considerably improve the precision & ability to apply with new unseen data for more trustworthy and interpretable results.

Training: Training a model involves using a data to teach the algorithm for making decisions or predictions & recognize patterns based on data. The process usually involves the following stages: selecting a model, training of the model and evaluation of the performance.

Validation: This involved the division of the given dataset into training set & testing set, which is a must for machine learning models to predict heart disease. The dataset is divided in two sections, one set to train the model & another set to evaluate its performance.

Testing: It is the procedure by which one checks how a trained model performs on another, unseen dataset in terms of generalizing to new data from the real world. It is a very important step since the purpose of the model is not just to learn about patterns in the training data but for making correct predictions on fresh unseen data as well.

4. PROPOSED MACHINE LEARNING TECHNIQUES:

4.1 SUPPORT VECTOR MACHINE

A SVM is a type of supervised learning technique of a machine that is powerful & widely used mainly because it can work well in high-dimensional spaces and is resistant to over fitting especially for higher dimensions than the numbers of data points. In SVM, the goal is to find a decision boundary that best separates the data into different classes. For binary classification, this hyper plane splits the feature space into two regions, each representing one class. In higher-dimensional spaces, the hyper plane is a generalization of a plane in three dimensions or a line in two dimensions. SVM is very powerful and flexible machine learning technique, especially good at high-dimensional datasets, and effective in situations where other algorithms may struggle. Its strength lies in creating very accurate classification models with clear decision boundaries, even if the data isn't perfectly separable. SVM is also ideal for problems where the number of features exceeds the number of samples. It doesn't need to store the whole data set, only the support vectors. Both classification and regression problems are possible to solve by its application.

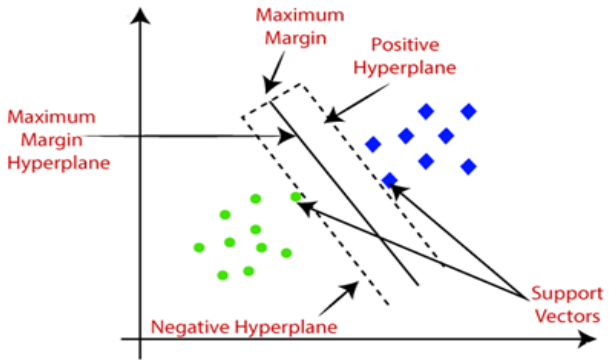

Figure 1 Support Vector Machine

4.2 K-NEAREST NEIGHBOURS

The (k-nn) K-Nearest Neighbors algorithm is a straightforward, non-parametric method. A Regression & classification algorithm used for both tasks supervised learning based on the principle that similar data points are likely to have the same label or output. It works by looking at the 'K' closest labelled data points in feature space and determining the most common class in case of averaging values in regression or classification. K is a hyper parameter that defines how many neighbors to consider in making a prediction. It is an important parameter that affects the performance of the algorithm: A small K, say K=1 can make the model susceptible to fluctuations or random variations in the data, that means overfitting. & if K is large, it makes the algorithm smoother and more robust, but too large can lead to underfitting. It is easy to understand and implement. No assumption on the underlying data distribution has to be made and that gives it flexibility and hence adaptability to a broad number of datasets. It can be utilized on either classification or regression problem sets. It goes great with small datasets when their distribution is not highly complicated.

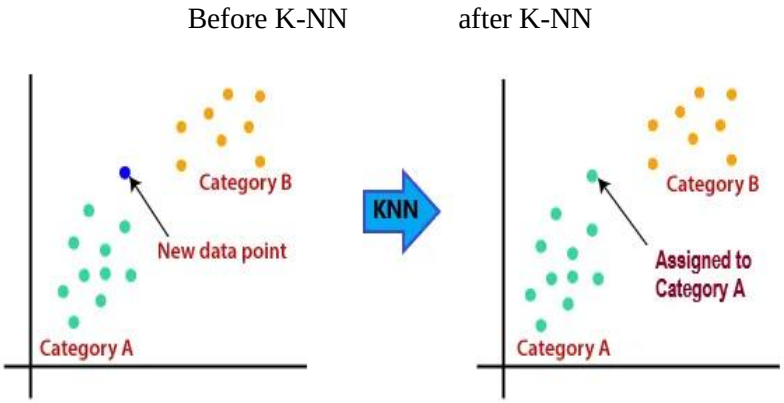

Figure 2 K-Nearest Neighbours

5. DISCUSSION:

As we have reviewed above K- Nearest Neighbour & SVM Machine Algorithms for the predicting heart disease, are summarized as given in below table.

METHODS OF MACHINE LEARNING	~APPROX. ACCURACY	
SVM	83%	91.80%

KNN	87%	90.16%

Table 2 Reviewed Comparison

6. CONCLUSION:

Dataset attributes are critical in the process of training and making forecasting with machine learning. Evaluating the performance of different ML methods is essential in selecting the most appropriate one for predicting heart disease. The different ML techniques will be examined based on the performance for better prediction of the Heart Disease Using UCI Dataset. The heart disease prediction is done using machine learning (ML) technique like SVM and K-Nearest Neighbours. By comparing multiple ML algorithms & analysing their own effectiveness, we can identify the most suitable algorithm for the prediction of heart disease based on the available dataset, ensuring an efficient & effective forecasting process.

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Analyzing the Evolution of Emotional Expression in Microblogging Platforms

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Abstract: In order to guide the correct direction of public opinion on public events and create a harmonious and healthy social atmosphere, this paper uses media dependency theory to study the current microblogging platform, which has the highest national discussion, for emotional expression. The rapid development of online social media has attracted a large number of users, and government microblogs have widely spread their influence by virtue of the openness of the social media platform itself. In recent years, government microblogs have gradually become important channels for the public to pay attention to government policy information and understand the effect of government policy.Any opinion/review given by any of an individual through which the feelings,text message, attitudes and thoughts can be expressed is known as sentiment. The kinds of data analysis which is attained from the news reports, user reviews, social media updates or microblogging sites is called sentiment analysis which is also known as opinion mining.it is an approach which is used to analyse sentiment of input data.The reviews of individuals towards certain events, brands, product or company can be known through sentiment analysis

Key Words: Micro blogging, evolution, topic identification, sentiment analysis, data analysis

INTRODUCTION:

The emergence of microblogging platforms like Twitter and others has profoundly changed the ways individuals and organizations communicate and express feelings. These platforms enable users toshare brief snippets of information and viewpoints, frequently reflecting personal and shared emotionsin reaction to events, trends, and social movements. The idea of emotion evolution on microblogging refers to the shifting patterns of emotional expression over time due to ongoing discussions, crises, or societal changes. This review of literature investigates key studies and theories that explore how emotions transform on microblogging platforms, emphasizing emotional spread, sentiment analysis, computational techniques, and the influence of collective emotional behavior.

Microblogging:

Microblogging is a form of online communication where users post short, frequent updates

or content,typically in the form of text, images, videos, or links. These posts are often brief (usually under 280 characters on platforms like Twitter) and are designed to be easily consumed and shared. Microblogging platforms enable users to express thoughts, share news, or engage in discussions quickly and publicly. Popular examples include Twitter, Tumblr, and Instagram, where users canshare their personal opinions, experiences, and media with a wide audience.

To work with microblogging, you need to follow these basic steps:

1. **Choose a Platform**: Select a microblogging site like Twitter, Tumblr, Instagram, or others that allow for brief updates and interactions.
2. **Create an Account**: Sign up on the platform by providing your information (like email, username, and password) to create an account.
3. **Post Content**: Write short posts (called tweets, posts, or updates) consisting of text, images, videos, or links. The content should be concise and engaging.
4. **Use Hashtags**: Hashtags help categorize your posts and make them discoverable to a wider audience. For example, using #travel or #technology helps people interested in those topics find your content.
5. **Engage with Others**: Interact with other users by liking, commenting, retweeting, or sharing their posts. Engagement builds your presence and connects you with a community.
6. **Follow Accounts**: Follow people, brands, or topics that interest you. This allows you to stay updated on the latest posts and trends in your areas of interest.
7. **Post Regularly**: Consistency is key in microblogging. Frequent posting helps keep your audience engaged and attract new followers.
8. **Monitor Analytics**: Many microblogging platforms offer analytics tools to track the performance of your posts, allowing you to adjust your content strategy based on what works.

Microblogging is about quick, informal communication with a broad audience, often on trending topics or personal updates

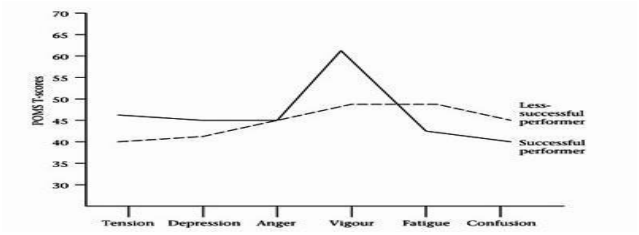
Use:

We use microblogging for quick, real-time communication, personal expression, sharing updates, engaging with others, following trends, and building online communities. It's also a tool for brand promotion and staying informed.

Types of Emotions :

1.1 Types of Emotions

PROFILE OF MOOD STATE (POMS) SIX MOOD STATE:



1.2 Mood State

Analyze emotion information challenges

Examine the difficulties in analyzing emotion information.addressing the loud nature of microblogs, which are typically written informally using colloquial phrases, acronyms, and other shorthand and are just 140 characters long. determining which particular keywords are pertinent to each general subject. It should be noted that, while being pertinent to a topic, each microblog only has a few words and may not contain the majority of the specified words.

LITERATURE REVIEW:

1. Title: Emotional Communication Analysis of Emergency Microblog Based on the Evolution LifeCycle of Public Opinion

Purpose: Microblog is one of the most crucial platforms for spreading public opinion about emergencies online. The practice of crisis management and other areas greatly benefit from an analysis of the characteristics and mechanisms of evolution of online public opinion on emergencies.This study examines the impact of various emotional microblogs (joy, anger,

sadness, fear, and disgust) and cyclic stages on the spread of information by combining the case of Hurricane Irma withthe life cycle of online public opinion evolution. Hurricane Irma and the volume of Tweets related to that incident served as the backdrop for our investigation. We discover that negative emotional content communicates well, and target audiences who are exposed to more depressing or frightening microblogs are more likely to retweet [2].

Author: Ling Zhang

2. Title: Understanding Environmental Posts: Sentiment and Emotion Analysis of Social Media Data

Purpose: Because social media allows for instant public response, it has become the most popular information source. Consequently, social media data has emerged as a useful tool for understanding public opinion. According to studies, it has the power to spread ideas and sway public opinion. This study examines how the general population views the environment and climate change during the ten- year period from 2014 to 2023. We analyze sentiment and investigate the most common emotions conveyed in environmental tweets on Twitter, Reddit, and YouTube using the Pointwise Mutual Information (PMI) method. On a dataset with human annotations, the accuracy was 0.65, which was greater than Vader's score but lower than an expert rater's (0.90).

Author: DANIYAR AMANGELDI

3. Title: A review on sentiment analysis and emotion detection from text

Purpose: Because social networking sites have grown so quickly in the Internet age, they are now a vital tool for sharing emotions with people all over the world. Many people convey their emotions or opinions through text, images, music, and video. However, using Web-based networking media for text conversation can be a little daunting. Social media sites create enormous amounts of unstructured data on the Internet every second. Sentiment analysis, which detects polarity in texts, can be used to process the data as quickly as it is generated in order to understand human psychology. It determinesif the author's opinion toward a thing, a person, an administration, or a place is neutral, favorable, or negative. Sentiment analysis alone isn't enough in some situations; emotion is needed instead.

Author: Pansy Nandwani

4. Title: Literature Review of Sentiment Analysis Techniques for Microblogging Site

Purpose: Sentiment is any opinion or assessment provided by an individual that allows for the expression of feelings, thoughts, attitudes, and text messages. Sentiment analysis, sometimes referred to as opinion mining, is the type of data analysis that is obtained from news articles, user reviews, social media updates, or microblogging websites.It is a method for analyzing the sentiment of input data. Sentiment analysis can be used to learn how people

feel about particular events, brands, products, or businesses. Researchers gather and improvise public answers in order to conduct assessments. Since more individuals are sharing their opinions on microblogging sites, sentiment analysis is becoming more and more popular.

Author: Priyanka Tyagi

RESEARCH METHOD:

The methodology for analyzing the evolution of emotional expression in microblogging platforms typically involves:

1. **Data Collection**: Gathering posts, comments, and interactions from platforms like Twitter orTumblr over a set period.
2. **Sentiment Analysis**: Using natural language processing (NLP) techniques to classify emotions (e.g., happiness, anger, sadness) in text.
3. **Trend Analysis**: Identifying patterns in emotional expressions across time, events, or userdemographics.
4. **Contextual Analysis**: Considering outside factors such as global actions or platform changesthat may influence emotional expression.
5. **Comparative Study**: Comparing emotional trends between different platforms or user groups.

NLP (Natural Language Processing) is a field of artificial intelligence (AI) that focuses on the interaction between computers and human language. It enables machines to understand, interpret, and generate human language in a way that is both meaningful and useful.

NLP's primary tasks include:
1. Text classification, which involves grouping text into predetermined categories (such as sentimentanalysis and spam detection).
2. Sentiment Analysis: Figuring out a text's sentiment, such as whether it is neutral, negative, orpositive.
3. Named Entity Recognition (NER): Recognizing and categorizing important textual elements(names, dates, and locations).
4. Machine translation, such as Google Translate, is the process of automatically translating textacross languages.
5. Speech Recognition: Translating spoken words into text (e.g., Siri and other voice assistants).
6. Content Generation: Producing meaningful and cohesive content from input; frequently utilized increative writing and catboats.
7. Question Answering: Providing automated responses to queries based on extensive data sets orcontext (e.g., Google Search).

NLP Methods:

- **Tokenization**: Breaking text into smaller parts.

- **Lemmatization and stemming:** Involve breaking words down into their most basic or rootforms.
- **Parsing**: Analyzing sentence structure and relationships between words.
- **Vectorization**: Converting text into numerical form

Applications such as chatbots, virtual assistants, content recommendation systems, and search enginesall make extensive use of natural language processing (NLP).

DISCUSSION:

Sentiment Trends: Tracking shifts in sentiment (positive, negative, neutral) over periods, such asduring major events or crises.
Emotional Intensity: Examining whether emotional expressions have become more intense or subtle. Platform Impact: Understanding how platform design or features influence emotional expression (e.g.,character limits, hashtags).
Cultural and Social Factors: Investigating how cultural trends, global events, or social movementsshape online emotional tone.
Demographic Differences: Analyzing emotional differences across age groups, regions, or userinterests.

CONCLUSION:

Emotion evolution on microblogging platforms is a dynamic and complex phenomenon, shaped by individual emotions, network interactions, and temporal dynamics. Through sentiment analysis, computational models, and network studies, researchers have made significant strides in understanding how emotions spread and evolve in real-time digital environments. The findings from these studies have broad applications in areas like public health, politics, and marketing, providing valuable insights into how emotions influence collective behaviour and decision-making in the digital age. As microblogging platforms continue to grow and evolve, the study of emotion evolution will remain an important field for researchers and practitioners alike.

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Motion Sensor-Based Fall Prevention for Child Care in IOT

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***Abstract*:** *This paper presents the design and development of a smart motion sensing system aimed at preventing child falls from heights, a leading cause of injury among young children. The system integrates motion sensors, including accelerometers, gyroscopes, and proximity detectors, to continuously monitor a child's position and behaviour in high-risk areas such as windows, balconies, and stairs. By analysing real-time data, the system detects potentially dangerous movements or posture shifts that indicate fall risks. In response, it triggers immediate alerts to caregivers via mobile apps or activates automated safety measures, such as locking windows or deploying barriers. Combining sensor fusion, data processing algorithms, and wireless communication, the system offers a scalable, non-intrusive solution for enhancing child safety. Prototype testing and simulations demonstrate its effectiveness as a preventive tool, highlighting its potential for both home and institutional use.*

Keywords: *Child fall prevention, Fall detection system, Fall risk assessment, Safety monitoring*

INTRODUCTION:

One of the main reasons kids are hurt is falls, especially in places like playgrounds, daycare facilities, and houses. For both parents and caregivers, preventing these situations is crucial because they have the potential to cause major physical harm. The potential to improve kid safety through intelligent, sensor-based systems is increasing as a result of the quick development of technology, especially in the field of the Internet of Things (IoT). These systems use Internet of Things (IoT) devices with sensors to track kids' movements in real time and identify possible falls.

What is a motion sensor?

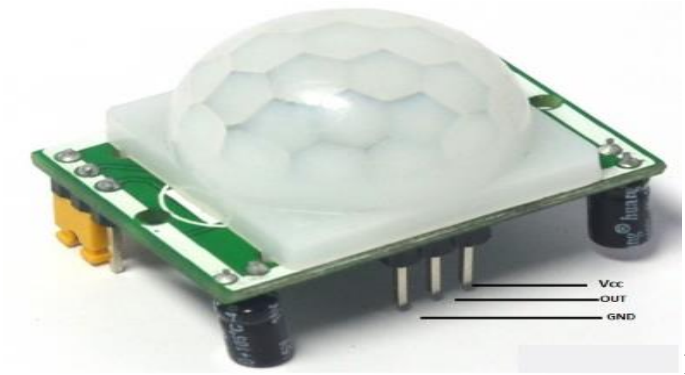
An electronic gadget called a motion sensor is made to recognize movement and alterations in the immediate surroundings. It is frequently utilized in home automation, lighting control, and security systems. The motion sensor can precisely detect motion and set off personalized reactions thanks to a variety of technologies, such as infrared, ultrasonic, and microwave detection. Motion sensors offer smooth automation and energy efficiency for everything from turning on lights to setting off alarms.

Types of Motion Sensors

There are many different types of motion sensors on the market, each with its own advantages and disadvantages. These include PIR, microwave, ultrasonic, tomographic, and hybrid varieties.

Passive Infrared (PIR) Sensor

Infrared radiation is produced by all warm-blooded creatures. The thin pyroelectric film material used in passive infrared sensors reacts to infrared radiation by producing electricity. Every time this electrical surge occurs, this sensor will sound the burglar alarm. These sensors are cost-effective, energy-efficient, and long-lasting. Indoor alarms frequently use these sensors.



Passive Infrared Sensor

Ultrasonic Sensor

Both active and passive ultrasonic sensors are possible; passive sensors listen for specific sounds, such as glass breaking or metal hitting metal. Despite their high sensitivity, these sensors are often costly and prone to false alarms. Active ones produce pulses of ultrasonic waves, also known as sound waves, and then measure how well they reflect off of moving objects. Because they can hear these sound waves, animals like fish, dogs, and cats may become agitated by an active ultrasonic alarm.

Ultrasonic Sensor

Microwave Sensor

To determine whether or not an object is moving, these sensors produce microwave pulses and then compute how much of them are reflected off of it. Although microwave sensors are extremely sensitive, they can occasionally detect moving items outside of their target range by detecting non-metallic objects. These sensors are often configured to cycle ON & OFF due to their high power consumption. If you are aware of the cycles, this makes it possible to get over them. Microwave sensors are used by electronic guard dogs.

Microwave Sensor

Tomographic Sensor

These sensors produce radio waves and identify disturbances in those waves. They are often positioned to create a radio wave net that covers wide regions and can see through buildings and objects. Due to their high cost, these sensors are typically found in storage facilities, warehouses, and other settings requiring a business-level level of protection.

Tomographic Sensor

Combined types of Motion Sensors

To reduce false alerts, several motion detector types include many sensors. However, only when both types detect motion do dual sensors become active. For example, because it uses less energy, a dual

microwave or PIR sensor will initially be set to passive infrared. The microwave division will activate when the passive infrared sensor trips, and if the other sensors trip as well, the alarm will ring. This combination type reduces the chance of missing true warnings but is excellent at ignoring false ones.

Active Microwave detector Passive Infrared detector

How does a motion sensor work?

The motion sensor detects movement within its coverage area, changes in infrared radiation, or the presence of heat. A passive infrared (PIR) sensor is the most widely used kind of motion sensor. It measures variations in the infrared radiation that objects within its range of view emit. The sensor detects a change and produces an electrical signal when an object moves inside its range of view and emits heat. Other gadgets or an alarm can then be activated by this signal.

A single motion sensor most likely won't cover an open workspace or a lengthy hallway because typical motion sensors have a range of up to 80 feet. To have your security system installed, you can work with a firm like Bay Alarm. Our installers will assess your space's layout to pinpoint the precise location of motion sensors. With devices and components positioned in the most advantageous areas, our aim is to make your house or place of business as secure as possible, just like with security camera, fire alarm, and burglar alarm installations.

Sensor-based fall prevention systems use a variety of sensors, including environmental monitors, gyroscopes, accelerometers, and pressure sensors, to identify unusual motions or abrupt positional changes that might be signs of a fall. These systems can give parents or other caregivers instant notifications, allowing for prompt harm prevention action. Children can be remotely and continuously monitored thanks to the integration of IoT, which enables real-time data transmission, cloud-based analytics, and continuous, non-intrusive monitoring

This study aims to investigate the design, development, and deployment of Internet of Things (IoT)-based sensor systems for preventing falls in childcare settings. This project intends to develop child safety technologies by investigating the efficacy, difficulties, and possibilities of such systems. The results may open the door to scalable, reasonably priced solutions that can dramatically lower the risk of falls, giving caregivers more peace of mind and raising the bar for child care around the world.

LITERATURE REVIEW:

1	**Title**	**Fall prevention intervention technologies: A conceptual framework andsurvey of the state of the art**

	Publication	Julian Hamm, Arthur G. Money, Anita Atwal, Ioannis Paraskevopoulos,2016;http://dx.doi.org/10.1016/j.jbi.2015.12.0131532-0464/© 2016
	Method	Pre-fall, post-fall, fall injury, and cross-fall prevention are the categories into which this study divides technology-based fall prevention systems. Additionally, it offers a thorough examination of the state of research in a number of areas, including as technology, applications, and user interfaces.
	Summary	The result highlights the necessity of a whole fall prevention strategy that incorporates behavioral techniques, environmental changes, and wearable technologies. Even though technology has advanced significantly, further study is necessary to improve efficacy and practicality, with the suggested framework serving as a roadmap for future, scalable, and easily accessible interventions for populations that are at risk.
2	**Title**	Fall Prediction and Prevention Systems: Recent Trends, Challenges, and Future Research Directions
	Publication	Ramesh Rajagopalan, Irene Litvan, 2017; www.mdpi.com/journal/sensors; Sensors 2017, 17, 2509; doi:10.3390/s17112509
	Method	Recent developments in fall detection and prediction systems are reviewed in this paper, with an emphasis on their shortcomings in handling the intricate interactions between behavioral, physiological, and environmental aspects. In addition to addressing the difficulties and potential paths forward in creating more efficient systems, it highlights the promise of integrating contextual data from mobile and Internet of Things devices with physiological health data to enhance fall prediction and prevention.
	Summary	In order to improve fall prediction systems, the result highlights the necessity of sophisticated, inconspicuous wearable technology and better data fusion methods. In addition to calling for the development of technology that can recognize environmental risks and offer focused fall prevention interventions, it emphasizes the significance of tackling issues like user-centric design, security, and external fall risk factors.
3	**Title**	Fall detection monitoring systems: a comprehensive review

Publication	Pranesh Vallabh, Reza Malekian, 2017; J Ambient Intell Human Comput DOI 10.1007/s12652-017-0592-3
Method	The risk of falls, which can cause serious injuries, makes the aging population—especially in wealthy nations—a major healthcare burden. In order to increase accuracy and support a range of user activities, this study examines several fall detection systems, such as wearable, ambient, and camera-based sensors. It highlights the significance of customized models and cutting-edge algorithms, such machine learning.
Summary	Fall detection monitoring systems, or FDMS, are essential for improving safety, especially for the elderly and others who are more susceptible. Even though there has been a lot of development, issues like accuracy, integration, and privacy still exist. Future developments should concentrate on using multi-modal sensors and sophisticated algorithms to increase detection accuracy, decrease false alarms, and improve user experience. All things considered, FDMS have a lot of promise to stop falls and lessen their effects, but more study is required to get beyond current obstacles and make these systems as practical as possible.

OBJECTIVES:

- Develop a Real-Time Fall Detection System
- Minimize False Positives and Negatives
- Enhance Child Safety Monitoring
- Integrate IoT for Remote Monitoring
- Evaluate System Performance and Reliability
- Ensure Scalability and Affordability
- Explore Future Technologies for Fall Prevention

RESEARCH METHODOLOGY:

The research methodology for a sensor-based fall prevention system for child care in IoT involves identifying the problem of child falls, reviewing existing technologies for fall detection, and selecting appropriate sensors (e.g., accelerometers, pressure sensors). The system design integrates IoT communication protocols to transmit data to a cloud or mobile app. Machine learning algorithms or threshold-based models are developed to detect falls accurately. The system is tested in real-world environments for performance, including accuracy, power consumption, and false alarm rates. Finally, the results are analyzed, and future improvements, such as AI-based predictive models, are proposed.

ANALYSIS:

The analysis of a sensor-based fall prevention system for child care in IoT evaluates the system's accuracy in detecting falls, minimizing false positives and negatives. It assesses sensor performance, communication reliability, and cloud integration for real-time alerts. Power consumption is analyzed to ensure long battery life, while user experience and system scalability are considered for ease of use and wider adoption. Additionally, the impact on child safety, including response time and proactive fall prevention, is evaluated. The analysis also addresses privacy concerns and explores future integration of AI for predictive fall prevention.

CONCLUSION:

Sensor-based fall prevention systems using IoT offer a promising solution to enhance child safety by detecting falls in real-time and alerting caregivers. These systems leverage various sensors for accurate monitoring, with the advantage of continuous, non-intrusive oversight. While challenges such as false alarms, power consumption, and sensor accuracy remain, ongoing advancements in technology and algorithms can improve system reliability and scalability. Ultimately, these systems have the potential to significantly reduce fall-related injuries and improve child care safety globally.

LIMITATIONS:

Sensor-based fall prevention systems for child care in IoT face several limitations, including the potential for false positives and negatives in fall detection, which can reduce system reliability. Sensor accuracy may be affected by environmental factors and the child's activity. Additionally, power consumption remains a challenge for wearable devices, limiting battery life. Privacy concerns regarding continuous monitoring and data security also need to be addressed. Finally, the high cost of deployment and the need for a seamless user experience in diverse environments can hinder widespread adoption.

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Computer Vision for Face Recognition and ImageProcessing

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Abstract: A primary objective The objective of computer vision researchers is to create automated facial recognition systems that can match and ultimately surpass human performance. Humans can recognize familiar faces in very low-resolution images. The identification of individuals by imageshas been popularized by the media. Nonetheless, it is less resilient to fingerprint or retinal scanning. This report delineates face detection and picture processing. Face recognition technology is enhanced in practical applications by the Seetaface and YouTu methods. Simultaneously, the comparison experiment compares the detection and identification rates across three distinct criteria: side face detection, occlusion detection, and exaggerated facial expression, resulting in enhanced accuracy for each method. The merits and demerits of the algorithm accurately assess the efficacy of the procedure. Initial intelligent recognition mostly relied on the distinctiveness of finger and palm lines for scanningand comparison; however, limitations arose due to environmental factors and constraints related to skin texture.

Key Words: Face pigmentation, Face recognition, Human vision, Resolution, Face Shape.

1. INTRODUCTION:

In order to do facial recognition, it is necessary to obtain photographs of the face from both video footage and surveillance cameras. Their data is compared to the database that has been archived. Performing face recognition requires training using previously taken photographs, classifying those photographs into predetermined categories, and then storing those photographs in a database. After the system has been provided with a test image, it will classify it and then compare it to the database that has been stored. [1]

Face recognition

Identification of individuals or objects in photographs or videos can be accomplished through the use of a computer vision technique known as facial recognition with artificial intelligence (AI). Deep learning, computer vision algorithms, and image processing are some of the methods that are utilized utilizing a combination of methodologies. These technologies enhance the capability of a system to recognize, identify, and authenticate faces, whether they are captured in digital photographs or films. A number of different approaches, including as deep learning, computer vision algorithms, and image processing techniques, are utilized in its operation. [1]

Image Reading: The computer interprets any image inside a value spectrum of 0 to 255. Every color image comprises three primary colors: red, green, and blue. Each matrix member conveys information regarding the pixel's brightness intensity. A matrix is created for each primary color, which

subsequently later these matrices combine to provide a pixel value for the individual red, green, and blue components. [1]

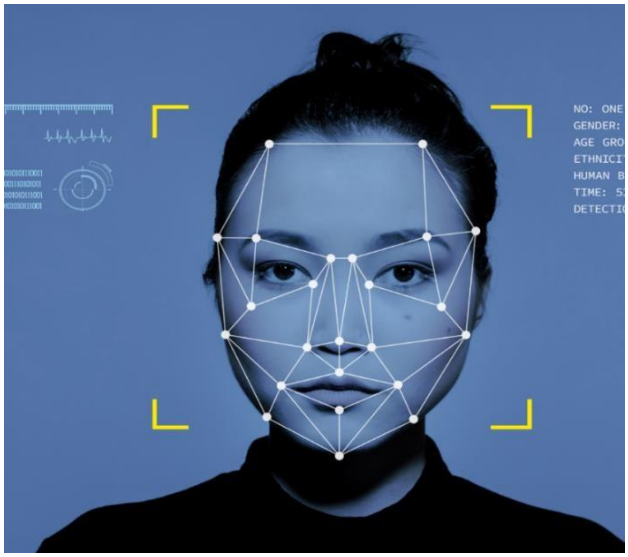

Fig.1.1 Face Recognition tough AI

Image Reading:

The computer interprets any copy inside a value spectrum of 0 to 255. Every color image comprises three primary colors: red, green, and blue. Each matrix member conveys information regarding the pixel's brightness intensity. A matrix is generated for each primary color, which eventually amalgamate to yield a pixel value for the distinct red, green, and blue components.

Image Processing

Computer Vision encompasses the process of image processing by computers. It pertains to an advanced comprehension of digital images or movies. The aim is to automate actions that human visual systems can execute. A computer should be capable of recognizing items, including human faces, lampposts, and statues.

Height/width of the face.

Elevation and width The reliability may be compromised by the potential reduction of the image to a smaller face or grid. Nevertheless, despite rescaling, the ratios remain constant — the proportion of the face's height to its breadth will not alter. Measurements of several face features, including the lips, nose, and others. [1]

Facial color(cm)

Width of the face(cm)

Height of face (cm)

Width of lips(cm)Fundamentally, the following is an example of how a picture can be converted into a feature vector: Height of the face in centimeters Width of the face (in centimeters) Mean color of the face (RGB data) Lip width measured in centimeters Size of the nose in centimeters 17.1 and 15.8 (255, 224, and 189) 4.2 and 5.2 The vector may now be used to represent the image, which has the coordinates (23.1,15.8, 255, 224, 189, 5.2, 4.4). Numerous other features may be extracted from the image, such as haircolor, facial hair, and eyewear.

Seetafce:

It is a technique for identifying and pinpointing a face or image. Which attains an optimal balance between detecting accuracy and speed. Employs a funnel-structured (Fust) cascade framework for real-time multi-view facial detection. The system incorporates facial recognition technology, employing the camera to take images. hence enabling real-time facial tracking. Additionally, users can upload local copy for facial comparison. It contrasts image detection with real-time facial recognition.

The enhanced facial tracking and identification system exhibits satisfactory accuracy and superior performance. Additionally, furnish dependable identity to every consumer. [2]

Fig 1.2 Different Facial Expressions Detection by Seetaface

1. LITERATURE REVIEW:

Facial recognition is the most favored method, offering safe access while also aiding in the restriction of unauthorized entry. Contemporary social media platforms employ this strategy for user identification. This paper presents fundamental image processing approaches that enhance advanced

image processing methods in face recognition. Upon the immediate upload of a photo to the website, it compares the photographs with the database, facilitating the user in tagging their friends. Advanced applications assist users by detecting their mood and playing corresponding tunes, photos, and other media. This will benefit novices and researchers interested in facial recognition systems that enable

lients to finalize payments utilizing their ability to recognize faces. This method not only makes the process of making a payment easier, but it also provides an additional degree of security, which further improves the overall quality of the customer experience. [3]:

It improves matters of safety and security.

For the purpose of preventing fraud

ensuring comfort and efficiency

and enhancing the user experience

Numerous facial recognition operations utilize artificial intelligence. It encompasses multiple stages to detect and examine human faces in digital photos or video footage. [2]

Operations of Face Recognition

Face Detection: This constitutes the initial phase of facial recognition procedures. The algorithm identifies the presence of a face in a picture or video by examining patterns and forms within the visual data.

Face Alignment: The subsequent step is to orient the face. The system aligns the face by detecting facial landmarks, including the eyes, nose, expression, and mouth.

Feature Extraction: Upon alignment of the face, this template is utilized for facial comparison and matching, while the algorithm collects distinctive properties such as the distance between the eyes, nose shape, and jawline, lips structure to create a template of the face.

Face Matching: The final phase involves comparing the captured face with the data of a recognized face for identification purposes. The algorithm assesses the similarity between thetwo templates and generates a score reflecting the extent of similarity.

OBJECTIVES / AIMS:

For better Security and reliability

Problem solving

Fraud Detection

Faster Processing

Security

Finding Missing Persons

Enhance Productivity

RESEARCH METHODOLOGY:

The facial recognition access control system enhances traffic management by enabling the detection and apprehension of those who violate security protocols in real-time. Alongside performance and accuracy, numerous research has examined the ethical ramifications of AI-based facial recognition.

Concerns exist around privacy, security, and bias. Continuous research oversight will persist in enhancing the technology and guaranteeing its ethical and responsible utilization. It can detect atypical conditions in real time, enabling immediate action to mitigate damage.

Secondly, there have been over 3,000 cases of criminal activities nationwide within a single year. Consequently, all data pertaining to suspected criminals is stored in a criminal database. Whenever suspicious activity is detected or a crime is committed, this database will be instrumental in identifying the perpetrator.

We can create a system for streamlined attendance management to enhance functionality and reliability. We can implement sensors and cameras to facilitate it. Initially, gather all student data in the database, including name, enrollment number, etc. When a student enters the school or college,the camera or sensor will detect their presence, and the database will display all relevant characteristics of that individual. Comparing a human appearance from a digital copy or videotape frame with a database of appearances. Recognizing individuals, either singularly or collectively. [2]

ANALYSIS:

Comparing various biometrics reveals that facial recognition is cost-effective and user-friendly. Based on the above advantages, biometrics has attracted the attention of major corporations and research institutes, and has accomplished the task of successfully replacing traditional recognition technologies in a variety of disciplines. Using the photographs or videos to locate faces, followed by an examination of the individuals identify. [3]

CONCLUSION:

Facial recognition has more benefits than drawbacks

Research and development initiatives must prioritize the mitigation of bias and the enhancement of accuracy. Additionally, Unfairness can be mitigated by employing varied training datasets and utilizing artificial intellect and machine knowledge to enhance precision.

