

6th National Conference of Institute of Pharmacy 2025

February 18-19, 2025

Conference Proceedings

NCIP-2025

Harnessing Artificial Intelligence / Machine Learning in Pharmaceutical Innovations to address

Global Health Challenges

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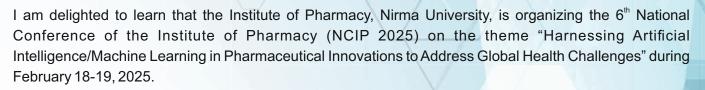
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Pharmaceutical sciences are undergoing a profound transformation, with Artificial Intelligence (AI) and Machine Learning (ML) revolutionizing drug discovery, personalized medicine, and healthcare solutions. This conference serves as a crucial platform for knowledge exchange, interdisciplinary collaboration, and scientific excellence. I am confident that the discussions and research findings shared here will pave the way for cutting-edge pharmaceutical advancements, fostering innovative solutions to address pressing global health challenges.

I extend my sincere appreciation to the Institute of Pharmacy, Nirma University, for leading this initiative and bringing together distinguished researchers, industry experts, and academicians. I wish the organizers and participants a highly successful and impactful conference that will significantly contribute to the progress of pharmaceutical sciences.

10Cm (Dr. Karsanbhai K. Patel)



Message from Vice President





I am pleased to know that the Institute of Pharmacy, Nirma University, is hosting the 6th National Conference of the Institute of Pharmacy (NCIP 2025) on the theme "Harnessing Artificial Intelligence/Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges" during February 18-19, 2025.

Al and ML hold immense potential to transform pharmaceutical research, drug discovery, and patient care. From enhancing precision medicine to streamlining healthcare accessibility, these technologies are reshaping the pharmaceutical landscape. This conference serves as an essential forum for academicians, researchers, and industry experts to exchange ground breaking ideas, foster collaboration, and drive innovation in pharmaceutical sciences.

I am confident that NCIP 2025 will ignite insightful discussions, facilitate knowledge sharing, and inspire novel approaches to address global healthcare challenges. My sincere appreciation goes to the Institute of Pharmacy, Nirma University, for spearheading this initiative. I extend my best wishes for the resounding success of this enriching and transformative conference.

Warm Wishes,

(Shri K.K. Patel)



Message from Director General





I extend my best wishes for the 6th National Conference of the Institute of Pharmacy (NCIP 2025), organized by the Institute of Pharmacy, Nirma University, from February 18-19, 2025. As a biennial event, this conference has continually set new benchmarks in pharmaceutical research and innovation.

The theme "Harnessing Artificial Intelligence/Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges" is both timely and transformative. Al and ML are revolutionizing drug discovery, personalized medicine, diagnostics, and patient care, making healthcare more efficient, precise, and accessible. This conference convenes leading researchers, industry pioneers, and experts to explore how these advanced technologies can accelerate drug development, optimize treatment strategies, and address global health crises

.The exchange of knowledge and ideas at this conference will play a pivotal role in driving breakthrough innovations, tackling chronic diseases, infectious threats, and healthcare accessibility challenges. As we advance into a new era of Al-driven pharmaceutical sciences, the significance of interdisciplinary collaboration cannot be overstated.

The Institute of Pharmacy, Nirma University, has always been at the forefront of excellence in pharmaceutical education and research, and NCIP 2025 is a testament to this unwavering commitment. I am confident that this conference will inspire groundbreaking discussions, foster innovative solutions, and motivate the next generation of researchers and practitioners.

I commend the organizing committee and participants for their dedication to advancing pharmaceutical sciences and extend my best wishes for the remarkable success of NCIP 2025.

Warm Regards

Anup Singh, Ph. D.



It is with immense pride and enthusiasm that I extend my warmest welcome to all esteemed delegates, researchers, academicians, and industry professionals attending the 6th National Conference of the Institute of Pharmacy (NCIP 2025) at Nirma University, Ahmedabad, on February 18-19, 2025. This conference serves as a premier platform for scientific exchange, collaboration and innovation in pharmaceutical sciences.

The theme of this year's conference, "Harnessing Artificial Intelligence Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges," is particularly significant in the wake of the ongoing digital revolution in healthcare. Al and ML are revolutionizing drug discovery, personalized medicine, pharmaceutical manufacturing, and healthcare accessibility, addressing critical global health challenges.

NCIP 2025 aims to bring together leading scientists, researchers, and industry pioneers to deliberate on cutting-edge AI/ML-driven pharmaceutical innovations. With dedicated sessions on predictive modeling, big data analytics, AI-enabled drug design, computational pharmacology, and regulatory perspectives, this conference will serve as a knowledge hub for interdisciplinary collaboration and translational research. We are honored to host renowned experts from academia, industry, and healthcare sectors who will share their vision, experiences, and breakthroughs in leveraging AI/ML for pharmaceutical advancements.

At the Institute of Pharmacy, Nirma University, we are dedicated to advancing pharmaceutical research by integrating cutting-edge technologies into education and innovation. This conference embodies our commitment to fostering scientific excellence and interdisciplinary collaboration.

I extend my heartfelt gratitude to the organizing committee, distinguished speakers, sponsors, and participants for their invaluable contributions in making NCIP 2025 a success. I am confident that the insightful discussions, collaborative engagements, and research presentations will inspire new ideas, foster meaningful partnerships, and propel pharmaceutical sciences towards a more advanced and patient-centric future.

Wishing you all an intellectually stimulating and enriching experience at NCIP 2025!

With Warm Regards

Prof Dr Gòpal Natsen Convener, NCIP 2025 Director, Institute of Pharmacy & Nirma University, Ahmedabad



Message from Organising Secretary





Dear Esteemed Colleagues,

It is my great honour and pleasure to welcome you to the National Conference on Harnessing AI/ML in Pharmaceutical Innovations to Address Global Health Challenges. This gathering brings together leading experts, researchers, industry professionals, and thought leaders from the fields of artificial intelligence, machine learning, and pharmaceutical sciences. Our goal is to explore innovative ways to apply these cutting-edge technologies to solve pressing global health challenges.

As the pharmaceutical industry continues to evolve, AI and ML offer transformative opportunities to enhance drug development, optimize clinical trials, personalize treatment strategies, and accelerate the discovery of life-saving therapies. The potential to leverage these technologies for more efficient and effective healthcare solutions is immense, and this conference provides a vital platform for collaboration, knowledge sharing, and networking.

We have an exciting line-up of two keynote speech, panel discussion, and plenary sessions designed to explore the latest trends, breakthroughs, and real-world applications of AI/ML in the pharmaceutical sector. The conference will also focus on the ethical, regulatory, and societal considerations that come with the integration of AI/ML in healthcare, ensuring that these innovations are harnessed for the benefit of all.

I encourage you to engage with fellow participants, ask questions, and take full advantage of the discussions and presentations that will unfold over the course of this event. Together, we can shape the future of healthcare and make significant strides in overcoming the global health challenges that affect millions of lives worldwide.

Thank you for being a part of this important conference. I look forward to a fruitful and inspiring exchange of ideas.

Warm regards,

Dr Priti J Mehta Organizing Secretary, NCIP 2025



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About Nirma University

Nirma University, Ahmedabad has been established in the year 2003 as a statutory university under the Gujarat State Act by the initiative of the Nirma Education & Research Foundation (NERF). The University is a value-driven, research-oriented and student centered not-for-profit institution. Within a short period of its existence, it has emerged as a nationally renowned higher education institution.

The University and its constituent institutes are highly ranked by different ranking agencies. The University is recognized by the University Grants Commission (UGC) under section 2(f) of the UGC Act. The achievement of 'A+' grade by NAAC by National Assessment and Accreditation Council (NAAC) in 2022 once again manifests that the University is committed to Quality Teaching-Learning and Research and is accomplishing the promise by making it the first private university of Gujarat to achieve such honour. Nirma University is a member of the Association of Indian Universities (AIU) and the Association of Commonwealth Universities (ACU). The University has SIRO (Scientific and Industrial Research Organization) recognition from DSIR, Department of Science and Technology, Government of India. Dr. Karsanbhai K. Patel, Chairman, Nirma Group of Companies and Chairman, NERF is the President of the University. Nirma University consists of Faculty of Engineering and Technology, Faculty of Management, Faculty of Pharmacy, Faculty of Science, Faculty of Doctoral Studies & Research, Faculty of Law, Faculty of Architecture and Planning, Faculty of Commerce and Department of Design. The graduate, post graduate, doctoral and post-doctoral level programmes offered by these faculties and planning are rated high by industry, business magazines and by the students.

Apart from these, the University also offers several certificate and diploma programmes. Innovation, excellence and quality are the driving forces on the campus and this has translated the vision of these institutions into a reality over a short period of time. The 125-acre sprawling green campus with serene picturesque landscape provides refreshing environment for intellectual and creative activities. Today the campus vibrates with not only world class curricular activities but also with myriad activities like international conventions symposia, conferences, student competitions, conclaves, short-term industry relevant programs, cultural activities, etc. Centre for Advanced Instrumentation (CAI) is sophisticated instrumentation facility with high-end instruments that provides a platform to students to develop their skills in handling latest instruments and is also helpful for pursuing research activities. The facility helps them to carry out cutting edge interdisciplinary research of national and international importance.





About Institute of Pharmacy

Institute of Pharmacy was established in the year 2003 under Nirma University with the aim of developing able professionals in the field of pharmaceutical sciences. In a short span of time, it has become one of the leading institutions in the country, offering pharmaceutical education at the undergraduate, postgraduate, doctoral and postdoctoral level.

Institute has been ranked 37 in India Ranking 2024 by Ministry of Human Resource Development, (MHRD), Government of India in its National Institutional Ranking Framework (NIRF) and continuously securing the top position among Pharmacy Institution in Gujarat state. The Institute offers B. Pharm, PharmD, M. Pharm, PhD programs (Full time and Part time). The Institute has adopted Outcome Based Education (OBE) to further advance the development of professional knowledge, inculcate employability skills in addition to development of character and social responsibility. To achieve the same objective, vision and mission of the institute was also defined in line with University's vision and mission. The Institute has also framed its programme educational objectives and programme outcomes. The Institute has more than 5.0 crore rupees grant from government agencies and has collaboration with various research centres and industries. The Institute houses state-of the-art instruments, like supercritical fluid extractor and chromatogram, HPTLC, HPLC, MPLC, GC, Fluorescence Spectrometer, Raman Spectrometer, UV-VIS-NIR Spectrophotometer, FTIR, DSC, ELISA, PCR, Electrophoresis, Texture Analyser, Automated Dissolution Apparatus, Extruder-Spheronizer, Multiple diffusion Assembly, High Pressure Homogenizer, Particle Size Analyser, Microwave synthesizer, Stereotaxic apparatus with Microdialysis, etc. The Institute also has the software, like Gold Suit, eCTD, Design Expert, etc.

The Institute has a two-storied animal house facility registered with the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Government of India. Besides, there is also a medicinal plant garden "Nirma Herbal Wealth", having an area of 3356.5 sqm with around 150 genera and 500 plants. Institute is equipped with Cell Culture Laboratory and Aseptic Laboratory (Class 1000) facilities for advanced research. It also has machine room with manufacturing and testing equipments.