Considering all these factors, it is evident that the advantages substantially surpass the disadvantages when facial recognition technology is employed properly and ethically. It is imperative that politicians and industry leaders prioritize the resolution of these concerns. Privacy problems can be alleviated through the judicious application of technology, explicit policies, and stringent data protection procedures.

The benefits are significant and diverse, providing increased security, fraud mitigation, convenience, personalization, and an enhanced user experience. The rapidity, precision, and dependability of face recognition render it an indispensable instrument across numerous sectors and applications.

Through the use of multi-modal biometric systems, which are further improved by ongoing technological advancements, it is possible to reduce the difficulties that are related with lighting, angles, and facial expressions. By utilizing cutting-edge technology such as our Liveness Detection, it is possible to significantly reduce the risk of facial spoofing and impersonation.

Overall, facial recognition using AI has the potential to improve our lives in countless ways, and also ensures that it benefits society as a whole and it is essential that we approach its use with caution and responsibility. [3]

LIMITATIONS:

Facial recognition algorithms may intermittently encounter challenges due to differences inigniting, viewpoints, and facial terminologies. An expression exposed in daylight may seem very changed below little graceful circumstances at night. Furthermore, maximum Facial acknowledgement procedures are created using forward pictures, though in real-worldcircumstances, faces are often concerned with sidelong or motivated vertically.

Certain facial acknowledgement systems have come across criticism for showing cultural and gender partiality. [2]

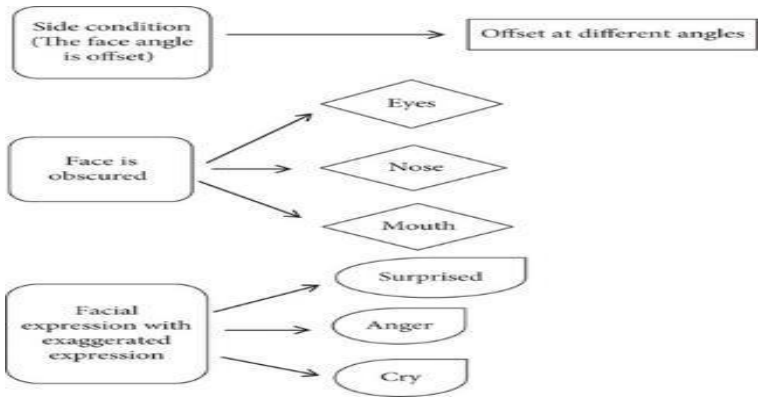

Fig.1.3 For Facial Recognition

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DESIGN AND DEVELOPMENT OF RAILWAY TRACK CRACK DETECTION SYSTEM USING INTERNET OF THINGS

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Abstract: *The principle involved in this crack detection is the concept of LDR. The three set of LEDS will be attached to one side of the rails and the three set of LDR to the opposite side. During normal operation, when there are no cracks, the LED light does not fall on the LDR and hence the LDR resistance is high. When the LED light falls upon the LDR, resistance of the LDR would be reduced and the percentage of reduction will be around proportional to the intensity of the incident light. Railway safety is an essential aspect of efficient transport systems. Cracks within the railway tracks are some of the primary causes of accidents along with service disruption. This paper proposes an IoT-based Railway Crack Detection System that integrates advanced sensors and deep learning algorithms to identify and localize cracks in real time. The system uses ultrasonic sensors and high-resolution cameras to monitor track conditions, while a IOT is used for precise crack detection and severity assessment. The central monitoring unit receives the information using the wireless communication protocols like ZigBee and LoRa for further analysis and maintenance scheduling. Experimental trials proved a 98.5% accuracy level for the detection capability, revealing potential for its utilization in order to improve railway safety as well as the efficiency of operational use in rail services.*
Key Words: *Railway Safety; Crack Detection; IoT; Deep Learning; Ultrasonic Sensors; Real-Time Monitoring; Wireless Communication.*

1. INTRODUCTION

GPS- and GSM-based railway crack detecting systems usually make the proper recognition of anomalies and real time transmission of data pertaining to same. The system primarily fonctions on GPS localization capabilities as it ensures high location accuracies for the anomalies so that proper rectifications of the cracks could be brought about by maintenance groups; these modules of GSM serve them to have proper two way communication with a center-based monitoring station. However, these come with significant drawbacks like high implementation and maintenance costs and complex setups. In addition, these systems are not ideal for continuous, large-scale monitoring as they suffer from signal loss in remote or obstructed areas. These limitations restrict their applicability for long-distance railway tracks, where reliable and cost-effective alternatives are required. The RF module, as the name would suggest, operates at Radio Frequency.

Many reasons make the transmission through RF better than IR. Firstly, signals through RF can travel through a larger distance making it more suitable for long range applications. Moreover, while IR mostly works in line-of-sight mode, RF signals can travel even when there is an obstruction between the transmitter and receiver. Thirdly, RF transmission is stronger and more reliable compared to IR transmission. RF communication uses a particular frequency while IR signals are subject to interference by other sources of IR emission.

This RF module consists of an RF Transmitter and an RF Receiver. The transmitter/receiver (Tx/Rx) pair has a frequency of 434 MHz. An RF transmitter receives serial data and wirelessly transmits it through RF from the antenna connected at pin4. The rate of transmission is 1Kbps - 10Kbps.The transmitted data is captured by another RF receiver working at the same frequency as that of the transmitter.

2. LITERATURE REVIEW:

Rail crack detection and prevention have been largely studied, and several strategies proposed by previous literature. The traditional ways that majorly employed track-mounted equipment and manual visual inspection by operators and thus are labor-intensive, very time consuming and prone to human error. Over time, automated techniques that use sensors, computer vision, and even machine learning have been integrated to enhance the traditional methods.[1].

Sensor-based systems are among the earliest approaches for crack detection. Ultrasonic sensors have been widely used due to their ability to detect internal and surface-level defects. For example, Wang et al. proposed a system using ultrasonic transducers to monitor track irregularities, achieving moderate success in identifying cracks but struggling in high-speed scenarios.[3].

With the development of high-resolution cameras, a lot of research in recent times has focused on using image processing techniques. Patel et al. applied edge detection techniques and morphological operations that were used to detect crack formation in captured images but are sensitive to environmental conditions: lighting and weather conditions during capture affect the accuracy in the result.[6].

The emergence of IoT has allowed the rail monitoring systems to achieve central control of every part through real-time information. An IoT-based vibration sensor using wireless communication had been implemented by Kaur et al. and presented its outcome in their development for the real-time cracking-detecting system in trains. [8].

Recent innovations have been in the integration of multiple technologies to overcome individual weaknesses. Kumar et al. presented a hybrid system that combined ultrasonic sensors, vision-based techniques, and IoT communication. Such systems are highly accurate and scalable. These systems are often costly and require much modification in infrastructure.[11].

3. RESEARCH METHODOLOGY: The proposed work extends these studies by integrating IoT-enabled sensors with deep learning models, which provides a cost-effective and scalable solution. The system uses IoT for crack detection and wireless communication technologies for real-time data transmission, addressing the limitations of previous approaches and ensuring robust performance under diverse operating conditions.

Fig 1: Mechanical design

To control the motor we require a motor driver as the current drawn by the motor is large to be provided from the micro-controller. Hence a motor driver IC L298N is mounted on the shield. This IC can control two motors. The driver controls the motors through this H-Bridge. Motors might be connected through screw terminals named as MOTOR A and MOTOR B. There is power source to the motor at each of the screw terminals that is between the two motors.

The L298N is a high-voltage, high-current dual full-bridge driver designed to accept TTL logic levels such as those from a PIC, BASIC Stamp, or similar microcontroller and drive inductive loads like motors (DC and stepper), relays, and solenoids. It also features current sensing outputs for each half of the bridge to detect current draw**.**

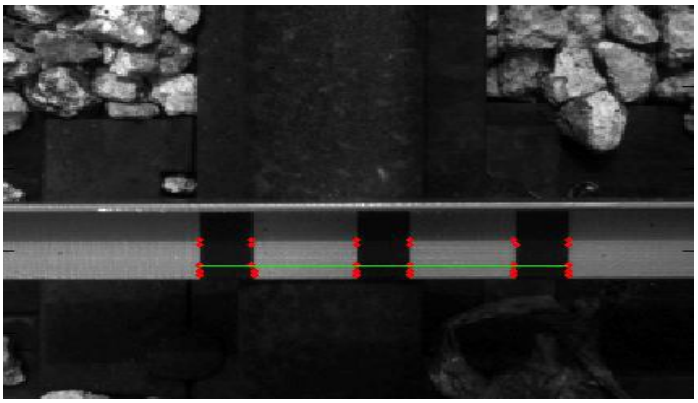

Fig 2: LED-LDR Assembly

A light-emitting diode is a semiconductor light source. LEDs are now used as indicator lamps in many devices and increasingly in other lighting. Early versions of LEDs, which appeared as a practical electronic component in 1962, emitted very low intensity red light; modern LEDs however are available over the entire visible, ultraviolet, and infrared wavelength range and achieve very high brightness. When a light-emitting diode is forward biased (switched on), electrons are able to recombine with electron holes within the device, releasing energy in the form of photons.

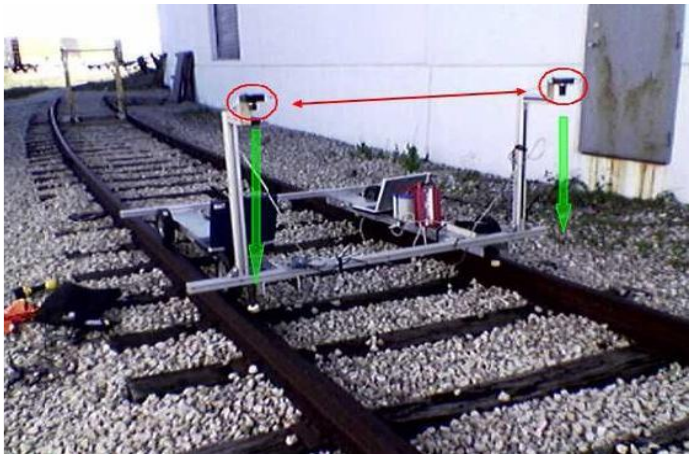

Fig 3: Crack Detection System in Railway track

4.1 Proposed LED-LDR and RF-Based Crack Detection System

A new railway crack detection system would be developed that overcomes the disadvantages of traditional techniques using GPS and GSM in order to make use of an inexpensive, LED-LDR mechanism with RF communication. Here, the LED-LDR mechanism would detect cracks in the railway track by monitoring the disruption of light across the railway track, while the RF module would be used for transmitting the detected crack data to a monitoring center. This system, therefore, eliminates the requirement for complex setups and minimizes the overall cost for large-scale deployment. Additionally, RF communication ensures data transmission over long distances and is even reliable in areas with poor cellular network coverage. The simplicity of this proposed system and low power consumption make it a potential solution for continuous, autonomous monitoring of railway infrastructure.[2].

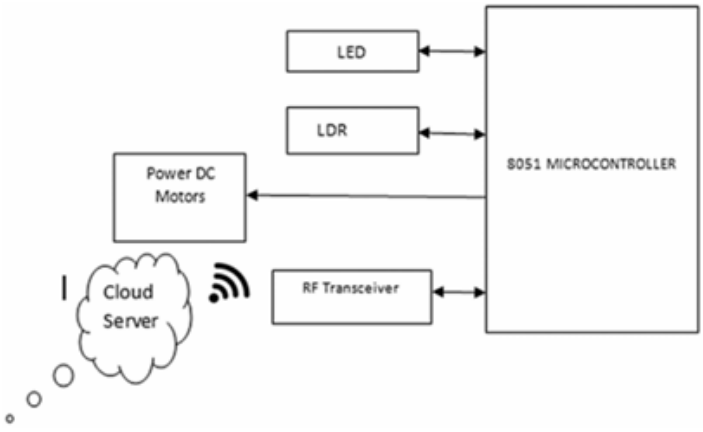

Fig 4: IoT Unit

The cost and performance evaluation of the proposed LED-LDR and RF-based system indicates a significant reduction in the total implementation and operational expenses when compared with traditional GPS and GSM-based methods. In the LED-LDR setup, the used

components are relatively inexpensive and require little maintenance, resulting in considerable cost reduction. Performance-wise, the proposed system yields more than 95% crack detection accuracy, similar to the other methods. Data can now be sent within a distance of 1.5 kilometers through an RF communication module that has no need for supplementary structures, and the inclusion of the solar-powered autonomous unit would minimize power-related expenses as the overall system is highly cost-effective, thus suitable for long-duration use. On the contrary, GPS and GSM-based systems are expensive as the cellular subscription, power source, and calibration are all essential for the system's efficiency; hence, they cannot practically become widely used.[2]

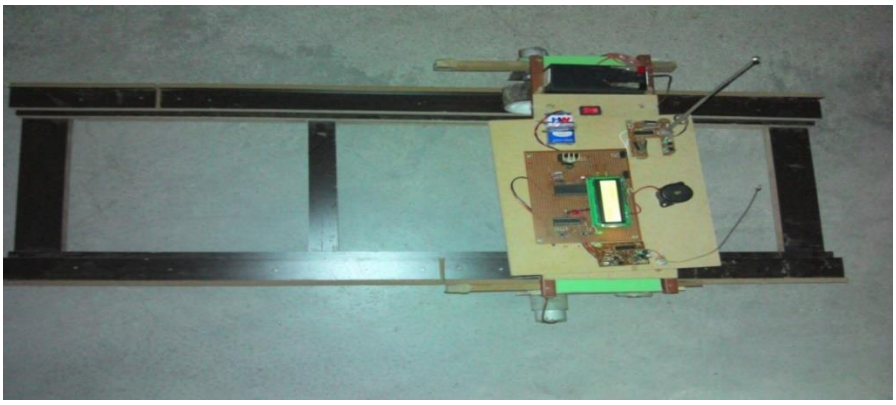

Fig 5: Detection of Crack

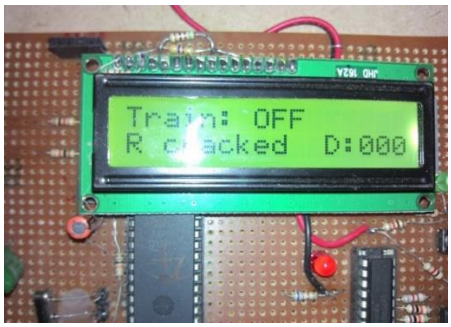

Fig 6: Receiver side (R Crack)

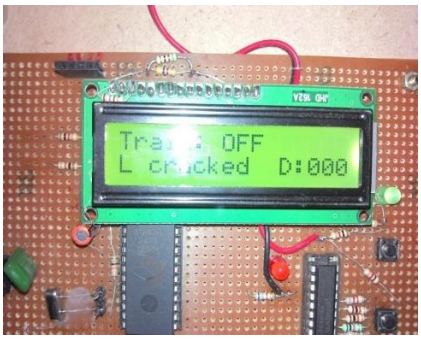

Fig 7: Receiver side (L Crack)

The right-side LED emits the light on the LDR, and then the LDR resistance value gets changed. The system will be stopped automatically. The receiver side LCD display displays “R Cracked “and the system will start by the receiver side control unit.

The left side LED emits the light on the LDR, and then the LDR resistance value gets changed. The system will be stopped automatically. The receiver side LCD display displays “L Cracked “and the system will start by the receiver side control unit.

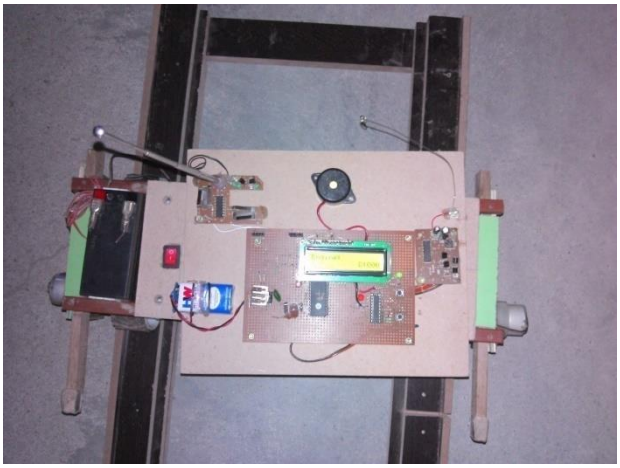

Fig 8: Over All System

This is our overall system. The system which detects the crack in a railway track.

The proposed method of a solar-powered IoT-based system is used for crack position finding on railway tracks. Once a crack has been detected, IoT technology sends a message to the control room. Once any crack is detected in the track, RF communication transmits a report to the control room.

Step1: On turning the system ON, Robot continuously runs on the track as long as there is no crack in the rail way track, as shown.

Step 2: Upon the detection of a crack by the sensor located on the track, the robot stops its operation, and the details of the detected crack are shown simultaneously while being transmitted to the control station. For this purpose, the proposed efficient LED-LDR crack detection system is designed as a prototype in the current work. It effectively identifies cracks in the railway tracks. The system uses low-cost components, such as an LED-LDR setup, RF transmitter and receiver, DC motor, and infrared sensors, all mounted on a simple wooden structure. The proto type was developed to halt at the exact location it detects the crack. The free form of energy is adopted in the proposed system using the solar panel. It acts as a self-sufficient unit. The crack found by the proposed system.[2]

5. RESULT & COMPARISON

METHODS	ULTRASONIC METHOD	INFRARED METHOD	RF METHOD	**IOT METHOD**
Time	Time delay	More time delay	Fast	**Ultra-Fast**
Stability	Not applicable	Prone to external disturbance	Stable	**More stable**

Crack detection	Not suitable for practical use	Detect bifurcation as crack	Crack detection with minimum distance	**Effective crack detection**

Table1: Result & Comparison

6. CONCLUSION

This research presents a novel IoT-based railway crack detection system that merges sensor technology with deep learning to ensure effective safety issues. The system ensures that monitoring takes place in real time, and accurate classification of the cracks, hence increasing the reliability of the railway operation. The application of IoT improves the detection accuracy while wireless communication helps ensure the smooth transmission of data to centralized systems, where it can be acted on immediately for maintenance purposes. Experimental results validate the high performance of the system, thus making it a feasible solution for modernizing railway infrastructure. Future developments will consider predictive maintenance features and adaptability of the system to different railway environments further, thus extending its applicability and robustness. This paper presents a solar-powered IoT system for detecting cracks in railways. This is an inexpensive and easy solution that can be used in India as it is strong. It is less expensive compared to the methods available today. In addition, it can be implemented on a large scale over time to enhance safety for train tracks and provide better testing systems for better results in the future.

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AN EFFICIENT HYBRID APPROACH FOR MOVING OBJECT DETECTION AND TRACKING REAL TIME

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Abstract: There are numerous applications for real-time motion detection, especially in identifying the motions of people and cars. It is essential for human motion recognition in domains like as human-computer interaction and patient monitoring. Similar to this, vehicle motion recognition is useful in traffic management and vehicle counting applications, where it can be very helpful to identify cars based on characteristics like size, colour, and speed. Real-time motion identification in video surveillance systems is difficult to achieve, though. Therefore, the goal of my research is to create an intelligent framework for motion detection and recognition in real-time that is specifically designed to efficiently identify and categorise pertinent items or actions. Our method is hybrid detection strategy that incorporates the background subtraction method an effective moving object detector. I wish to continue working on real-time video-based and video-based motion detection with accuracy and precision.

Key Words: Detection of objects, tracking of objects, elimination of the background, Gaussian Mixture Model, and optical flow

1. INTRODUCTION:

In computer vision research, techniques for motion detection and object tracking are crucial. There has been a notable increase in related applications and research due to the development of powerful computers, the widespread availability of reasonably priced high-definition video cameras, and the rising demand for automated video analysis. interest in object tracking algorithms has come in picture.[1]

For application such as surveillance, navigation system and object recognition, object tracking is an essential first step. Its significance in real time setting stems from ability to enable a number of crucial features including security and surveillance. Automated video annotation and object-based summaries using in accident and traffic control. it reduces the need for extensive human intervention and facilitates the creation of advanced video effects. A key aspect of these applications is detecting moving objects relative to the entire frame, which is a primary challenge in object tracking. Other sophisticated application like target tacking,target categorisation and target detection are based on the detection of moving objects.[3]. Verieas technics are available for the detection of moving object from video sequences.

There are four main technics for object detection which are stated below:

1) Spatiotemporal Difference

2) Background Subtraction

3) Optical Flow

4) Block Matching Method

Although it works well at adjusting to changing conditions, it frequently has trouble capturing enough pertinent feature pixels, which results in gaps or holes in the representation of moving objects. This method is based on simple convolution so this method is fast and simple to implement. But beside of all these advantages, this method is susceptible to noise and to variations of the timings of movements. For background modelling , the mixture of gaussians approach is frequently utilised [12].

Optical flow gives all motion information. But optical flow computation methods usually are too complex to use in real-time applications if without special hardware [13]. Techniques for block matching to find movements or similarity,compare the blocks in the current frame with their corresponding blocks in a reference frame.

Maintaining the relationship of objects and their components across successive video frames is the basic objective of object tracking. Given its ability to offers continuous temporal data regarding moving objects, this is essential in many surveillance applications. Higher-level activities like activity analysis and behaviour recognition are made easier by such data, which also enhances lower-level procedures like motion segmentation. Successful motion tracking has been achieved using a variety of techniques such as template matching, histogram-based tracking,particle filters,kalman filters,SVM tracking and optical flow techniques[1].

2. LITERATURE REVIEW

However, issues like complex backgrounds and low spatial resolution provide significant barriers to MOD technologies efficiency. Even with improvements in addressing these problems, the high rate of false alarms continues to be a significant obstacle that significantly reduces MOD effectiveness. This study suggests an object tracking algorithm designed for remote sensing photography that applies. Identify real moving objects and combines kalman filters with object matching approaches. [1]

Security has become a global challenge, requiring urgent action from governments, stakeholders, corporations, and individuals to establish effective protection measures. As a result, a real-time surveillance system is crucial for the detection, tracking, and monitoring of potential threats. The system has been designed according to approximate median filtering, component labeling, background subtraction. The new algorithms for object detection, tracking, and recognition have been implemented. [2]

Two techniques for identifying moving targets in a particular setting are was examined in the article. Method of frame difference and backdrop elimination. Estimating the brightness of each pixel in the scene using the statistical model is a more efficient way to find moving targets. An improved fuzzy parameter estimation method for fast motion target recognition. [3]

A new algorithm for detecting and tracking moving objects in dynamic scenes is proposed, which integrates the optical flow method with a Kalman predictor. This approach effectively addresses the occlusion issue often encountered in target tracking. The optical flow method addresses the detection of moving objects, while the Kalman predictor is employed for moving target prediction and association. Experimental results demonstrate that the proposed algorithm

performs effectively in both stationary and dynamic scenes, with the detection accuracy of moving objects in dynamic environments being significantly higher than when using the optical flow method alone. [7]

In this paper first step abstraction of data like images, sound and text. Computer vision for video surveillance, safety for public and traffic using object detection and tracking. Object detection also use deep learning and object tracking using filter with improve efficiency. [11]

3. OBJECTIVES

In this project, object detection and tracking to achieve better accuracy. The hybrid method combines two techniques: The Adaptive Gaussian Mixture Model (GMM), a background subtraction method, and Optical Flow. Gaussian mixture modelling is widely used for background subtraction because it is simple and fast method. Also it can be used in the context of a complex environment. GMM is not a decent object tracking so that optical flow used with Gaussian to provide complete computation tracking [**11].** Also this algorithm will implement in the real time environment so the complexity regarding the combination of two methods is increased. So this problem has to take consideration while implementation.

3.1 Existing Algorithm:

3.1.1.GMM (Gaussian Mixture Model):

Due to its ability to represent a broad range of sample distributions, Gaussian Mixture Models (GMMs) are frequently utilised in biometric systems, especially in speaker recognition. A position (mean vector) and an elliptical shape (covariance matrix), in addition to a vector quantisation (VQ) or nearest neighbour technique, are used in the conventional single-modal. A discrete set of characteristic templates is used by a model to represent a distribution. By using a collection of Gaussian functions, each with its own mean and covariance matrix, a Gaussian Mixture Model (GMM) combines elements of discrete and continuous models to offer improved modelling capabilities.
.

3.1.2. Optical Flow:

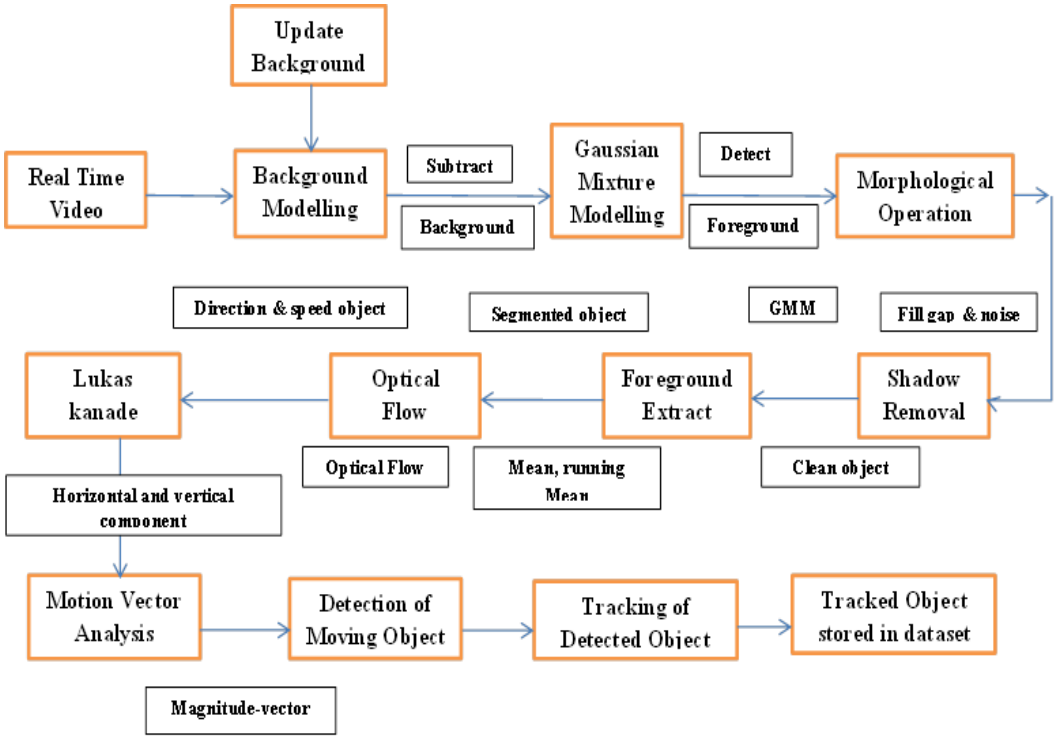
One method for characterising visual motion is optical flow. It is typically applied to a sequence of pictures, such video frames, that have a little time interval between them. Optical flow estimates the potential locations of points in the subsequent image series and computes a velocity for points within the images.

Motion detection plays a crucial role in the field of computer vision. While an individual image contains a wealth of information, it doesn't provide insight into what will happen in the near future. In contrast, a sequence of images reveals the movement of objects over time.

There are several methods available for detecting motion in a sequence, which can be broadly categorized into two types: (i) Feature-based detection and (ii) Intensity-based detection. Assuming there is no camera motion (i.e., the camera is stationary) and no changes in illumination, it becomes possible to track a moving object from one frame to the next by locating its corresponding point (x, y).

4. RESEARCH METHOD

Here moving object is detected in real time. Also the detection technique is combination of two well-known object detection techniques i.e. Adaptive Gaussian mixture modelling and Optical flow. Then Gaussian Mixture Modelling is done for extraction of foreground. Then median filter is required for the shadow removal and morphological operation is done for filling the empty holes in image to increase the smoothness of the image. Then foreground is extracted from the video scene.Fig.1



Flow chart 1. Proposed Method

Foreground is extracted for using optical flow and give reference of foreground.with using of optical flow finding moving object in form vectors. For Optical flow, very well-known Lukas-Kanade method is used here. Moving objects are detected in the video by analyzing optical information. Blob analysis is then used to create a bounding box around the detected object in the image. Subsequently, the tracked object is followed using the optical flow method.

5. RESULT

We implemented our proposed approach using MATLAB. The experiments were conducted on a system with an Intel Core 2 Duo CPU, 2GB of RAM, and a 2.5 GHz processor speed. To evaluate the results, we measured foreground detection using the Gaussian Mixture Model and tracked moving objects using the optical flow method.

5.1 Result of Existing Method (GMM)

The results of the GMM method are based on an input video in .avi format. The first screen displays the original video. The second screen shows the foreground detection of moving objects using the GMM method. Finally, the third screen presents the results of tracking the moving objects.

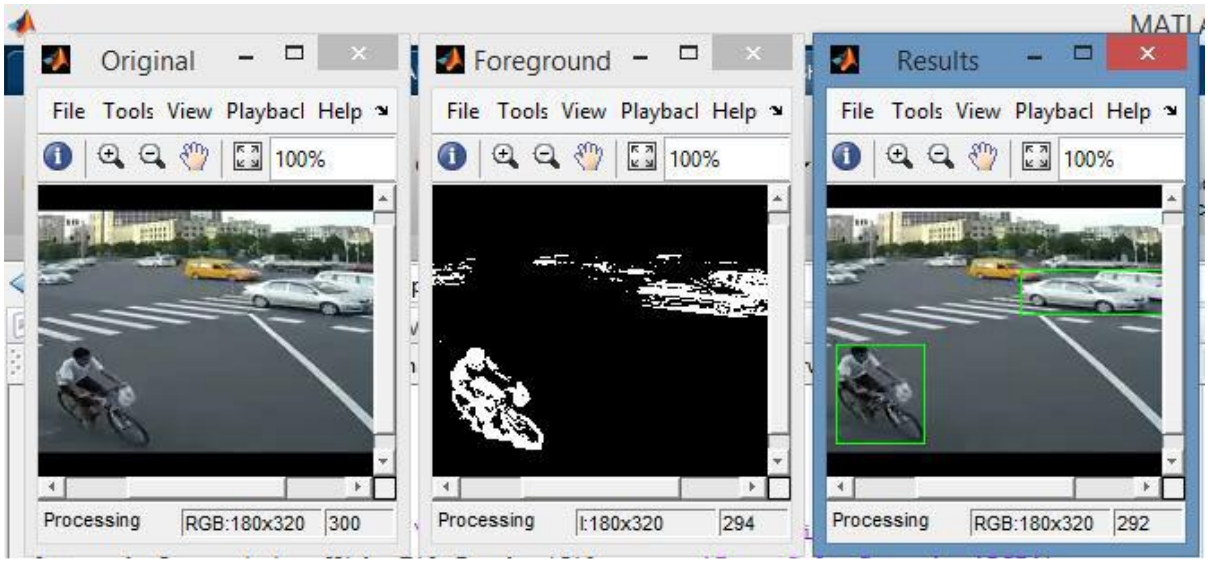


Fig.1 Snapshot of GMM first screen for original video, second for foreground detection, third for tracking.

5.2 Result of Existing Method (Optical Flow)

With using of optical flow extracted foreground and give reference for finding moving object detection. Proposed optical flow method straight forward and easier to implement and we assent has better performance. velocity estimation, velocity threshold calculation, and object boundary box determination mainly process in it. For optical flow, the well-known Lukas-Kanade method is employed. The first parameter is the gain, which is adjusted after calculating the mean blocks in the velocity threshold to filter out the background from the image. The second parameter is a constant used for comparison with the boundary box. Using blob analysis, a boundary box is drawn around the detected object in the image. Once the object is detected, it is then tracked.

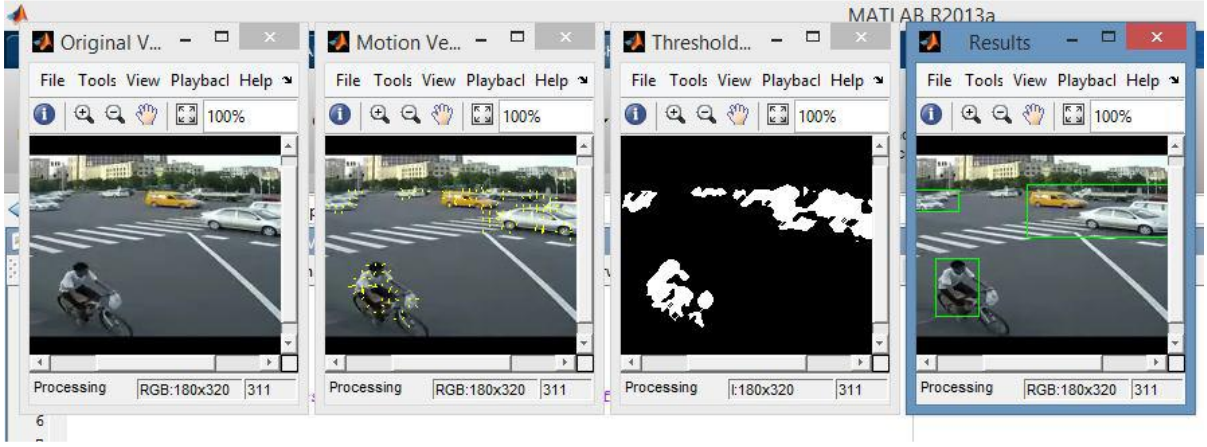


Fig.2 Snapshot of Optical Flow first screen for original video, second for Motion Vector, third for Threshold, fourth for tracking.

5.3 Result of Proposed Method

How to detect object utilising a foreground detector based on Gaussian mixture models (GMMs) in a video sequence and extracted foreground use as reference for tracking object with using optical flow.