Local Organizing Committee

List of Committees	Coordinators	Organising Committee Members	Student Volunteers
Scientific Committee	Dr. Tejal Mehta	Dr. Snehal Patel Dr. Tejas Dhameliya Mr. Mukesh Patel	Ms. Lajja Patel Ms. Shalvi Shah Ms. Anam Sami Mr. Ayush Sharma Mr. Srashti Verma Mr. Akash Kumar Mr. Parin Patel
Abstract (Oral/poster) Committee	Dr. Shital Butani	Dr. Richa Gupta Dr. Misari Patel Dr. Mohit Shah Dr. Vanrajsinh Thakor Ms. Dharti Patel Mr.Shreyas Bhuva	Ms. Charmi Dudhat Ms. Dhvani Padhiyar Ms. Mitali Paryani Mr. Atul Nagar Mr. Yash Joshi Mr. Shreyansh Chauhan Ms. Vidhi Ghataliya
Printing and Souvenir committee	Dr. Charmy Kothari	Dr. Udit Chaube Dr. Mithun Singh Rajput Ms. Hiral Patel Mr. Jignesh Patel	Ms. Krishna Bhalodi Ms. Raveena Udhani Ms. Dhruvi Solanki
Finance Committee	Dr. Jigna Shah	Dr. Bhumika Patel Ms. Telgy James Mr. Devendra Vaghela Mr. Nityanandan Mudaliar	Ms. Ruchi Yadav Ms. Shaikh Jahara Ms. Magdum Shahnaz Ms.Khushboo Faldu Ms. Ritu Soni Mr. Deepak Solanki
Registration & Correspondence	Dr. Hardik Bhat	Dr. Shital Panchal Dr. Anshu Srivastava Ms. Pooja Pandey Ms. Jigisha Patel	Mr. Rajdeep Dey Ms. Suman Shaw Ms. Samriti Rana Ms. Sakshi Saini Ms. Amanpreet Kalra Ms. Pratiksha Bang
Transport & Logistics	Dr. Jigar Shah	Mr. Shailesh Patel Mr. Chetan Patel	Mr. Vivek Mewada Mr. Pallav Gandhi Mr. Akash Kumar Mr. Abu Chippa
Accommodation & Logistics	Dr. Mayur Patel		Mr. Jai Naik Ms. Priyanka Verma Mr. Shreyansh Chauhan Mr. Dhaval Solanki

q



Local Organizing Committee

Venue management	Venue	Management
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Dr. Vivek Vyas

Catering committee Dr. Nrupesh Patel

Hospitality & Reception Dr. Niyati Acharya

Dr. Bhagwati Saxena Ms. Dharmi Patel

Mr. Hasmukh Rathod Mr. Rohit Patel

Dr. Shruti Rawal, Ms. Kalpana Patel Mr. Manmohan Sharma Ms. Bhawna Bohra Mr. Shaival Bhatt

Ms.Aabir pramanik Ms. Anvi Nikhil Ms. Aditi Gupta Ms. Preksha

Tour & Sightseeing

Dr. Dipal Gandhi

Website Management

Dr. Dhaivat Parikh

Ms. Dharmi Shah

Ms. Drashti Patel

Mr. Mohit Ghataliya

Media Publicity

Dr. Nagja Tripathi

Ms Rushil Shah Ms Manali Patel



Day 1: February 18, 2025 (Tuesday) **Venue:** Main Auditorium, M-Block, Nirma University

Time	Agenda
0900	Breakfast and Registration
1000	Inaugural Function
1030	Keynote Speaker 1 A paradigm shift in drug design and discovery using AI/ML and free energy perturbation Dr. Raghu Rangaswamy <i>Molecular Solutions Software Pvt Ltd, Bengaluru</i>
	Moderator: Prof Priti J Mehta, IPNU
1115	Coffee Break and Networking
1130	Plenary Speaker 1 Innovative drug discovery research and industry-academia collaboration in ICU Dr Sanjay Kumar <i>BITS Pilani, K K Birla Goa Campus</i>
	Moderator: Assoc Prof Hardik G Bhatt, IPNU
1200	Industry Speaker 1 Revolutionizing clinical research with AI based diagnostics Mr Ajit Deshpande Rises Analytics Solutions Pvt Ltd, Pune Moderator: Prof Jigna S Shah, IPNU
1230	Plenary Speaker 2 Research directions in Al for Healthcare Prof Ketan Kotecha Symbiosis International University, Pune
	Moderator: Assoc Prof Mayur M Patel, IPNU
1300	Lunch Break, Poster Viewing & Judging and Networking Poster Presentation – I (<i>Track:</i> PTP) Venue: Back Lawn, New Building



Day 1: February 18, 2025 (Tuesday) **Venue:** Main Auditorium, M-Block, Nirma University

genda

1400 Industry Speaker 2 Al/ML in clinical research Dr Kiran Marthak Veeda Clinical Research Pvt Ltd, Ahmedabad

Moderator: Assoc Prof Shital S Panchal, IPNU

1430 Plenary Speaker 3 Role of AI and AR in Performance Enhancement and hyper-personalisation of Cosmetic Products Prof Sanju Nanda Maharshi Dayanand University, Rohtak Moderator: Dr Niyati S Acharya, IPNU

1500 Panel Discussion

Revolutionizing Pharma with AI: Innovations Shaping the Future of Global Health

Moderator Dr Jayathirtha Gopalakrishna, Tata Consultancy Services, Bangalore

Panellist

· Dr. Raghu Rangaswamy, Molecular Solutions Software Pvt Ltd, Bengaluru

- · Prof. Sanju Nanda, Maharshi Dayanand University, Rohtak
- · Prof. Ketan Kotecha, Symbiosis International University, Pune
- · Dr. Kiran Marthak, Veeda Clinical Research Pvt Ltd, Ahmedabad
- · Dr. Sanjay Kumar, BITS Pilani, K K Birla Goa Campus

1600 Coffee Break

1615 **Parallel Oral Presentation** Venue: M-Block (*Track:* PTO & HTO) T1 (*Track:* CHO & PAO) T3 (*Track:* PLO)

Poster Viewing & Judging and Networking

Poster Presentation – II (*Track:* PAP & CHP) Venue: Back Lawn, New Building



Day 2: February 19, 2025 (Wednesday) **Venue:** Main Auditorium, M-Block, Nirma University

- Time Agenda
- 0930 Breakfast & Networking
- 1000 **Keynote Speaker 2** Artificial intelligence and machine learning- Redefining processes in the pharmaceutical industry **Prof Dr Shubhini A Saraf** National Institute of Pharmaceutical Education and Research (NIPER), Raebareli

Moderator: Prof Tejal A Mehta, IPNU

1045 Industry Speaker 3 Innovating Tomorrow: AI and Generative AI in Drug Development Dr Jayathirtha Gopalakrishna Tata Consultancy Services, Bangalore

Moderator: Dr Vivek K Vyas, IPNU

1115 Plenary Speaker 4 Strategic approach for delivery of drugs for the treatment of breast cancer Prof Dr Javed Ali School of Pharmaceutical Education & Research, Jamia Hamdard, New Delhi

Moderator: Assoc Prof Shital B Butani, IPNU

- 1145 **Coffee Break, Poster Viewing & Networki** Poster Presentation – III (*Track:* PLP & HTP) Venue: Back Lawn, New Building
- 1200 Industry Speaker 4 Digitalization & automation in pharma manufacturing industry Mr Naresh Kumar Gaur Amneal Pharmaceuticals, Ahmedabad

Moderator: Dr Dhaivat C Parikh, IPNU

1230 Plenary Speaker 5 Artificial intelligence in healthcare: Clinical applications to empower clinicians Dr Abhishek Prajapati Bhaikaka University, Anand

Moderator: Assoc Prof Snehal S Patel, IPNU



Day 2: February 19, 2025 (Wednesday) Venue: Main Auditorium, M-Block, Nirma University

Time	Agenda
1300	Lunch Break, Poster Viewing & Judging and Networking Poster Presentation – III (<i>Track:</i> PLP & HTP) Venue: Back Lawn, New Building
1330	Industry Speaker 5 Artificial intelligence in accelerating drug discovery and development Dr A. Sankaranaryanan Vivo Bio Tech. Ltd, Hyderabad
	Moderator: Dr Bhumika D Patel, IPNU
1430	Industry Speaker 6 Technological interventions in bioanalytical research Dr Shrinivas S Savale AIC-LMCP Foundation, Ahmedabad
	Moderator: Assoc Prof Charmy S Kothari, IPNU
1500	Industry Sponsored Talk A Platform for Automated qNMR Data Analysis for Development of Digital Reference Standard
	Dr Arunima Pola Analytical Research & Development, USP
1520	Plenary Speaker 6 Regulatory Bodies and Their Influence on Health Care Standards, Ethical Practices, and AI/ML Integration
	Dr Atul Nasa SGT University, Gurugram
	Moderator: Prof Tejal A Mehta, IPNU
1550	Coffee Break & Networking
1600	Valedictory Function



About NICP-2025

The National Conference of Institute of Pharmacy (NCIP), organized biennially by the Institute of Pharmacy, Nirma University (IPNU), is a prestigious event dedicated to exploring emerging trends and challenges in the pharmaceutical field. Each edition of NCIP focuses on a unique theme, encouraging innovative approaches to pressing issues in healthcare and pharmaceutical sciences. For NCIP 2025, the 6 edition, IPNU will emphasize the theme "Harnessing Artificial Intelligence (AI) and Machine Learning (ML) in Pharmaceutical Innovations to Address Global Health Challenges."

This conference aims to explore how AI and ML can drive breakthroughs in drug discovery, personalized medicine, diagnostics, and global healthcare solutions. With sessions on topics like predictive modeling, drug delivery systems, and data-driven drug design, NCIP2025 will highlight the transformative role of AI/ML in accelerating pharmaceutical advancements.

Speakers from both academic and industry backgrounds will provide insights into cutting-edge research and practical applications of AI in pharma, addressing key health challenges such as infectious diseases, chronic conditions, and global health inequalities. Panel discussions, Oral and Poster sessions will also allow participants to engage, collaborate, and share their findings on AI-enabled innovations. Through this initiative, the Institute of Pharmacy at Nirma University reaffirms its commitment to advancing pharmaceutical research and fostering a community dedicated to improving global health outcomes through technology.

Thrust Areas:

- Computer Aided Drug Design & Medicinal Chemistry
- Pharmaceutical Formulation Development, Biotechnology & Nanotechnology
- Pharmacology, Clinical Pharmacy, Pharmacovigilance & Pharmacy Practice
- Pharmaceutical Analysis, Regulatory Affairs & Quality Assurance



SCIENTIFIC SESSIONS

KEYNOTE SPEAKERS



A Paradigm Shift in Drug Design and Discovery using AI/ML and Free Energy Perturbation

Dr Raghu Rangaswamy

CEO, Molecular Solutions Software Pvt. Ltd. Bangalore.



BIOGRAPHY

Dr. Raghu Rangaswamy is the CEO of Molecular Solutions Software Pvt. Ltd., an organization providing cutting-edge software solutions across diverse domains, including Genomics, Biology R&D, Chemistry R&D, Al/ML, DMPK, ADMET, Molecular modeling, Virtual Reality, and Clinical Trials. With over 25 years of experience in bioinformatics and computational drug discovery. He played a pivotal role in the successful introduction of Molecular Operating Environment (MOE) and Schrödinger software in India, significantly advancing the adoption of computational tools in pharmaceutical research. A university topper in M.Pharm, he also holds an MBA, an Advanced Diploma in Bioinformatics, and a Ph.D. from Alagappa University. Dr. Raghu has held diverse roles throughout his illustrious career as a scientist: DSQ Biotech and Biocon Assistant Professor: PSG Medical College, Vice President (20 years): Schrödinger, where he led transformative initiatives in computational chemistry and molecular modeling. In addition to his professional accomplishments, Dr. Raghu is a sought-after speaker at national and international conferences and serves on advisory boards for leading Indian universities. He is a Governing Council Member of PSG College of Pharmacy and actively contributes to philanthropic causes.His commitment to social impact is reflected in his roles as: Trustee and Vice President of Friends of Camphill India Trust, supporting individuals with mental disabilities, Vice President of Vallal V. Dasappa Gowder Trust, dedicated to educating rural children

ABSTRACT

The traditional drug discovery process is inherently complex, time-intensive, and costly, with high attrition rates and significant challenges in bringing viable therapeutics to market. However, the emergence of Artificial Intelligence (AI) and Machine Learning (ML) has introduced a paradigm shift, accelerating innovation, efficiency, and precision in drug design and discovery. This presentation explores how AI/ML technologies are transforming critical stages of pharmaceutical research, from screening billions of compounds to optimizing ADMET and DMPK properties. Special emphasis will be placed on Generative AI and Free Energy Prediction, two ground breaking approaches reshaping structure-based drug design (SBDD). The presentation will cover

- Advanced AI/ML methodologies for rapid screening of vast chemical libraries.
- AI-driven ADMET, PK/PD property prediction to enhance drug-like characteristics.
- Application of Free Energy Perturbation (FEP) for high-precision molecular selection.
- AI/ML-assisted retrosynthetic analysis for predicting synthetic routes in pharmaceutical R&D.