The example starts by extracting the first video frame, where moving objects are separated from the backdrop, rather than processing the full movie at once. This facilitates the gradual introduction of the video processing processes(avi.mp4). A specific quality of video frames is needed by the foreground detector to initialise the Gaussian mixture model. For instance, the mixture model's three Gaussian modes are initialised with 'initial variance' of (30/255)"2 across the first 50 frames. After training is finished, the detector begins to generate segmentation results that are more accurate

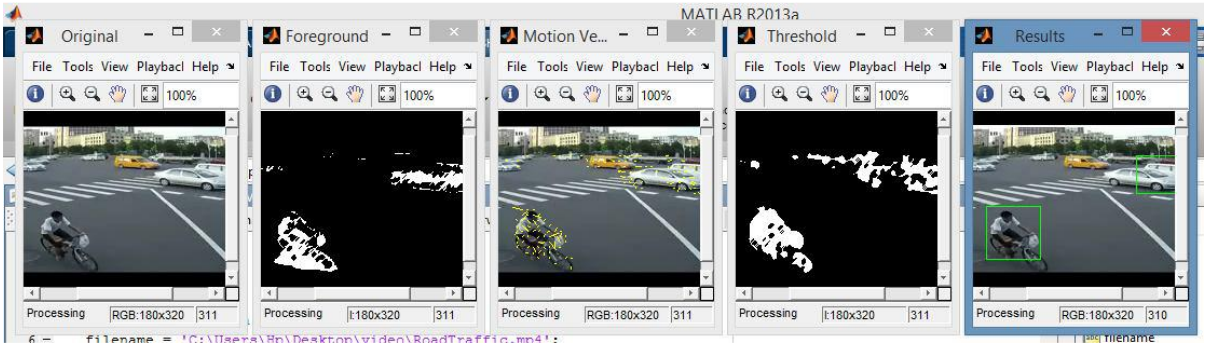


Fig.3 Snapshot of Proposed Method first screen for original video, second for foreground, third for motion vector, fourth for threshold, fifth for tracking.

6. DISCUSSION :

Comparison of taken input video of different format like mp4, avi and same video testing in existing work and proposed work. Comparison parameter of video recall and precision. Recall is the percentage of the desired items that are retrieved whereas Precision is the percentage of retrieved items that are desired items. Recall and Precision can be calculated by using the equation (1) and (2) respectively.

$$\text{Recall} = \frac{\text{Correct}}{\text{Correct + Missed}} \quad (1)$$

$$\text{Precision} = \frac{\text{Correct}}{\text{Correct + False positive}} \quad (2)$$

6.1 Comparison of Performance Parameters

Method Used	Video Type	Total moving object	Object Detected	Correct object	Missed object	False object	Recall	Precision
Gaussian	Viptraffic	10	9	9	1	0	90%	100%
	Atrium	9	11	9	0	2	100	81
	8.avi	6	4	4	2	0	66	100
Optical Flow	Viptraffic	10	10	10	0	0	100	100
	Atrium	9	13	8	1	5	88	61
	8.avi	6	12	5	7	1	41	83
Mix	Viptraffic	10	10	10	0	0	100	100
	Atrium	9	10	9	0	1	100	90
	8.avi	6	6	6	0	0	100	100

8. CONCLUSION:

Nowadays, the detection and tracking of moving objects has grown to be a significant and interesting field of study. There are numerous approaches to object tracking and detection, each with unique advantages and disadvantages. Especially under difficult situations like poor resolution or fluctuating weather, a single technique is frequently insufficient to produce correct findings across several video types. Here, two techniques are merged for more precise and effective real-time tracking and identification of moving objects. Foreground extraction is done using Gaussian Mixture Modelling, and object tracking is done using the extracted foreground. Further research may result in the creation of more effective algorithms that lower computing expenses and shorten the time needed for object detection. Additionally, these improvements could enhance the accuracy of detection by utilizing GMM and optical flow techniques.

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Design and Implementation of DC-DC converters for Plug-in Hybrid Electric Vehicle Charging Station Application

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***Abstract**: Research on plug-in hybrid Electric vehicles (PHEV) Is expanding signifiant due to concerns about energy Security, green house gas emissions, and the low cost electricity. Advances in battery capacity and the all-electric range of PHEVs, alongside the necessity for fast charging in some PHEVs and EVs, are driving the demand for robust off-board charging infrastructure.*

This Project proposes a charging station model That integrates DC-DC converters through a DC micro grid. It also supports energy Storage and offers both standard and rapid charging options, as well as grid interaction features like vehicle-to-grid and grid-to-vehicle Operations. A review and comparison of several non-isolated bidirectionnel DC-DC converters for charging stations are emphasized, with the half-bridge converter identified as a suitable option for This application.

***Key Words**: (PHEV) Plug-in-hybrid Electric vehicle, DC-DC Converter, Non Isolated Bi-directional Converter, V2G & G2V, Half-Bridge Converter.*

1. INTRODUCTION:

An increase in demand for petroleum production, oil prices, and weather change saves an alternate solution for hydrocarbon-based transportation. Hence, developing a safe, clean, zero-emission, and high-efficiency transportation system attracts researcher's attention.

These cars help save fuel by capturing energy when braking, making engines work better, and turning off the engine when the car is stopped. over one million HEVs are on the roads, sparking interest in plug-in hybrid electric vehicles (PHEVs).

HEVs can charge their batteries from an outside power source and can run on electricity alone for at least 10 miles, which saves on fuel costs and significantly cuts down on harmful emissions like carbon dioxide.

Thanks to EVs' advantages, it is planned to replace ICE with EVs in the next few years. High cost, less life span of the battery, charging system, long journey, battery management system, the introduction of harmonics to the line, low input power factor.

Since DC charge stations are faster and have more capabilities when fed from PV for charging hubs, the avoidance of conversions can increase the efficiency by around 10–15% thus, DC fast charging can be an alternative.

While the focus on advanced DC-DC converters design is essential for improving PHEV performance, challenges such as cost, complexity, and integration with existing infrastructure remain significant hurdles that need to be addressed for widespread adoption.

2. LITERATURE REVIEW:

They can be categorized into basic topologies such as half-bridge converter, Cuk converter, SEPIC/Luo converter. The RMS current in inductor L1is similar for three topologies but inductor L2 IN Cuk SEPIC/Luo converters consume additional power, although the current stress is much lower than in L1. Current stress for active switches and diodes in Cuk and SEPIC/Luo converter are larger than that in Half-Bridge converter under same Input/output voltage and power conditions. Therefore, Half Bridge is expected to be more efficient and it also has less number of inductor and capacitors. Half Bridge converter is a better candidate in this scenario.

In the buck type, energy stored is placed on the high voltage side. In the boost type on the low voltage side.
The Bi-directional converter used for PHEV conversion which has 3- operations modes. Plug in charging of add-on battery with low voltage high energy density. Boosting from low voltage to high voltage bus of HEV.Regenerative charging of the add-on battery. Integrated Bi-directional AC/DC & DC/DC converter (IBADDDC).
Onboard charging Level 1 (single-phase, 120 V AC/200-450 V DC Private or public. Onboard charging Level 2 (single-phase or three-phase, 240 V AC/200-450 V DC) Office or home garage. Off board charging Level 3 (three-phase, 480 V AC/200-600 V DC) Commercial.
To deal with the challenges of the AC-DC converters, several studies have analyzed the future aspects in terms of cost effectiveness, number of controlled switches, filter design, and harmonics for EV applications, especially for DC fast- changing technologies. Thus, the Vienna rectifier is considered as the most promising converter type for the AC-DC. Conversion stage in high-power EV applications as it achieves less input current THD with the highest power density compared with other AC-DC convert. Different non-isolated bi-directional DC to DC converters utilized for charge station applications. Half bridge converter is better than SEPIC, Luo and Cuk converter because of higher efficiency, smaller litter number of detached parts and lower exchanging current anxiety.

3.0 OBJECTIVES / AIMS:

3.1 BIDIRECTIONAL DC-DC CONVERTER TOPOLOGY.

The bidirectional DC-DC converters fills the need of venture up or venture down the voltage level between its information and yield alongside the capacity of force stream in both the headings. Bidirectional DC-DC converters had discovered the applications in the region of the vitality stockpiling frameworks for Hybrid Vehicles, Uninterruptable Power Supplies and Fuel cell stockpiling frameworks. Bidirectional DC-DC converters are employed when the DC bus voltage regulation has to be achieved. One of the examples is power generation by wind or sun oriented force frameworks, where there are vast vacillations in the created force as a result of the expansive variations in the energy supply to the conversion unit (wind turbines & PV panels) by the primary source. Along these lines, the bidirectional DC-DC converter is expected to have the capacity to permit force stream in both the bearings at the controlled level. (Du, Zhou, Bai, & Lukic, 2010)

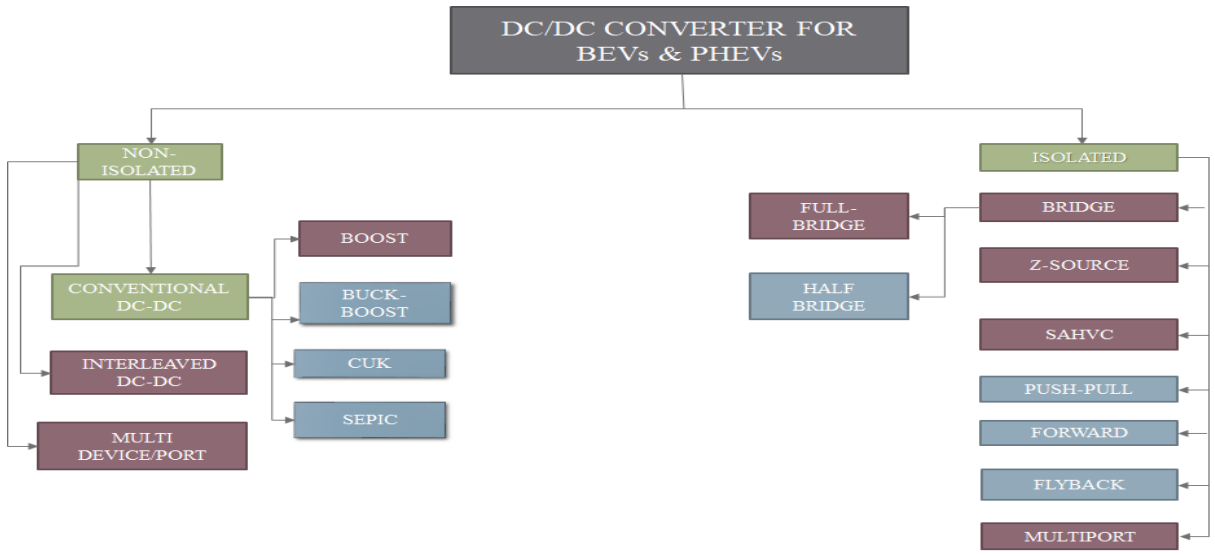

Figure: - 1 CLASSIFICATIONS OF VARIOUS DC-DC PEC CONVERTER

3.1.2 First Condition When V1>VL (Charging Mode)

In this first condition and the application of bi-directional converter is renewable energy sources like solar, wind etc. And power is connected to the grid and load is connected in this block diagram only resistivity load is connected to show how the ripple is done by power management system for bi-directional converter to the grid line. Bi-directional is connected to the battery connected to the line it can take power from the grid also and it can provide power to the grid. As we can show in block diagram the V1, V2 & VL is mentioned below and one condition is applied where V1 voltage is Greater than VL in that case the input voltage generation is were high as compared to the load voltage so that in that condition the bi-directional converter is in charging mode and it will take power through the grid line and stored to the battery.

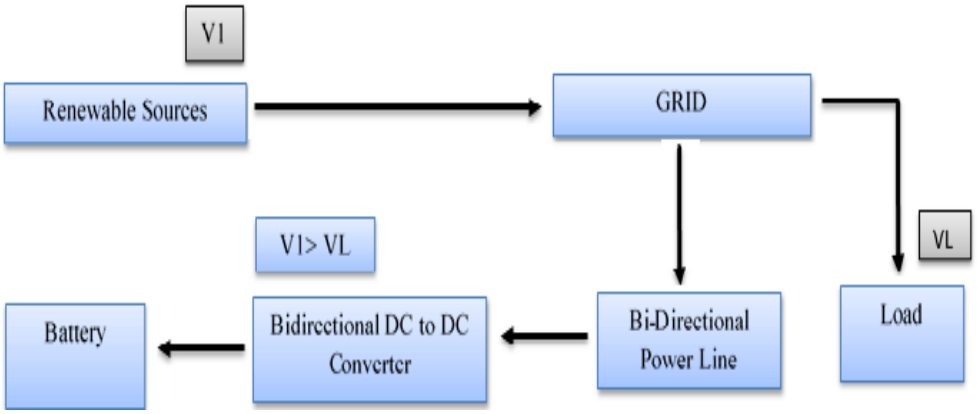

Figure: - 2 Block Diagram for Charging Mode When V1>VL

3.1.2 Second Condition When VL>V1 (Dis-charging Mode)

In this second condition when VL is greater than V1 the discharging mode in this case the load voltage demand is higher in this case the battery is in discharging mode we need to supply the voltage again to the grid using this bi-directional converter. This bi-directional connected to the DC grid with the help of VFD variable frequency drive, in that case the load voltage is higher than V1 battery is going to discharge and generated power given to the grid it will go demand power to load.

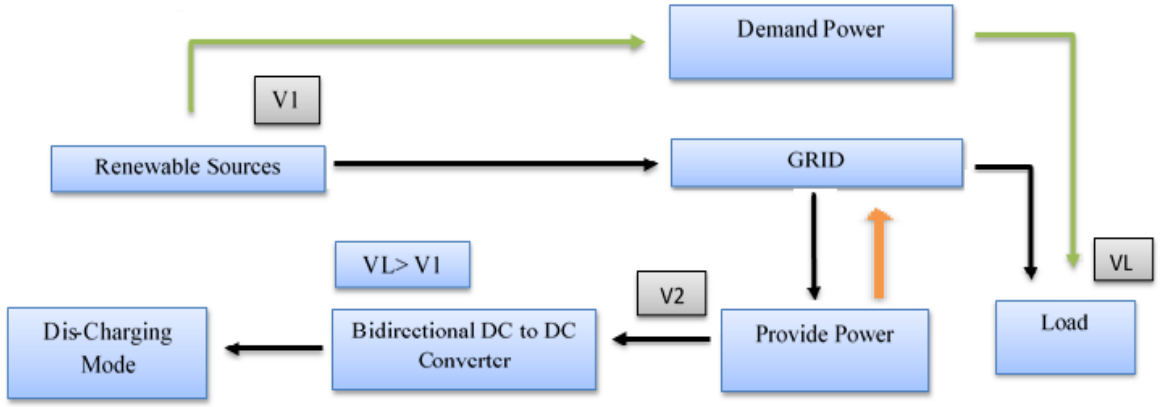

Figure: - 3 Block Diagram for Dis-Charging Mode When VL>V1

3.1.3 Third Condition When V1=0V (Dis-charging no supply voltage)

In this third condition when V1=0V no supply voltage when the power plant or renewable system goes under maintenance than also we can transfer power form grid to bi-directional converter.

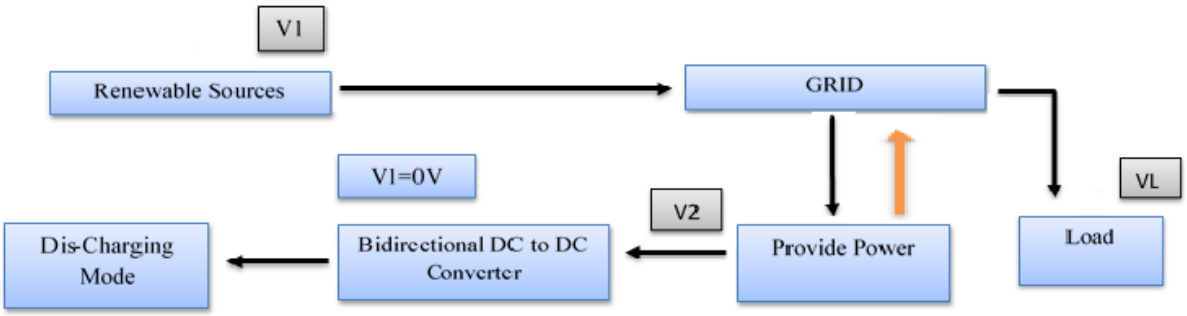

Figure: - 4 Block Diagram for Dis-charging no supply voltage When V1=0V

3.2 Classification of Bidirectional DC-DC converter

Basically, the bi-directional DC to DC converters can be classified into two types depending on the galvanic isolation between input and output side.

1. Non-Isolated Bidirectional DC-DC converters

2. Isolated Bidirectional DC-DC converters

3.2.1 Non-Isolated Bidirectional DC-DC converters

The non-isolated bidirectional DC-DC converter can be gotten from the unidirectional DC-DC converters by giving the unidirectional conduction capacity of the traditional converters by the bidirectional directing switches. Due to the vicinity of diode in the fundamental buck and help converters indicated in they don't have the property of the bidirectional force stream. This impediment can be uprooted by presenting an IGBT or a Power MOSFET having an against parallel diode crosswise over them to frame a bidirectional switch and thus to permit the present conduction in both headings for bidirectional force stream as per the controlled exchanging operation. (Joshi, 2013)

3.2.2 Buck Converter

In this buck mode first we need to turn on first MOSFET Q1 and turn off the second MOSFET Q2. In that case turn off the second MOSFET completely remove form the circuit and Q1 is in ON. Diode is also remove an in reverse bias condition show as we can see that in circuit works in buck mode.

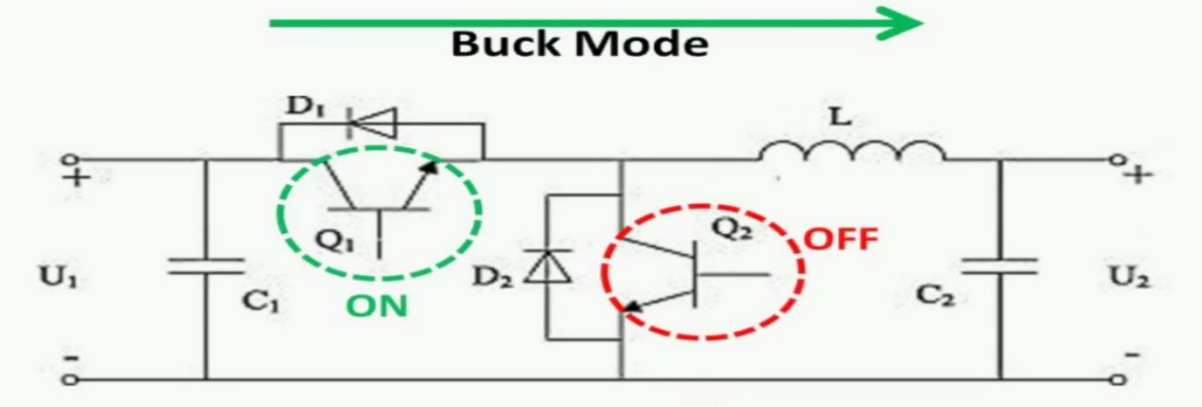

Figure: - 5 Buck Converter Circuit

3.2.3 Boost Converter

In this boost mode first we need to turn on second MOSFET Q2 and turn off the first MOSEFET Q1. In that case turn off the first MOSFET completely remove from the circuit and Q2 is in ON. Diode is Also remove as in reverse bias condition show as we can see that in circuit works in boost mode

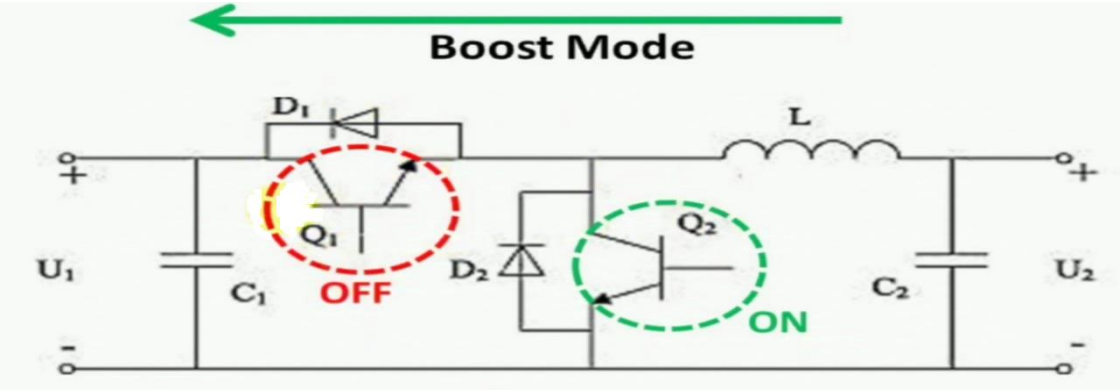

Figure: - 6 Boost Converter Circuit

3.2.4 Buck Boost Converter

In this bi-directional topology that as we can show in figure that MOSFET Q1 & MOSFET Q2, inductor and a capacitor in this both side capacitor is connected so the circuit works in buck mode and boost mode as we can see the power goes left side to right side it will work in buck mode and power goes form right to left it will work in boost mode. In this circuit there are two condition is applied first one is when the Q1 is switch will turn on and Q2 will turn off and the second condition when Q2 switch will turn on and Q1 will turn off. And in both in both the condition bi-directional converter works in buck mode and boost mode as show in figure.

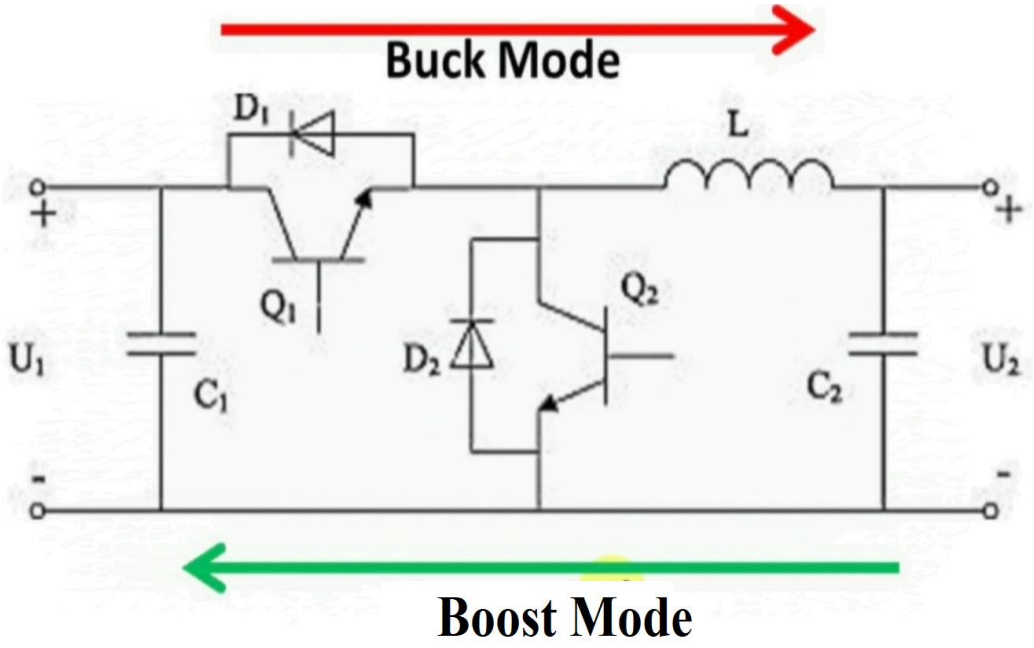

Figure: - 7 Bidirectional Buck Boost Converter

3.2.5 Half-Bridge DC-DC converter

When Buck and boost converters are connected in anti-parallel with each other, the resulting circuit is basically having the same structure as the fundamental Boost and Buck structure but with the added feature of bidirectional power flow. The below fig shows the basic structure of the Non-Isolated Half-Bridge Bidirectional DC-DC converter

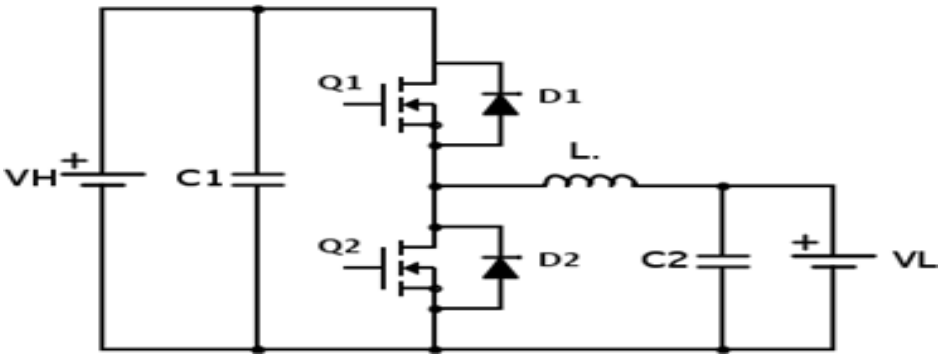

Figure: - 8 Non Isolated Half-Bridge Bidirectional DC-DC Converter

The above circuit can be made to work in buck or boost mode depending on the switching of

the MOSFETs Q_1 and Q_2. The switches Q_1 and Q_2 in combination with the anti-parallel diodes D_1 and D_2 makes the circuit step up or step down the voltage applied across them. The bi-directional operation of this circuit can be clarified in the two modes as:

Mode 1 (Boost Mode): In this mode switch Q_2 and diode D_1 goes into conduction relies on upon the obligation cycle. While the switch Q_1 and diode D_2 are off constantly. This mode can again be isolated into two interim relying upon the conduction on the switch Q_1 and diode D_2 as demonstrated in the Fig 6.

Interval 1 (Q_2-on, D_2-off; Q_1-off, D_1-Off): In this mode Q_2 is on and hence can be considered to be short circuited, therefore the lower voltage battery charges the inductor and the inductor current goes on increasing till not the gate pulse is removed from the Q_2. Also since the diode D_1 is reversed biased in this mode and the switch Q_1 is off, no current flows through the switch Q_1.

Interval 2 (Q_1-off, D_1-off; Q_2-off, D_2-on): In this mode Q_2 and Q_1 both are off and hence can be considered to be opened circuited. Now since the current owing through the inductor cannot change instantaneously, the polarity of the voltage across it reverses and hence it starts acting in series with the input voltage. Therefore, the diode D_1 is forward biased and hence the inductor current charges the yield capacitor C_2 to a higher voltage. Hence the yield voltage supports up.

Mode 2 (Buck Mode): In this mode switch Q_1 and diode D_2 are leading relies onupon the obligation cycle while the switch Q_2 and diode D_1 are not directing. This mode can further be isolated into two interim relying upon the conduction on the switch Q_2 and diode D_1 as demonstrated in the Fig 6.

Interval 1 (Q_2-on, D_2-off; Q_1-off, D_1-Off): In this mode Q_1 is on and Q_2 is offand hence the equivalent circuit is as shown in the Fig below. The higher voltage battery will charge the inductor and the output capacitor will getcharged by it.

Interval 2 (Q_1-off, D_1-off; Q_2-off, D_2-on): In this mode Q_2 and Q_1 both are off. Again since the inductor current cannot change instantaneously, it gets discharged through the freewheeling diode D_2. The voltage across the load is stepped down as compared to the input voltage.

4.0 RESEARCH METHOD / METHODOLOGY:

4.1 Architecture of Plug-in Hybrid Electric Vehicle Charging Station

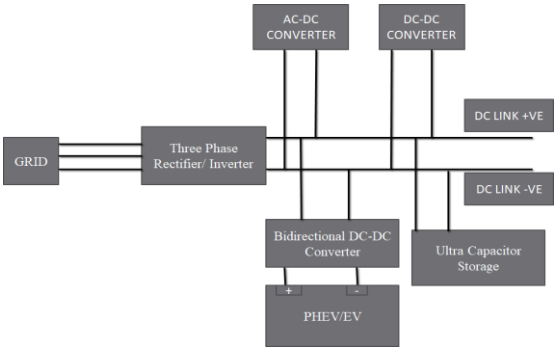

Figure: - 9 Architecture of Charging Station with DC Power Distribution

The architecture of Plug-in Hybrid Electric Vehicle (PHEV) charging stations, particularly those utilizing high-power AC-DC converters, presents several advantages over traditional discrete systems. This approach not only reduces costs but also enhances efficiency and functionality, particularly with the integration of bi-directional DC-DC converters for vehicle-to-grid (V2G) operations. The following sections elaborate on these key aspects.

Cost Efficiency High-power AC-DC converters are more cost-effective than multiple low-power discrete converters when utilizing AC power distribution. The three-stage rectifier can be optimized for average power ratings, further reducing costs when paired with ultra-capacitor energy storage to manage ripple power Enhanced Charging Capabilities.

Enhanced Charging Capabilities The parallel operation of multiple DC-DC converters allows for rapid charging, accommodating the needs of a small fraction of PHEVs requiring this service The proposed three-port partial power conversion system improves efficiency and reduces component count, facilitating faster charging rates

V2G Integration Bi-directional DC-DC converters enable energy stored in PHEV batteries to be fed back into the grid, enhancing grid stability and energy management. Conversely, while the integration of advanced charging architectures offers significant benefits, challenges such as control complexity and the need for robust infrastructure remain critical considerations for widespread adoption. The design of a plug-in hybrid electric vehicle (PHEVS) charging station, with the help of renewable sources and ultra-capacitors, and includes other several essential components to enhancing the sustainability and efficiency of the PHEVS.

In this charging station is the use of the solar panels and when possible small wind turbines to convert renewable energy into electricity. This electricity is then stored in ultracapitors, which enable quick power delivery during peak charging times. Additionally, lithium-ion batteries may be utilized for longer-duration storage, ensuring a consistent energy supply.

5.0 RESULT / FINDINGS:

5.1 Circuit specifications:

Parameter	Values
Battery Voltage B1	6 V1
Battery Voltage B2	12 V2
Initial State Of Charging	20%

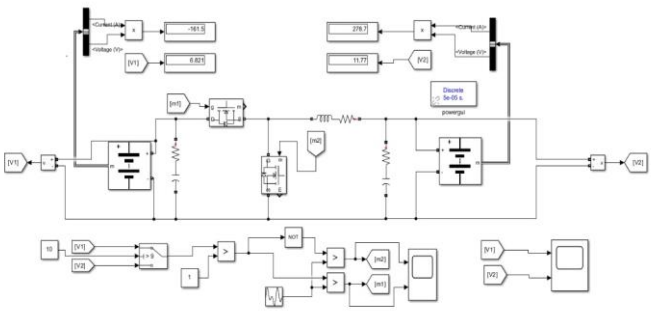

Figure: - 10 Boost Operation First Condition

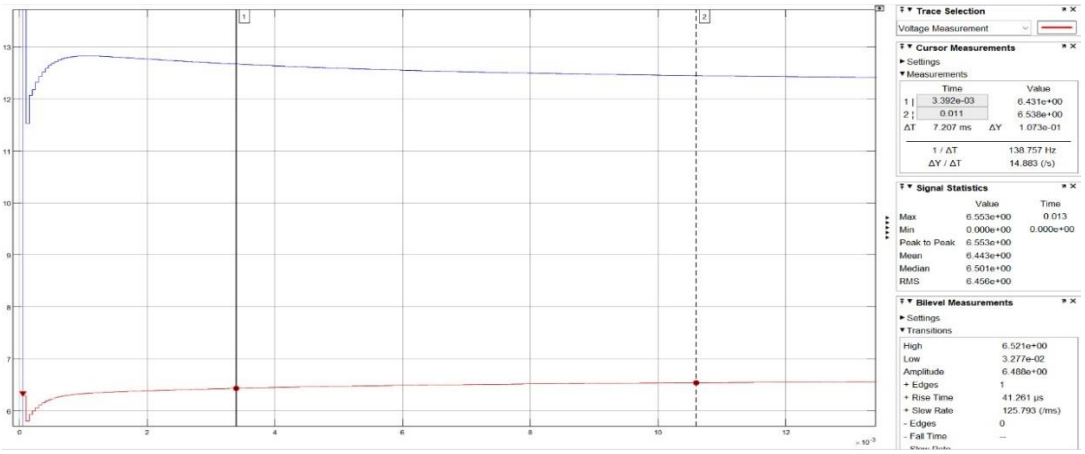

Figure: - 11 Waveform of Voltage Measurement 1 for 6V & 12V

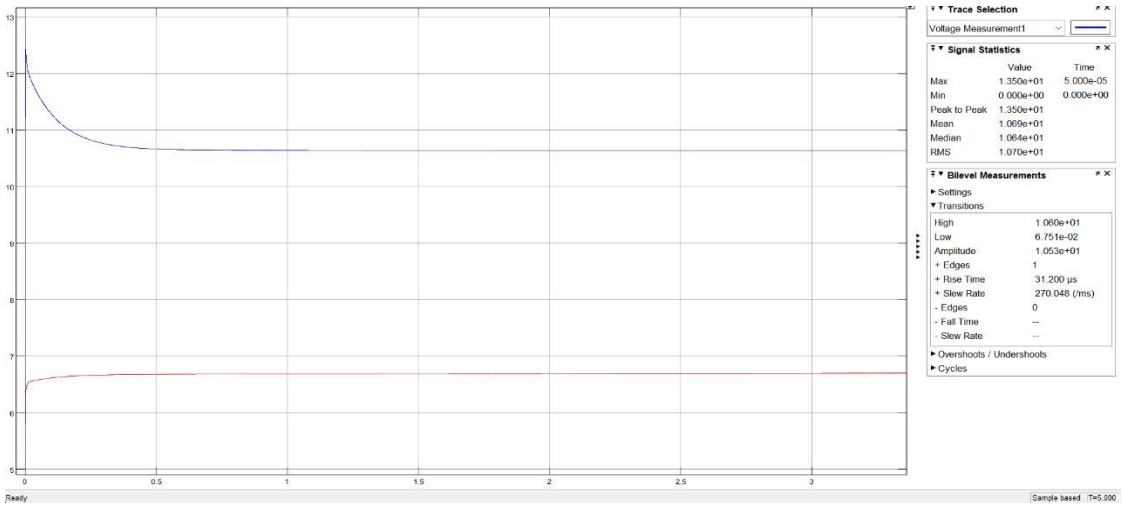

Figure: - 12 Waveform of Voltage Measurement 2 for 6V & 12V

5.2.1 Circuit specifications:

Parameter	Values
Battery Voltage B1	24 V1
Battery Voltage B2	8 V2
Initial State Of Charging	45%

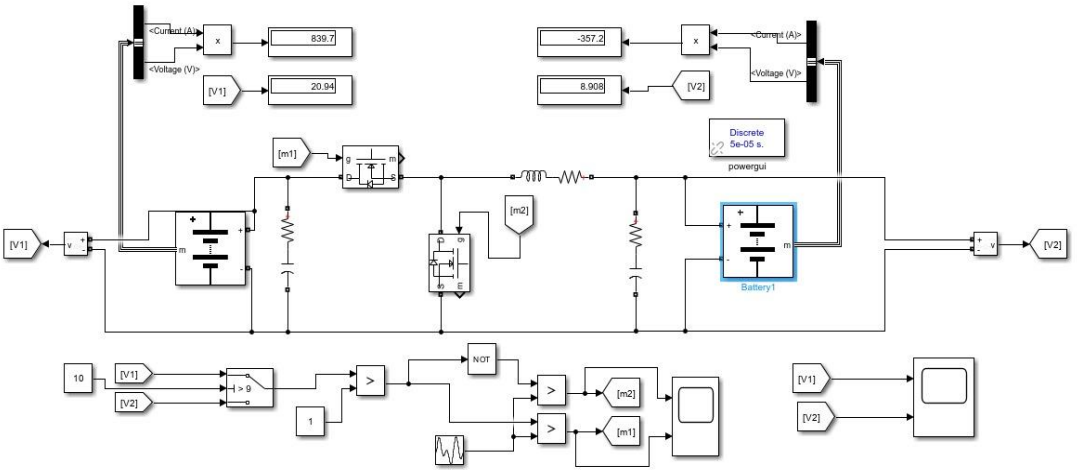

Figure: - 13 Buck Operation Second Condition

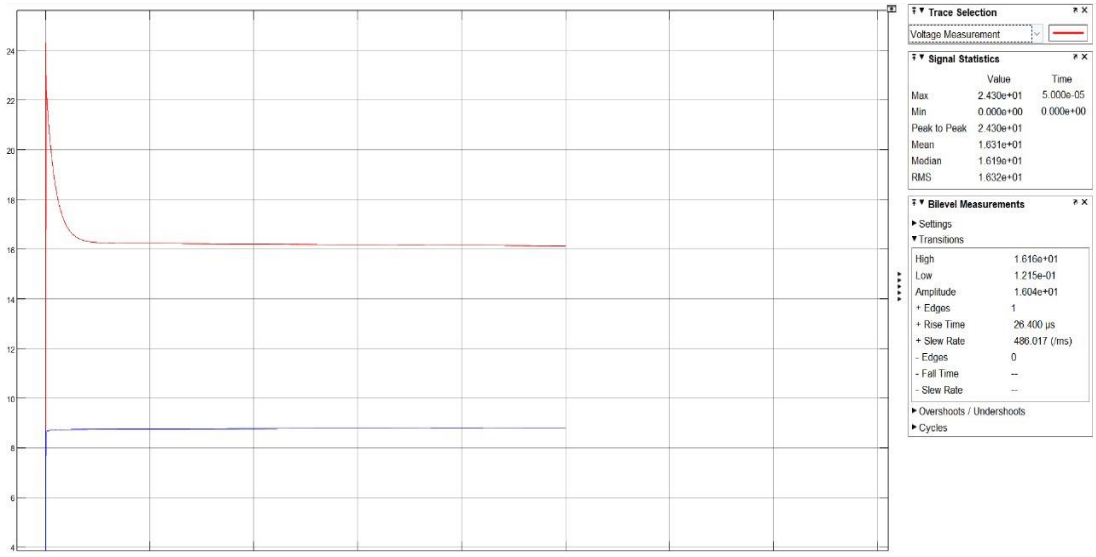

Figure: - 14 Waveform of Voltage Measurement 1 for 24V & 8V

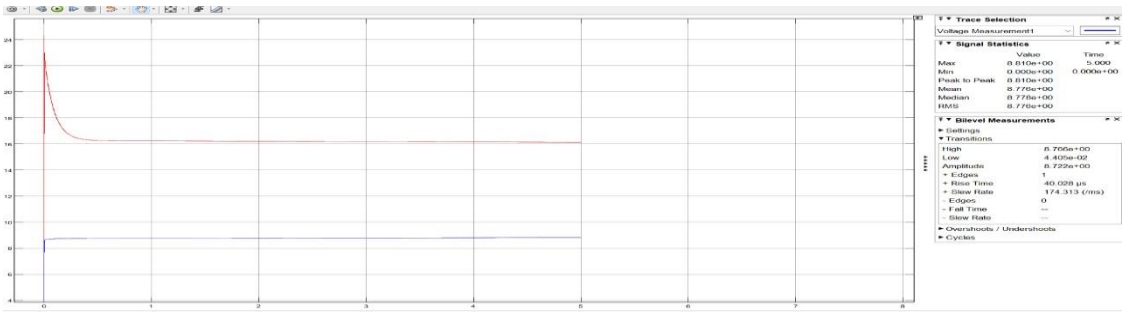

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Figure: - 15 Waveform of Voltage Measurement 2 for 24V & 8V

6.0 CONCLUSION / SUMMARY:

Several low cost non-isolated bi-directional DC-DC converters suited for Plug- in hybrid electric vehicle charge station infrastructure have been investigated and analyzed. Half bridge converter is better than the other non-isolated bi-directional DC- DC converters like SEPIC, Luo and Cuk converter because of lower switch are used in half bridge current stress, smaller number of passive components and higher efficiency. The topology is suitable for high power applications, in particular for controlling the charge discharge of ultra-capacitors that can be used in plug-in hybrid electric vehicle.