• Cutting-edge innovations such as Large Language Models (LLMs), generative AI for de novo molecular design, and AI-driven atomistic simulations.

The session will feature real-world case studies demonstrating how AI/ML integration is reducing costs, enhancing efficiency, and increasing success rates across the drug discovery pipeline. Additionally, we will address future directions and emerging trends in AI/ML-driven drug discovery. This presentation aims to provide a comprehensive, forward-looking perspective on how AI, ML, and Free Energy Calculations are redefining the future of pharmaceutical innovation, paving the way for faster, more efficient, and highly targeted drug development.



Artificial intelligence and machine learning- Redefining processes in the pharmaceutical industry

Dr Shubhini A Saraf

Professor and Director, National Institute of Pharmaceutical Education and Research (NIPER), Raebareli

BIOGRAPHY

Prof. Shubhini A Saraf is working as the Director of the National Institute of Pharmaceutical Education and Research (NIPER), Raebareli at Lucknow and NIPER Hajipur, additional charge. Before joining NIPER, Raebareli she worked as a Professor in the Department of Pharmaceutical Sciences and Director (R&D) at Babasaheb Bhimrao Ambedkar University (A Central University), Lucknow. She also served in various administrative positions. She has more than 29 years of teaching and research experience. She featured in the Inspirational Women Leaders in STEM 2024 edition by CII.

Prof. Shubhini is an Illustrious alumnus awardee. She received a citation from the prestigious Department of Pharmaceutical Sciences, Dr. Harisingh Gour University, Sagar, where she pursued her B. Pharm, M. Pharm., and Ph.D.in Pharmacy. She also did the Leadership for Academicians Program (LEAP) offered at I.I.T. (B.H.U.) and Penn State University, U.S.A., in 2019, sponsored by MHRD, Government of India. She has been the Principal Investigator for Technology Policy Interventions for Health Care at the Policy Research Centre of BBAU. She actively contributed to the 5th Science Technology and Innovation Policy, 2022 and the Niti Aayog Document for sharing of common resources for pharmaceuticals, among other policies. She is a member of the DBT Steering Committee on HRD and Skill Vigyan. She is a resource person for training regarding NEP2020 sensitisation in the Malaviya Mission Teacher Training programme.

Her research interests include Nanotechnology & Drug Targeting. She has attained a significant place in developing lipid surface functionalized nano-biomaterials for therapeutic applications and elucidated the mechanistic aspect of its cellular translocation. Her focus is on establishing specific delivery of drugs through innovative nano-therapeutics by bypassing the otherwise established biological barriers. She has more than 175 peer-reviewed high-impact publications and has actively contributed to advancing green nanotechnology through lipid nano-formulations. She has authored 07 books and written 22 chapters in various texts and reference books published by national and foreign publishers. Prof. Shubhini has completed research projects worth Rs 1.5 crore and is currently setting up a Centre of Excellence in novel drug delivery systems at NIPER Raebareli, worth 100 crore. Her administrative and research work has been recognized at various National and International forums. Prof. Shubhini is a sincere administrator, academician, and researcher.

ABSTRACT

Artificial intelligence (AI) powered solutions, particularly advanced analytics, digital twins, and predictive modelling tools, are increasingly recognized for their transformative impact across various domains of pharmaceutical research. By facilitating data-driven decision-making, AI technologies have markedly streamlined product development processes, yielding substantial reductions in both costs and timelines while minimizing the incidence of errors. In the discovery phase, AI algorithms are adept at identifying potential therapeutic targets through the analysis of extensive data sets. These tools can evaluate vast libraries of biological and chemical data to recommend the most promising targets for drug development.



Furthermore, generative AI techniques can be employed to suggest optimal starting materials and methodologies for synthesizing desired molecules or lead compounds, thus accelerating the research timeline. Machine learning models can predict interactions between drugs and excipients by leveraging existing chemical libraries, thus informing formulation strategies and safety assessments. The utilization of AI extends to non-clinical assessments, where it facilitates comprehensive analyses of clinical data on a large scale, allowing for more robust insights into drug efficacy and safety profiles. Moreover, AI systems play a crucial role in processing and analyzing post-marketing surveillance data, thereby enhancing the monitoring of drug safety and adverse event reporting. Beyond drug development, AI applications are also evident in smart technologies within the pharmaceutical sector, including QR code integration for inventory management and patient engagement. Furthermore, in nanomedicine, AI-driven diagnostic evaluations and imaging technologies, alongside innovations such as implantable devices, probes, drug-device combinations, and wearable technologies, have revolutionized patient care. These advancements enable precise diagnostics, real-time monitoring, and personalized treatment approaches, ultimately enhancing clinical outcomes and patient quality of life.

PLENARY & INDUSTRY SPEAKERS



Innovative drug discovery research and industry-academia collaboration in ICU

Dr Sanjay Kumar

Professor, BITS Pilani, K K Birla Goa campus, Goa.



BIOGRAPHY

Prof Sanjay has 25 years of experience in integrated drug discovery and development, involving the creation of research strategies from target selection to IND candidate selection. He has a proven record of success across several programs. Over the last 2 decades, his teamwork and collaborative research have delivered more than 10 NCEs to IND-enabling studies for various therapeutic areas, such as oncology, inflammatory disorders, metabolic disorders, antimicrobials, and anemia. Four NCEs have advanced to clinical trial (phase I, phase II), and one has been approved for anemia. Prof Sanjay is currently a Professor in Department of chemistry at BITS Pilani, Goa Campus. He has extensive experience in both industrial and academic research. Before joining BITS Pilani, Goa Campus, he worked in NCE R & D centers of Piramal Life Sciences, Mumbai, and Zydus Life Sciences, Ahmedabad. With 20 years of industrial pharmaceutical R & D experience, he is effectively bridging gap between industry and academia. He is currently leading multiple industry-sponsored research projects at BITS Pilani, Goa Campus. Prof Sanjay obtained his Ph.D. in Organic Chemistry from Department of Chemistry, University of Allahabad, India. He has also worked as postdoctoral fellow at IISC Bangalore and Complex Carbohydrate Research Center (CCRC), University of Georgia, USA in subject areas such as bioorganic medicinal chemistry, biochemistry, molecular biology, immunology and biophysics. Prof Sanjay has over 65 publications, including 30 patents and 1 book chapter. He has delivered more than 60 lectures at various institutes, universities & colleges. For his outstanding contributions in the field of drug discovery, Sanjay has been honored with the prestigious "OPPI Scientist Award-2011" (Rs. One Lakh cash award) and "ISCB-2012 Industry Scientist Award

ABSTRACT

India, China, and the USA (ICU) are three influential world powers, and their growth is driven by their innovation and technological advancements. These three countries collectively comprise nearly 40% of the world's population and account for over 50% of global GDP, reflecting their massive economic influence on the world stage. The USA, the world's largest economy, and a world leader in innovative drug discovery research (IDDR), has a highly mature and effective collaboration model supported by times-tested policies. In contrast, China & India, the world's two most populous countries (>35% of global population) and top consumers of resources, contribute far less to IDDR compared to the USA (4.2% of global population). However, they are on rapidly growing trajectory due to their strategic investments, forward looking policies and initiatives like "Made in China" & "Make in India".

Despite this growth, current trends in IDDR are not optimal, due to the shifting priorities of its two main pillars: industry & academia. Factors such as cost sensitiveness, a focus on low- hanging fruit, short term profitability over long-term investment, and the rising cost of R & D have pushed pharmaceutical industries to prioritize generic business over innovation. This talk will highlight the need for global attention and provide tools to reverse this this decline in R & D efforts by fostering industry-academia collaborative innovation, offering incentives to encourage R & D investments, and adapting emerging technologies such as AIML, and digital tools to streamline processes, reduce time and lower costs.



Revolutionizing clinical research with AI based diagnostics

Mr Ajit Deshpande

Founder Director, Rises Analytics Solutions Pvt Ltd. Pune.



BIOGRAPHY

Ajit Deshpande is founder, CEO at rises.Al. An entrepreneur, business leader & technologist. During his saucerful career of 30 years in IT industry, Ajit managed technically complex projects, building and handling large teams, the strategy, scaling the business and industry collaborations. Before starting, Rises Analytics Solutions, he worked for HSBC, TCS, Sungard, SAS, Veritas & C-DAC. He worked in California for 5 years. Holds master degree from NITRR (National Institute of Technology Raipur Chhattisgarh). At HSBC, he was Head of Big Data Analytics Factory. With TCS multiple roles, Delivery Partner for Big Data Analytics, with a large team. He was Head of Capital Markets Innovation Lab, presales and solutioning at TCS. Under strong leadership of Ajit, Rises has developed high-tech solutions in healthcare. Technologies include Machine Learning, Deep Learning, Big Data, Blockchain and Cloud. The Clinical Decision Support Software Solution based on rises.Al platform, caters to diseases including Cancer, TB & Pulmonary Conditions, for Screening as well as Treatment Response Assessment using medical imaging and overall patient data. Ajit is speaker at various forums, the topics of interest include application of Al GenAl to Healthcare & Life Sciences and Banking & Financial Services.

ABSTRACT

Al is transforming clinical research by improving accuracy and efficiency along with flexibility. One of the key pillars of clinical research is based on clinical setup & especially on diagnostics data. The Al based solutions are making these processes more configurable and improved patient outcomes. This is disrupting the pharma & life sciences industry, right from drug discovery to clinical trials, product R&D to product launch. Multi-modal clinical data including medical imaging like X-Ray, CT, MRI, Mammography, histopathology as well as genomics is analysed and correlated to patient specific clinical data as well as treatment data. The Al algorithms help with detection, tracking the responses to the treatment and predictions. The entire Al-based systems would drastically reduce time to market and reduce the costs considerably, keeping all the scientific metrics intact as per industry standard.



Research directions in AI for Healthcare

Dr Ketan Kotecha Professor and Dean, Faculty of engineering,

Symbiosis International University, Pune.



BIOGRAPHY

Dr. Ketan Kotecha is a globally celebrated researcher and educator in artificial intelligence, deep learning, computer algorithms, and machine learning. An alumnus of IIT Bombay, he is recognized among the top 2% of scientists worldwide, a distinction awarded by Stanford University. With an illustrious career spanning over three decades, Dr. Kotecha has left an indelible mark on AI research, evidenced by 450+ Scopus indexed publications, 21 patents, and over 11,000 citations. A dedicated mentor, Dr. Kotecha has guided 25 PhD scholars, advancing AI research across diverse domains. He has grabbed more than 20+ fundings as PI amounts to over INR 15 crores from prestigious national and international organizations. He actively collaborates with top-tier global universities, including Arizona State University USA, Brunel University UK, Aston University UK, Swinburne University Australia, and the University of Milan, Italy. His expertise has earned him invitations to deliver lectures at over 25 esteemed institutions, such as Imperial College London, Cambridge University, and RUDN University in Russia. Further recognition of his contributions includes appointments as Visiting Research Professor at Aston University (UK) and Swinburne University (Australia), as well as Visiting Professor at UCSI in Malaysia. Dr. Kotecha's influence extends beyond academia. As Dean of Engineering at Nirma University for seven years and Vice-Chancellor of Gujarat's largest university for three years, he spearheaded transformative changes. Currently, as Dean of Faculty at Symbiosis International University, he has secured substantial funding for groundbreaking initiatives, including the INR 30 crore Bajaj Engineering Skills Training Centre and a cutting-edge INR 50 lakh 5G use-case lab in Al telemedicine. Recently, established Maker lab which is sponsored by Infosys at Symbiosis Institute of Technology. He also worked as CEO of Technology business incubator sponsored by DST for 3 years. He is founding Head of Symbiosis Centre for Applied Artificial Intelligence. Bridging academia and industry, Dr. Kotecha has provided consultancy for leading organizations like Philips, Avegen UK, ArcOne USA, and Dassault Systems. His visionary leadership, innovative research, and commitment to applied artificial intelligence continue to drive advancements, inspire critical thinking, and shape the global future of education and technology.