Simulation for bidirectional DC-DC Converter is completed and Half-bridge converter operates in both modes, boost mode and buck mode.

7.1 FUTURE SCOPE

- Interconnect with Micro grids system and smart Grids.
- Implementation of bi-directional DC-DC converter in Hybrid Renewable systems.
- Integration with Al and Iot.

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"A comprehensive review on isolated and non-isolated converter configuration and fast charging technology: For battery and plug in hybrid electric vehicle" M.C. Annamalai, N. Amutha prabha. 28 July 2023.

"A comprehensive review on isolated and non-isolated converter configuration and fast charging technology: For battery and plug in hybrid electric vehicle" M.C. Annamalai, N. Amutha prabha * School of Electrical Engineering, Vellore Institute of Technology (VIT), Vellore, India.

"A Review of Non-Isolated Bidirectional DC-DC Converters for Energy Storage Systems" Kostiantyn Tytelmaier1, Oleksandr Husev1, Oleksandr Veligorskyi1, Roman Yershov2 Biomedical Radio-electronic Apparatus and Systems Department1, Department of Industrial Electronics2 Chernihiv National University of Technology (CNUT) Chernihiv, Ukraine. 14 November 2017

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Yu Du, Xiaohu Zhou, Sanzhong Bai, ''Review of non-isolated bi-directional dc-dc converters for plug-in hybrid electric vehicle charge station application at municipal parking decks'', Applied Power Electronics Conference and Exposition (APEC), 2010 Twenty-Fifth Annual IEEE.

1st International Conference on Research and Innovation in Multidisciplinary Domains.
NOBCON-2024
Noble University Campus, Junagadh
Junagadh, India, December 27-28, 2024

LockBit 3.0 Black Ransomware: Analysis of Infection

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Abstract: *The research focuses on the prevalence of ransomware attacks, particularly the LockBit 3.0 ransomware, which is a concern in the world. The study uses static and dynamic analysis methods to investigate the infection and persistence of the ransomware. The static analysis involves reverse engineering the portable executable file, while the dynamic analysis involves running the ransomware. The study examines the operating activities, resources, and network activities of the ransomware, as well as its impact on the affected operating system. The findings provide a scenario for prevention methods, highlighting the real impact of the LockBit 3.0 ransomware attacks, which are part of ransomware-as-a-services (Raas).*

Key Words: *Ransomware, LockBit, LockBit 3.0 Black, RAAS*

1. INTRODUCTION:

Nowadays the network is expanding its infrastructure hugely and widely. Many new technologies are introduced between us day-by-day. As these technologies are up-to-scratch but risky for our personalization too and cybercrimes are on its peak.Use the enter key to start a new paragraph. The appropriate spacing and indent are automatically applied.

One of the most popular and oftenly discussable cybercrime latterly is Ransomware. Ransomware has been around since 1989 invented by Joseph L. Popp and wrote the first known malware “AIDS Trojan”. It has been a key element behind the surge of cyberattacks. Cybercriminals oftenly use Ransomware Thrust and access the victim’s data or encrypt it and demand a payment to make money off of victims.

Ransomware has many types and one of the most talked over/active is lockbit ransomware. Lockbit poses a significant cybersecurity threat by primarily gaining access to targeted networks through purchased access. It establishes a control over the victim's system and collects network information and achieves primary goals like encrypting and stealing data. It has evolved from being transmitted through physical storage devices.

Lockbit was formerly known as “.abcd virus”. In September 2019, a Ransomware-as-a-Service (RaaS) was released, transforming the risk landscape by allowing malicious actors to execute attacks for a fee. [1]

Lockbit 2.0 also known as Lockbit Red as it includes stealbit which is built-in information stealing tool. It has been operating since 2021.Through stealbit reconnaissance and exploitation is done. So basically it includes the features of stealing private data,and attacks on systems by performing some hacking

techniques. In this way it is misused for performing malicious attacks and payloads fromusers. In this way lockbit 2.0 has features of stealing information through tools. [2]

Lockbit 3.0 is also known as lockbit black. Lockbit 3.0 was launched in late June 2022 after Beta Testing. It is an advanced version of ransomware and it's known for its highly sophisticated encryption techniques. It is designed to hack systems encrypt privacy data and render them unusable until a payload is given. Once it is infected to a system it searches for files based on specific extensions and encrypts them using a strong algorithm. It can be delivered through multiple attack vectors. Once an attack is completed a ransome note is displayed on screen of the victim's system with instructions of payloads and how to obtain a description key. [3]

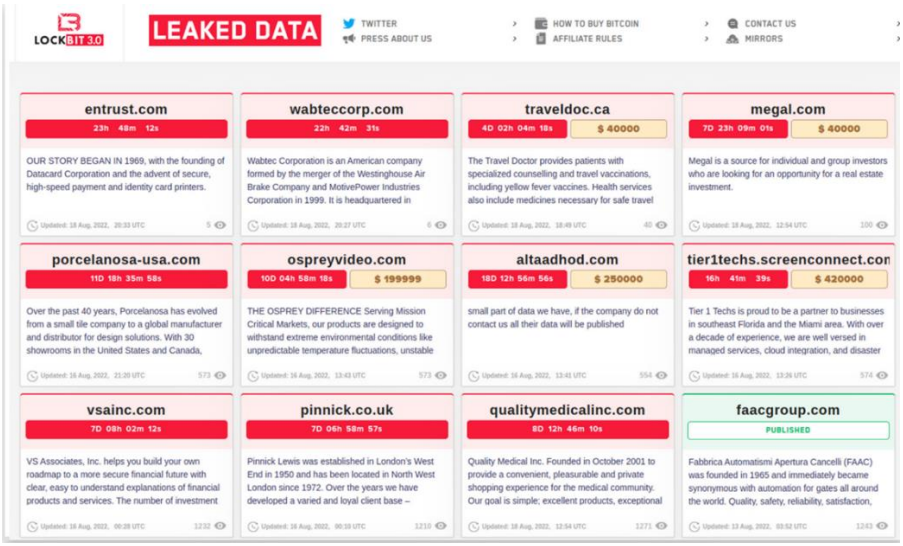


Figure 1. LockBit data auction leak site — August 2022

LockBit continued its attacks, claiming several high-profile organizations as victims. LockBit, unlike Mandiant, was not involved in a PR stunt when other companies were named victims. LockBit has launched attacks on Foxconn, a major global technology manufacturer, and Entrust, a security technology company, among other companies. Figure 19 displays a portion of companies on LockBit's data auction site in mid-August 2022. [4]

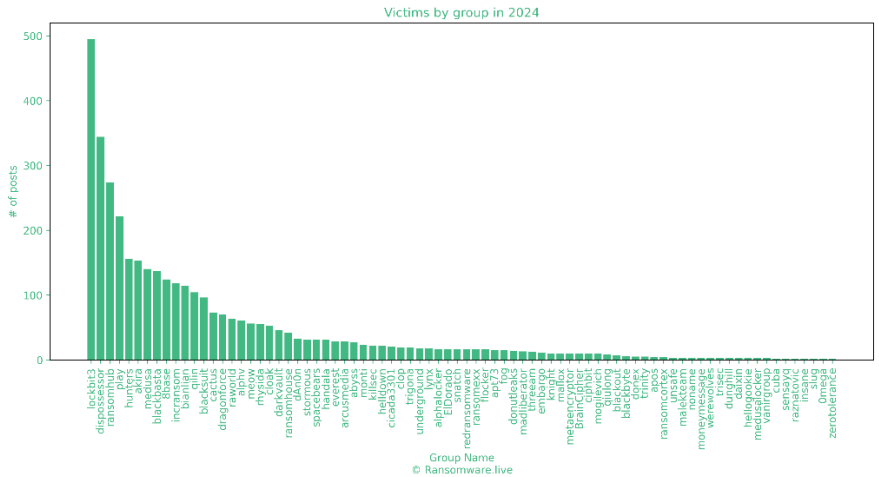


Figure 2. Lockbit 3, as per a 2024 Ransomware report by ransomware.live, is deemed the most dangerous malware globally.[5]

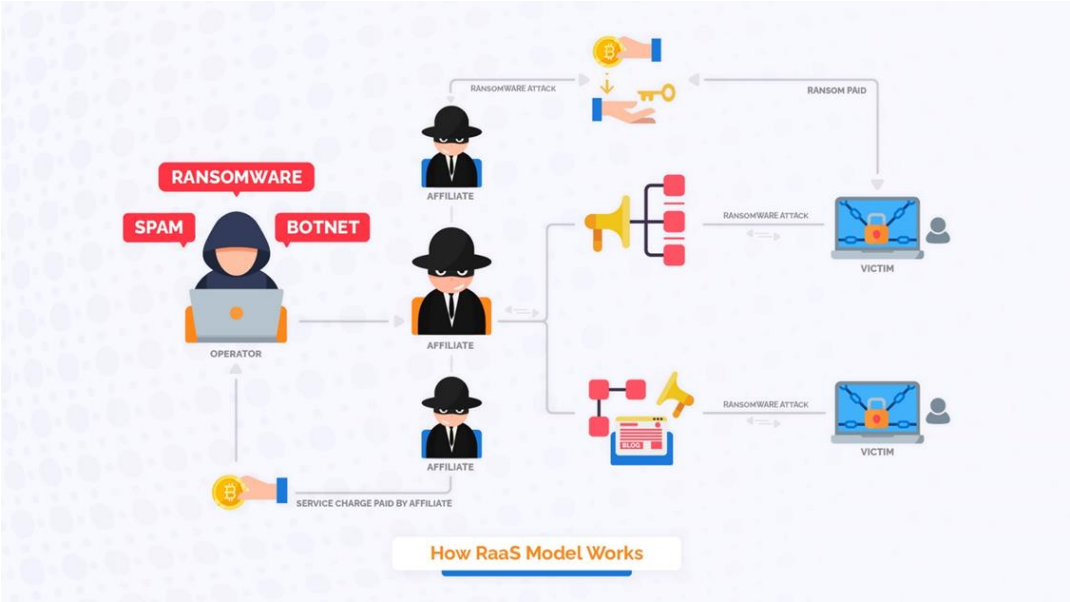


Figure 3. RaaS stands for Ransomware-as-a-Service

RaaS stands for Ransomware-as-a-Service. It's a business model in the world of cybercrime where attackers lease or sell ransomware tools to other criminals who may not have the technical skills to create their own malicious software. This model allows non-expert individuals to launch ransomware attacks, typically in exchange for a portion of the ransom paid by the victim. [6]

1. Creation of Ransomware

The creators of the ransomware (often experienced cybercriminals or hacking groups) develop the malicious software.

2. Configuring the RaaS System

1. **Online Platform**: RaaS providers often set up a platform on the dark web or other encrypted channels where affiliates can sign up, access the ransomware tools, and track their attacks.

2. **Dashboard**: Affiliates can log into a dashboard that allows them to monitor infections, communicate with victims, manage payments, and get updates about their campaigns. Some RaaS providers also offer a "backend" for tracking the ransom money and managing negotiations.

3. Launching an Attack

1. **Phishing emails**: Trick victims into opening infected attachments or clicking malicious links.

2. **Exploit kits**: Take advantage of vulnerabilities in outdated software or systems to distribute the ransomware.

3. **Remote Desktop Protocol (RDP):** Brute force or exploit weak passwords to gain access to remote desktops or servers.

4. Payment and Decryption

1. **Ransom Note**: The ransomware displays a message instructing the victim to pay the ransom within a specified time frame (usually 24–72 hours). It often includes threats, such as permanent data loss or public exposure of sensitive data if the payment isn't made.
2. **Payment**: Victims are typically asked to pay in cryptocurrencies like Bitcoin or Monero, which are harder to trace.
3. **Decryption**: The ransom payment may or may not result in the attacker providing a decryption key for file restoration, with no guarantee of the attacker's compliance. Some attackers simply take the money and disappear without providing a decryption key.

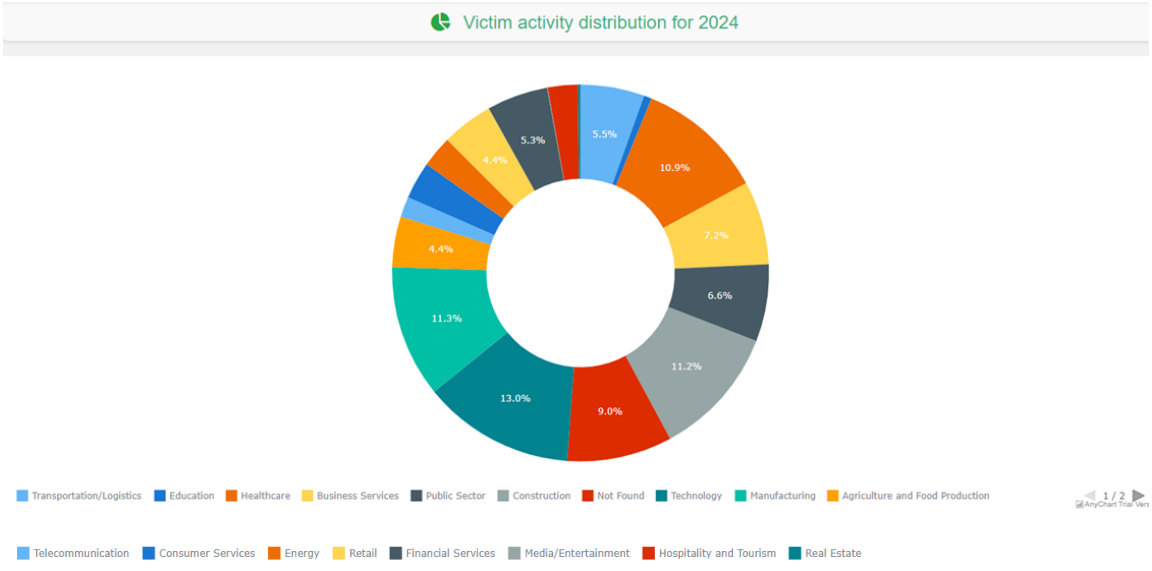


Figure 4. 2024 ransomware.live report indicates that the technology sector is the most affected by lockbit3 ransomware attacks.

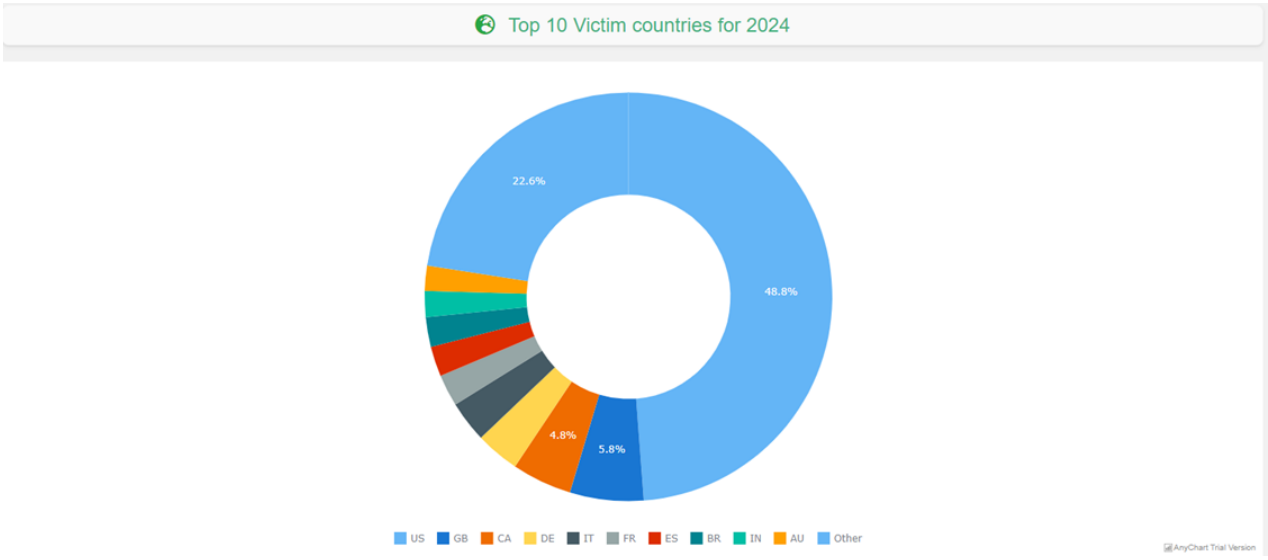


Figure 5. The United States placed top with a 48.8% encryption rate in ransomware attacks, according to a ransomware.live report on ransomware for 2024.

2. RESEARCH METHOD :

The methods for analyzing Malware are applicable to LockBit 3.0 ransomware, with the sample for this study sourced from MalwareBazaar, complete with hash details.

Table 1 LockBit 3.0 Components

	Mutation LockBit 3.0 Components
MD5	294e9f64cb1642dd89229fff0592856b
SHA1	97b148c27f3da29ba7b18d6aee8a0db9102f47c9
SHA256	917e115cc403e29b4388e0d175cbfac3e7e40ca1742299fbdb353847db2de7c2
File Type	Win32 EXE, executable, windows, win32, pe, peexe
Size	14.00 KB (14336 bytes)

2.1 Static Analysis

Static Analysis is the initial technique for identifying suspected malware files. This method helps determine if a file contains malicious code, categorizing it as malware through various evaluative steps.

1. In static analysis, a file undergoes disassembly and unpacking to determine if it is benign or malware.
2. Hexadecimal analysis helps identify file types, particularly executables which feature a 4D 5A signature. Tools like IDAPro Free and PEid are essential for analyzing PE (Part Executable) files associated with Windows or DOS. [8]
3. The static analysis method aims to identify a file using CRC32 as an identifier. The hash function is utilized to detect data corruption during transmission or storage from the source to the destination.[9]

2.2 Dynamic Analysis

The second approach is dynamic analysis, which involves examining the network of the compromised virtual system and tracking the network, operating system, and process actions of the virus that has compromised a system in the hopes of observing the deployment

1. technique used by the ransomware or virus and the actions it generates. To examine this,
2. Tools like Process Hacker, Process Monitor, Wireshark, and others are required to assist.

Table 2 Tools for malware analysis

No.	Tools	Function
1.	Wireshark	used on Linux systems for packet capture and analysis

2.	Process Monitor + Noriben script	used to record filtered (required) Windows system activity. Registry, files, processes, DLLs, and other things are among the activities.
3.	Process Hacker	used to track process activity on Windows systems.
4.	Pestudio	includes the VirusTotal plugin and is utilised for Windows system static analysis.

platforms offered free Additionally, the ransomware sample was examined using five distinct online malware analysis programs in order to confirm the results of the manual examination. These access and produced thorough reports on the sample's traits and behavior. Table 3 provides a list of various platforms.

Table 3 Online Malware analysis platforms

No.	Tools	Function
1.	Any Run	https://app.any.run/
2.	Hybrid Analysis	https://www.hybrid-analysis.com/
3.	Intezer Analyze	https://www.hybrid-analysis.com/
4.	JoeSandbox	https://www.joesandbox.com/
5	virustotal	https://www.virustotal.com/gui/home/upload

How Does LockBit Ransomware Attack

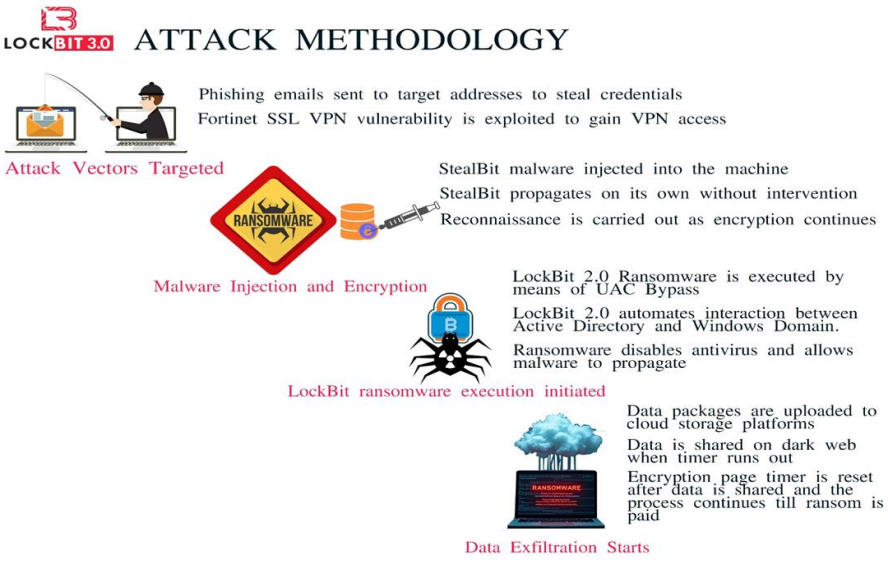


Figure 6 :Recent Attacks

Maximum Industries: SpaceX purchases rocket components from this firm. The LockBit gang claimed to have stolen 3,000 proprietary schematics and designs during an attack in mid-March 2023. [15]

Royal postal: Package deliveries were disrupted in early January 2023 after the LockBit ransomware gang compromised the computers of the UK's top postal delivery provider, Royal Mail. [16]

Entrust: The LockBit ransomware group stole critical data from the security behemoth Entrust's network in June 2022. In an intriguing turn of events, Entrust prevented LockBit from disclosing the stolen data by installing Denial-of-Service malware on their servers. [17]

Italian Revenue Agency: In July 2022, the LockBit gang conducted the largest cyberattack on the Italian Revenue Agency, stealing 78 GB of data from its servers.. The revenue agency and the LockBit gang are now in discussions about ransom payments. [18]

Essendant: In March 2023, a major cyberattack occurred against a wholesale distributor of office supplies. On March 14th, the LockBit group took control. [19]

3. RESULT :

The analysis of source code strings using tools strings.exe and floss.exe(available at https://docs.microsoft.com/en-us/sysinternals/downloads/strings) and floss.exe (accessible at https://github.com/mandiant/flarefloss/releases), enabled the extraction of both ASCII and Unicode strings, resulting in a list of strings as shown in Figure 8.

Figure 7. Strings Analysis

Exeinfo PE:

The MD5 input hash and portable executable format file in the research sample are shown. The Byte Analyzer from Exeinfo PE reveals the file is encrypted with a zero value test of 1.5414%, indicating it is a pure LockBit 3.0 ransomware. [10]

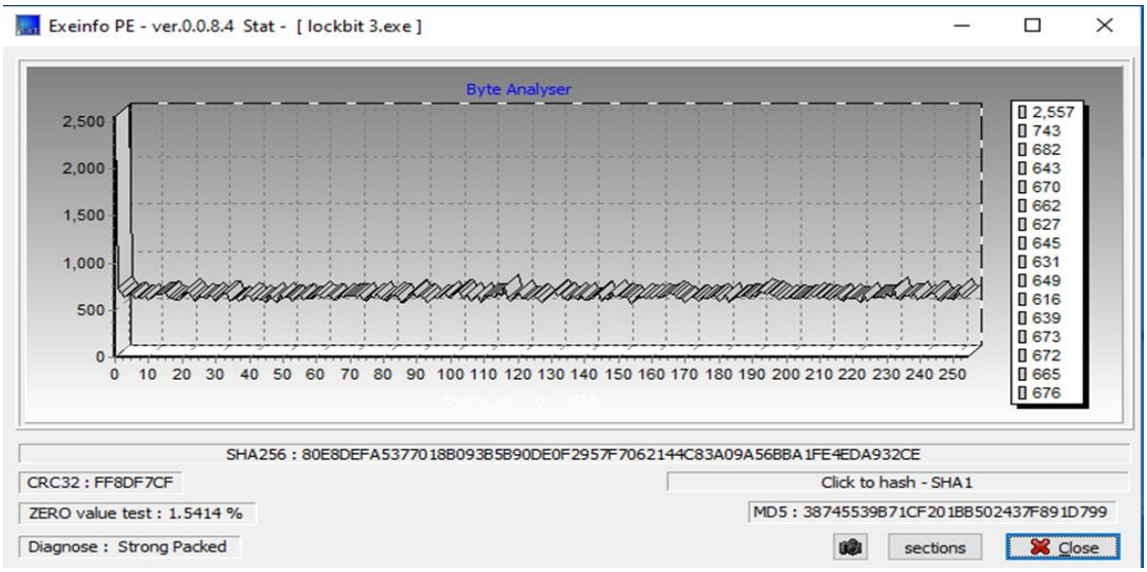


Figure 8. Byte Analyser

Virustotal:

Analyzing malware requires a number of steps, one of which is running it through several antivirus programs. A well-known internet service that offers a platform for examining dubious files and URLs is called VirusTotal. VirusTotal, which is widely used in research, combines several antivirus engines and additional analysis tools to scan for and identify possible malware. Figure 10 displays the results, which are available at https://www.virustotal.com/gui/file/917e115cc403e29b4388e0d175cbfac3e7e40ca1742299fbdb353847db2de7c2/details. [11]

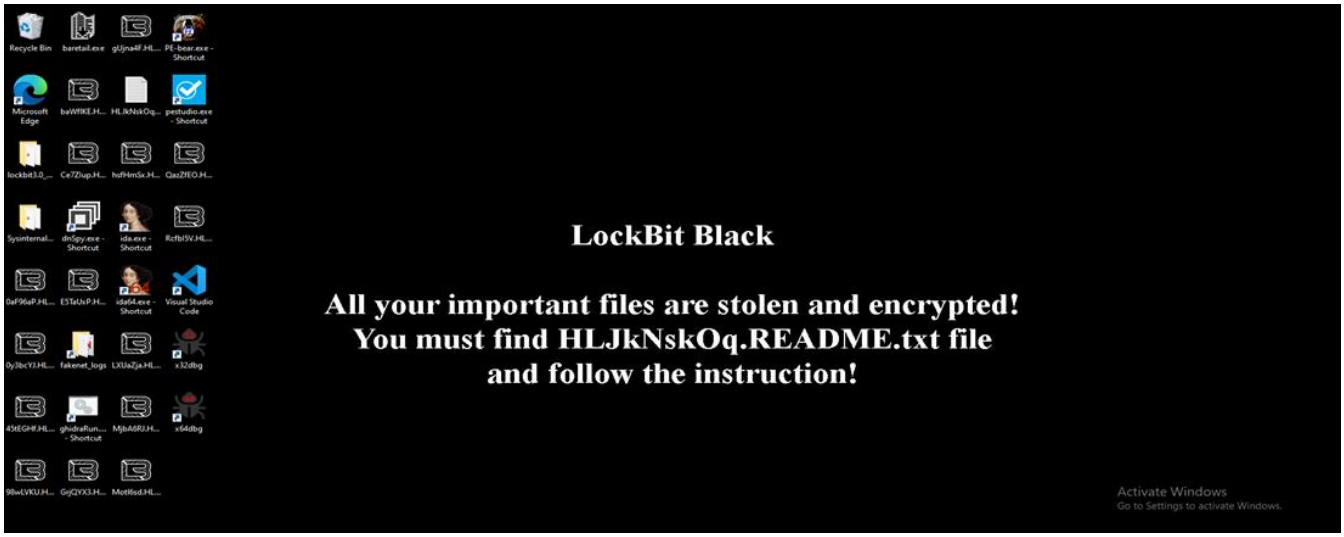
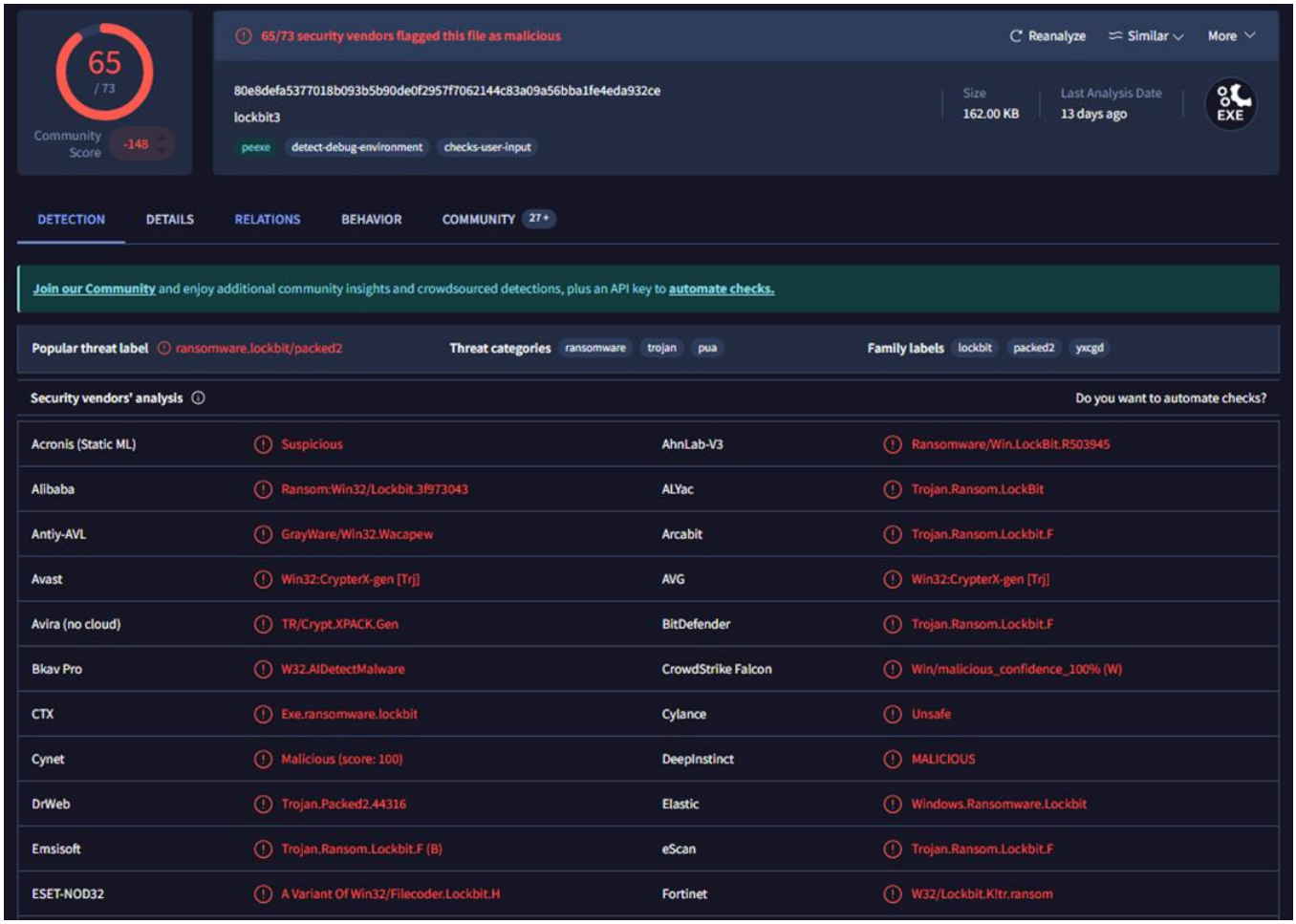