ABSTRACT

In recent years, artificial intelligence has been transforming healthcare tremendously as an assistive technology in diverse settings and application domains, from early detection, diagnosis, and prognosis of diseases to providing real-time patient care, disease progression, and readmissions in medical interventions. They analyze medical images and pathology reports faster than radiologists, surpass human capabilities, use predictive analytics and patient monitoring, and provide personalized medicine and complex disease diagnosis. They are providing tailored treatments with precision medicine and optimizing therapeutic outcomes. Al-driven drug discovery and clinical trials are widely applied in fields such as neurology and oncology, providing clinical decision support for improved and informed decision-making. Al-assisted surgery is non-invasive and improves precision and recovery time. Chatbots and virtual assistants assist in mental health and behavior analysis. IoT wearable sensors and remote monitoring systems aid in



timely care. Preventive medicine aims to identify health risks and enhance data sharing and security in healthcare with blockchain and federated learning, improving operational efficiency, quality, and accessibility globally. Multimodal AI-based technologies integrate and process high dimensional complex heterogeneous data from diverse modalities, streams E.H.R., medical images, lab reports, and wearable sensor devices, and improve decision-making by building comprehensive and holistic pictures by blending computer vision and natural language processing domains.

Al-powered deep learning-based systems are accurate and perform well but are primarily considered complex black boxes with little to no understanding of underlying working mechanics and decision-making. Explainable AI involves the essential tools and techniques for providing human-understandable rationale reasoning and interpretations of model outcomes. In mission-critical highstake applications such as healthcare, when AI is deployed for diagnosis, treatment, planning, and monitoring, it is crucial to understand how and why the system arrived at a specific outcome or decision, exploring the underlying mechanics and principles to establish trust, transparency, accountability among stakeholders. Talk will give a food for thought for research directions in these areas.



AI/ML in clinical research

Dr Kiran Marthak Director, Medical Affairs and Regulatory Affairs, Veeda C R Pvt. Ltd. Ahmedabad.



BIOGRAPHY

In the Indian Clinical Research industry, Dr. Kiran Marthak is one of pioneering leaders with a fabulous list of accomplishments and a rich experience of more than four decades. Dr. Kiran Marthak has conducted numerous Phase 1 studies including First in Human studies, and complex clinical trials and has held senior positions in several Indian and Global pharmaceutical companies such as Ciba – Geigy (Novartis), GSK, Pfizer and Ranbaxy. He has very rich experience in conducting clinical trials across several geographies including USA, UK, Europe, China, Japan and South Africa. Dr. Marthak is highly respected amongst regulatory authorities for his knowledge of international clinical research guidelines. He is one of the accredited members for GCP training by Clinical Development Services Agency (CDSA), India and contributed to the New Clinical Trial Rules implemented in March 2019. Dr. Marthak is a qualified M.D. in Internal Medicine from Grant Medical College, one of the oldest premier and pioneer medical institution run having 175 years of existence in the country. Additionally, Dr. Marthak is a Fellow of American College of Clinical Pharmacology, Fellow of Royal Society of Medicine, U.K. and Fellow of Faculty of Pharmacology, University of London. He has been awarded with 'Vishist Chikitsa Medal' in 1994, by the Association of College of Chest Physicians, India, ("ACCP") in recognition of his services and was accepted as the honorary life member of the ACCP.

ABSTRACT

The presentation titled "Harnessing AI/ML in Pharmaceutical Innovations to Address Global Health Challenges" provides a comprehensive overview of how artificial intelligence (AI) and machine learning (ML) are revolutionizing the pharmaceutical industry to tackle global health issues. It begins with an introduction to AI/ML in pharmaceuticals, highlighting their growing importance and historical adoption. The presentation outlines major global health challenges, such as infectious diseases, chronic illnesses, and access to medications. Key areas of AI/ML application in pharmaceuticals include drug discovery, development, clinical trials, manufacturing, and supply chain management. Notable examples include DeepMind's AlphaFold for protein structure prediction and IBM Watson for drug discovery. The presentation also presents case studies on AI's impact on infectious disease research, chronic disease management, and improving access to medications. Future trends discussed include quantum computing, advanced natural language processing, federated learning, AI-human collaboration, and blockchain in pharmaceutical supply chains. Ethical considerations, regulatory challenges, and recommendations for stakeholders, pharmaceutical companies, healthcare providers, policymakers, and patients are also addressed. The presentation concludes by emphasizing the transformative potential of AI/ML in addressing global health challenges and the importance of responsible and ethical AI adoption.



Role of AI and AR in Performance Enhancement and hyperpersonalisation of Cosmetic Products

Dr Sanju Nanda

Professor, Faculty of Pharmaceutical Sciences, Maharshi Dayanand University, Rohtak



BIOGRAPHY

Professor Sanju Nanda is a distinguished academician in pharmaceutical sciences with extensive experience in teaching, research, and administration. She has served as the HOD, Dean, and Chairman of the Faculty of Pharmaceutical Sciences at Maharshi Dayanand University, Rohtak. With a B. Pharm and M. Pharm from Dr. Hari Singh Gour Vishwavidyalaya, a Ph.D. from IIT Delhi, and an LLB from MDU, she has held several administrative positions, including Chief Warden and Chairman of various committees. With over 30 years of teaching and 19 years of research experience, she has guided numerous scholars and published extensively, focusing on cosmeceuticals, plant-based therapeutics, and regulatory affairs. She has authored six books, contributed to multiple book chapters, and delivered numerous keynote addresses. Recognized for her contributions, she has received several awards, including the Illustrious Alumnus Award and a mention in Stanford University's Top 2% Scientists list (2024).

ABSTRACT

Like all other technologies in the past, Artificial Intelligence along with digital technology has not only impacted the cosmetic- consumer relationship but started transforming the beauty and cosmetic industry rapidly by providing a personalized and data driven experience. The present scenario includes personalization of beauty solutions and services by virtual try ons, leading to improved accuracy of beauty solutions due to personalized recommendations for different skin and hair types which have become possible due to virtual and augmented reality features on the Apps. The data so generated is also helping improvisation and modification in formulations. It can be very confidently visualized that Artificial Intelligence has the potential to reshape the future of the beauty industry.



Innovating Tomorrow: AI and Generative AI in Drug Development

Dr Jayathirtha Gopalakrishna

Associate Vice President, Tata Consultancy Services, Bangalore.

BIOGRAPHY

Dr. Jayathirtha comes with two decades of Pharmaceutical/ Clinical Research experience. Prior joining TCS advisory group, he was in TCS's Clinical Services [BPS] Organization as Offering Lead-Clinical Data Management, where he was responsible to do necessary interventions to assess quality of delivery, mining new service lines, sharing PoVs and supported TCS's account IT teams to develop bespoke solutions for customers. Earlier to TCS, he served in leading Pharmaceutical and Clinical Research organizations such as, Covance, ICON, Ranbaxy, and Quintiles across clinical R&D including Technology Organizations such as Oracle & Veeva, in sales/solution consulting for APAC customers in Clinical & Safety Areas. Published several research/white papers in international/national scientific journals. He chaired several sessions in several Pharmaceutical/ Academic/ Pharmacovigilance symposiums/ DIA, ISCR forums on various Clinical/ Pharma R&D Topics. He has done his Ph.D. in Pharmaceutical Sciences from The MS University of Baroda. He is recipient of CSIR & Sarabhai fellowships during his academic stint.

ABSTRACT

There have been numerous challenges that entire Pharma world is facing such as cost pressure, operational inefficiencies, low pipeline of drug candidates, new disease areas to get explored and find alternatives for routine/ repetitive tasks. To address AI & Generative AI is transforming the way Pharma companies decide which disease areas to invest in. They are being used to identify targets, develop molecules, use of digital twins, streamline and accelerate end to end clinical development till regulatory submission. However, the rapid advances in generative AI capabilities have opened many opportunities, but also present significant challenges that need to be grappled with. The rapid advances in generative AI capabilities have opened many possibilities, but also present significant challenges such as data privacy, ethical concerns, high computation costs etc. which need to be grappled with. This presentation would broadly cover foundational understanding of AI & generative AI, typical use cases including those that are in production, across drug development value chain





Strategic Approach for delivery of drugs for the treatment of breast cancer

Dr Javed Ali

Professor and Head, Department of Pharmaceutics, School of Pharmaceutical Education & Research, Jamia Hamdard, New Delhi.



BIOGRAPHY

Prof. Javed Ali currently holds the position of Full Professor & Head, the Department of Pharmaceutics, School of Pharmaceutical Education and Research, and is in charge of the Intellectual Property Management Cell, Jamia Hamdard, New Delhi. He passed his B. Pharm. and M. Pharm. with distinction from Jamia Hamdard and bagged gold medals in 1994 and 1996, respectively. He earned a Ph.D. in the year 2000. He was a postdoctoral fellow at the Institute of Pharmaceutical Technology, University of Frankfurt, Germany in 2005. He has been involved in teaching, research, mentoring, advising, and administration for the past 28 years.

Prof. Ali has received numerous accolades for his exceptional teaching methods and research contributions, including:

- The Indian Pharmaceutical Association Medal (1994)
- Development Grant from the International Pharmaceutical Federation, Netherlands (2002)
- Motan Devi Dandiya Award in Pharmacy (2004) by the Prof. P. C. Dandidya Endowment trust
- Career Award for Young Teachers by the All-India Council of Technical Education (2003)
- SERC- fast track research project award for young scientists by Department of Science and Technology, Govt. of India (2003, 2006)
- APTI Young Pharmacy Teacher of the Year (2004)
- BOYSCAST Fellowship from the Department of Science and Technology, Government of India (2005)
- Prof. M.L. Khorana Memorial Prize for Best Paper in Pharmaceutics & Biopharmaceutics (2006 and 2009)
- AAiPS-IPA Distinguished Educator and Researcher Award (2007) at the Association meeting at San Diego, USA
- UGC Research Award (2014)
- INSA Teachers Award (2018)
- National Technical Teachers' Award (2022) by AICTE
- Distinguished Scientist Fellow by King Saud University, Saudi Arabia (grant of \$125,000)
- APTI- Pharmacy Teacher of the Year (2024), by Association of Pharmacy Teachers of India

Prof. Ali has received research grants from all the leading sponsoring bodies in India, such as UGC, CSIR, ICMR, SERB-DST, AICTE, and DBT including FIP (the Netherlands) and industries. He is actively involved in the field of drug delivery, which includes (1) improvement in oral bioavailability of BCS classes II and IV drugs by polymeric conjugates and nanolipid-based systems (2) nanoparticulate drug delivery systems for brain delivery for the treatment of CNS disorders, and (3) nanoparticulate systems for phytoconstituents. He is supervising scientific research at the postgraduation and doctoral levels. He has guided 96 theses of M. Pharm. and 52 theses of Ph.D. presently; 08 Ph.D. theses are under his supervision. He is an external expert for Ph.D. theses at a large number of Indian and foreign universities.

Prof. Ali has written several books and has contributed several invited book chapters on controlled and novel drug delivery systems in edited books of reputed Indian and international publishers. A widely travelled



person, he has presented his research work at more than 100 conferences held in India and abroad. He has produced over 360 manuscripts in journals of repute and five Indian patents granted/applied. He has an h-index of 85, with more than 28300 citations to his credit as per Google Scholar, and an h-index of 72 and more than 18,700 citations as per Scopus bibliometric data in Dec., 2024. He has been featured as 'World's top 2% scientists (Pharmacy and Pharmacology) from India in an independent study conducted by Stanford University, USA for a single year and career-long in 2020 onwards. He has been associated with the UGC ePathshala project of the Ministry of Education, Government of India, as a paper coordinator for two papers namely Biopharmaceutics and Pharmacokinetics and Cosmetics of Pharmaceutical Sciences.

Prof. Ali is also actively engaged in committees of various Central and State Universities, the Pharmacy Council of India, the All-India Council of Technical Education, the National Testing Agency (NTA), the National Board of Accreditation (NBA), National Assessment and Accreditation Council (NAAC) and Union & State Public service commissions, etc. He has been an executive member of the Indian Pharmaceutical Association (Delhi Branch) from 2012 to date. He has been a member of the local organizing scientific committees of conferences. He has delivered about 90 invited talks at national and international conferences in India and abroad. He is a resource person and has organized staff development/ refresher/short-term training programs from time to time. He is a member/life member of 20 Indian and international scientific organizations.

ABSTRACT

Breast cancer remains one of the leading causes of mortality among women worldwide, necessitating the exploration of innovative therapeutic strategies. Conventional chemotherapy, though widely used, is often associated with systemic toxicity, poor therapeutic outcomes, and multidrug resistance, highlighting the urgent need for alternative drug delivery approaches. Nanomedicine has emerged as a transformative tool, offering enhanced efficacy, reduced side effects, and targeted delivery mechanisms. Among the various nanocarriers, lipid-based systems such as Nanostructured Lipid Carriers (NLCs) have gained significant attention for their ability to encapsulate hydrophilic and lipophilic drugs, improving drug stability, bioavailability, and therapeutic performance. This presentation explores the strategic development of lipidic nanocarriers, focusing on NLCs, as a novel approach for breast cancer treatment. Key topics include the mechanism of cellular uptake post-oral administration, preparation methods, and an overview of research outcomes showcasing the potential of NLC formulations encapsulating various anticancer agents. Additionally, targeted delivery approaches utilizing ligands such as folic acid, transferrin, and peptides are discussed, emphasizing their role in achieving active targeting and enhanced drug accumulation at tumor sites. Overall, this presentation highlights the potential of NLCs to overcome the limitations of conventional chemotherapy, paving the way for next-generation, patient-centric treatment modalities. By integrating nanotechnology with breast cancer therapy, this approach holds promise for achieving precision medicine and improving the quality of life for breast cancer patients.



Digitalization & Automation in Pharma Manufacturing Industry

Mr Naresh Kumar Gaur Senior Vice President, Manufacturing Operations, Amneal Pharmaceuticals, Ahmedabad



BIOGRAPHY

Mr Naresh Kumar Gaur is postgraduate in pharmaceutical sciences, and has done M. Pharm in Pharmaceutics, in 1983 from Dr. H. S. Gour Vishwavidyalaya, Saugor, He has also done Diploma in Packaging from IIP in 2003. He started professional career on 3rd Jan 1984 from Ipca Labs, Ratlam, tried hands on a small venture 1986 to 96. Came back to Industry in 96 with Ipca, Micro labs, Hosur, Cadila Pharmaceuticals, Dholka, Sun Pharma Dadra, Torrent Pharma, Ahmedabad, Ranbaxy Labs Mohali & currently working with Amneal Pharmaceuticals, Ahmedabad as Sr. V.P. Mfg Ops. A hardcore orals manufacturing professional who thrives on innovation, continuous improvement & CGMP compliance. Has faced more than 25 USFDA inspections, numerous other country's regulatory inspections & customer audits. Has big outlook on digitalization & automation initiatives in manufacturing systems. Has been an practitioner of operation excellence, drive innovation and out of the box thinking in plant operations. I have been creating hard working winning teams all throughout my career, surpassing all the goals and setting up several benchmarking standards. Was instrumental in commercialization of products from various facilities be it Ipca labs or Sun Pharma, Ranbaxy or Amneal Pharmaceuticals. Dr Naresh has been a regular guest speaker in various public speaking forums and panel discussions with a variety of topics and more recently on Pharma 4.0, Digitalization & Automation in pharma manufacturing in Ahmedabad & Hyderabad.

ABSTRACT

This PPT details about the recent trends in Pharma manufacturing industry with respect to Digitalization & Automation. Explanation of various basic terms that are being used in the industry providing the clarity. A brief on the industry progression to Pharma 4.0, futuristic industry 5.0, IOT, PAT, predictive maintenance, outlines on factory of future, digital lean, AI & ML use, use cases in industry, regulatory aspects with respect to USFDA & 21 CFR, Industry Challenges with some examples.



Artificial Intelligence in Healthcare: Clinical Applications to Empower Clinicians

Dr Abhishek Prajapati

Consultant Pulmonary & Critical Care, Shree Krishna Hospital, Bhai kaka University, Anand.

BIOGRAPHY

Dr. Abhishek M. Prajapati is a distinguished Consultant in Pulmonary and Critical Care at Shree Krishna Hospital, Bhai Kaka University, Karamsad, Gujarat. Holding multiple prestigious qualifications, including an MBBS, a PhD (P), and diplomas from India and Europe in Intensive and Respiratory Care, he has significantly contributed to the field through education, research, and clinical practice. As a key academic leader, he has organized major conferences such as Gujarat Criticon and KIPS 2024, trained over 700 clinicians, and played a pivotal role in critical care education, including during the COVID-19 pandemic. With multiple publications, book chapters, and leadership roles in ISCCM, his expertise spans high-risk pulmonary interventions, sepsis management, and artificial intelligence in healthcare. His dedication to advancing medical knowledge and patient care makes him a prominent figure in the field of Pulmonary and Critical Care Medicine.

ABSTRACT

Artificial intelligence (AI) is rapidly transforming healthcare, offering clinicians powerful tools to enhance patient care. This presentation will explore the clinical applications of AI, with a focus on how it can support clinicians in their daily practice. As a Pulmonary & Critical Care physician, I will share insights into how AI is being used to improve diagnostics, treatment planning, and patient monitoring in my field.

Al algorithms can analyze vast amounts of data, including medical images, electronic health records, and genomic information, to identify patterns and insights that may not be apparent to human observers. This can lead to earlier and more accurate diagnoses, personalized treatment plans, and improved patient outcomes. For example, AI can assist in the diagnosis of lung diseases like pneumonia and predict the need for mechanical ventilation. In pulmonary and critical care medicine, AI is being used to identify patients at risk of developing acute respiratory distress syndrome (ARDS), predict essential outcomes of care, and personalize treatment plans for respiratory conditions. Al can also accelerate drug development for respiratory conditions by aiding in target identification and drug design. While AI offers tremendous potential, it is important to acknowledge its limitations. Ethical considerations, data privacy, and the need for rigorous validation are crucial factors that must be addressed. This presentation will discuss AI's benefits and challenges in healthcare, emphasizing the importance of responsible implementation and collaboration between clinicians and AI developers. Importantly, AI can help address the global health challenge of limited access to specialists, particularly in pulmonary and critical care, by providing decision support to healthcare providers in underserved areas. By integrating AI into pulmonary and critical care, we can enhance clinical decision-making, improve patient outcomes, and contribute to a more equitable and accessible healthcare system worldwide.





Artificial Intelligence in accelerating drug discovery and development

Dr A Sankaranaryanan President, Vivo Bio Tech. Ltd. Hyderabad.



BIOGRAPHY

Dr. Sankaranarayanan is a pharmacologist with extensive experience in research and teaching in pharmacology and related disciplines in the academia and the Pharma industry. He got his Ph.D. in Pharmacology from the Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh in 1975. He has been an Additional Professor of Pharmacology at the PGIMER and taught pharmacology for the MD, PhD and DM (Clinical Pharmacology) courses and guided several research theses in Pharmacology, Psychiatry, Gynaecology, Surgery, Urology etc. He has held leadership positions in the industry as the (a) Chief, Drug discovery, Torrent Research Centre, Ahmedabad, (b) Head, Discovery Biology, GVK Biosciences, Hyderabad and (c) CEO, Vivo Bio Tech Ltd, Hyderabad. He has organized research teams in these centres for innovative drug research and pre-clinical safety. He has published about 70 research papers in Pharmacology and related disciplines and has presented his research in about 80 scientific conferences including IUPHARs held in Amsterdam and Sydney. He has about 40 patents on NCEs in cardiovascular diseases and diabetes. He is a life-member of the Indian Pharmacological Society, Indian Society for Medical Statistics, Emeritus Member, ASPET and Fellow, American College of Clinical Pharmacology. He is currently the President, Vivo Bio Tech Ltd, Hyderabad.

ABSTRACT

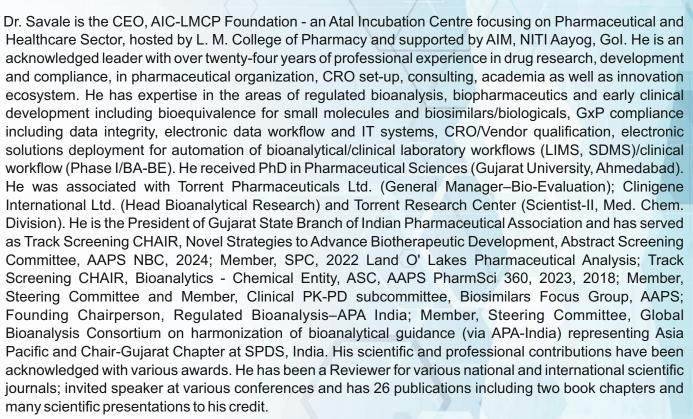
Artificial Intelligence (AI) has brought about enormous changes in almost all scientific disciplines. Its growing applications in drug research is quite impressive. Identifying and developing new medicines is a complex and time-consuming process and rely on labour intensive trial-and-error experimentation. Deep Learning and Natural Language Processing accelerate and improve these processes. AI systems take advantage of the improved efficiency and accurate analysis of 'big data' for generating causality models and identify drug targets. Deep Neural Networks (DNNs) trained on thousands of chemical structures enable rapid and efficient design of compounds with novel structures and desirable properties. Development of AI systems like AlphaFold has enabled prediction of 3D-protein structures and contribute to structure-based drug design of novel targets. Several innovative pharma companies have demonstrated their ability in accelerating their discovery pipelines using generative adversarial network (GAN)-based AI platforms. Examples of such successful innovations shall be presented in detail. All these point out that, in future, AI technology shall play a significant role in new drug discovery and development



Technological interventions in Bio-analytical Research

Dr Shrinivas S. Savale CEO, AIC-LMCP Foundation, L. M. College of Pharmacy, Ahmedabad.

BIOGRAPHY



ABSTRACT

Bioanalytical Research is evolving at a rapid pace with development of novel drug modalities. The tools and technologies deployed in bioanalysis are also emerging very fast. Further, bioanalytical support in the drug development life cycle is on the cusp of major technological interventions such as automation, AI, ML and DL which will lead to exponential improvements in the operational efficiencies, decision making and optimized efforts, translating to faster drug development. AI bears a huge potential to overcome the complexities of current approaches and support near real-me to real-me decision making by analyzing enormous data generated from variety of analytical tools. Further, it is also making big inroads in regulatory decision making. However, it is important to ponder upon 'are we there yet to embrace AI, ML and DL in development of drug and biological products?'.



"Regulatory Bodies and Their Influence on Health Care Standards, Ethical Practices, and AI/ML Integration."

Dr Atul Nasa Professor & Pro Vice-Chancellor at SGT University, Gurugram



BIOGRAPHY

Dr. Atul Nasa is currently serving as the Pro Vice-Chancellor at SGT University, Gurugram. Previously, he held the position of Head of Office/Controlling & Licensing Authority at the Drugs Control Department, Government of NCT of Delhi. He is actively involved in policy formulation as a member of various government committees. He holds a Ph.D. in Pharmaceutical Sciences from Amity University, Noida, and a Postgraduate degree in Pharmacy from Delhi University. With over 37 years of professional experience, including 30 years in drug regulation, he has expertise in enforcing the Drugs & Cosmetics Act, Drug Price Control Order, and Medical Devices Rules. Dr. Nasa has played a key role in professional organizations, serving as a member of the Pharmacy Council of India (PCI), the Drugs Consultative Committee (DCC), and several other regulatory bodies. He has represented India at national and international conferences, including FIP meetings in Dublin, Glasgow, and Abu Dhabi. His contributions to the pharmacy profession have been widely recognized. He has been honored with numerous awards, including the Best Drugs Control Officer Award (2017), KC Chatterjee Memorial Award (2015), and Regulatory Person of the Year Award (2009). He is also the President of the Indian Pharmacy Graduates' Association (IPGA) and Vice President of the All-India Drugs Control Officers' Confederation (AIDCOC). Dr. Nasa has significantly contributed to academics, research, and professional development, publishing papers at national and international levels and serving as an examiner for various universities. His leadership, regulatory expertise, and dedication to the pharmacy profession have earned him a distinguished reputation in the field.