Figure 9. Windows infected by LockBit Black



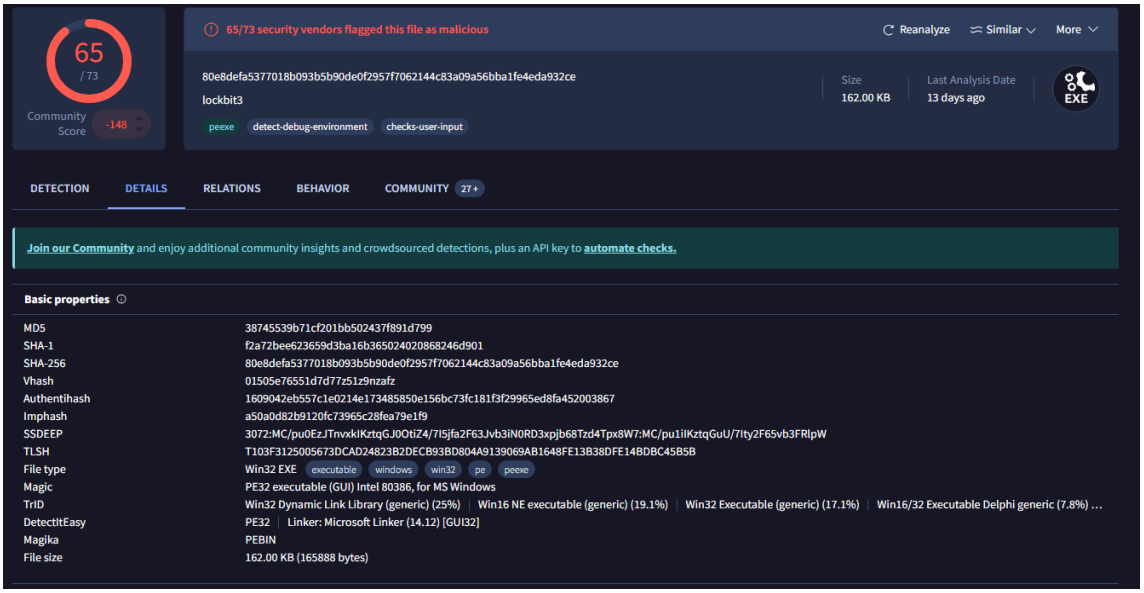


Figure 10. VirusTotal Displays The Results

4. ANALYSIS:

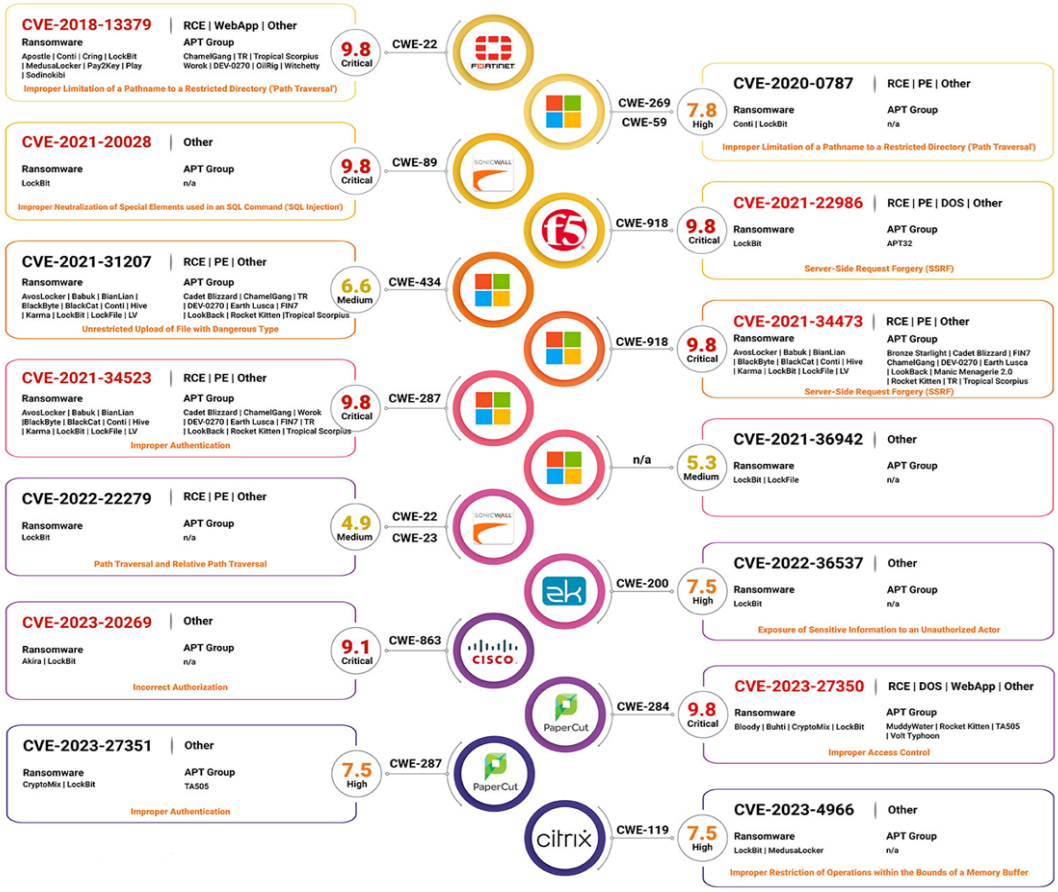


Figure 11. Byte Analyser

1. In all, LockBit has the ability to attack 14 CVEs found in well-known products, including Microsoft Windows Server, Microsoft Exchange, F5 Big IP, and FortiOS.
2. 6 Vulnerabilities can be leveraged to remotely execute arbitrary code over public or external networks.
3. Six flaws allow unauthorized users to access parts of the open network and increase privileges.
4. Seven flaws make it possible for online apps to infiltrate networks.
5. The vulnerability arsenal includes the ProxyShell exploit chain(CVE-2021-34473, CVE-2021-34523, CVE-2021-31207), PaperCut exploit (CVE-2023-27350),, and Citrix Bleed vulnerability(CVE-2023-4966), which are experiencing significant exploitation.
6. CVE-2022-22279 is a post-authentication vulnerability affecting end-of-life SonicWall Secure Remote Access products and older firmware versions of Secure Mobile Access 100 series, highlighting the potential danger to organizations.
7. CISA has warned about numerous vulnerabilities, including CVE-2021-31207 and CVE-2023-4966, due to multiple attacks by LockBit and other ransomware groups in their #StopRansomware campaign.[12]

Sites

TITLE	AVAILABLE	LAST VISIT	FQDN	SCREENSHOT
Title	🔴	2024-02-25 01:59:21.000387	lockbitapt2d73krlbewgv27tquljgxr33xbwwsp6rkyieto7u4ncead.onion	N/A
Title	🔴	2024-02-25 01:59:49.310482	lockbitapt2yfbt7lchxejug47kmqvqqxvvjpqkmevv4l3azl3gy6pyd.onion	N/A
Title	🔴	2024-02-25 02:00:21.061242	lockbitapt34kvrip6xojylohhxrwsvpzdffgs5z4pbbsywnzsbdguqd.onion	N/A
Title	🔴	2024-02-25 02:00:52.914149	lockbitapt5x4zkjbcqmz6frdhecqqgadevyiwqxukksspnlidyvd7qd.onion	N/A
Title	🔴	2024-02-25 02:01:32.172463	lockbitapt6vx57t3eeqjofwgcglmutr3a35nygvokja5uuccip4ykyd.onion	N/A
Title	🔴	2024-02-25 02:02:06.070749	lockbitapt72iw55njgnqpymggskg5yp75ry7rirtdg4m7i42artsbqd.onion	N/A
Title	🔴	2024-02-25 02:02:39.610053	lockbitaptawjl6udhpd323uehekiyatj6ftcxmkwe5sezs4fqgpjpid.onion	N/A
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Title	🔴	2024-02-25 02:03:40.788734	lockbitaptc2iq4atewz2ise62q63wfktyrl4qtwuk5qax262kgtzjqd.onion	N/A
Title	🔴	2024-02-25 02:04:07.703558	lockbitapt72iw55njgnqpymggskg5yp75ry7rirtdg4m7i42artsbqd.onion	N/A
LockBit LOGIN	🔴	2024-02-19 20:10:51.497426	lockbitsupa7e3b4pkn4mgkgojrl5iqgx24clbzc4xm7i6jeetsia3qd.onion	N/A
LockBit LOGIN	🔴	2024-02-19 20:11:22.533791	lockbitsupdwon76nzykzblcplixwts4n4zoecugz2bxabtapqvmzqqd.onion	N/A
LockBit LOGIN	🔴	2024-02-19 20:12:01.149485	lockbitsupn2h6be2cnqpvncyhj4rgmnwn44633hnzzmtxdvjoqlp7yd.onion	N/A
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LockBit LOGIN	🔴	2024-02-19 20:13:36.377908	lockbitsupt7nr3fa6e7xyb73lk6bw6rcneqhoyblniiabj4uwvzapqd.onion	N/A
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None	🔴	2024-06-23 14:08:03.158787	lockbit7ouvrsdgtojeoj5hvu6bljqtghitekwpdy3b6y62ixtsu5jqd.onion	N/A
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LockBit BLOG	🔴	2024-06-15 14:14:18.259081	lockbit3g3ohd3katajf6zaehxz4h4cnhmz5t735zpltywhwpc6oy3id.onion	N/A
None	🟢	2024-09-22 12:56:56.414168	lockbit3753ekiocyo5epmpy6klmejchjtzddoekjlnt6mu3qh4de2id.onion	📷
504 Gateway Time-out	🔴	2024-06-26 15:04:21.123492	ofj3oaltwaf67qtd7oafk5r44upm6wkc2jurpsdyih2c7mbrbshuwayd.onion	N/A
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None	🟢	2024-09-22 12:57:37.432710	lockbitw2ygzasbt35ffpdb46r4vkej6flm3siyabaxzdodwpiatfgqd.onion	📷

Humanity check	🟢	2024-09-22 12:58:21.461997	lockbitck6escin3p33v3f5uef3mr5fx335oyqon2uqoyxuraieuhiqd.onion	📸
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Humanity check	🟢	2024-09-22 12:59:55.187953	lockbitkwkmhfb2zr3ngduaa6sd6munslzkbtqhn5ifmwqml4sl7znad.onion	📸
Humanity check	🟢	2024-09-22 13:00:10.448930	lockbitqfj7mmhrfa7lznj47ogknqanskj7hyk2vistn2ju5ufrhbpyd.onion	📸