CON N





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HTP025	Prince Tripathi	Evaluation of the efficacy and safety of a polyherbal formulation in hemorrhoid management
HTP026	Devang Kumar Prajapati	Development of Pongamia Pinnata extract loaded mouth dissolving film for the oral hygiene
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ABSTRACT- ORAL PRESENTATIONS

(Pharmaceutical Formulation, Biotechnology & Nanotechnology)





PTO001

Advanced Pegylation for the Development of Antihyperlipidemic Drug Ezetimibe

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Introduction: The aim of study was to enhance dissolution rate of drug Ezetimibe (Ez) and to prepare tablets by pegylation to achieve delivery in small intestine. Ez prevents transport of cholesterol across intestinal wall by binding to the Niemann-Pick C1-like protein on enterocyte membranes. It suffers from highly erratic low dissolution profile due to first pass effect, enterohepatic recirculation, P-gp efflux and susceptibility of degradation in stomach due to B lactam ring present in drug. Pegylation with PEG 35000 may sustain the dissolution of drug till it reaches small intestine to get absorbed completely.

Methods: PEG Conjugates were prepared with Drug:PEG in wt ratio of 1:0.25, 1:0.5, 1:0.75, 1:1 and 1:1.25 by preparing kneading mixtures using acetone as a common solvent. Purity of drug and compatibility with polymer was confirmed with the FTIR study. 1:0.5 conjugate exhibited highest dissolution rate of 99.23 % at in vitro level among all conjugates. Tablets of EZ were prepared by 1:0.5 kneading mixture equivalent to 10mg of drug using crosscarmellose sodium by direct compression technique and evaluated.

Results: FTIR analysis of drug indicated compatibility with polymer PEG35000. Formation of amorphous kneading mixture was confirmed by less intensified peaks of drug in X Ray powder diffraction study and absence of melting point peak of drug in DSC study. The prepared tablets exhibited optimum drug release characteristics of 99.23 in 120 minutes and physical characteristics of friability less than 1%, drug content 99.81+/- 0.23.

Conclusion: Pegylation of Ez could enhance the dissolution rate of the drug in the small intestine region.

Keywords: Pegylation, Ezetimibe, Kneading Mixture, Conjugate, Bioavailability.

PTO002

From Vision to Treatment: Sustained Drug Delivery via Carbon-Dots Laden Soft Contact Lenses

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Introduction: Dry eye syndrome (DES) is a prevalent condition characterized by inadequate tear production and ocular discomfort. Current treatments, such as cyclosporine eye drops, face challenges including poor bioavailability, short retention time, and adverse effects. This study explores the use of carbon dot (CD)-laden soft contact lenses (SCLs) as a novel drug delivery system to address these limitations.

Methods: CDs were synthesized via a solid-state reaction and integrated into SCLs through soaking and direct loading methods. Key physicochemical properties of CDs were characterized, and their effects on drug loading, release kinetics, and lens properties were evaluated. In vitro analyses and in vivo studies using rabbit models assessed drug release, pharmacokinetics, biocompatibility, and therapeutic efficacy.

Results: CDs significantly enhanced lens properties, including optical transmittance, water content, and wettability, facilitating improved cyclosporine uptake and sustained release. The direct-loading approach (DL-CDs-CYS-250ng) demonstrated optimal release kinetics, achieving prolonged drug delivery with superior pharmacokinetic parameters compared to eye drops. In vivo studies confirmed enhanced cyclosporine retention, reduced inflammatory interleukin-6 (IL-6) levels, and improved drug distribution in ocular tissues. Safety evaluations, including cytotoxicity and histological analyses, established biocompatibility.

Conclusion: CD-laden SCLs represent a transformative approach to ocular drug delivery, offering sustained and targeted release of cyclosporine with improved therapeutic outcomes. This platform has the potential to replace conventional eye drops, providing enhanced efficacy, reduced dosing frequency, and improved patient compliance in DES treatment.





Keywords: Carbon dots, Dry eye syndrome, Soft contact lens, Cyclosporine, In-vivo study.

PTO004

Development of Deep Eutectic Solvent-Based Topical Formulation for the Treatment of Psoriasis

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Introduction: Psoriasis is a chronic autoimmune skin disorder marked by red scaly plaques on the skin. Apremilast, a PDE-4 inhibitor, is used to treat psoriasis but being a BCS Class IV drug, it faces certain challenges such as poor solubility, permeability, and bioavailability. This study aims to enhance the solubility and permeability of Apremilast by using a new emerging class of green solvents, known as Deep Eutectic Solvents (DES). DES offer several advantages over conventional organic solvents, such as biocompatibility, biodegradability, cost-effectiveness, enhanced drug solubility, and permeability.

Methods: DES were prepared by combining a hydrogen bond donor (HBD) and a hydrogen bond acceptor (HBA) through a simple heating and stirring method, resulting in a clear liquid solution at room temperature. Various DES were prepared using HBAs like menthol, choline chloride (ChCl), and thymol, and HBDs like urea, caprylic acid, propylene glycol, and oleic acid. Apremilast was incorporated into each DES, and its solubility, viscosity, and drug diffusion were evaluated.

Results: The Menthol:Caprylic Acid DES formulation showed a 146.62-fold increase in solubility and a 5.62-fold improvement in permeability of Apremilast. The other formulations, such as ChCl:Urea (14.66-fold) and ChCl:Propylene Glycol (87.97-fold), also demonstrated significant solubility improvements.

Conclusion: This study demonstrates that DES can significantly enhance the solubility and permeability of Apremilast, with the Menthol:Caprylic Acid formulation showing the most promising results. These findings highlight the potential of DES as an efficient green solvent system for improving drug delivery in the treatment of chronic skin disorders like psoriasis.

Keywords: Psoriasis, Deep Eutectic Solvent, Apremilast, Green Solvent, Solubility Enhancement.

PTO005

Design and Development of In-Situ Stimuli Responsive Ocular Cyclosporin Formulation for Management of Dry Eye Disease

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Introduction: The purpose of this study was to develop and characterize stimuli responsive Cyclosporin formulation that is capable to increase bioavailability, sustained release of drug and manage the Dry Eye Disease.

Materials and Methods: Cyclosporin is employed as a therapeutic drug, while Capmul MCM serves as an oil, and Acconon MC8-2 acts as a surfactant, with PEG 400 serving as a cosurfactant. Additionally, Poloxamer 188 functions as an In-situ gelling polymer in this formulation. Pre formulation studies were conducted to assess the feasibility of the formulation. Optimization and characterization of the formulation were performed. Physical and chemical characteristics, including drug incorporation, transmittance, and pH compatibility, were evaluated. Key parameters such as globule size, gelation temperature, and viscosity were determined. Safety assessments,





including isotonicity, sterility, and ocular irritation, were conducted. Ex vivo experiments evaluated corneal permeation, while In-vitro studies assessed sustained drug release.

Results and Discussion: The formulation demonstrated high drug incorporation (98.28%) and excellent transmittance (99.56%). It exhibited ideal physical characteristics, including small globule size (118.1 nm) and optimal gelation temperature ($36 \pm 0.54^{\circ}$ C). The formulation displayed pseudoplastic flow behavior and suitable viscosity before and after gelation. Safety assessments confirmed ocular compatibility, meeting requirements for isotonicity, sterility, and non-irritating qualities. Ex-vivo experiments showed enhanced corneal permeation, while In-vitro studies demonstrated sustained drug release.

Conclusion: We found that the novel in-situ ocular formulation of Cyclosporin shows promise for DED treatment. Its unique characteristics and performance indicate potential for improved patient outcomes. This formulation has the potential to significantly enhance quality of life for millions affected by DED worldwide.

Keywords: Dry eye disease, Cyclosporin/Cyclosporine, In-situ gel, Ocular formulation.

PTO006

Formulation Development and Evaluation of Cocrystals Embedded Alginate Beads for Bilastine

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Introduction: This research focuses on developing and evaluating cocrystals embedded within alginate beads for delivering Bilastine, a selective H1 receptor antagonist used in allergic rhinitis treatment. Allergic rhinitis, affecting a significant portion of the global population, is characterized by nasal inflammation due to allergens. Bilastine, known for its safety profile and efficacy in improving quality of life by alleviating nasal and ocular symptoms, faces challenges such as low dissolution and poor bioavailability as a BCS Class II drug. By incorporating Bilastine into beads, advantages like reduced drug toxicity and versatility in hydrophobic drug inclusion are achieved, making it suitable for sustained release formulations to manage chronic allergic rhinitis effectively.

Methods: The cocrystals, prepared using the solvent exchange method with acetic acid, and the beads, fabricated via ionotropic gelation, underwent comprehensive evaluation including organoleptic properties, melting point, solubility, UV spectroscopy, and assessment of cocrystal and bead characteristics.

Results: By applying design of experiment in a trial of nine batches of Bilastine beads, five batches were found to be the best based on various evaluation parameters such as DSC, XRD, SEM, FTIR, UV and dissolution. An in-vitro dissolution study revealed 94.90.21% drug release in 18 hours, proving that Bilastine beads are effective for long-term drug delivery.

Conclusion: Solubility of Bilastine was increased by preparing chitosan co-crystal using chitosan as a coformer and sodium citrate as a salting out agent. In the present work, the Bilastine co-crystal beads was prepared by ionotropic gelation method using sodium alginate as a gelling agent. This bead was prepared to improve the patient compliance and the time of drug release. The prepared formulation is stable at $40 \pm 2^{\circ}$ C/75 ± 5 %. From this study, it could be concluded that formulation of Bilastine Alginate beads after enhancing its solubility is one of the novel approaches.

Keywords: Allergic rhinitis, Cocrystals, Bilastine, Alginate beads.





ABSTRACT- ORAL PRESENTATIONS

(Pharmacology, Clinical Pharmacy, Pharmacovigilance & Pharmacy Practice)





PLO001

Fostering Medication Adherence in Chronic Illness Management: The Significance of Patient Counselling and Personality Assessments

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Introduction: Medication adherence is essential for managing chronic conditions like diabetes mellitus type 2, hypertension, and tuberculosis. Non-adherence holds a significant barrier to achieving superlative health outcomes. This study aims to evaluate impact of tailored patient counselling on medication adherence and role of personality traits in influencing adherence.

Methods: A prospective interventional study with 360 patients (95% CI and including 10% dropouts) diagnosed with diabetes, hypertension, and/or pulmonary tuberculosis will be conducted. Participants will be receiving tailored counselling in addition to the ongoing treatment and care. Adherence will be measured using the Modified Morisky Medication Adherence Scale, and personality traits will be assessed using the DISC assessment tool.

Results: Structured patient counselling has demonstrated to dramatically improve drug adherence in chronic conditions such as Diabetes, Hypertension and Tuberculosis with studies estimating increases of up to 30%. Regular counselling can improve adherence by 60-85 percentage. In addition, personality qualities influence adherence; people with high degrees of conscientiousness and agreeableness are more likely to comply. A meta-analysis discovered that personality factors could account for up to 25% of the variability in adherence. Incorporating personality tests into counselling processes improve outcomes, with personalized approach resulting in 40% increased adherence when compared to typical counselling methods.

Conclusion: Combining personalized counselling with personality assessment provides a more specialized approach to improving adherence. Considering these influences could amplify the effectiveness of counselling strategies and highlight the significance of psychological factor in adherence program. Future research should investigate the long-term effects of the interventions.

Keywords: DISC-Assessment, Adherence, Counselling, MMAS, Prognosis.

PLO002

A Study on the Clinical Characteristics and Causal Factors of Headache Among Pharmacy Students: A Cross-Sectional Survey

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Introduction: Headache, or cephalgia, is pain occurring above the orbitomeatal line, in the nuchal ridge. Primary headaches arise independently, while secondary headaches result from other conditions. According to the global burden of disease (GBD), headaches are a significant global health challenge, yet studies show that most young adults (12–29 years) do not seek medical care for headaches, with 85% of males and 72% of females preferring self-management. While self-management may provide short-term relief, it often leads to underdiagnosis, inappropriate medication use, and adverse outcomes in the long term.