Figure 12. Ransomware Group: Lockbit3 [13]

~~~ LockBit 3.0 the world's fastest and most stable ransomware from 2019~~~
>>>>> Your data is stolen and encrypted.
If you don't pay the ransom, the data will be published on our TOR darknet sites. Keep in mind that once your data appears on our leak site, it could be bought by your competitors at any second, so don't hesitate for a long time. The sooner you pay the ransom, the sooner your company will be safe.
Tor Browser Links:
http://lockbitapt2d73krlbewgv27tquljgxr33xbwwsp6rkyieto7u4ncead.onion
http://lockbitapt2yfbt7lchxejug47kmqvqqxvvjpqkmevv4l3azl3gy6pyd.onion
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Links for normal browser:
http://lockbitapt2d73krlbewgv27tquljgxr33xbwwsp6rkyieto7u4ncead.onion.ly
http://lockbitapt2yfbt7lchxejug47kmqvqqxvvjpqkmevv4l3azl3gy6pyd.onion.ly
http://lockbitapt34kvrip6xojylohhxrwsvpzdffgs5z4pbbsywnzsbdguqd.onion.ly
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http://lockbitaptc2iq4atewz2ise62q63wfktyrl4qtwuk5qax262kgtzjqd.onion.ly
>>>>> What guarantee is there that we won't cheat you?
We are the oldest ransomware affiliate program on the planet, nothing is more important than our reputation. We are not a politically motivated group and we want nothing more than money. If you pay, we will provide you with decryption software and destroy the stolen data. After you pay the ransom, you will quickly make even more money. Treat this situation simply as a paid training for your system administrators, because it is due to your corporate network not being properly configured that we were able to attack you. Our pentest services should be paid just like you pay the salaries of your system administrators. Get over it and pay for it. If we don't give you a decryptor or delete your data after you pay, no one will pay us in the future. You can get more information about us on Ilon Musk's Twitter https://twitter.com/hashtag/lockbit?f=live
>>>>> You need to contact us and decrypt one file for free on TOR darknet sites with your personal ID
Download and install Tor Browser https://www.torproject.org/
Write to the chat room and wait for an answer, we'll guarantee a response from you. If you need a unique ID for correspondence with us that no one will know about, tell it in the chat, we will generate a secret chat for you and give you his ID via private one-time memos service, no one can find out this ID but you. Sometimes you will have to wait some time for our reply, this is because we have a lot of work and we attack hundreds of companies around the world.
Tor Browser Links for chat:
http://lockbitsupa7e3b4pkn4mgkgojrl5iqgx24clbzc4xm7i6jeetsia3qd.onion
http://lockbitsupdwon76nzykzblcplixwts4n4zoecugz2bxabtapqvmzqqd.onion
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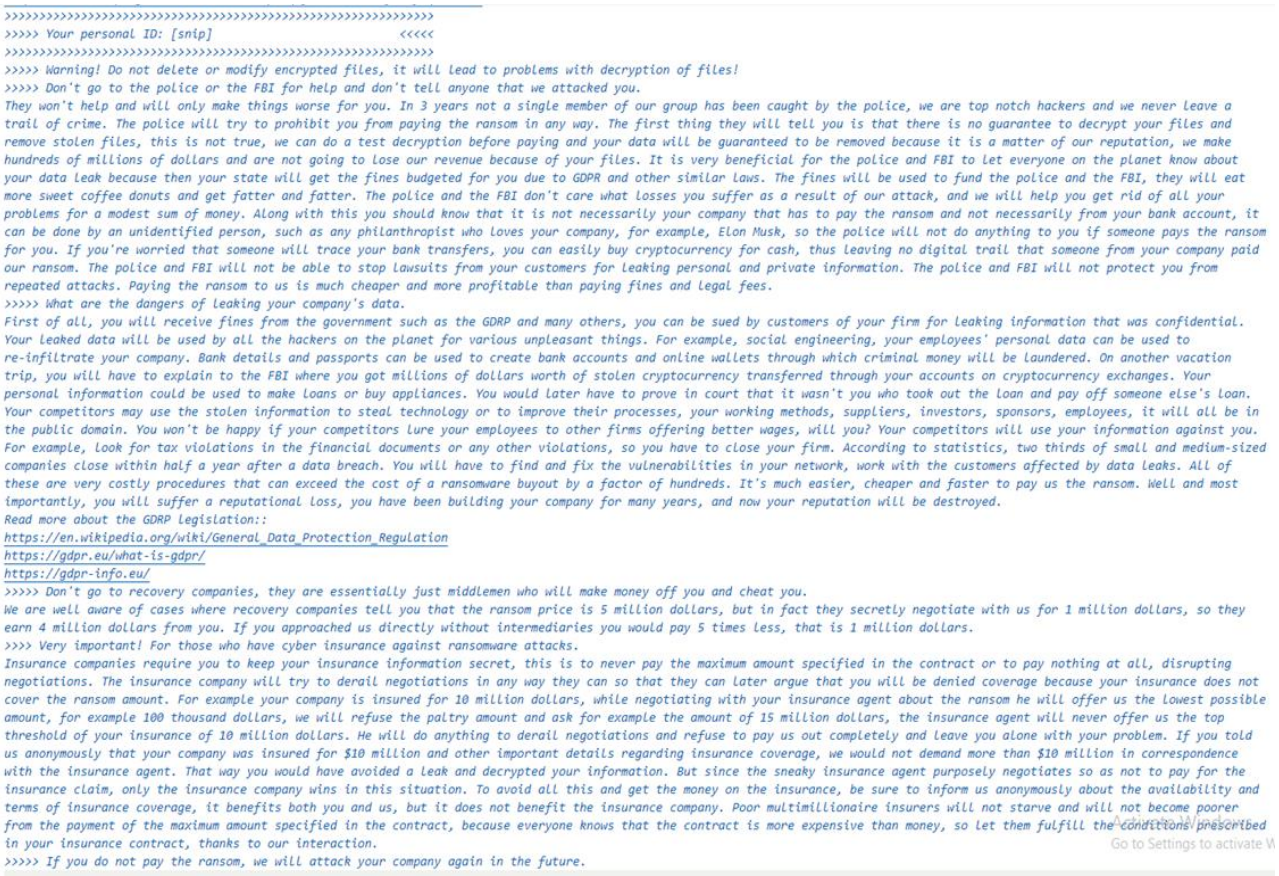

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>>>
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17. https://www.securin.io/articles/all-about-lockbit-ransomware/
18. https://www.ransomware.live/group/lockbit3
19. https://www.ransomware.live/ransomnotes/lockbit
20. https://www.theregister.com/2023/03/13/lockbit_spacex_ransomware/?&web_view=true
21. https://www.bleepingcomputer.com/news/security/lockbit-ransomware-gang-claims-royal-mail-cyberattack/
22. https://www.bleepingcomputer.com/news/security/lockbit-claims-ransomware-attack-on-security-giant-entrust-leaks-data/
23. https://securityaffairs.com/133640/cyber-crime/lockbit-ransomware-italian-revenue-agency.html
24. https://www.bleepingcomputer.com/news/security/lockbit-ransomware-claims-essendant-attack-company-says-network-outage-/

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Noble University Campus, Junagadh
Junagadh, India, December 27-28, 2024

Efficient Model on Orthogonal Frequency Division Multiplexing Using 5G Technology

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Abstract: *The construction and implementation of an OFDM modem used in wireless communication are discussed in this article. Orthogonal rate of Division Multiplexing, abbreviated as OFDM is among the most recent modulation methods used to counteract frequency-selectivity in transmission channels, delivering significant data rates without inter-symbol disruption. Real testing for future remote exchange framework design includes increased spectrum efficiency and enhanced connection dependability. These radio channels are a risky proliferation medium that suffers from blurring and interference from other users. The need for high-speed data services has been rising with the evolution of the wireless system, which is hard to satisfy by the standard serial data transmission system without a trade-off between high- speed data services and QOS without extending the bandwidth of the system. The performance of an OFDM system may be increased further by employing numerous antennas on both the transmitting and receiving sides to create spatial diversity.*

Key Words: *Inter Carrier Interference (ICI), OFDM significance, MIMO*

1. INTRODUCTION:

OFDM is a novel and appealing modulation programmed with very efficient overall bandwidth utilization, immunity to multipath fading environments, lower ICI, and ISI, and improved spectral and power proficiency. Inter-symbol disruption is an issue that arises in high-speed communication (ISI) It looks like you're working on a technical passage about the challenges and evolution of communication systems, specifically in the context of 5G technology. The limitations of modulation methods in current communication systems have become a significant barrier to further increasing data rates. As a result, Orthogonal Frequency Division Multiplexing (OFDM) has emerged as a key solution to this challenge. Looking ahead, the next generation of mobile communication systems will require more sophisticated modulation techniques and advanced information transmission structures. In this regard, the integration of Multiple Input Multiple Output (MIMO) technology with OFDM offers a robust framework that supports high-speed, secure data delivery. This combination enables the transmission of voice, data, and media content to users at any time and place, meeting the growing demand for higher data rates compared to previous generations of mobile networks. Given that bandwidth resources in 5G mobile

communication networks remain limited, achieving a wireless transmission rate of up to 100 Mbps demands the adoption of advanced techniques. As the modulation schemes in existing systems become increasingly inadequate to meet these requirements, the use of MIMO and OFDM has been embraced as a solution. Due to their superior performance, these technologies are expected to play a central role in the transition from 4G to 5G systems, driving the evolution of high-speed wireless communications.

2. LITERATURE REVIEW:

Orthogonal Frequency Division Multiplexing (OFDM) is an efficient modulation format used in modern wireless communication systems including 5G. OFDM combines the benefits of Quadrature Amplitude Modulation (QAM) and Frequency Division Multiplexing (FDM) to produce a high-data-rate communication system. QAM refers to a variety of specific modulation types: BPSK (Binary Phase Shift Keying), QPSK (Quadrature Phase Shift Keying), 16QAM (16-state QAM), 64QAM (64-state QAM), etc. Refer to Refs. 1 and 2 for more information on QAM.BThe basic concept of OFDM was first proposed by R. W. Chang [see Ref 3], recognizing that bandlimited orthogonal signals can be combined with *significant overlap* while avoiding inter channel interference. Using OFDM, we can create an array of subcarriers that all work together to transmit information over a range of frequencies. These subcarriers must be orthogonal functions. The precise mathematical definition for orthogonality between two functions is that the integral of their product over the designated time interval is zero. More loosely, we can consider orthogonal functions to be statistically unrelated.

2.1 Block diagram of a system based on Orthogonal Frequency Division Multiplexing (OFDM)

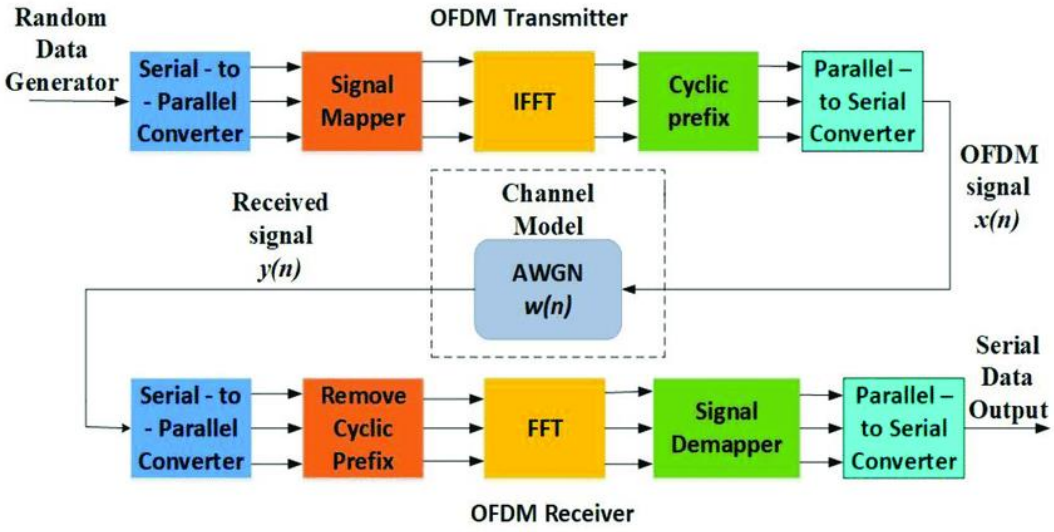


Figure 1 Process of OFDM

3. OBJECTIVES:

In this dissertation we propose diversity for the transmission which can employ and provides a better way of diversity gain after using the n number of or multiple antennas which can gave the higher space-time coding diversity gain and the better performance of system. we can apply the receive and transmit diversity by applying coherent binary phase-shift keying [BPSK] modulation over flat-fading Rayleigh channels for transmit diversity we can use 1*1,1*2,2*1,2*2,4*1,4*2 etc. antenna combinations. The final value is to showing the transmitted and received channel mode in encoded and transmitting with the demodulation of the received transmitted signal. The static nature of the system means channel having the knowledge of each system at the receiver end. For instance if we are Utilizing two transmit antenna and one accept radio wire gives the same assorted qualities request likewise those maximal-ratio consolidated [MRC] framework of person transmit radio wire and two accept antennas. After experimentation we likewise understand that tansmit differences need a 3db hindrance at contrasted with MRC accept differences. In light of those transmitted control to both in the transmitted and the getting body of evidence should be same.

4. RESEARCH METHOD :

In the OFDM modulation domain representation consider the time domain sinusoidal signal of the form ejwct, where 2ccw = pf. The frequency domain representation of the signal is an impulse at the center frequency ω=ω0\omega = \omega_0ω=ω0. Now, this signal is sampled using a rectangular window of period TTT seconds, with NNN samples taken at intervals of TN\frac{T}{N}NT seconds. Assuming that the frequency of interest lies within the Nyquist interval, the resulting samples are given by: X(n)={gloct,if 0≤n<N−10,otherwiseX(n) = \begin{cases} \text{gloct}, & \text{if } 0 \leq n < N-1 \\ 0, & \text{otherwise} \end{cases}X(n)={gloct,0,if 0≤n<N−1otherwise In the time domain, this corresponds to the product of a rectangular window of length NNN with a sinusoidal function. This process results in the convolution of the Discrete Fourier Transform (DFT) of the two components.

5. PROPOSED METHOD:

Magnitude Spectrum of 64 sample rectangular window

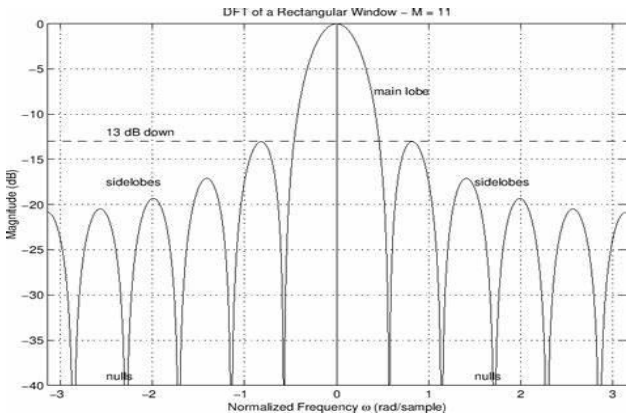


Figure 2 Magnitude Spectrum of 64 sample rectangular window

Magnitude Spectrum of 64 sample rectangular window The zeros of the function occur at angular frequency.

$$\omega = \pm \frac{2\pi}{1} \pm \frac{4\pi}{\ldots\ldots}$$

The effect of the convolution with an impulse at cf=f is to shift the sinc function from peak at omega[w]=0 to peak at the angular frequency that corresponds to cw=w. the zeros occur at angular frequencies to cw=w. the zeros occur at angular frequencies.

, Where $\omega_c=2\pi f_c$. $\omega = \frac{\omega_c}{} \pm \frac{2\pi}{}, \omega_c \pm \frac{4\pi}{}$

6. MODELLING AND ANALYSIS:

In this dissertation we propose diversity for the transmission which can employ and provides a better way of diversity gain after using the number of or multiple antennas which can gave higher space-time coding Diversity gain and the improved performance of the system. we can apply the Receive and transmit diversity by applying coherent binary phase-shift keying [BPSK] modulation over at-fading Rayleigh channels for transmit diversity we can use 1*1,1*2,2*1,2*2,4*1,4*2 etc. antenna combinations. The final value is to showing the transmitted and received channel mode in encoded and transmitting with the demodulation of f the received transmitted signal. The means channel having knowledge of each system at receiver end. For instance if we are Utilizing two transmit antenna and one accept radio wire gives the same assorted qualities request likewise those maximal-ratio consolidated [MRC] framework of person transmit radio wire and two accept antennas. After experimentation we likewise understand that tansmit differences need a 3db hindrance at contrasted with MRC accept differences. In light of those transmitted control to both in the transmitted and the getting body of evidence should be same.

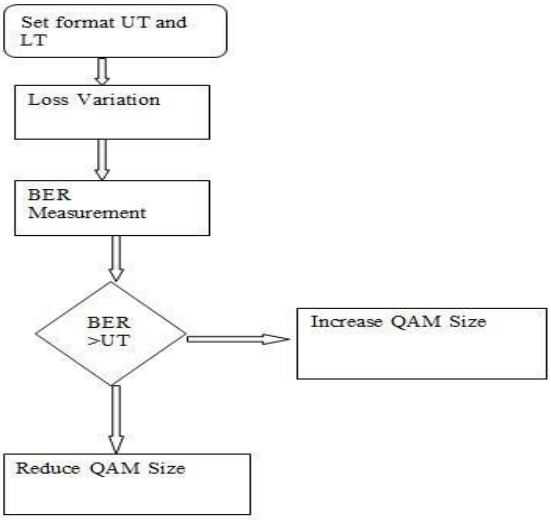
6.1 CHANNEL ESTIMATION :

In the channel estimation the number of transmitter antennas, which synthesize the concept of space-time square codes fabricating on the hypothesis of orthogonal plans. It will make appropriate looking into transmit differences plan to an discretionary amount for transmitter antennas. To perplexing indicator constellation, they demonstrated that Alamouti's plan will be those best full-rate plan to two transmit antennas. We additionally ponder those execution of such a plan for distinctive receive antenna and analysis with different respects. In the practical situation the data will be extracted from the receiver side knowing the visible states of all other system status. the orthogonal signal which is send with the every packet data transmitted to the receiver for the channel estimators. It may be accepted that the channel remains unaltered to those period of the packet, due to the moderate blurring. Compare able experimentation may be also received which heads us should gauge the BER execution for spacetime piece coded framework utilizing two transmit and two get antennas. Likewise for every our show is a indistinguishable twin differences request to each framework we watch comparable slopes of the BER curves for those 4*1,4*2,2*2and 1*4frameworks shows an indistinguishable twin assorted qualities request to each framework.

7. ALGORITHM AND FLOWCHART:

An algorithm must be in the order to assign the modulation format of the prposed transmitter in order to either gurantee the signal quality at the receiver side or maximize the spectral efficiency, it is necessary to automatically assign a proper modulation format and or a transmission rate of the optical signal in accordance with the links condition. for this purpose first we continuously check the signal's quality by monitoring BER of the signal.

Flow chart Shows the modulation of transmitter and Receiver



Flowchart 1

8. RESULT :

The effect of various parameters was examined during the Bit Error Rate (BER) analysis for a Rayleigh fading channel. In this analysis, the diversity order was varied, while the channel type was fixed as Rayleigh, the modulation type as PSK, and the modulation order remained constant. The results showed that the BER decreases more rapidly as the Signal-to-Noise Ratio (SNR) increases, especially when the diversity order is higher. Diversity refers to the number of independent fading propagation paths in a communication system. A higher diversity order means a greater number of independent paths through which the signal can travel. This increases the chances that at least one of the paths will experience favorable conditions, thereby improving the overall signal reception at the receiving end. As a result, higher diversity order leads to better performance, reducing the BER more effectively as the SNR improves.**BER Analysis**

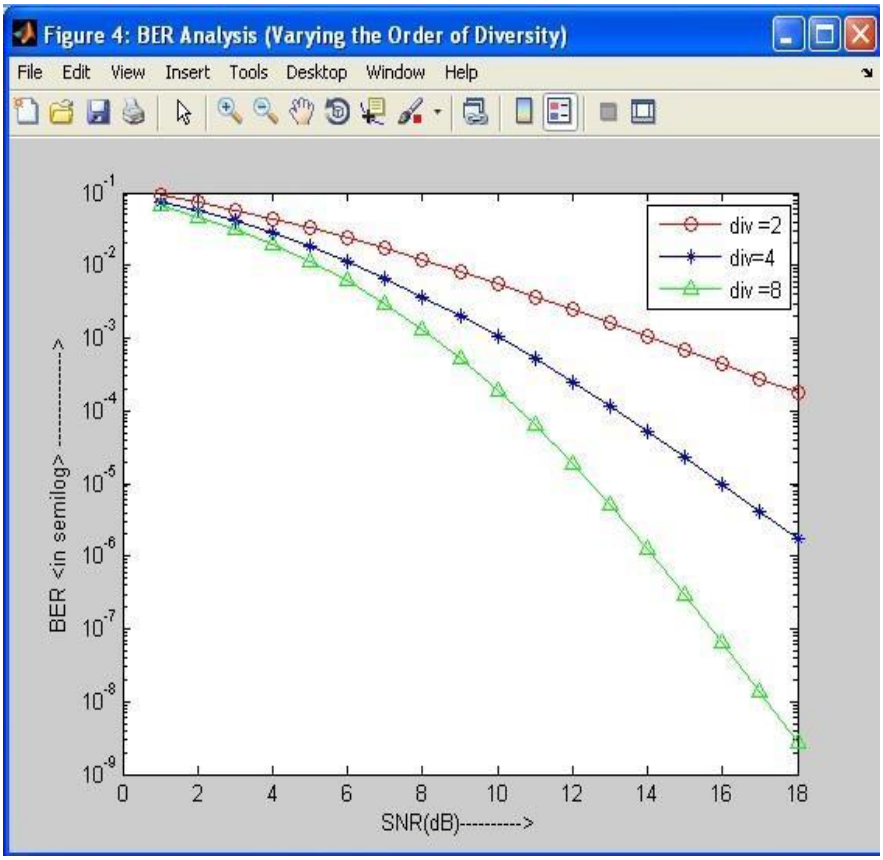


Figure 4 BER Analysis Varying the order Diversity

Secondly, the modulation order was varied while keeping the other parameters fixed. For this analysis, a diversity order of 1 and a modulation type of PSK were used. The modulation order refers to the number of bits that can be transmitted in a single signal. For instance, a modulation order of 16 means that 16 bits of data can be transmitted within the same frequency bandwidth. While this allows for higher data rates, it is also more susceptible to errors, as the signal becomes more complex.

As a result, for any given Signal-to-Noise Ratio (SNR), it was observed that the Bit Error Rate (BER) is higher for higher modulation orders. This occurs because with higher modulation orders, the signal points are more closely spaced in the signal constellation, making the system more prone to errors caused by noise or interference

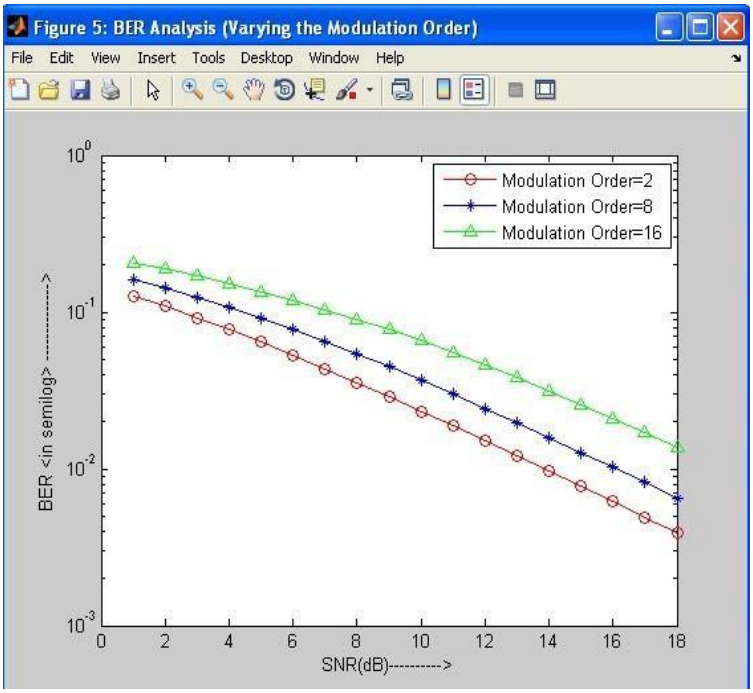


Figure 5: BER Analysis (Varying the Modulation)

9. DISCUSSION:

In practical scenarios, data is extracted from the receiver, assuming that all other system states are known. We assume that the orthogonal signal transmitted in each packet, with zero signals, follows a distribution identical to the Rayleigh distribution. At very high values of the Signal-to-Noise Ratio (SNR), the Rayleigh distribution can be approximated by a Gaussian distribution, resembling Additive White Gaussian Noise (AWGN).

While it may seem tempting to simulate a Rician-distributed signal by adding Rayleigh or Gaussian noise depending on the SNR to the existing signal, it's important to note that AWGN can reduce to a Rayleigh distribution when the power ratio remains constant. This behavior is illustrated in the final output (Figure No. 5).

Table 1 Modulation Respect with different Channel

Modulation Rician Channel (SNR | AWGN Channel Rayleigh Channel Techniques in dB) (SNR in dB) (SNR in dB)
QPSK - 22.01 26.50
BPSK -.0039 24.00
Table 1 Modulation Respect with different Channel
From part of comparison table 1, it is obvious that the AWGN channel shows the median

SNR than the AWGN and Rician. the modelling of the multi path fading channel is based on the Rayleigh modelling and it gives the similar performance.

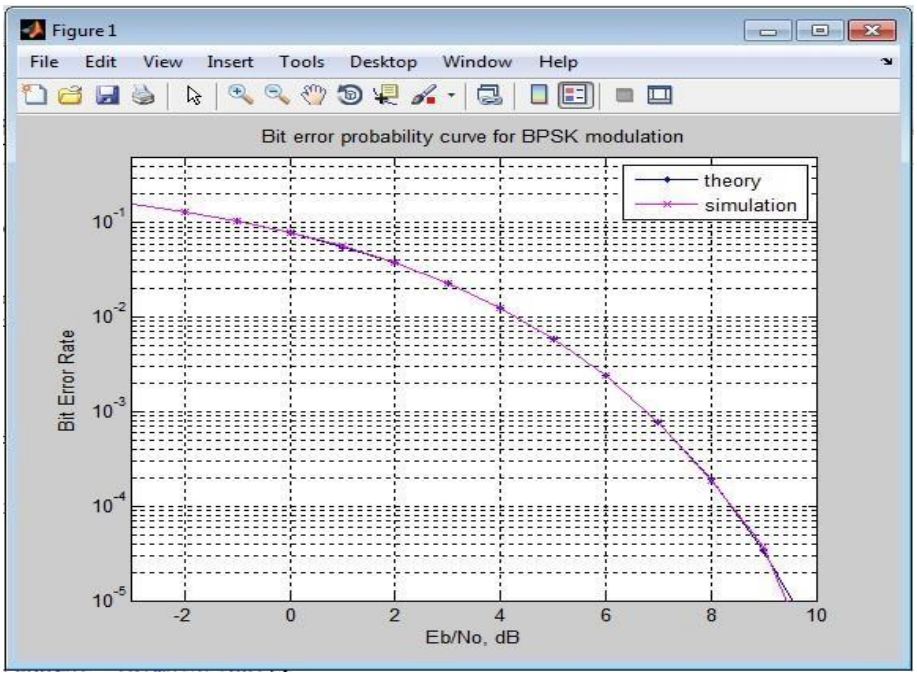


Figure 5 Final output BER probabilities curve for BPSK modulation

10. CONCLUSION:

This proposal aims to apply space-time coding to multiple-input/multiple-output (MIMO) systems. The concept of space-time coding will be explained in detail, highlighting its execution in remote multiple-antenna systems, both with and without Channel State Information (CSI) at the transmitters. The characteristics of a MIMO system are examined, particularly focusing on the effects of noise in a recursive fading channel due to the system's configuration. The performance of the system is evaluated through advanced simulations implemented in MATLAB. Simulation results demonstrate that the compact MIMO scheme achieves a lower bit error rate (BER) compared to traditional MIMO techniques. Therefore, the proposed method is better suited

for high-speed data rate MIMO systems, offering improved performance under various conditions.

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AI POWERED FACE RECOGNITION FOR AUTOMATED CUSTOMER SUPPORT USING ENHANCED SECURITY

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Abstract:

This paper presents the development of a face recognition-based attendance monitoring system designed to automate the process of taking attendance in educational institutions. Smart Attendance Management System is an application that was developed for daily college student attendance. Schools. This project attempts to record attendance through face detection. This system marks the attendance using a live video stream. The frames are extracted from the video using OpenCV. This system uses facial recognition technology to record attendance through a high-resolution digital camera/webcam that detects and recognizes faces and compares the recognized faces with students/known faces images stored in the faces database in CSV format.

Key Words: Face recognition, Attendance monitoring system, Face detection, OpenCV, Facial recognition technology

1. INTRODUCTION

Every organization needs a proper system for recording student attendance. Some take attendance manually with a sheet of paper by calling their names during lecture hours, while others adopt biometric systems like fingerprints or iris scanning. However, these systems have issues such as manual methods, which take time and effort. In contrast, other biometrics, such as fingerprint, iris or voice recognition, all have faults and must be more accurate.

Face recognition, however, is faster, more accurate, and reduces the chance of proxy attendance. This system uses artificial intelligence and OpenCV for face recognition, capturing student images and comparing them by analysis with a set of reference images of each student and marking their attendance.

2. LITERATURE REVIEW

In [1], The authors conclude that face detection and recognition technology has extensive potential for practical applications, including automated attendance systems, security, and identification tasks. In this study, the authors developed a Face recognition-based attendance system aimed at educational settings to streamline attendance management, reduce manual

errors, and save time for educators. The system captures and records attendance accurately, enabling its integration into other academic processes like exam management. This system highlights the efficiency and scalability of facial recognition in large groups, underscoring the value of automation in administrative tasks

In [2], The authors conclude that a face recognition-based attendance management system offers a reliable, efficient solution for tracking student attendance. The system reduces administrative burdens and improves accuracy by replacing traditional manual methods with automated facial recognition.

It adapts to various environmental conditions and facial expressions, ensuring consistent performance. The system also integrates well with educational infrastructure, enhancing security and streamlining attendance processes for large classes. This technology represents a modern, user-friendly approach to attendance management, benefiting both academic institutions and students.

In [3], The author presents a comprehensive review of the Face Recognition Attendance System (FRAS), highlighting its benefits over traditional attendance methods. The paper emphasizes how FRAS uses advanced technologies like computer vision and machine learning to provide a contactless, efficient, and accurate solution for tracking attendance. Unlike manual or biometric systems, FRAS eliminates time delays, reduces administrative work, and minimizes fraudulent practices.

Through a survey of existing literature, the author identifies key trends, challenges, and future directions in face recognition technology, underscoring its potential for broad implementation across various environments, from educational institutions to corporate offices.

In [4], the author concludes that Face recognition-based attendance Management Systems transform classroom attendance tracking. They offer superior accuracy and efficiency, requiring only basic hardware. By leveraging facial recognition technology, attendance-taking becomes automated, fast, and reliable, reducing errors and saving time. This modern solution outshines traditional biometric and manual methods, making it the ideal choice for educational institutions seeking optimized attendance management.

In [5], The authors aim to highlight the development and benefits of a Smart Attendance Monitoring System (SAMS) that uses face recognition technology. They argue that traditional manual attendance methods are time-consuming and prone to issues like proxy attendance. SAMS automates attendance tracking, ensuring accuracy and efficiency by detecting and recognizing faces in real time. Despite its effectiveness, the authors acknowledge some limitations and suggest future improvements to enhance performance.

3. OBJECTIVES

The current research paper is aimed to achieve the following objectives:

1. Exploratory Research: Investigate existing face recognition systems, focusing on those designed for attendance monitoring in academic institutions.

2. Limitation Analysis: Identify the shortcomings of existing face recognition systems and develop strategies to overcome these limitations. This analysis will ensure that our proposed system addresses the gaps in current technology.

3. Design and Implementation: Develop a face recognition system tailored to academic institutions, minimizing human intervention. This system will provide accurate attendance tracking, enhanced security, and streamlined administrative processes.

4. RESEARCH METHOD / METHODOLOGY

This section outlines the step-by-step approach for developing an efficient face recognition-based attendance monitoring system.

a. User Registration

A user-friendly graphical user interface (GUI) will be designed to facilitate new user registration. This process involves:

- Collecting user information: name and unique student ID (USN).
- Capturing images of the user's frontal face under varying lighting conditions.
- Converting the images to grayscale and storing them in a database for future reference.

b. Training the AI Module

After registering new users, the AI module will be trained using the collected images. This process involves:

- Updating the "studentdetails.csv" file with the new user's information.
- Integrating the new user's images into the database.

c. Face Recognition and Attendance Marking system

To mark attendance, users will face a web camera, which will scan their frontal faces. The system will perform the following functions.

- Compare the scanned face with the images stored in the database.
- Automatically update the attendance database with the timestamp if a match is found.

d. Viewing Student Details and Attendance Data

A web application will be developed to enable users to:

- View registered students' details.
- Access attendance records.
- Retrieve other relevant information.

e. Notifications and Reports

The system will email faculty members attendance data, ensuring they stay informed about student attendance.

f. Feedback and Support

Users can provide feedback on the system and contact the administrator for further improvements and support.

8. CONCLUSION

The face recognition attendance system using dlib and OpenCV offers a precise, contactless, and efficient solution for attendance management. The surveyed literature covers various aspects, including facial feature extraction techniques, recognition algorithms, dataset characteristics, and performance evaluation metrics. We identify common trends and divergent approaches adopted by researchers, shedding light on the evolution of face recognition.

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Application of Permanent Magnet Synchronous Generator in Wind Mill

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Abstract: *This paper presents a comprehensive overview of application of permanent magnet synchronous generator for wind system. Wind turbine controls are provided. The permanent magnet synchronous generator is introduced as construction and model. Configurations of power converters are presented for use with permanent magnet synchronous generator in wind systems at variable speed operation for power generation. Control techniques for the system are discussed for both side in details.*

Key-Words: *Wind turbine, power converter controller, PMSG.*

1. INTRODUCTION FOR WIND SYSTEM

Wind power is an important renewable energy resource and the fastest growing technology amongst different renewable energy generation technologies [4]. Many developed generation systems are used to extract maximum wind energy. Optimum wind energy extraction system is achieved by running wind turbine generator in a variable speed mode because of the higher energy gain and reduced stresses [2]. Wind turbines are classified with a view to the rotational speed, the power regulation, and the generator system. When considering the construction of the drive system, the turbines are classified into the geared and the direct-driven types [1, 3]. The direct-driven type is known with its advantages, as it has a lower cost, smaller size, and consequently its weight is reduced [7]. Geared systems with different generator types are used in wind power generation, while the use of PM generator with direct-driven system has many competitive advantages, because of its great energy yield, noise reduction, good reliability, and high efficiency [5, 6]. PM generators can readily deliver power without undergoing the process of voltage build up and there is no danger of loss of excitation. With the development of the power electronics and permanent magnets materials, such as (neodymium-iron-boron) [9], a rapid development in PM generators is achieved. Recent techniques such as field orientation control of the PMSG allow control of active and reactive power in the machine-side and also can be applied to the grid-side [7, 8].

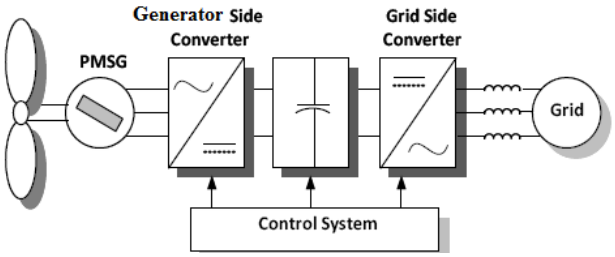

Fig.1 Main components of permanent magnet synchronous generator wind turbine system

2. WIND TURBINE SYSTEM

2.1 Model of Wind turbine

In order to investigate the effectiveness of the energy conversion in wind energy conversion systems, first the available energy stored in the wind needs to be determined. Actually, the energy in the wind can be treated as the kinetic energy of a large amount of air particles with a total mass, m, moving at a wind velocity. Assuming that all the air particles are moving at the same speed and direction before impacting the rotor blades of the turbine, the potential available kinetic energy stored in the wind can be expressed according to the following expression [9]:

$$Ec = \frac{1}{2}mv^2 \tag{1}$$

Where, Ec, is the kinetic energy of the moving air particles, and is the total mass of the air particles, while ,v , is the velocity of the air particles. Since the air particles are moving at a speed, v, the total mass, m can be rewritten as follows:

$$Pw = \frac{d}{dt}Ec$$

$$= \frac{1}{2}psv^3 \tag{2}$$

The actual wind power at any instant of time can be measured by:

$$p_{wind} = \frac{1}{2}p\pi R^3 v^3 \tag{3}$$

Where, *P wind*, is the potentially available power in the wind. We can observe that the wind power is proportional to the cube of the wind speed, which means that a small increase of the wind speed will result in a large increase of the wind power. According to Betz's idea, after impacting the rotor blades of the wind turbine, the velocity of the wind decreases form v to v2 which means that when the wind

passes through the wind turbine blades, there is still some kinetic power left in the wind. The relationship between the power that is captured by the wind turbine and the potential maximum power in the wind can be measured as follows:

$$Cp = \frac{Pm}{Pw} \tag{4}$$

Where, Pm is the mechanical power captured by the wind turbine, and Cp is the power coefficient of the wind turbine which can be measured as follows:

$$Cp(\lambda, \beta) = C1\left(\frac{C_2}{\gamma} - C_3\beta - C_4\beta - C_5\right)e^{-C_6}\frac{1}{\gamma} \tag{5}$$

Where, y is the blade angle and is the tip speed ratio of the wind turbine, while, w, is the angular speed of the wind turbine generator. The values of the coefficients (c1-c6) depend on the type of the wind turbine. Accordingly, the power captured by the wind turbine can be rewritten as:

$$Pm = \frac{1}{2}\, p\pi R^2 v^3 Cp \tag{6}$$

The wind turbine torque on the shaft *Tm* is :

$$Tm = \frac{1}{2}\, p\pi R^2 v^3 \frac{Cp}{\omega} \tag{7}$$

2.2 Control of Turbine

Active stall control and pitch control methods use pitch mechanism to limit the output power. Active stall control method is also used for larger fixed speed turbines. At low wind speeds the blades are pitched as in pitch control achieving maximum efficiency, while at high wind speeds the blades are pitched slightly into the direction opposite to that of a pitch-controlled turbine. This pitching method makes emergency stopping and starting of the wind turbine easier. [11] (Kante & Khan, 2014)

In pitch control method the pitch angle is varied in a wider range if compared with active stall control. During high wind speed situations, the angle of attack can be maintained to a lower value by varying the pitch angle. This control method enables better exploitation of the system during high wind situations and decreasing the thrust force on the turbine and the emergency stopping can also be performed. This control method is used for medium and large variable speed turbines [10].

3. PERMANENT MAGNET SYNCHRONOUS GENERATOR (PMSG)

Direct-driven permanent magnet synchronous generator has large number of poles to operate at low speed as it works in a gearless drive train system. To reduce the weight of the active parts and increase

the efficiency, direct-driven generators are usually designed with a small pole pitch and large diameter. Regarding electrically losses, the wound rotor excitation has higher losses than PM excitation which increases with number of poles, although permanent magnet also has low losses because of the circulation of eddy currents in the permanent magnet volume. This advantage is not important in variable speed wind driven systems since they are connected to grid via power electronic interface [8].

Modular design of 3 MW permanent magnet synchronous generator allows simplicity of manufacturing process. High quality magnets have large life time. The generator coil can be protected against environment conditions to satisfy working in offshore farms. The stator direct flux is constant since the excitation is provided by the magnets unlike that in the electrically excited generator. It is common in large-scale stability analysis to neglect the stator flux transients of synchronous generators.

The mathematical model of the permanent magnet synchronous generator in the synchronous reference frame is given by,

$$\frac{dI_d}{dt} = \frac{1}{Ld_s + Ll_s}\left(-R_s I_d + \omega_e\left(Lq_s + Ll_s\right)I_q + V_d\right) \tag{8}$$

$$\frac{dI_q}{dt} = \frac{1}{Lq_s + Ll_s}\left(-R_s I_q + \omega_e\left[\left(Ld_s + Ll_s\right)I_q + \psi f\right] + V_q\right) \tag{9}$$

Where subscripts d and q refer to the physical quantities that have been transformed into the d-q synchronous rotating reference frame, Rs , is the stator resistance, Ld and Lq are the inductances of the generator on the d and q axis, LId and Llq are the leakage inductances of the generator on the d and q axis, respectively, is the permanent magnetic flux and We is the electrical rotating speed of the generator, represent by,

$$\omega_e = \rho\omega_g \tag{10}$$

Where p is the number of pole pairs of the generator. In order to complete the mathematical model of the permanent magnet synchronous generator the mechanical equation is needed, and it is described by the following electromagnetic torque equation [9].

$$T_e = 1.5\, p\,((L_{ds} - L_{ls})I_d I_q + I_q\psi_f \tag{11}$$

4. CONTROL OF SYSTEM

Development of the power electronics converters and switching devices, especially those having higher reliability and lower cost, makes many of converter topologies incorporated to wind systems to improve control, and to increase the reliability of the system. where a 25% power converter

is placed in series with the stator winding to actively damp the generator. since it is the main type and the most used one. Full scale converters are divided into two main categories and they are as follows[9].

4.1 Generator side convertor

The controller of the machine-side converter normally has a fast inner current loop, controlling the stator Isd or Isq current components, where the d-axis current component is normally used to control flux and the q-axis current component utilized to control the torque, combined with an outer slower loop for torque and/or stator reactive power control [10].

4.1.1 Control of Torque

In torque control method the control is done as illustrated through the direct and the quadrature current components Id and Iq which generate the reference voltages Vdref and Vqref. The PWM for desired generator voltages are generated after inversion the direct and quadrature reference voltages to three phase system [10].

If the stator current is controlled to have the q-component only the generator will provide the maximum torque. With this control, the machine torque is coordinated with the magnitude of the q-axis current, while the d-axis current is always kept at zero. According to the rotor-flux-oriented strategy, the stator current vector should always be kept aligned with the back EMF of the PMSG. In other words, the torque angle δ is controlled. [12] (Archana & Karuvelam, 2018)

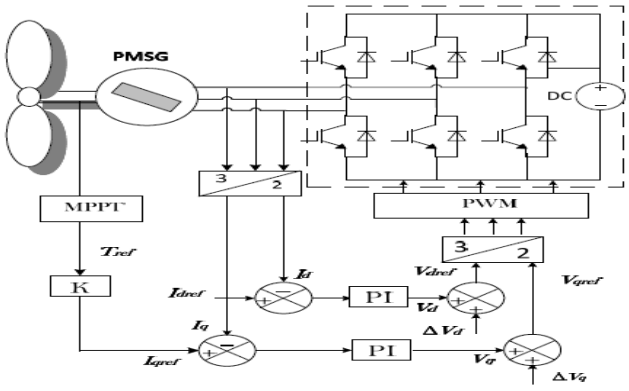

Fig.2 Basic generator side convertor

4.2 Grid side convertor

The grid-side converter is normally controlled in such a way to maintain the DC-link capacitor voltage in a set value and to maintain the converter operation with a desired power factor.

4.2.1 Pulse width modulation Controlled Inverter with PI Current Controllers

This control technique is similar to the previous one as illustrated in Fig. 3 where the LC filter was replaced by RL filter[9]. The reference quadrature and direct voltage components are generated using PI controllers.

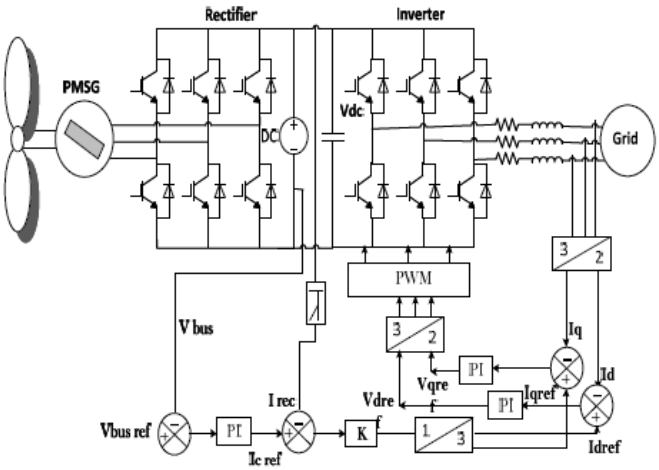

Fig.3 Pulse width modulation controlled inverter with PI current Controller scheme

4.2.2 Pulse width modulation -inverter with active and reactive power control

The inverter current references are generated using the desired active and reactive values and then the reference voltage components are generated by PI controllers where,

$$P = V_{sd}I_{sd} + V_{sq}I_{sq} \tag{12}$$

$$Q = V_{sq}I_{sq} - V_{sd}I_{sd} \tag{13}$$

As illustrated in Fig.4 the active power is generated using DC bus voltage and the reactive is set as the requirements of the grid [6, 9] and will be omitted if a unity power factor is a demand.

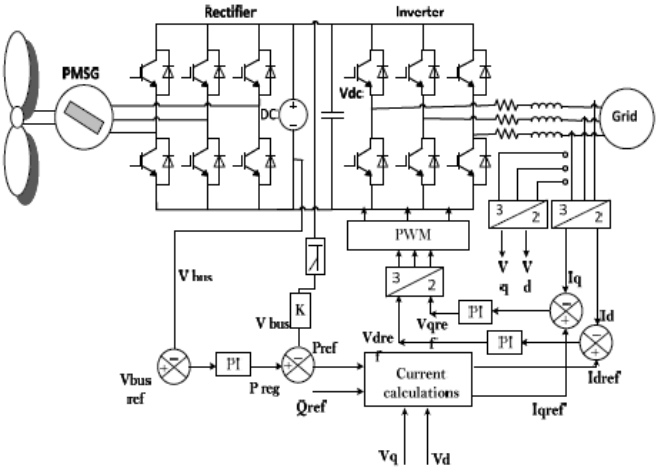

Fig. 4 Pulse width modulation inverter with active and reactive power control scheme

5. CONCLUSION

This paper presents a comprehensive overview study of permanent magnet synchronous generator for wind application. The permanent magnet synchronous generator is introduced as construction and models with some information about generators already available in the market. Various control methods and techniques for generator side and grid-side converters are presented in details for the purpose of satisfaction of technical requirements. Such requirements are control of active and reactive power for high quality of power delivered to the grid. (Gupta & Yadav, 2016)

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Stocksense: Machine Learning-Driven Market Insights

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Abstract: *StockSense is a leading charge in the use of machine learning (ML) to transform financial markets. It is a technology that, using cutting-edge techniques such as sentiment analysis, predictive modelling, and portfolio optimization, is going to enable financial analysts and investors to make better decisions. This analysis focuses on some of the techniques used in machine learning, traces the development of StockSense, and discusses a few innovative innovations such as transformer networks and hybrid models. However, despite such barriers in areas like transparency, scalability, and ethical frameworks, these new technologies of natural language processing and reinforcement learning will, of course, be assimilated into the market analysis as well.*

Key Words: *Machine Learning, Stock Market, Predictive Models, Sentiment Analysis, Portfolio Optimization, Financial Analytics.*

1. INTRODUCTION:

While complexity in financial markets grows in concert with the computer power and data available, they leave far behind the older style analytics tools. "StockSense" is what would explain ML-driven insights regarding the market if it uses advanced algorithms that will help predict trends as well as analyze the direction of market sentiment to tailor best-fit portfolios. Over the last decade, StockSense has become a critical research area in finance. Although powerful, those tools come with their inherent challenges, such as their need for better model interpretability and addressing ethical concerns. This review explores how these ML techniques are changing the landscape of financial forecasting, and what challenges need to be overcome for wider adoption.

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2. LITERATURE REVIEW:

2.1 Chronological Development

Over the years, the field of StockSense has evolved, beginning with simpler models, and growing into the complex, cutting-edge techniques we see today.

1. Early Research (2000–2010):

   Initially, financial forecasting relied on statistical models such as ARIMA and machine learning algorithms like SVM (Support Vector Machines). While these methods provided foundational tools, they were limited in their ability to handle the increasing complexity and volume of market data. This period marked the beginning of a shift toward incorporating computational

power into financial analysis, but it was clear that these models were not enough to capture the full range of market behaviors (Aich and Kim, 2021).

2. Growth Phase (2010–2020):

   The new, deep learning models, in particular Long Short-Term Memory networks, revolutionize how we look at making predictions in markets. It's possible to model temporal dependencies in financial time series, thereby greatly improving the accuracy. Around this time, sentiment analysis also became popular, sifting through unstructured data coming from social media and news articles. This is a big deal in terms of incorporating market sentiment into traditional financial indicators that improve predictive accuracy (Bollen et al., 2011; Zhang et al., 2021).