Methodology: A survey was conducted among 861 pharmacy students from various colleges in Anand district. Participants were enrolled after providing informed consent and were surveyed on demographics, clinical characteristics of headaches, associated symptoms, triggers, relieving factors, and medication use.

Result: The study involved 362 pharmacy students aged between 18-29, with 61.3% females and 38.7% males. Students experienced headaches that last for a few hours on a monthly basis. Headaches were typically one-sided with a sensation of pressure, moderate pain levels, and tension headaches being common. Factors like stress, unhealthy eating habits, and environmental changes triggered headaches. Participants found relief through sleep and over-the-counter medications like NSAIDS.





Conclusion: Headaches are a significant health concern for pharmacy students with low awareness of the need for medical attention. Tension-type headaches are more common, influenced by sleep disturbance, stress, noise, and smartphone usage. Many uses self-medication, potentially causing gastric irritation and liver toxicity.

Keywords: Headache, Migraine, Tension-type Headache, Clinical Characteristics, Triggering Factors, Pharmacy Students.

PLO003

Assessment of Risk Factors and Pharmacoeconomic Evaluation of Diabetic Nephropathy in Tertiary Care Hospital

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Introduction: Diabetes mellitus can lead to complications such as diabetic nephropathy (DN), a major cause of chronic kidney disease (CKD). In India, approximately 40% of diabetic patients develop DN, which is strongly associated with cardiovascular disease and high mortality. Pharmacoeconomic analyses, which assess the cost-effectiveness of treatments, are essential for determining the value of interventions like kidney replacement therapy (KRT), dialysis and kidney transplantation. The societal perspective of healthcare costs, including both direct medical costs and indirect losses, should be considered in economic evaluations to optimize resource allocation and improve healthcare outcomes.

Methodology: This was cross sectional study. The patient data were obtained from hospital record. The data collected was analysed to fulfill the objectives in order to obtain the results. Results were expressed as actual values, mean and percentage.

Results: In a study of 203 patients, the most common risk factors for diabetic nephropathy were prolonged diabetes duration (87.19%), hypertension (72.91%), and poor glycemic control (72.41%). The average direct medical costs increased with DN progression, ranging from ₹3280 for Stage-2 to ₹5436.22 for Stage-5. Patients in higher stages experienced incremental cost increases of 10.57%, 30.84%, 11.96%, and 2.31%, respectively. Direct medical costs were 477.43% higher than non-medical costs, highlighting pharmacoeconomic burden of DN.

Conclusion: Progression of CKD in diabetes patients drives substantial medical care costs. Results indicate prolonged duration of diabetes to be the highest risk factor. Economic burden increases exponentially as DN progresses from Stage3A to 3B.

Key Words: Diabetic nephropathy, Risk factors, Pharmacoeconomic burden.

PLO004

Comparative Evaluation of Probiotics in DSS-Induced Ulcerative Colitis in Mice Model

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Introduction: Inflammatory bowel disease disrupts the gut microbiota, impairs mucosal barrier function, and leads to abnormal immune responses against microbial stimulation. Probiotic therapies offer potential benefits in restoring gut homeostasis and relieving inflammation. This study focuses on a comparative evaluation of two probiotic strains, *Bacillus coagulans* and *bacillus subtilis*, in treating dextran sulfate sodium induced ulcerative colitis.

Methods: Colitis was induced in C57/BL6 mice by administering 3% dextran sulfate sodium in drinking water and probiotic treatments were given simultaneously for 7 days. Disease progression was monitored daily using the disease activity index, which included body weight, stool consistency, and hemoccult test. At the end of treatment, blood was collected to analyze C-reactive proteins. The colon was isolated and divided into fragments of proximal, mid, and distal sections for cytokine assay, oxidative parameters, and histological score respectively.





Results: Probiotic treatment with *Bacillus coagulans* and *bacillus subtilis* significantly reduced disease activity scores compared to the disease control group. Colon lengths in both the probiotic treated groups were comparable to normal controls, whereas disease control animals showed shortened colons. Cytokine assays and C- reactive protein levels revealed a significant reduction in inflammatory markers, and oxidative stress parameters in probiotic groups. Furthermore, histological analysis and zonula occluden-1 assay of the colon demonstrated improved tissue structure and tight junction adhesion in both treatment groups.

Conclusion: This study highlights the preventive and ameliorative potential of both probiotics by demonstrating anti-inflammatory and antioxidant effects, reducing disease severity, and restoring colonic integrity.

Keywords: Inflammatory bowel disease, Ulcerative colitis, Probiotics, Gut microbiota, Dextran sulfate sodium.

PLO006

Sub-acute toxicity study of *Bacillus subtilis* BSP110 (MTCC 25471) in Wistar rats

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Introduction: The current study used Wistar Rats as an animal model to conduct sub-acute (28-day repeated dose) toxicity experiments in order to investigate the safety of *Bacillus subtilis* BSP110 (MTCC- 25471). **Methods:** *Bacillus subtilis* BSP110 was administered to six groups of rats for four weeks at doses of 250 mg, 500 mg, and 1000 mg/kg/day (400 billion colony-forming units/gm) to test for repeated dosage toxicity. The control group was given only water. Rats' body weight was recorded once a week, morbidity and mortality were examined twice daily, and clinical signs and symptoms were monitored daily. Hematological, biochemical, and detailed urinalysis tests were conducted at the end of the research period. After four weeks, the rats in the four treatment groups were euthanized, while the two remaining groups were selected as recovery groups and euthanized six weeks later for histology and gross pathology.

Results: According to the study's findings, following four weeks of consistent *Bacillus subtilis* dose, there were no treatment-related changes in the parameters measured i.e. diet, clinical symptoms, body mass, hematological, urine, bioanalysis, and histopathology.

Conclusion: From this experiment, *Bacillus subtilis* BSP110 No-observed-adverse-effect level (NOAEL) was found to be 1000 mg/kg/day for four weeks based on the results obtained.

Keywords: Bacillus subtilis, NOAEL, Acute Toxicity, Subacute Toxicity, Histopathology.

PLO007

Exploring the Potential of Antimicrobial Agents by Inhibiting Proteasome as A Novel Approach for Anticancer Therapy

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Background: Proteasome inhibitors hold significant potential in cancer therapy by disrupting protein homeostasis within cancer cells. However, the clinical efficacy of FDA-approved proteasome inhibitors such as Carfilzomib, Oprozomib, and Marizomib in breast cancer, including TNBC and ER+ subtypes, remains limited. This study explores antimicrobial compounds with enhanced proteasome inhibitory activity through in-silico screening and molecular docking, aiming to identify more potent and selective candidates with favorable pharmacokinetic profiles.

Methods: A comprehensive library of 19,927 antimicrobial compounds, including antibacterial, antimalarial, and antiviral agents, was screened. The β 5 subunit of the proteasome responsible for its chymotrypsin-like activity, was prepared as the target by removing water molecules, adding polar hydrogens, and assigning charges, served as the target for molecular docking, conducted using AutoDock Vina. Docking results were





validated using reference compounds with binding affinities ranging from -7.5 to -6.6 kcal/mol. Top candidates were subjected to ADMET profiling using PreADMET and SwissADME tools to assess drug-likeness and safety.

Results: Molecular docking identified 30 lead compounds with binding affinities ranging from -10.3 to -9.0 kcal/mol, surpassing reference compounds. The top-performing candidates exhibited strong hydrogen bonding interactions and stable positioning within the active site. ADMET analysis revealed favorable pharmacokinetic properties for key compounds, including high intestinal absorption (98.48%), optimal BBB penetration (Cbrain/Cblood = 2.85), and minimal cytochrome P450 interactions. Toxicological profiling identified low AMES toxicity and non-carcinogenic potential for standout candidates such as AVSL 30-56 and AVSL 30-51. **Conclusion:** This study highlights the potential of antimicrobial compounds as proteasome inhibitors with superior efficacy and drug-like properties. The identified candidates warrant further in-vitro and in-vivo validation to establish their therapeutic potential in cancer and antimicrobial applications.

Keywords: Proteasome inhibitors, β5 subunit, Breast cancer, Molecular docking, ADME-T.

PLO008

In-Silico & In-Vitro Evaluation of Novel Tyrosine Kinase Inhibitors as a Partial Agonist of Peroxisome Proliferator-Activated Receptor-Gamma for the Treatment of Diabetes Mellitus

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Background: Insulin resistance is a major contributing factor to Type-2 Diabetes Mellitus. Peroxisome Proliferator-Activated Receptor-gamma (PPAR- γ) agonists were previously used to improve insulin sensitivity. However, due to cardiovascular and other side effects, these drugs were withdrawn from the market. Recent research has suggested that Tyrosine Kinase Inhibitors (TKIs) might interact with the PPAR- γ protein and help to regulate blood glucose levels.

Objective: This study aimed at in-silico and in-vitro analysis of the novel TKIs as partial agonists of the PPAR- γ receptor.

Methods: In this study, several novel TKIs were screened by molecular docking techniques using AutoDockTools-1.5.6. The selected ligands with the highest binding affinity were then screened through various ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) filters using SwissADME, and ProTox-II software. The top ligands with the highest binding affinity, and found to be safest were further analyzed by in-vitro assays like glucose uptake assay and ORO-staining

Results: The molecular docking study revealed that all the screened ligands were able to interact with the catalytic domain of the PPAR- γ receptor. The top five ligands were found to have a good pharmacokinetic, and drug likeliness profile. PKPS1A and PKPS4B were found to have the safest toxicity profile. The glucose uptake assay revealed that both ligands increase the uptake of glucose. Test compounds have also shown less accumulation of lipid droplets compared to PPAR- γ agonists in ORO staining.

Conclusion: These findings suggest that TKIs could be a promising partial agonist for PPAR- γ and should be explored further.

Keywords: Type 2 Diabetes Mellitus, Insulin Resistance, PPAR-γ, Tyrosine Kinase Inhibitors and 3T3-L1 adipocytes.

PLO009

Efficacy of Various Terpenoids on L-glutamate Exposed Human Neuroblastoma SH-SY5Y cells Through Mitigation of Oxidative Damage

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Introduction: Inspite of being the most common and prevalent neurological disorders, epilepsy is yet a condition without any long-term treatment due to its resistance to most of the pharmacological approaches. Epileptogenesis or repetitive episodes of seizures is considered as one of the major mechanism behind this drug-resistance. Indeed, oxidative stress, and imbalance in glutamate neurotransmission are the hallmarks for the recurrent seizures in the neurons. A well-established literature has proven the efficacy of various terpenoids as anti-oxidative and anti-inflammatory agents in various neurological conditions.

Methods: The neuroprotective potential of various terpenoids was evaluated on L-glutamate exposed SH-SY5Y cells through MTT assay, 2', 7'-dichlorodihydrofluorescein diacetate (DCFDA) assay and γ - 4', 6-diamidino-2-phenylindole (DAPI) staining.

Results: L-glutamate (*at 45mM concentration*) in SH-SY5Y cells for 24 hrs. caused cellular damage through decrease in cell viability, increase in reactive oxidative species and its related apoptotic morphological changes. **Conclusion:** The data revealed that the long-term exposure of L-glutamate causes oxidative stress and apoptosis-mediated cellular damage through cytotoxicity, formation of reactive oxidative species and nuclear condensation in SH-SY5Y cells.

Keywords: Epilepsy, L-glutamate, Terpenoids, cell viability, oxidative stress, SH-SY5Y cells.





ABSTRACT- ORAL PRESENTATIONS

(*Computer Aided Drug Design & Medicinal Chemistry***)**





CHO001

Design, Synthesis, And Biological Evaluation of Some Imidazo[1,2-A] Pyridine Derivatives as Anti-Tubercular Agents

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Introduction: Tuberculosis (TB) is a serious infectious disease caused by *Mycobacterium tuberculosis* (Mtb) that affects millions of people worldwide. The emergence of drug-resistant strains of Mtb poses a major challenge for the development of effective anti-TB drugs. Imidazo[1,2-*a*]pyridine derivatives are a class of heterocyclic compounds that have shown promising anti-TB activity.