3. Recent Advancements (2021–2024):

   - Hybrid Models: The latest models combine multiple algorithms, such as Random Forest, XGBoost, and LSTM, to exploit their strengths. Hybrid models have outperformed other models and handled structured and unstructured data more effectively (Doreswamy and Bhat, 2023).
   - Transformer Models: The transformer models, originally used in NLP applications, have begun to exhibit great potential in market prediction tasks. They are greatly useful in the processing of financial data, due to the ability to process large amounts of sequential data (Vaswani et al., 2017).
   - Portfolio Optimization with Reinforcement Learning: Much reinforcement learning has been undertaken in portfolio optimization. By ensuring that systems have the option to make real-time choices and decisions, the possibility offered by RL allowed for highly dynamic and adaptable financial strategies greater than those conceived earlier (Li et al., 2020).

2.2 Methodological Comparisons

The methodologies used in StockSense can broadly be grouped into qualitative and quantitative approaches and theoretical and experimental, each with its unique advantages and challenges.

1. Qualitative vs. Quantitative Approaches:

   - Qualitative Methods: These methods are focused mainly on sentiment analysis. They entail using NLP techniques to scan through unstructured data, for instance, social media posts or news articles, for the sake of gauging market sentiment. This is very important because public sentiment drives the behavior of markets, as pointed out by Bollen et al. (2011).
   - Quantitative Approaches: These approaches are based on several data, such as historical stock prices and volumes. However, even though it was once the gold standard, recent years have seen deep learning models such as LSTM outperform methods such as ARIMA, given that they can process vast time-series data (Doreswamy and Bhat, 2023).

2. Theoretical vs. Experimental Studies:

- Theoretical Models: For the first experiments on StockSense, theoretical models had already been developed to define how these alternate ways of machine learning would be combined to take better advantage of improved predictability. It is against these models that the follow-up experimental studies were done in part (Jain and Vanzara, 2023).
- Experimental Studies: Recent efforts are concentrated on applying those theoretical frameworks to real-life financial data. Experimental studies concluded that hybrid models, above all, are very effective tools for actual market conditions of both stock prediction and portfolio optimization (Aich et al., 2022).

2.3 Thematic and Theoretical Approaches

1. Thematic Approach:
   - Predictive Modeling: Be it market trends or the price of stocks, what lies at the core of StockSense is the process of prediction. Deep learning ensemble techniques have flourished in capturing the fluctuation of markets in the short as well as the long term (Zhang et al., 2021).
   - Sentiment Analysis: The most basic idea of the stock price movement prediction is to determine the market sentiment. NLP techniques have assisted analysts in incorporating news and social media data into financial models, which enhance the forecasts and give an overall view of the dynamics of the market (Bollen et al., 2011).
2. Theoretical Approach:
   - Deep Learning and Transformer Models: These technologies changed the way we could consider market prediction, especially for handling sequential and unstructured data. Transformers are highly promising in financial applications where the scaling and accuracy of the prediction are improved (Vaswani et al., 2017).
   - Reinforcement Learning (RL): RL provides dynamic decision-making, learning from real-time market data to improve its actions. This is particularly effective in portfolio management as it allows the adaptation of strategies according to changing market conditions (Li et al., 2020).

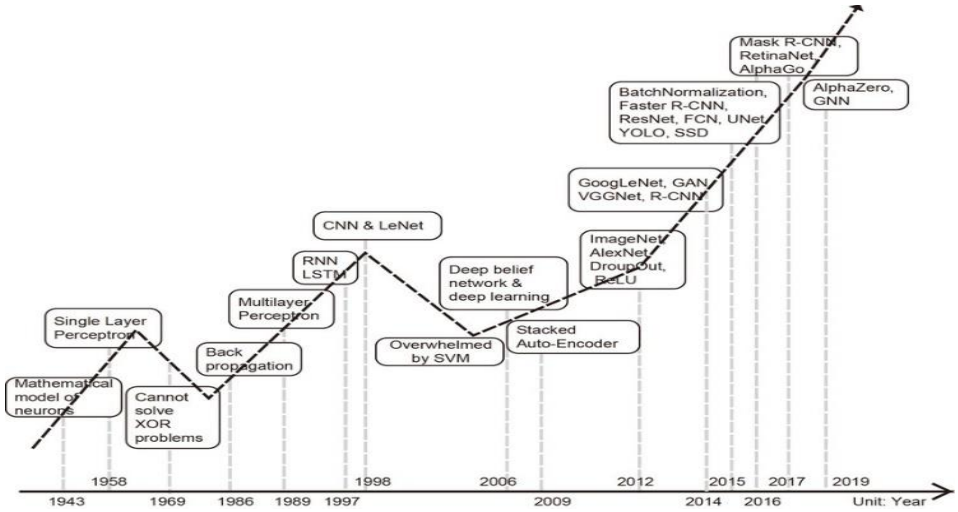

Fig.1. History and Development of Models

3. OBJECTIVES / AIMS:

The objectives of this review are:

- To explain how the system of StockSense started with statistical models before being developed into the machine learning methods it currently applies.
- Reinforcement learning, deep learning, as well as ensemble approaches for financial decision-making and stock prediction.
- New trends such as transformer models and sentiment analysis change and evolve financial analytics.

4. RESEARCH METHODOLOGY:

This review brings together different journal articles, conference papers, and systematic reviews of 2021-2024. The key sources have been chosen based on relevance, especially to the hybrid model, deep learning, and reinforcement learning applied in predicting the stock market and portfolio management.

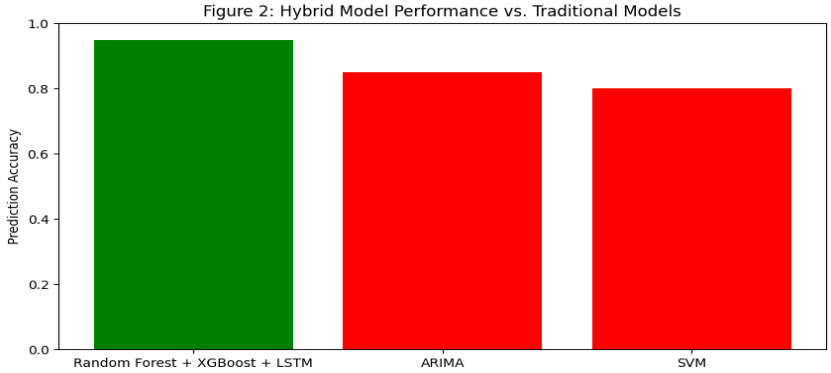

Fig.2. Hybrid Model Performance vs Traditional Models

5. DISCUSSION / ANALYSIS:

In short, the literature suggests significant improvement in the accuracy of stock market prediction with recent machine learning techniques, but there are still open areas, such as the interpretability of predictive models and real-time usability. Hybrid and transformer types of models are highly advanced but consume much more than computing resources and may not be readily available to smaller financial institutions; still, reinforcement learning shows fantastic progress, especially within volatile markets, and still requires better confirmation.

Table 1: Comparative Analysis of ML Models for Stock Market Prediction

Model Type	Advantages	Disadvantages	Use Case
ARIMA	Simple to implement, interpretable	Struggles with non-linear relationships	Basic trend forecasting
SVM	Good for classification tasks, effective for small datasets	High complexity with large datasets	Stock movement classification
LSTM	Captures temporal dependencies, handles large datasets	Requires large computational resources	Time-series forecasting
Random Forest	Robust, handles missing data	Can overfit with noisy data	Predicting stock prices and risk assessment
XGBoost	Fast, high accuracy	Requires careful tuning of hyperparameters	Hybrid models for enhanced stock prediction
Transformer	Efficient with sequential data, scalable	Computationally expensive, complex	Textual data analysis (e.g., sentiment analysis)

6. CONCLUSION / SUMMARY:

StockSense is a new leap in the analysis of financial markets. It shows how machine learning can increase the precision of predictions and decisions. Integration of hybrid models, transformer-based architectures, and reinforcement learning opens an interesting path for financial analytics. The challenges of transparency, scalability, and ethics are crucial steps to be undertaken to make StockSense

continue to soar. The near future research will surely focus on developing the pragmatic implementation of such models into real-time decision-making.

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Comparative Analysis of Perturb & Observe, Incremental Conductance, and Fuzzy Logic Based Maximum Power Point Tracking Methods

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***Abstract**: This paper investigates three widely used Maximum Power Point Tracking (MPPT) methods: Perturb and Observe (P&O), Incremental Conductance (Inc.Cond.), and Fuzzy Logic Control (FLC). A photovoltaic (PV) system with a capacity of 10.5 kW, coupled with a boost converter and a resistive load, has been simulated using MATLAB/Simulink. Key performance indicators such as tracking speed, accuracy, and voltage fluctuations were analyzed. The comparative analysis underscores the advantages and limitations of each technique, offering valuable insights into their adaptability to varying PV system operating conditions.*

***Keywords**: Perturb & Observe, Incremental Conductance, Fuzzy Logic Control, MPPT*

1. INTRODUCTION

India stands as a global leader in renewable energy production. Solar energy, a key component of this renewable energy landscape, harnesses the sun's power to generate clean and sustainable electricity. Photovoltaic (PV) systems, which convert sunlight into electricity, can be either standalone or grid-connected.

To maximize the power output of these PV systems, a technology called Maximum Power Point Tracking (MPPT) is employed. MPPT optimizes the system's performance by adjusting the load characteristics to align with the PV module's maximum power points. The effectiveness of MPPT techniques is assessed using criteria such as efficiency, tracking precision, response speed, and stability.

Recently, numerous techniques have been proposed to optimize the power output of photovoltaic (PV) systems. This study focuses on three specific MPPT methods: Perturb and Observe (P&O), Incremental Conductance (Inc.Cond.), and Fuzzy Logic Control (FLC). A comparative evaluation of these techniques will be carried out through simulations in MATLAB/Simulink.

II. IMPORTANCE OF MPPT FOR SOLAR ENERGY SYSTEMS

Figure 1 demonstrates the nonlinear power output characteristics of a photovoltaic (PV) source under varying conditions, along with multiple load power curves that represent different power demands. The operating point of the system is determined by the intersection of a PV curve and a load curve.

Three primary scenarios are highlighted:

1. **Variable Load**: When irradiance and temperature remain constant, changes in load demand (S1) require adjustments to ensure maximum power extraction.
2. **Variable Irradiance**: With constant temperature and load demand, variations in irradiance (S2) necessitate modifying the load resistance to achieve optimal power output.
3. **Variable Temperature**: Under constant irradiance and load demand, temperature fluctuations (S3) also demand changes to the load resistance to maintain peak performance.

For a specific irradiance level (G1) and temperature (T1), maximum power is achieved at a particular load resistance (R). Any deviation from this optimal resistance (e.g., R11, R12) in scenario S1 results in suboptimal power extraction, even though the PV source can deliver more power. Similarly, changes in irradiance (from G1 to G2) or temperature (from T1 to T2) require adjusting the load resistance (from R1 to Rs21 or R1 to Rs31) to sustain maximum power output.

Since the load resistance is dictated by user demand and cannot be dynamically adjusted to match varying irradiance and temperature conditions, DC-DC converters are employed as virtual impedance elements. These converters efficiently isolate the PV source from the load, minimizing the influence of external factors.

The connection between input resistance and duty cycle varies for buck and boost converters, respectively. These converters serve as interfaces between the PV source and the load, enabling the adjustment of the effective resistance seen by the PV source. This flexibility allows for optimal power extraction under diverse operating conditions.

III BOOST CONVERTER-BASED VIRTUAL IMPEDANCE FOR PV SYSTEMS

A photovoltaic (PV) power generation system utilizes a boost converter as a virtual impedance to bridge the PV source and the load.

The PV source is modeled as a current source in the diagram, representing the ability of PV panels to provide a constant current below their maximum power point voltage.

Input and output capacitors (C_{in} and C_{out}) are used to filter high-frequency components from the input and output voltages, respectively. This filtering improves the dynamic and steady-state performance of the maximum power point tracking (MPPT) algorithm.

As illustrated, the MPPT algorithms (explained in the following section) require the PV array voltage (V_{Array}) and current (I_{Array}) to produce a control signal (V_{Duty}). An operational amplifier (op-amp) comparator compares the control signal (V_{Duty}) with a sawtooth carrier signal ($V_{carrier}$) to generate a pulse-width-modulated (PWM) signal for driving the IGBT.

A. Source of Photovoltaic Energy

The photovoltaic system analyzed in this study incorporated Vikram Solar ELDORA 270 modules, which exhibit a maximum power point of 270.66 watts at a voltage of 34.7 volts and a current of 7.8 amperes. To generate a 10.5-kilowatt power output at a voltage surpassing 100 volts, a photovoltaic array was designed, comprising 13 parallel strings, each string containing 3 series-connected modules.

B. Designing a Voltage-Increasing Converter

The configuration of a boost converter in two states: (A) when the switch is closed and (B) when the switch is open.

Similarly, Figure 7 depicts these two states.

The duty cycle, D, signifies the proportion of the switching period (T_S) during which the switch remains closed.

Under these circumstances, the inductor voltage (V_L) and the capacitor current (I_C) are represented as follows:

When the switch is closed ($D*T_S$):

$$V_L = VArray$$

$$I_C = -I_{OUT} = -V_{OUT}/R$$

*When the switch is open ($(1-D)T_S$):

$$V_L = V_{Array} - V_{OUT}$$

$$I_C = I - V_{OUT}/R$$

Figure 6 showcases the inductor voltage waveform over a single switching cycle.

By applying volt-second balance to the circuit, a relationship between the input voltage (V_{Array}) and the output voltage (V_{OUT}) can be derived.

IV ALGORITHM FOR MAXIMIZING POWER OUTPUT

MPPT algorithms enhance the power output of a PV system by adjusting its operating point to maximize energy extraction. This is vital because the power generated by PV systems fluctuates with factors such as sunlight intensity, temperature, and load demand. By continuously monitoring the system's operating point and modifying the duty cycle of the interface converter, MPPT algorithms maintain efficient performance under varying conditions. The next section explores three widely used MPPT methods: Perturb & Observe, Incremental Conductance, and Fuzzy Logic Control.

A. Perturb & Observe (P&O)

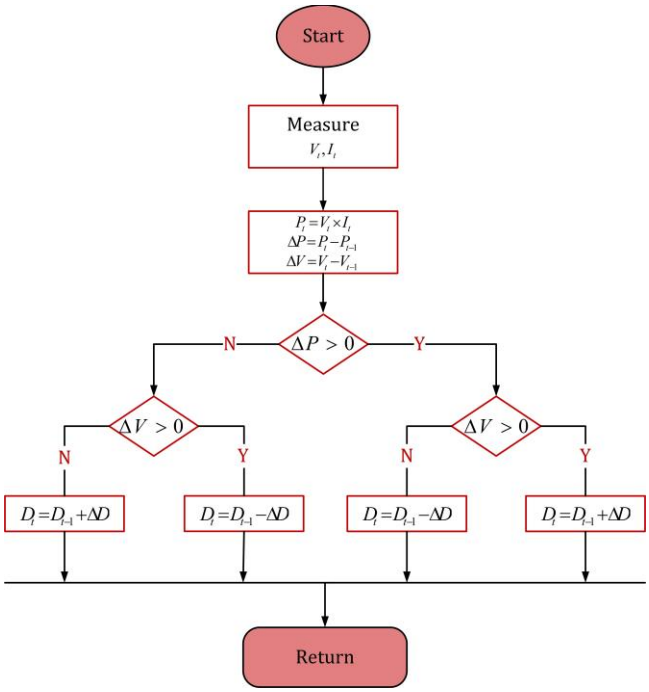

Figure 18 Perturb & Observe

Perturb and Observe (P&O) is a widely used Maximum Power Point Tracking (MPPT) method in photovoltaic (PV) systems. As shown in Figure 10(a), the P&O algorithm involves making small adjustments to the system's operating point and observing the resulting change in power output. This feedback is then used to optimize the operating point for maximum power generation [6].

P&O is a simple, reliable, and efficient technique, making it a popular choice for solar power systems. The conventional method uses a fixed increment (ΔD) in the duty cycle, which affects the system's precision and efficiency.

B. Incremental Conductance (IC)

The Incremental Conductance (IC) MPPT algorithm determines the Maximum Power Point (MPP) by analyzing the slope of the power-voltage curve of a photovoltaic (PV) array. The algorithm is based on the principle that the MPP is achieved when the slopes of the instantaneous power and the previous power sample are equal. If the slopes are different, the algorithm adjusts the system's operating point towards the steeper slope to move closer to the MPP. The flowchart of the IC MPPT is illustrated in the figure. The IC algorithm is recognized for its fast response and accuracy in tracking the MPP, even in changing weather and load conditions. However, it requires a more complex control system and may be more sensitive to noise and measurement inaccuracies than other MPPT techniques.

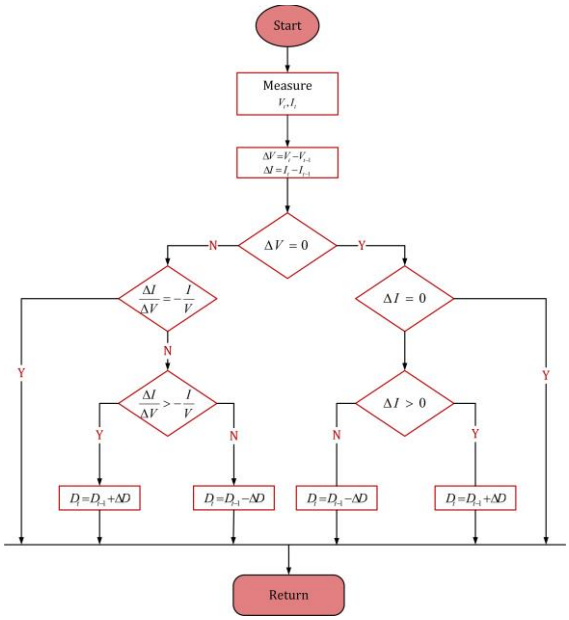

Figure 19 Incremental Conductance

Fuzzy Logic Control (FLC)

Fuzzy Logic Control (FLC) is a method used to control systems by utilizing fuzzy set theory to handle uncertainty. In photovoltaic (PV) systems, FLC can optimize power generation by adjusting the voltage and current applied to the system. As shown in Fig. 10(c), the FLC algorithm processes data such as voltage, current, and temperature to determine the Maximum Power Point (MPP). It then adjusts the operating point of the panel to match the MPP, thereby maximizing efficiency and power output.

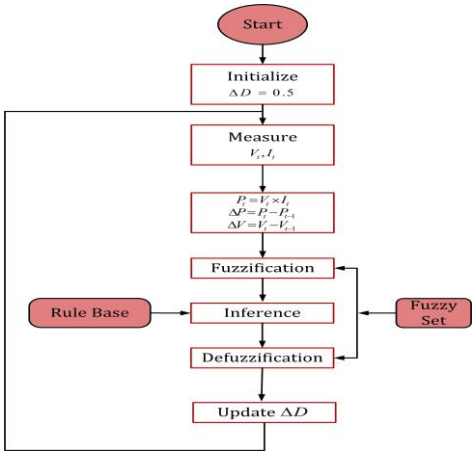

Figure 20 Fuzzy Logic Method

2. METHODOLOGY

A 10.5 kW PV array, using Vikram Solar ELDORA 270 modules, was modeled. The array comprised three series-connected panels per string and 13 parallel strings. A boost converter was used as a

virtual impedance, interfacing the PV array with the load. Performance metrics for each MPPT technique were analyzed under three scenarios:

1. Variable Load Demand: Constant irradiance and temperature with varying load resistance.
2. Variable Irradiance: Constant temperature and load with fluctuating irradiance.
3. Variable Temperature: Constant irradiance and load with temperature changes.

3. RESULTS AND DISCUSSION

3.1 Scenario 1: Variable Load Demand

Performance analysis under constant irradiance (1000 W/m²) and temperature (25°C) revealed:

- P&O and Inc.Cond.: Similar power ripples and steady response times.
- FLC: Faster response time but higher power and voltage ripples due to dynamic duty cycle adjustments.

3.2 Scenario 2: Variable Irradiance

Under varying irradiance levels:

- All methods successfully tracked the maximum power point.
- FLC exhibited the smallest rise time but larger power ripples compared to P&O and Inc.Cond.

3.3 Scenario 3: Variable Temperature

With changes in ambient temperature:

- PV power output decreased with temperature increases.
- FLC maintained fast response times but showed slightly higher ripple compared to other techniques.

4. CONCLUSION

This comparative analysis highlights that P&O and Inc.Cond. offer reliable performance with minimal ripples, making them suitable for stable conditions. FLC, while demonstrating superior response times, is better suited for dynamic environments where speed is prioritized over precision. These findings provide a framework for selecting MPPT techniques based on specific operational requirements.

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AI-Powered Metaverse Classrooms: Redefining Education Through Immersive and Interactive Learning Technologies

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Abstract: *The integration of Artificial Intelligence (AI) and the metaverse in education marks a transformative shift in how learning environments are designed and experienced. The framework analysis delves into the design and implementation strategies that form the foundation of metaverse-based educational platforms. The advent of AI-powered metaverse classrooms is revolutionizing education by introducing immersive and interactive learning environments. These classrooms leverage artificial intelligence to create adaptive, personalized experiences that cater to individual student needs while enhancing engagement and collaboration. Within the metaverse, students and educators interact in highly realistic virtual settings, enabling hands-on learning, real-time feedback, and AI-driven instructional support. It explores key features such as virtual simulations, intelligent tutoring systems, and AI-enabled analytics that optimize teaching strategies and learning outcomes. Additionally, the paper evaluates the ethical, technical, and social implications of implementing such systems, including concerns around data privacy, digital equity, and user dependency.*

Key Words: *Metaverse; Higher Education; Machine Learning; Personalized Learning; Deep Learning; Artificial Intelligences*

1. INTRODUCTION:

The integration of the Metaverse into the education sector marks a revolutionary shift in how educational content is delivered and experienced. This immersive, digital universe offers a new dimension of interactive learning where physical boundaries are transcended, allowing for a more engaging, personalized, and flexible learning environment. The potential of the Metaverse in education lies in its ability to simulate real-world scenarios and complex environments that can be used for a wide range of educational purpose, from K-12 to higher education and beyond.

The use of the Metaverse in education not only enhances student engagement through gamified learning and virtual reality experiences but also facilitates remote learning, making education more accessible to students regardless of geographical constraints. Moreover, it supports the development of digital literacy and prepares students for future technological landscapes. As educational institutions begin to explore and adopt this technology, the Metaverse is set to transform traditional learning paradigms, offering students a dynamic and interactive way to learn and explore.

Metaverse:

A collective virtual shared place, the Metaverse is the result of the convergence of physically persistent virtual spaces and virtually improved physical reality. It includes. This digital realm allows users to interact with an environment created by computers and other users. Originating in Neal Stephenson's science fiction book "Snow Crash" from 1992, the phrase has come to refer to a wide range of immersive and interactive experiences made possible by VR (Virtual Reality) and AR (Augmented Reality) technologies.

In the context of education, the Metaverse offers a platform where students can engage in a 3D learning environment, experiencing educational content in a more impactful and memorable way. This could range from virtual field trips to historical sites, interactive and collaborative science experiments, or simulated business environments for commerce students. Complex instructional content can be delivered in a more palatable and captivating way thanks to the Metaverse's immersive nature.

Metaverse technology primarily involves Virtual Reality (VR), Augmented Reality (AR), and Mixed Reality (MR), which are the key components that create immersive and interactive experiences. VR immerses users in a fully artificial digital environment, AR overlays digital information onto the real world, and MR combines elements of both Complex instructional content can be delivered in a more palatable and captivating way thanks to the Metaverse's immersive nature. These technologies are supported by advanced computing power, sophisticated graphics, and high-speed internet connectivity.

The backbone of Metaverse technology also includes blockchain, which ensures security and user identity verification, and Artificial Intelligence (AI), which enhances the personalization of learning experiences. AI, for example, can modify instructional materials according to a student's learning pace and style. The integration of these technologies within the Metaverse enables a seamless and scalable virtual learning environment that can be accessed by anyone, anywhere, at any time.

As the technology continues to develop, the educational applications of the Metaverse are expected to become more sophisticated, with more institutions adopting this innovative approach to teaching and learning. This not only prepares students for a future dominated by digital interactions but also revolutionizes the educational landscape by making learning a more immersive and enjoyable experience.

Current Trends in Educational Technology:

Educational technology is rapidly evolving, integrating more sophisticated tools and methodologies to enhance learning experiences. One of the most significant trends is the adoption of Artificial Intelligence (AI). AI is being used to personalize learning experiences by tailoring the material to each student's unique requirements, which enhances engagement and results. For example, platforms like Coursera and Khan Academy use AI to analyze student data and provide customized resources and learning paths.

Another trend is the increased use of Augmented reality (AR) and virtual reality (VR) in the classroom. Immersion experiences provided by these technologies have the potential to improve learning effectiveness and engagement. For instance, medical students can practice procedures using virtual reality. or explore human anatomy in a 3D space, which can enhance understanding and retention of complex information. More about these technologies can be explored on websites like EdTech Magazine.

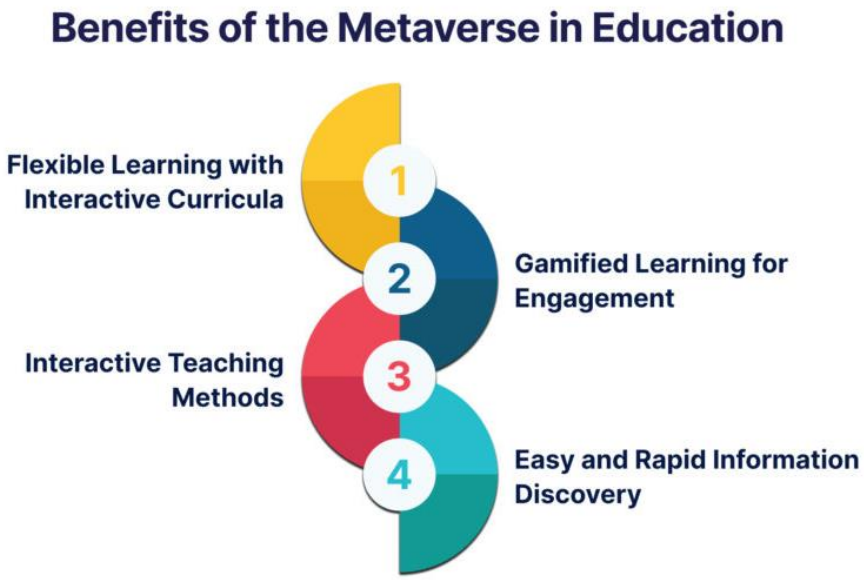
Virtual Reality (VR) Classrooms:

Virtual Reality (VR) classrooms are transforming the educational landscape by providing immersive learning experience that were once unimaginable. In a VR classroom, students wear VR headsets that transport them to a three-dimensional world where educational content comes to life. This technology enables students to explore historical sites, dissect complex molecules, or even travel through the human bloodstream, all from the comfort of their classroom.

The benefits of VR classrooms are numerous. They provide a highly engaging learning environment that can lead to improved retention rates. Pupils actively participate in their educational journeys rather than being passive consumers of knowledge. For example, a VR simulation of a historical event allows students to experience the event from multiple perspectives, enhancing their understanding and empathy. Moreover, VR can cater to different learn styles, making education more inclusive and personalized.

However, implementing VR in education is not without challenges. The cost of VR equipment and the need for robust IT infrastructure can be significant barriers, especially in under-resourced schools. Additionally, there is a need for educators to received proper training to effective integrate VR into their teaching practices. Despite these challenges, the potential of VR classrooms to enhance.

BENEFITS OF THE METAVERSE IN EDUCATION:



Flexible Learning with Interactive Curricula: The metaverse allow students to learn at their own pace, offering tailored and interactive content that adapts to individual needs.
Gamified Learning for Engagement: Incorporating game-like elements can enhance student motivation and involvement, making the learning process more enjoyable and dynamic.
Interactive Teaching Methods: Teachers can use immersive, hands-on techniques in virtual environments, promoting active learning and deeper understanding of complex concepts.
Easy and Rapid Information Discovery: The metaverse provides quick access to a wealth of information, enabling students to explore and find resources seamlessly within the virtual space.

2. LITERATURE REVIEW:

1. **Title:** First Steps in Constructing an AI-Powered Digital Twin Teacher: Harnessing Large Language Models in a Metaverse Classroom.
   Summary: AI-powered Digital Twin instructor for Metaverse-based classrooms, leveraging Large Language Models to enable dynamic, personalized interactions. The Digital Twin aims to address student doubts, enhance teaching effectiveness, and improve classroom management.
   Based on: Metaverse Classroom

2. OBJECTIVES:

Here are some possible objectives for AI-powered metaverse classrooms:

- ✓ Enhance Immersive Learning Experiences
- ✓ Personalize Education
- ✓ Foster Global Collaboration
- ✓ Improve Student Engagement
- ✓ Facilitate Experiential Learning
- ✓ Enhance Accessibility and Inclusivity
- ✓ Enable Data-Driven Decision Making
- ✓ Reduce Resource Constraints

3. RESEARCH METHODOLOGY :

AI-powered metaverse classrooms involves gathering data through survey, interview, and focus group with students and teachers to understand their experience. It also includes analyzing performance data to compare learning outcomes in metaverse classrooms versus traditional ones. A combination of qualitative and quantitative methods ensures a comprehensive understanding, while ethical practices like informed consent and data privacy are prioritized. Finally, the study reviews existing literature and real-world case studies to provide context and validate findings.

4. ANALYSIS:

The analysis of AI-powered metaverse classrooms highlights their transformative potential in education. These classrooms combine advanced AI capabilities with immersive virtual environments to create highly interactive and engaging learning experiences. Through AI, learning can be tailored to individual students, with personalized lesson plans, real-time feedback, and adaptive content delivery. This ensures that each learner progresses at their own pace, addressing unique strengths and weaknesses. Moreover, the metaverse offers experiential learning opportunities, such as virtual field trips and simulations, that make complex concepts easier to grasp and apply.

One significant advantage of metaverse classrooms is their ability to foster collaboration and inclusivity. Students from different geographical location can participate in the same virtual space, breaking down barriers and promoting cultural exchange. Additionally, these environments can be made accessible to individuals with disabilities, providing tools like voice-to-text, AI-guided navigation, and customizable interfaces.

However, challenges must be considered. The high cost of implementing and maintaining AI-powered metaverse systems can limit accessibility for underfunded schools or institutions. Technical issues, such as internet connectivity, hardware requirements, and software glitches, can also disrupt learning. Moreover, there are concerns about data privacy and the ethical use of AI, especially when handling sensitive student information.

In conclusion, while AI-powered metaverse classrooms have the potential to revolutionize education by making it more engaging, personalized, and inclusive, careful planning and resource allocation are required to address the associated challenges. Continued research and development are essential to ensure that these technologies are accessible and beneficial to all learners.

5. CONCLUSION:

The concept of AI-powered metaverse classrooms represents a ground-breaking shift in education, blending advanced technology with immersive virtual environments to create a more dynamic, personalized, and inclusive learning experience. By leveraging AI, these classrooms can adapt to Assess each student's needs and give them immediate feedback., and enable hands-on learning through virtual simulations. The potential for global collaboration and experiential learning offers exciting opportunities to bridge cultural and geographical gaps, making education more accessible and engaging for diverse groups of learners.

However, the adoption of AI-powered metaverse classrooms is not without challenges. High costs, technical barriers, and concerns about data privacy and ethical AI use must be addressed to ensure equitable access and responsible implementation. Additionally, teachers and students need adequate training and resources to fully harness the benefits of this technology.

In conclusion, AI-powered metaverse classrooms have the potential to revolutionize schooling through fostering innovation and enhancing learning outcomes. To maximize their impact, stakeholders must work collaboratively to overcome implementation hurdles, prioritize inclusivity, and ensure that this cutting-edge approach aligns with the broader goals of education. With continued investment and research, these classrooms could redefine how knowledge is delivered and experienced in the digital age.

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Revolutionizing with Li-Fi Data Transfer Technology

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Abstract:

The rapid expansion of IoT (Internet of Things) has created a growing need for secure, high-speed, and interference-free data transfer methods. Traditional wireless communication technologies, such as Wi-Fi and Bluetooth, face challenges related to limited bandwidth, security vulnerabilities, and susceptibility to interference. This work explores the implementation of Li-Fi (Light Fidelity) technology for data transmission within IoT networks, leveraging visible light as a medium for communication.

Li-Fi technology transmits data by modulating light waves from an LED (*Light Emitting Diode)* which a photodiode receives and decodes. This method offers significant advantages, including higher bandwidth, enhanced security due to the physical containment of light, and immunity to electromagnetic interference. The proposed system integrates IoT sensors for data collection, a microcontroller for encoding and transmitting data via light beams, and a photodetector for receiving and decoding the signals. The received data is then processed and displayed on an interfaced computer or device for analysis.

Key Words: *Li-fi technology, Internet of Things, Light Emitting Diode, Bluetooth*

1. INTRODUCTION:

The Internet of Things (IoT) has revolutionized how devices communicate, enabling seamless data exchange and automation in various sectors, including healthcare, industry, and smart homes. However, the reliance on traditional wireless communication methods such as Wi-Fi and Bluetooth presents significant limitations. These technologies often suffer from bandwidth constraints, electromagnetic interference, and security vulnerabilities, which can impede their performance and reliability in environments that demand high-speed, secure data transmission.

Li-Fi (Light Fidelity) has emerged as a promising alternative to address these challenges. Li-Fi utilizes visible light for data transmission, offering several advantages over conventional wireless methods. With its higher bandwidth potential, improved security due to limited physical propagation of light, and immunity to electromagnetic interference, Li-Fi presents an innovative solution for enhancing IoT communication.

This paper named the Light Beam IoT Data Transfer System, investigates the use of Li-Fi technology for secure and interference-free data transmission within IoT networks. By leveraging LED-based light modulation and photodetection, the system seeks to showcase the feasibility and practicality of Li-Fi in real-world IoT applications.

2. OBJECTIVES

1. Develop a Li-Fi-based communication system that demonstrates the feasibility of data transfer using visible light within an IoT network.
2. Integrate IoT sensors to collect and transmit real-time data through the Li-Fi system.
3. Ensure secure and interference-free data transmission, emphasizing the physical containment benefits of light-based communication.
4. Address technical challenges such as ambient light interference and signal degradation by implementing narrow-band filters and focusing lenses.
5. Validate system performance by analysing the reliability and speed of data transfer in confined spaces.
6. Explore practical applications of the developed Li-Fi system in high-security environments, medical facilities, and smart home systems.

3. RESEARCH METHODOLOGY:

As IoT networks continue to expand, existing wireless communication methods such as Wi-Fi and Bluetooth face limitations that hinder their effectiveness. These include bandwidth constraints, susceptibility to electromagnetic interference, and potential security vulnerabilities, particularly in environments requiring high confidentiality. The need for an alternative solution that provides high-speed, secure, and interference-free data transmission is critical. Li-Fi technology, which uses light waves for communication, presents an opportunity to address these challenges. However, implementing and optimizing Li-Fi systems for IoT applications involves overcoming obstacles such as ambient light interference and distance-related signal degradation. This project aims to demonstrate the potential of Li-Fi as a reliable alternative for IoT data transfer, exploring practical solutions to the technical challenges.

The Light Beam IoT Data Transfer System Leverages Li-Fi technology to provide a secure, high-speed, and interference-free data communication method for IoT applications. The solution is implemented through the following steps:

1. System Design and Setup:
    - Integrate IoT sensors to collect environmental data (e.g., temperature, motion).
    - Connect a microcontroller to encode and modulate data for light transmission.
    - An LED transmitter emits modulated light waves containing the sensor data.

2. Data Transmission via Li-Fi:
    - Modulate the LED light source using a microcontroller to create a rapid on/off switching pattern that encodes binary data.
    - Ensure data transmission is optimized with focused, narrow-band light sources to reduce ambient light interference.
3. Data Reception and Decoding:
    - Employ a photodetector to capture and convert incoming modulated light signals to electrical signals.
    - Utilize a signal processing unit to decode the received data and ensure accuracy.
4. Data Display and Analysis:
    - Interface with a display unit to present the decoded data for user interaction and analysis.
    - Implement software tools to enhance data visualization and provide detailed feedback on system performance.
5. Addressing Challenges:
    - Integrate narrow-band filters and optical lenses to minimize the effects of ambient light.
    - Utilize error-checking algorithms to improve signal reliability over various distances.

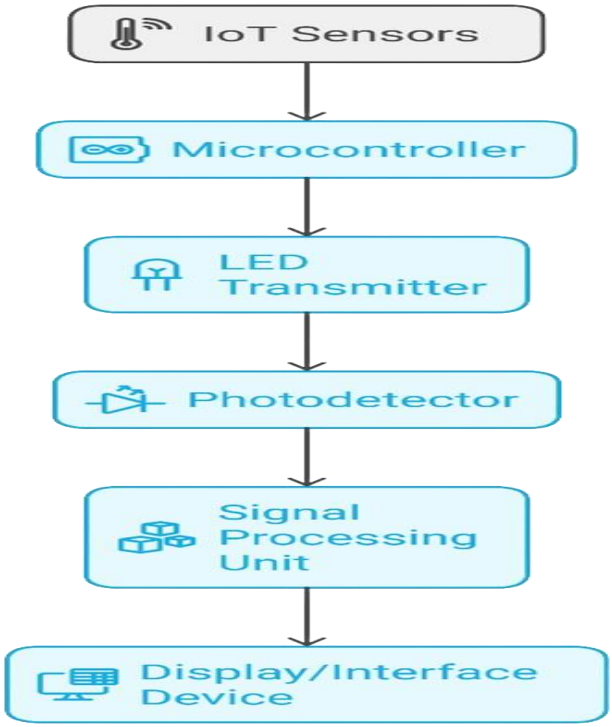

Fig 1: Architectural diagram

The overall system diagram illustrates the architecture of the Light Beam IoT Data Transfer System:

1. IoT Sensors: Collect environmental data such as temperature, humidity, or motion.
2. Microcontroller: Encodes the sensor data and modulates the LED light for transmission.
3. LED Transmitter: Emits modulated light signals containing the encoded data.
4. Photodetector: Captures the incoming light signal and converts it back into electrical signals.
5. Signal Processing Unit: Decodes the received signals and processes the data for output.
6. Display/Interface Device: Displays or further processes the data for analysis and user interaction.

4. CONCLUSION:

The Light Beam Data Transfer System is a promising high-speed, secure, and interference-free communication solution. Its ability to use visible or infrared light for data transmission opens up new possibilities for specialized applications in various fields, including

telecommunications, IoT networks, and secure data communication setups. The modular and scalable design allows for easy adaptation and future enhancements, making it a versatile choice for modern communication needs.

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ROLE OF PRACCHAN KARMA AND TRIPHALADI SHIRO LEPA IN THE MANAGEMENT OF KHALITYA

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ABSTRACT

Hair fall is one of the minor diseases which is affecting approximately 1.7% of the world population and challenging task for physicians. Hair fall has been described in Ayurveda by the name of khalitya roga under the heading of kshudra roga (minor disease) or shiroroga (diseases of head & scalp). It is progressing disorder people living in sedentary ways of life, stress induced hectic schedules along with indiscriminate dietary habits result in many disturbance and deficiencies in the body which directly reflect in loss of hair. We can reduce & manage this rising problem of hair fall through modifying life style, purification therapy and medication practicing in Ayurveda.

Deficiency of Protein, Iron and Biotin and Anemia also cause of Hair fall. Patients of hair fall should be diagnosed by using Trividha pareeksha. In general line of treatment of the khalitya Sodhan karma, Prachaan karma and application of lepa should be beneficial. Thus Ayurveda may play a major role to manage the hair fall by using basic Principle of Ayurveda and its formulations.

KEYWORDS: Khalitya, Prachaan karma, Lepa, Rasayan.

INTRODUCTION

Healthy, long and vibrant hair helps a lot in improvement of personality. Therefore, to keep hair in healthy state is entirely duty of human being, because just like face, hair is also a mirror of healthy state of body. In this advanced modernized era, the humans are gifted with lot of sophistication, luxuries but at the same time left with sedentary life style, stress induced hectic schedules along with faulty dietary habits. These all habits influences the homeostasis of the body and with many other health problems, fall is one of them. Problem of falling of hair is progressively increasing in society which is also affecting quality of life. Many years of hair loss have impact on mental health. Dermatology life quality index scores in patients with hair loss were similar to those recorded in severe psoriasis. This study specifically identify the

feeling of self - confidence, low self - esteem and heightened self-consciousness in people affected by hair loss!" Hair fall has been described in almost all the Ayurvedic literatures as Khalitya. It has been included in Shiroroga by Acharya Charaka & Ashtanga hridayakar. It is clearly mentioned in Ashtanghridaya that nine diseases occurring on the outer part of head over scalp should be called shiroroga.

LITRATURE REVIEW

Sushrut Samhita, Ashtangsamgrah, Yoga Ratnakar and Madhav Nidan, has included Khalitya diseases under kshudra roga. This inclusion in kshudra roga is due to mildness of disease.!3)

These diseases are not life threatening and are of less severity in comparison to other major diseases.

Causes of Khalitya Roga

Due to usna guna of pitta dosha individual of pitta raivit alsos bher dos a prateying of hair earlier than The hair has tendency to lose its natural colour with advancing age.

Although, Aging is genetically predetermined but lifestyle, dietary habits, mental status, social & family life and many other environmental factors may influence the aging process and their unfavourable effects cause premature aging. In a survey study, 81.66% patients of pre-mature aging of 30-40 years age had complaint of hair fall. Pre-mature aging could be a cause of increasing hair fall in peoples.

Causative factor of shiroroga are too much exposure to smoke, sunlight, mist, indulge in water sports; excessive sleep or avoiding sleep, sweating, eastern breeze or direct breeze, control of tars, weeping too much, drinking water & wine in large quantity, presence of warms in side body, suppression of urges, avoiding the use of pillow, bath and oil anointing, always looking downwards, unaccustomed, unhealthy, vitiated or raw smell, too much speaking etc; by indulgence in these and similar causes the dosha get aggravated and produces diseases in head. This can produce khalitya because of same place of manifestation.

MATERIALS AND METHOD

Age	34yrs
Gender	Male
Address	Junagadh
Occupation	Public Relationship Officer (stress full)
Educational Status	Graduated
Economical Status	Middle Class
Habits	Tobacco Chewing
Any Major Illness	Not Significant
Vitals	Normal

Sleep	Disturbed
Mala-Mutra	Prakruta (Occasionally constipation)
Appetite	Samyaka

CHEIF COMPLAINTS

Visible hair loss from frontline Visible hair loss from parietal region Thinning of hair

White hair - Since : 1-2 years

Distance of hairline from eyebrow : 10.7 cm

TREATMENT PROTOCOL

1st Sitting	
Day 1	Prachana karma(In Evening)
Day 2,4,6	Shirolepa With Haridra, Triphala, Kukkutanda lepa
Day 3,5,7	Shirolepa With - Haridra, Triphala, Bhringraja Swarasa
2nd Sitting	
Day 37	Prachana karma(In Evening)
Day 39,41,43	Shirolepa With - Haridra, Triphala, Kukkutanda lepa
Day 40,42,44	Shirolepa With - Haridra, Triphala, Bhringraja Swarasa

Inervention

Inervention Oral Medication

Rasayana Vati (1 BD A/f With Water)

Bhringraja Ghanvati (2 BD A/f With Water)

Bhringraja Oil for Local Application - 3 times/ week.

Advice to Patient

1. To maintain proper daily routine, i.e. time of taking meals, Time of Sleeping.
2. He must Avoid :

Occurrence of constipation Ratri jagrana

Hot & Spicy foods, Junk foods, Fried items

Probable mode of action

Pracchan karma

Pracchan karma enables the damaged hair follicles to recover through their inherent regenerative capacity.

It relieves the blockage at the root of hairs, "Pracchane Pinditehitam" & stimulates scalp metabolism by increasing blood circulation. - Su. Sha. 8/ 26.

Drugs of shirolepa

Triphala, Kukkutanda, Haridra, Bhringraja swarasa

Other Medications

Rasayana vati

Bhringraja ghanvati

Bhringraja hair oil

Only virya of aushadhi will be absorbed - Su. Sha. 9/9

DISCUSSION

Khalitya is a common but very challenging and capricious disease of the world population and can have a profound effect on physical and emotional state.

Viruddha ahara, pitta vardhak ahara vihara, abhishyandi ahara, sedentary lifestyle increases Pitta and Vata which leads to khalitya.

For the patient of Khalitya Vaman, Virechan, Vasti and Rakta mokshana should be done according to the dosha involve. Because of involvement of mainly pitta dosha. virechana and rakta mokshan are commonly indicated in falling of hair & baldness.

Shirolepan karma which performed by vatahar, pittahar and kaphahar dravyas normalizes vata, pitta and kapha dosha accordingly. Shodhana is a procedure which takes out the doshas from the nearest route of its vitiation. Rasayana therapy has immune-modulators, antioxidant properties and rejuvenating action which very beneficial for the hair fall caused by any chronic illness, pre mature aging or nutrition deficiency.

CONCLUSION

Khalitya is wicked disease which needs proper management. Some minor changes of life style and dietary habits can prevent Khalitya. Proper hair care life oiling, washing, protection from external factors like environment, chemicals, heating etc is important for preventing hair fall and keeping them healthy. Before starting treatment of hair fall, physician should identify the cause and first treatment should be Nidanparivarjana or management of that cause. Than after other therapies like prachhama karma, Abhyang, lepana, shodhan, nasya, Rasayana should be prescribed accordingly. In this way, we can treat the khalitya roga or hair fall effectively.

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YOGA AND MENTAL HEALTH

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Abstract:
The need for effective population mental health promotion approaches is urgent as mental health concerns are escalating globally and current allopathic treatment regimens are insufficient to bring people towards the state of mental well-being (citation). Yoga has been used for millennia as a tool for self-improvement, with the ultimate goal of uniting the individual consciousness with the universal whereas mental health is a state of wellbeing in every possible aspect of life. The focus of this paper is to present the yoga as an aid to improve mental health. Yoga has numerous influences on mental health such as improving focus, reducing stress and light up moods and many more and for there are different yoga for different mental health issues listed in this paper. Recent research has also shown significant benefits of yoga in mental disorders such as depression, anxiety, and psychosis. This paper discusses the place of yoga not just as an aid but also a tool to prevent mental health problems.

Key Words: *Yoga, Mental health, Quality of life, Therapeutic*

1. INTRODUCTION:

By 2020, the World Health Organization predicts that depression will be the second largest contributor to the global disease burden, after ischemic heart disease (cite). Anxiety is also being diagnosed at a greater rate than it was in the past. Despite these increases in diagnosis, treatment regimens typically include pharmaceutical therapies that are not sufficient to prevent further illness or promote mental well-being. Effectively addressing mental health concerns entails a comprehensive approach that addresses the root of the problem(s) [1-3]

In this paper, we provide evidence for yoga as a form of health promotion, illness prevention and treatment for depression and other mental health imbalances. Like other therapies, yoga is not a complete solution to mental health concerns. In conjunction with other approaches, yoga has great potential to lead people towards greater mental well-being.

What is Yoga?

The eight limbed path of yoga includes: Yama (moral codes), Niyama (self-discipline), Asana (postures), Pranyama (breath practices promoting life force), Pratyahara (sensory transcendence), Dharana (concentration), Dhyana (meditation), Samadhi (state of bliss). The word roots of yoga mean “to join” in Sanskrit. Joining mind and body, and individual and collective selves is the essence of this ancient South Asian practice [4]. Yogic philosophy posits that every life form is interconnected and united [5]. “Yoga exists in the world because everything is linked” [6]. Yoga’s greatest aim is to create compassion within and a deep sense of unity and oneness with all forms of life [7]. Yoga is an individual activity that has social implications. Those who regularly participate in yoga typically interact with the world in calmer and more reasonable ways. More positive social interactions and relationships are one of the ripple effects of individual yoga practice. Accessible or complementary yoga classes offer low income people the opportunity to experience the benefits of inner peace and healthier body. When practices such as yoga are accessible to all, larger effects are possible. Without overstating the impacts, potential consequences of large scale population mental well-being initiatives such as this are less violence in society, less addiction, greater ability to be authentic with one and others.

Mental Health

Mental health is a person's emotional, psychological, and social well-being. It's an important part of overall health, and it affects how people think, feel, and act. Mental health is important at every stage of life, from childhood through adulthood and aging. Mental health can affect daily living, relationships, and physical health. However, this link also works in the other direction. Factors in people's lives, interpersonal connections, and physical factors can all contribute to mental health disruptions. Looking after mental health can preserve a person's ability to enjoy life. Doing this involves reaching a balance between life activities, responsibilities, and efforts to achieve psychological resilience.

According to WHO mental health is a state of wellbeing in which an individual realizes his / her own abilities can cope with the normal stresses of life, can work productively and is able to make a contribution to their community.

The WHO stress that mental health is "more than just the absence of mental disorders or disabilities." Peak mental health is about not only avoiding active conditions but also looking after ongoing wellness and happiness. They also emphasize that preserving and restoring mental health is crucial on an individual basis, as well as throughout different communities and societies the world over.

Over the course of your life, if you experience mental health problems, your thinking, mood, and behavior could be affected. Many factors contribute to mental health problems, including:

- Biological factors, such as genes or brain chemistry
- Life experiences, such as trauma or abuse
- Family history of mental health problems

Mental health problems are common but help is available. People with mental health problems can get better and many recover completely.

2. LITERATURE REVIEW:

We found approximately 30 review articles and 300 separate studies in the area of yoga and mental health in the peer-reviewed medical literature. Because this is a relatively new area of research, it is difficult to compare one study to the next partly because of sample size variation, differences in trial length, and variances in the kind of yoga. Some studies tested Iyengar (primarily asanas) while others tested Sudarshan kriya (patterned pranayam exercises, moving from slow and calming to rapid and stimulating, followed by emotional self-expression in a supine position), savasana (deep relaxation), Sahaja yoga (a type of meditation), or pranayam. Varying time periods, from 2 week to 6 months of yogic interventions, also made studies difficult to compare and contrast. Overall, studies of yoga and mental health would improve from greater methodological rigor, particularly better randomization [8].

A brief summary of peer-reviewed literature on yoga and mental health

As the Patanjali Sutras notes: "Yoga is the practice of quieting the mind" [9]. Positive mental health is "a state of well-being in which every individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community [10]". We searched for articles that examined yoga as a form of promoting mental wellbeing for healthy people. However most of the literature in this area focuses on improving quality of life for people with cancer and other afflictions. The literature on mental health and yoga is biased towards individualized mental health imbalances in a similar way as literature in physical health is biased towards individualized disease.

We found approximately 30 review articles (2002-2014) on yoga as a treatment for various mental health disorders, including Major Depressive Disorder (MDD), Anxiety Disorders, Obsessive Compulsive Disorder (OCD), Schizophrenia and others. The most significant results were for yoga as treatment for depression. More research is required for conclusive evidence-based recommendations; so far, peer-reviewed literature appears promising for yoga as mental health promotion and treatment particularly for depression.

How Does Yoga Work?

Psychological benefit of yoga

- **Calms the Mind**

  By activating the parasympathetic nervous system

  Yoga's combination of poses, breathing, and mental focus activates the parasympathetic nervous system, which reduces stress hormones and initiates

  By changing brain signals

  Yoga can change the signals sent to the brain, such as those related to safety and well-being. This can help counteract the "fight, flight, or freeze" response that can arise in stressful situations.

- **Improves Mood**

  By increasing feel-good chemicals
  Yoga increases the production of endorphins and gamma-aminobutyric acid (GABA), which can help improve mood and decrease anxiety.
  By Reducing stress hormones
  Yoga can lower stress hormones in the body.

- **Helps Focus**

  Those who have disorders like ADHD are often asked to try yoga because it helps to relax and centre the body while helping the mind focus. **ADHD** is a disorder that directly affects focus and attention retention, doing poses that incorporate breathing techniques and promote focus can help.

- **Helps Build Confidence**

  Yoga can help those suffering from self-esteem issues, a loss in confidence or self-esteem is often considered a cause for depression and anxiety. Performing yoga regularly helps centre your body and develop it slowly. It improves your confidence. The breathing in yoga also helps rid your mind of self-doubt.

- **Improves Patience**

  A common side-effect of disorders like anxiety, depression and bipolar is a lack of patience. This leads to uncontrolled angry outbursts. Yoga incorporates numerous breathing activities known as **pranayama** which help clear body and mind.

Effective Yoga Poses to Improve Mental Health

In this paper here 10 yoga asanas mentioned for improving mental health. These asanas impact to induce global functioning of an individual.

- **Anjaneyasana:** Anjaneyasana, also known as the low lunge pose or crescent moon pose, has many health benefits, including:

  Strengthens: Builds muscle in the legs, back, shoulders, quads, and glutes

  Stretches: Stretches the hips, thighs, feet, chest, back, groin, and inner thighs

  Improves: Improves balance, stability, posture, breathing, and blood circulation

  Relieves: Relieves stress, tension, and sciatica pain

- **Garudasana:** It also known as the Eagle Pose, has many benefits, including:

  Flexibility: Improves flexibility in the body

Balance: Increases balance and focus

Strength: Strengthens the core, knees, and elbows

Circulation: Improves blood circulation in the arms, glutes, and legs

Breathing: Promotes deep breathing

Posture: Improves posture

Mental focus: Increases awareness and mental focus

Abdominal organs: Stimulates abdominal organ function

Fat loss: Burns excess fat around the arms, abdomen, glutes, and legs

Nervous system: Activates the vertebrate and improves nervous system function

- **Natarajasana:** "Nata" is dance, Raja stands for king and the meaning of Asana is Pose or posture. Natarajasana is the lord of dance pose. This asana is beautiful combination of structure and movement. It symbolises the dance of the graceful Nataraja. It helps to make you strong, and opens up your mind and body, giving them so much grace and power.

- **Virabhadrasana:** The warrior pose, also known as Virabhadrasana, is a foundational asana in yoga practice that builds strength, flexibility, and concentration. It engages multiple muscle groups, including the legs, core, and arms, and promotes stability and endurance.

- **Adho Mukha Vakraasana:** This is not a pose for beginners, this *asana* is a basic handstand; It calm the mind and relieves headache, fatigue and reduce the symptoms of insomnia.

- **Vajrasana:** Vajrasana is more than just a pose for physical wellness; it is a vital tool for mental and emotional health. Its ability to induce relaxation, improve breathing, stimulate key nerves, and regulate hormonal balance makes it an excellent practice for those suffering from anxiety.

- **Padmasana:** padmasan or Lotus Pose, is a classic yoga asana that involve sitting cross-legged with each foot placed on the opposite thigh. It's considered as foundational yoga pose and it often used to meditation. Known for promoting mental calmness and physical stability.

- **Vriksasana:** Vrikshasana (v-rook-shA suh-nuh), also known as the Tree Pose, is a remarkable Asana for improving balance. Its name is derived from the Sanskrit words Vriksha (meaning tree) and Asana (meaning a posture). This asana, where your leg takes charge as the roots of a tree, encapsulates the essence of a deep-rooted tree which denotes strength and steadiness. It is a simple yet beneficial Asana. While practicing this posture, your entire body weight is placed on to one leg, strengthening that particular leg. Vrikshasana not only improves bodily and mental balance, but also bestows stability and poise.

- **Savasana:** Known as "the dead body pose", this *asana* is similar to lying down to take a nap. It is extremely easy to do. Savasana can help reduce stress and anxiety by activating the parasympathetic nervous system, which counteracts the body's stress response. This can lead to decreased levels of cortisol, the stress hormone.

- **Chakrasana:** Known as the circle pose, this is a bit of a tricky *asana* but it helps your calmness and focus. This pose triggers parasympathetic nervous system, reduces stress and soothes the nerves.

EFFECT OF YOGA ON MENTAL HEALTH

Regulates Adrenal Gland

Yoga decreases volumes in the cortical. If it doesn't seem like anything, think about this. Usually, in reaction to an immediate situation, the adrenal glands secrete the cortical, briefly improving immune function. If even after the crisis the cortical rates stay high, they can weaken the immune system. Temporary increases in long-term memory cortical aid, however consistently elevated rates weaken performance, and can contribute to irreversible brain changes. In fact, toxic cortical substances have been related to severe depression, osteoporosis (it absorbs calcium and other nutrients from bones and interferes with fresh bone laying), elevated blood pressure, and insulin resistance. High cortical rates in rats contribute to what researchers term "food seeking activity" (the sort that causes you to eat when you're irritated, frustrated, or stressed out). The body absorbs and distributes such excess calories as fat in the belly, leading to weight gain and risk of diabetes and heart attack.

Increases self-esteem

Most of them have a consistently weak self-esteem. When you treat such negative-taking medications, overeat, work too long, sleep around-you might be emotionally, psychologically, and morally paying the price for the reduced health. When you adopt a constructive stance and pursue meditation, you'll know whether you're worthy or, as yogic theory says, you 're a reflection of the Almighty, first in fleeting glimpses then then in more prolonged experiences. If you consistently train with an aim of self-examination and improvement-not only as a replacement for an aerobics class you will reach a new part of yourself. You will feel feelings of appreciation, remorse, and redemption, as well as a feeling of being part of something greater. Although better health is not the goal of spirituality, it is often a by-product, as numerous clinical studies have recorded.

Create peace of mind

According to Patanjali's Yoga Sutra, meditation quenches the emotional disturbances. To put it another way, it speeds down the inner cycles of disappointment, guilt, rage, anxiety and attraction that can trigger tension. And because depression causes too many health issues — from migraines and anxiety to lupus, MS, eczema, elevated blood pressure, and heart attacks — if you learn to relax your mind, you are likely to live longer and safer.

Build up immune system

Asana and pranayama are known to improve immune function but meditation has the greatest research evidence in this field to date. This tends to have a positive impact on the immune system’s functioning, improving it when required (for example, increasing antibody rates in reaction to a vaccine) and reducing it when required (for example, minimizing an overly violent immune function in an autoimmune disorder such as psoriasis).

Releases tension in limbs

Keeping the handset or a steering wheel with a death grip or scrunching your nose as you glance at a computer screen, do you ever see yourself? Such involuntary patterns in the hands, arms, legs, back, and face can contribute to constant discomfort, muscle weakness, and soreness, which can exacerbate stress and deteriorate the mood. You tend to note that you retain stress as you practice yoga: it could be in your mouth, your hair, or your face and neck muscles.

Maintains nervous system

Some experienced yogis can exercise exceptional influence over their bodies, many of which are controlled by the nervous system. Scientists have studied yogis who could trigger irregular heart rhythms, produce unique brain-wave patterns and increase the temperature of their hands by 15 degrees Fahrenheit using a mediation technique. If you can use yoga to do that, you may learn to increase the blood flow to the pelvis if you want to get pregnant or relax when you have difficulty sleeping.

Yoga decreases involuntary reactive behavior by improving sensitivity and improves pro-activity in challenging circumstances that impel frustration or anxiety. If lifestyle changes are paired with yoga practice, anxiety and depression can be minimized in regular teenagers in people with gastrointestinal illness and loneliness and poor body image. Because of its beneficial role in improving endurance and consciousness of the mind-body, it will help people change their activities according to environmental need and personal feelings. Doing group yoga will improve teamwork and collectivism among participants of the party. This may be seen as a possible solution to pharmacological treatment for patients with depression and anxiety by rising stress responses like blood pressure, stress hormone cortisol levels.

Anxiety, tension and depression sometimes pervade our life. They sometimes view them as small issues, but they may escalate to serious psychiatric conditions if they stay untreated and unmanaged. Research shows that yoga is unique in its positive ability to relieve fear, tension and depression. In view of the positive impact on the feel-good neurotransmitters, alpha-wave function, vagal sound, serum prolactin yet declining oxidative stress, lipid level, serum cortisol, decreased control of the hypothalamic pituitary-adrenal axis and alkalinity, yoga could have enormous utility for soothing the anxiety, distress , depression, feelings of shame, suicidal ideation and a sense of peace, balance; Training of postures may increase the degree of distress-tolerance in tense circumstances and decrease emotional eating habits. None of the leisure practices, like smiling, socializing, playing fun games or shopping, will relax our emotional condition to a larger degree than meditation, as both of these experiences involve a degree of nervous system relaxation. Also walking has not been documented to cause greater effects than yoga on our mental function and degree of anxiety.

CONCLUSION / SUMMARY:

With sufficient evidence of causal association between stress and several chronic diseases (i.e., cardiac disease, cancer, stroke, diabetes, etc.), yoga can be effective as a stress management method not just to reduce emotional dissatisfaction, but also to reduce the burden of stressed diseases generated. Irritations that are part of daily life may be minimized by Yoga practice. This can reduce exhaustion and anxiety in patients suffering from life-threatening diseases as well.

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A growing **number of studies** from the 1970s through to today, suggest that yoga can have a positive outcome for people managing symptoms of depression, anxiety or stress, among other benefits. In fact, Harvard Medical School believes there is growing evidence that yoga practice is a relatively low risk, high-benefit approach to improving overall health.

Marked the month of June, the UN International Day of Yoga on June 21 aims to raise awareness of the many benefits, including physical and psychological, of practicing yoga.

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A REVIEW ON UNMADA (MENTAL DISORDERS) CAUSED DUE TO CHRONIC MEDICINAL INTAKE WITH REFERENCE TO DUSHI VISHA (CUMULATIVE POISON).

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Abstract:
Today, Health factor is considered to be a priority. But still having options available today, many people still lack interest in maintaining a healthy lifestyle. An interest is grown when a person is full of feelings for a particular reason, but sometimes people go into flight mode. Psychiatrists have claimed that any lack of interest for more than 2 weeks can be considered a prodromal stage of upcoming mental disorders. Research has also shown that some of the underlying facts of these disorders are caused after going through a chronic diseased condition. It has shown that the clinical manifestations of mental disorders are also caused due to chronic drug interventions (CDR) of any underlying disease leading to drug-induced toxicity.
Dushi Visha is one of the major concepts mentioned in Ayurveda Classical texts. It is caused by Sevan (intake) of Dushit Desha (Environment), Kala (Period), Anna (Food), Vihar (Activities), Aushadha (Medicines), Divaswapna (Sleeping during day-time), and so on. It vitiates Dhatu and gets Prakopa after a long time (Kalantarprakopa). Its references proclaim how it is defined, how it accumulates in the body, what can cause Dushi Visha, what the factors causing Dushi Visha, Chikitsa (treatment modalities) and its Updrava (complications), specially Unmada (Manas Roga/Mental disorders).
Any drug intervention for a longer period can be considered to have a cumulative toxicity effect and hence it can be considered under Dushi Visha. Dushi Visha/ CDR may result in Mental disorders which can be considered under Unmada as an Updrava.
Key Words: *Unmada, Mental disorders, Dushi visha, Cumulative Poison, Chronic Drug Intervention*

1. INTRODUCTION: (11BOLD)

The person having knowledge about *Visha* and its treatment in detail is called as *Raj Vaidya*. He is also responsible to look after any cumulative poisoning effect seen, and its treatment accordingly for the benefit of the society. This concept is called as *Dushi Visha*.[1]

Dushi Visha is one the major concept mentioned in Ayurveda Classical texts. It is caused to Sevan of *Dushit Desha* (Environment), *Kala* (Period), Anna (Food), *Vihar* (Activities), *Aushadha* (Medicines), *Divaswapna* (Sleeping during day time), and so on. It vitiates Dhatu and gets *Prakopa* after long time (*Kalantarprakopa*). Its references proclaim about how it is defined, how it is accumulated in body, what can cause *Dushi Visha*, what are the factors causing *Dushi Visha*, *Chikitsa* (treatment modalities) and its *Updrava* (complications), specially *Unmada* (*Manas Roga*).[1]

Today, Health factor is considered to be a priority. We see people acknowledging the importance of healthy body by indulging in healthy diet and lifestyle. But still having options available today, many people still lack their interests in maintaining healthy lifestyle.

An interest is grown when a person is full of feelings for a particular reason, but sometimes people go on a flight mode. Psychiatrist has claimed that any lack of interest for more than 2 weeks can be considered as prodromal stage of upcoming mental disorders.[2]

Researches have also shown that some of the underlying facts of these disorders are caused after going through a chronic diseased condition.[3] It has shown that the clinical manifestations of mental disorders are also caused due to chronic drug interventions (CDR) of any underlying disease leading to drug-induced toxicity.[4]

Any drug-intervention for a longer period can be considered to have cumulative toxicity effect and hence it can be considered under *Dushi Visha*. *Dushi Visha*/ CDR may result into Mental disorders which can be considered under *Unmada* as a *Updrava*.

2. LITERATURE REVIEW:

Studies has been done on understanding the concept of *Dushi visha* as a cumulative poison or as a latent poison. Research also showed it as one of the reasons for Stress and Sleep disorders.

3. OBJECTIVES / AIMS :

1. To establish relationship between *Dushi visha* and its *updrava Unmada*
2. To design a questionnaire to assess the prevalence of *Unmada* as updrava as complications in *Dushi Visha*.
3. Validate the results of the duly filled in questionnaire by conducting a survey.
4. Define the most common and/or aggravating etiological factors of *Dushi Visha* w.r.t. to *Aahar, Vihar, Aushadh Kalpana* in detail used routinely by general public.
5. To study in detail about *Dushi Visha*
6. To study in detail about *Unmada*
7. To study in detail about Mental disorders caused in Chronic systemic disorders patients.

4. RESEARCH METHOD / METHODOLOGY :

- **Type of Study**: Quantitative Research Method and Cross-sectional studies
- **Source of Data**: Random Patients from nearby Registered Hospitals and Clinics.
- **Inclusion criteria**
  a. Patients suffering from Mental Disorders will be included as per the assessment criteria.
  b. Patients taking treatment for more than 1 year for any underlying diseases (Chronic Systemic Disease).
  c. Patients irrespective of Sex

d. Patients from age group of 25 to 70 years

- **Exclusion criteria**
  a. Patients with Bed-ridden complications
  b. Patients aged below 25 and more than 70.
  c. Patients who are unable the answer the questionnaire
  d. Patients admitted in ICU/NICU

Criteria of Mental Assessment:

The following criteria are in accordance with the signs and symptoms of Mental Health Assessment as per the *Brihatrayi* and Diagnostic and Statistical Manual of Mental Diseases.

Asthavibhrama:[5]

Mano vibhrama (Psyche)

Buddhi vibhrama (Intellect)

Bhakti vibhrama (Likes and Dislikes)

Sila vibhrama (Manners)

Chestha vibhram (Behavior)

Aachar vibhrama (Conduct)

Sangyna vibhrama (Consciousness)

Smrit vibhrama (Memory)

Parameters:[6]

Biological functioning (sleep, appetite, bowel, bladder functions)

Social functioning (managing day activities, hobbies, leisure time activities)

Occupational functioning

Mental functioning (Concentration, thought content, speech, mood states, abnormal perception, interest, attitude, etc)

Interpersonal relations (quality of relationship with family members)

Loses beloved persons, property, financial matters

Aspects of Mental Status examination:

1. General appearance and behavior
2. Speech or Talk (Attitude)
3. Mood or Affect
4. Thought
5. Perceptual changes
6. Consciousness
7. Orientation
8. Attention and Concentration
9. Memory
10. Fund of Knowledge
11. Abstraction
12. Judgement
13. Insight

Study Design:

- A questionnaire was designed to assess the prevalence of *Unmada* as *Updrava* as complications in *Dushi Visha*.
- It was duly filled in by conducting a survey, and results were validated.
- Informed consent was taken from each patient prior to the survey participation.
- A total sample of 50 patients was evaluated for the survey.
- A Retrospective study was conducted with duly filled knowledge of clinical study.

5. RESULT / FINDINGS :

This study was for the patients who took any medications for more than 6 months.

70% data was about male patients varying from age 40-65. 30% females were found to be in menopause stage.

Almost 73% patients showed with present complaints as Weight gain, Mood disorders, Dry skin, Pain for more than 6 months and Fatigue.

Approx. 64% patients were suffering from symptoms like Felling worried/ anxious, High-risk behavior, Sleep problems.

Major patients were found of Heart diseases, Diabetes Mellitius-2, Anta-acids, and OTC use of Analgesics and Multi-vitamin supplements.

30% patients were aware of the mental disorders ongoing with them and out of them 10-15% were ready to make any change.

6. DISCUSSION / ANALYSIS:

As per the survey taken, it was found that major patients drug use revolved around Heart and GIT systems.

Study has shown that chronic use of such drugs can cause many side effects, including mental disorders.

Studies on Beta-blockers, Statins, Metformin, and many more has proven to cause mental disorders or cognitive dysfunction, if taken for long term.

The awareness among the patients is very low, and the blind side of this can lead to major disturbances in their livelihood.

All this factors can be considered as *hetus* (causes) of *Dushi visha vishtakta*.

8. CONCLUSION / SUMMARY:

The concept of *Dushi visha* corelates with the use of long- term medications and *Unmada* is generated in patients in the form of mental disorders.

9. LIMITATIONS:

Limited group numbers may lead to the query of prevalence.

10. RECOMMENDATIONS:

A study on major group scale is required for proper validation.

Figures/ Tables/Charts: (with numbering eg. 1, 1.1, 2, 2.1) at proper place and in center.

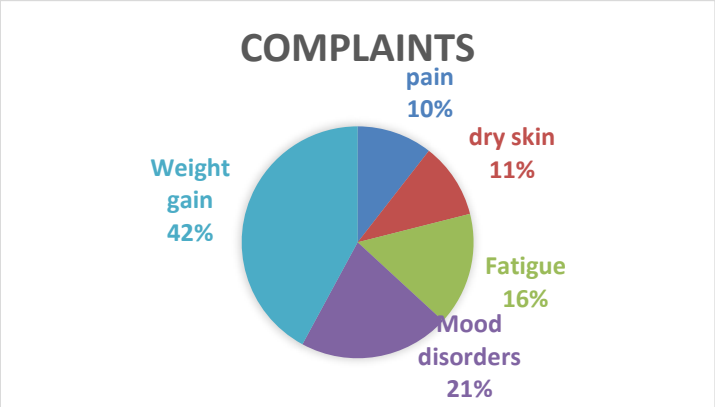

Fig.1.1 Showing Prevalence of the complaints present in the patients.

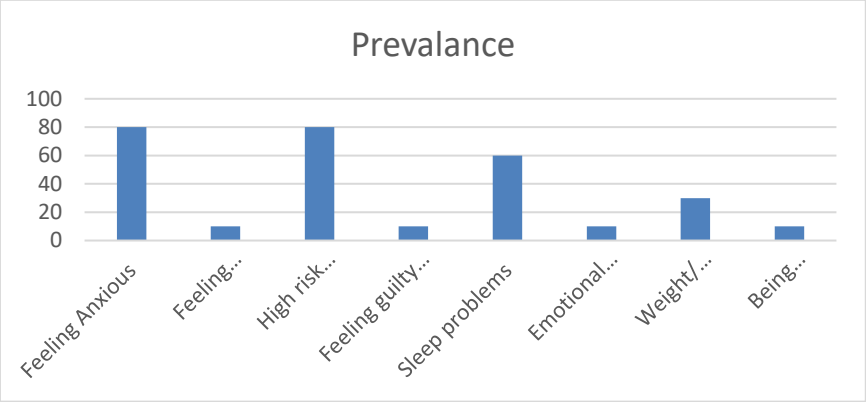

Fig.1.2 Prevalence of Present Mental disorders complaints

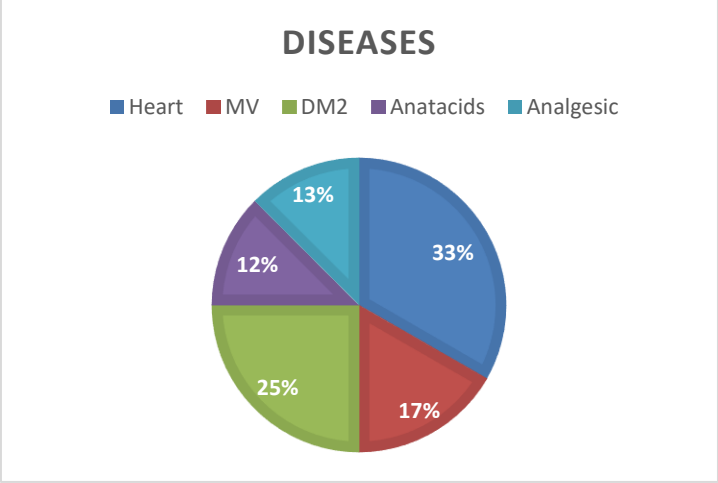

Fig. 1.3 Prevalence of Usage of long-term Diseases medications.

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THE IMPACT OF SOCIAL MEDIA ON MENTAL HEALTH

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Abstract:
Extreme social media use has the likely to increase susceptibility to the development of psychological disorders, specifically growing psychological distress and increasing depressive symptoms. With social media use on the rise among people of all ages, it is important to understand the potential adverse effects so that usage guidelines and interventions can be developed. This is a proposed study to determine what the effects of using Instagram, Facebook, whats up, snap chat will have on mental health.
Key Words: social media, mental health

Mental Health

Mental health mentions to intellectual, behavioral, and emotional well-being. It is all about how people thinking, feel, and behave. People sometimes use the term "mental health" to mean the absence of a mental disorder. Mental health can affect daily living, relationships, and physical health. Looking after mental health can preserve a person's ability to enjoy life. Doing this involves reaching a balance between life activities, responsibilities, and efforts to achieve psychosomatic flexibility.

According to WHO mental health is a state of wellbeing in which an individual realizes his / her own abilities can survive with the normal stresses of life, can work productively and is able to make a contribution to their community.

The WHO stress that mental health is "more than just the absence of mental disorders or disabilities." Peak mental health is about not only avoiding active conditions but also looking after ongoing wellness and pleasure.

Over the course of your life, if you experience mental health problems, you're thinking, mood, and behavior could be affected. Many factors contribute to mental health problems, including:

- Biological factors, such as genetic factor or brain chemistry
- Life experiences, such as disturbance or misapplication
- Family history of mental health problem

2. LITERATURE REVIEW:

Social media has become an integral part of everyday life for many individuals. Social media platforms such as Facebook, Twitter, and Instagram, Snapchat, allow users to join with friends and family, share data and experiences, and participate in online communities. While social media has many positive effects, concerns have been raised about its impact on mental health. Some studies have suggested that social media use can lead to negative mental health outcomes such as depression, anxiety, and compulsion. However, other studies have found no significant relationship between social media use and mental health outcomes. This article aims to review the current literature on the effects of social media on mental health.[1]

The addictive nature of social media activates the brain's reward center by releasing dopamine. This is a "feel-good chemical" linked to pleasurable activities. When we post something, our friends and family can "like" it, giving us a boost of dopamine. However, when we don't get that boost or approval, it can impact our sense of self and adequacy.

Filters: Social media heavily focuses on physical appearance. Many social media platforms – such as Snapchat, Instagram, and TikTok – provide users with the option to use filters on an image. Filters can be great for a laugh, but the ability to easily alter physical appearance and hide imperfections can create false illusions. Constant exposure to altered images can also lead you to feel self-conscious and dislike the way you look.

The Positive Effects:

1. Social Support- Social media has found to be useful in connecting with friends, family and people across countries. In the case of mental health, issues such as anxiety, and depression, often find it useful to connect with the right professionals who can help them or connect with people with similar experiences virtually. Research suggests that maintaining online social connections can have a positive impact on overall mental health (Kross et al., 2013)[2].

2. Awareness and Education: Social media platforms provide more valuable information about mental health. These platforms are used at various levels to provide awareness and fight against stigma linked with mental health issues.

3. Expression and Creativity: Sharing personal experiences, creativity and work is often empowering and helps to boost self-esteem. It hence has a positive impact on mental well-being. Studies have indicated that engaging in creative activities can reduce stress and improve mood (Stuckey & Nobel, 2010).

The Negative Effects:

1.Addiction and Time Consumption: Social media is designed to take the attention of users and as a result, it can lead to more time spent on screen. The outcome of increased screen time are varied; ranging from disturbance in sleep, overlooking real-life relationships leading to loneliness, affecting physical health and lifestyle and reduced self-confidence.

2.Comparison and Desire: One of the most significant negative impacts of social media is the tendency for users to engage in social assessment. There are feelings of shortage that can also cause low self-esteem, anxiety and depression. A study by Chou and Edge (2012) found that increased social comparison on Facebook led to decreased self-confidence.

3. Cyberbullying: Cyberbullying is also known as online bullying. It occurs on digital platforms such as social media. The impact of cyberbullying can top to severe consequences such as stress, depression, anxiety, low self-esteem, isolation and aloneness.

4. Fear of Missing Out (FOMO): It is mainly the pressure to check feeds as a consequence of anxiety associated with the fear of missing out on things on social media. It can prime to disturbed sleep, lower life fulfilment, decreased attitude and impatience. This affects overall mental happiness.

Ways to safely use social media

A great way to improve your relationship with social media and help decrease the negative effects is to decrease your daily screen time. Tips to decrease screen time include:

- Set time limits on social media apps within your phone settings
- Designate specific hours for social media usage
- Look through your friends and followers list and unfriend people whose accounts make you feel bad about yourself

Find fulfillment and happiness outside of social media

Prioritize in-person connections and activities to help improve your mental health. This can also lead to decreased screen time.

Find activities that fulfill you outside of your phone. Hiking, picnics with friends, painting, pickleball, reading, or walking your dog can be great ways to connect with others. Activities you enjoy can also improve your physical and mental health.

CONCLUSION / SUMMARY:

Social media has become an essential part of unremarkable life for many persons. While social media has many positive effects, concerns have been raised about its impact on mental health. The current literature suggests that the relationship between social media use and mental health outcomes is compound and multifaceted. There is a need for further research to better understand this relationship and to develop policies to promote positive mental health outcomes amongst social media users.