Methods: Analogs of imidazo[1,2-a] pyridine fused ring system were designed using molecular docking on InhA, a vital enzyme involved in the cell wall synthesis of M.tb. Compounds (**5a-5o**) showing promising docking scores were synthesized.

Results: All the synthesized compounds were evaluated for their in-vitro anti-tubercular activity against H37Rv strain by Alamar Blue assay method. Most of the synthesized compounds displayed potent anti-tubercular activities. The most potent compound was further evaluated against am MDR-TB strain. To assess the stability of the protein-ligand complex of two most potent compounds, molecular dynamics simulations were conducted for duration of 100 ns.

Conclusion: All these results indicate that the synthesized compounds could prove to be potential leads for further development of new potent anti-tubercular agents.

Keywords: Imidazo[1,2-*a*] pyridine, *Mycobacterium tuberculosis*, Anti-TB, Molecular docking studies and Molecular dynamics simulations.

CHO002

Designing of Dog Bone-Shaped Novel Tacrine Analogs as Telomerase Inhibitors via 3D QSAR, Molecular Docking, Simulation, MD simulation, mm/GBSA, PCA analysis, and free energy landscape Approach

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Introduction: Telomerase, a ribonucleoprotein enzyme, is a promising therapeutic target for cancer treatment because it maintains telomere integrity and enables cancer cell immortality. This study explores the potential of novel tacrine analogs, designed in a characteristic dog-bone shape, as telomerase inhibitors.

Methods: Two series of molecules, N-benzoyl-N-(1,2,3,4-tetrahydroacridin-9-yl)benzamide and N-(1,2,3,4-tetrahydroacridin-9-yl)benzamide, were developed through 3D-QSAR modeling, molecular docking, and molecular dynamics (MD) simulations. The structural features of tacrine were optimized to enhance binding affinity while minimizing toxicity, leveraging the geometric and physicochemical requirements for telomerase inhibition.

Results: Molecular docking revealed significant binding affinities for the designed compounds compared to the standards BIBR1532 and BRACO-19, with the lead compounds HB_01 and HB_02 achieving binding energies of -10.45 and -9.86 kcal/mol, respectively. MD simulations validated the stability of protein-ligand complexes under physiological conditions, with RMSD values below 3 Å. Binding free energy analysis (MM/GBSA) supported favorable interactions, with ΔG_{bind} values of -69.79 kcal/mol for HB_01 and -56.97 kcal/mol for HB_02. Principal component and free energy landscape analyses confirmed stable conformational dynamics. Furthermore, ADMET studies predicted good drug-likeness and safety profiles for the designed compounds.





Conclusion: This comprehensive computational approach highlights the potential of these novel tacrine analogs as effective telomerase inhibitors and provides a foundation for future experimental validation to advance cancer therapeutics.

Keywords: *h*TERT, Telomerase, cancer, QSAR, MM/GBSA.

CHO003

Structural Insights of Pd-1/Pd-L1 Axis: An Insilico Approach

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Introduction: Interaction of PD-1 protein (present on immune T-cell) with its ligand PD-L1 (over-expressed on cancerous cell), makes the cancerous cell survive and thrive. The association of PD-1/PD-L1 represents a classical protein-protein interaction (PPI), where the receptor and ligand bind through a large flat surface. Blocking of PD-1/PDL-1 complex formation can restore the normal immune mechanism, thereby destroying cancerous cells. However, PD-1/PD-L1 interactions are only partially characterized. We aim to comprehend the time-dependent behavior of PD-1 upon its binding with PD-L1.

Method: The current work focuses on a molecular dynamics simulation (MDs) study of *apo* and ligand-bound PD-1.

Results: Our simulation reveals the flexible nature of PD-1, both in *apo* and bound form. Moreover, the current study also differentiates the type of strong and weak interactions that could be targeted to overcome the complex formation.

Conclusion: The current article could provide valuable structural insight about the target protein (PD-1) and its ligand (PD-L1) which could open new opportunities in developing small molecule inhibitors (SMIs) targeting either PD-1 or PD-L1.

Keywords: PD-1: Programmed cell death protein-1, PD-L1: Programmed death ligand-1, MD: Molecular dynamics simulations, PD-1/PD-L1 interactions, SMIs: Small molecule inhibitors.

CHO004

Synthesis And Modification In The Side Chain Of Tigecycline Molecule For Reduced Side Effects

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Introduction: Tigecycline is a broad-spectrum antibiotic from the glycylcycline class, primarily used to treat bacterial infections caused by multidrug-resistant organisms like MRSA (Methicillin-resistant Staphylococcus aureus) and Acinetobacter baumannii. It works by inhibiting bacterial protein synthesis, which makes it effective against both Gram-positive and Gram-negative bacteria. Tigecycline is typically used in cases where other antibiotics are ineffective or not suitable due to resistance. Administered intravenously, it is recognized for its effectiveness against a wide range of pathogens, making it an essential option for challenging infections. However, one of the common side effects of tigecycline is nausea and vomiting, which can hinder patient





compliance. These side effects are thought to result from the activation of the chemoreceptor trigger zone (CTZ) in the brain, or due to gastrointestinal irritation caused by the drug.

Method(s): To address these issues, a modified version of tigecycline was developed to reduce nausea and vomiting, while improving its bioavailability. Using Swiss ADME software, data showed that this modification enhances the drug's effectiveness while minimizing side effects. Additionally, the synthesis of the modified tigecycline molecule was designed using BIOVIA Draw, another computer-aided drug design tool.

Result: The result is a modified tigecycline molecule with better bioavailability and fewer side effects, particularly nausea and vomiting.

Conclusion: This approach not only enhances the drug's utility but also aligns with the broader goal of combating antimicrobial resistance by improving existing treatments.

Keywords: Tigecycline, antimicrobial, bioavailability, ADME.





ABSTRACT- ORAL PRESENTATIONS

(Pharmaceutical Analysis, Regulatory Affairs & QualityAssurance)





PAO002

Integrated AQbD Framework for RP-HPLC Method Validation: A Case Study on Indacaterol and Budesonide

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Introduction: This study focuses on the systematic development and validation of a reversed-phase highperformance liquid chromatography (RP-HPLC) method for the simultaneous estimation of Indacaterol and Budesonide in a synthetic mixture, using the Analytical Quality by Design (AQbD) framework. By applying principles of Quality Risk Management (QRM), critical method parameters (CMPs) were identified and optimized to ensure robust method performance.

Methods: The method development utilized a Box-Behnken Design (BBD) to optimize CMPs, including flow rate and methanol composition, and evaluated critical quality attributes (CQAs) such as resolution and the number of theoretical plates. Statistical analysis and optimization were performed using Design Expert software (Version 13.0.1.0, Stat-Ease Inc., Minneapolis, MN, USA). The optimized method employed an AGILENT (1100) HPLC system with a C18 column (4.6×250 mm, 5 µm), a mobile phase of methanol and 0.1% orthophosphoric acid (OPA) in a 60:40 (v/v) ratio, a flow rate of 0.9 mL/min, and detection at 255 nm using a photodiode array detector.

Results: Indacaterol and Budesonide were eluted at retention times of 3.5 min and 5.1 min, respectively, with excellent resolution and compliance with system suitability parameters. Linearity studies showed coefficients of determination (R²) of 0.9995 and 0.9994 for Indacaterol ($3.75-18.75 \mu g/mL$) and Budesonide ($10-50 \mu g/mL$), respectively. Accuracy studies demonstrated % recoveries ranging from 98.25% to 102%. All validation parameters, including precision, robustness, and assay, were within ICH Q2 (R2) acceptance criteria. The method was successfully applied to the analysis of synthetic mixture, with assay values for both analytes ranging between 98% and 102%.

Conclusion: This study highlights the successful application of AQbD principles and statistical tools in developing and validating a robust RP-HPLC method for Indacaterol and Budesonide. The optimized method demonstrated high reliability, precision, and compliance with regulatory guidelines, making it suitable for routine analysis in pharmaceutical formulations.

Key Words: Indacaterol, Budesonide, Box behnken.

PAO003

Next Generation Point-of-Care Assay: A Novel Iron Diagnostic Approach using Smartphone

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Introduction: Iron (Fe) is essential for oxygen transport, energy production, and immune function. Abnormal levels can indicate conditions such as anemia, hemochromatosis, or chronic inflammation. Accurate Fe measurement is crucial for diagnosis and management. This innovative approach provides a low-cost, portable, and rapid detection method, ideal for real-time point-of-care diagnostics, eliminating the need for complex instruments.

Method: Polymer-based devices were fabricated using a tube containing a Fe-sensitive dye embedded within a polymer matrix. The dye was designed to operate optimally in an acidic pH environment, ensuring distinct and measurable colorimetric changes upon interaction with Fe ions. The detection zone of the device was calibrated to require a maximum liquid volume of 50 μ L, ensuring precise and reproducible measurements. RGB analysis was performed by introducing Fe standard solutions. The resultant colour changes were captured under controlled lighting conditions using a digital imaging system. Images were analysed using colour quantification by ImageJ software to extract RGB values, which were then correlated to calcium concentrations using a





calibration curve. Optimal conditions for dye performance, including pH, dye concentration, and polymer composition, were identified to enhance sensitivity and reproducibility.

Results: Under optimal conditions, the polymer-based device exhibited a Qualitative, semi-quantitative and quantitative linear response across the calcium concentration range of 25 μ g/mL to 75 μ g/mL, with a detection limit of 20 μ g/mL. The RGB values extracted from the detection zone showed a strong correlation with calcium concentrations, as demonstrated by a regression coefficient value of R² = 0.99. The device's performance was validated by comparing the results with a commercial kit (E-lab Bioscience), showing excellent agreement and reliability. The system demonstrated high reproducibility, with minimal variability observed across repeated measurements. The method effectively quantified calcium concentrations with precision, supporting its potential as a viable alternative to existing laboratory methods.

Conclusion: Developed device follows every aspect WHO guideline for point of care device as REASSURED. The combination of simplicity, speed, and suitability for on-site detection makes this method a promising tool for efficient and accessible Fe detection in various healthcare settings.

Keywords: Iron, Micronutrient, Diagnostic, POC.

PAO004

Accessing the Utility of Circular Dichroism, FTIR and NIR Spectroscopy in Monoclonal Antibody Comparitibility Studies

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Introduction: Protein characterization is a necessary activity during development, technical transfers, and licensure. One important aspect of protein characterization is higher order structure assessment, which can be accomplished in a variety of ways. Circular Dichroism (CD) and Fourier transform infrared (FTIR) spectroscopy provide global higher order structure and are routinely used to measure the overall structure for product characterization. Also nowadays NIR is used orthogonally with FTIR in Process development and is gaining quite popularity.

Methods: We use a monoclonal antibody (mAb) to explore the usefulness of CD and FTIR and NIR. A panel of degraded samples of a mAb was generated; their higher order structure evaluated using CD and FTIR and NIR.

Results: The higher order structure evaluated using CD, FTIR and NIR was found to be largely unchanged for control samples. However, the degraded samples were found to have measurable changes.

Conclusion: All the three CD, FTIR and NIR can elucidate the overall structure of the protein in a sample with adequate accuracy and relatively efficiently compared with various other higher order structure techniques. This characterization is essential information because the protein's overall structure can correlate with its function. In addition, higher order structure data has been used to make process development decisions.

Key Words: Circular Dichroism, FTIR, NIR, Higher order Structure, Characterization.





ABSTRACT- ORAL PRESENTATIONS

(Herbal Technology & Natural Products)





HTO001

Method Development and Validation of Multi Elements Present in *Abhrak Bhasma* by Using Inductive Coupled Plasma Optical Emission Spectroscopy (ICP-OES)

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Introduction: The importance and demand of Ayurveda has skyrocketed since COVID-19. This makes the standardization of Ayurvedic formulations is the most necessary for global acceptance. Objective of the present study is to develop and validate the method for the simultaneous estimation of multi-elements in Abhrak Bhasma using ICP-OES. Abharak Bhasma is an Ayurvedic preparation containing multi-minerals like iron, calcium, magnesium, potassium etc. which is mainly used for anaemia, asthma, diabetes etc.

Method: Standard preparation: combined standard solutions were prepared using purified water as diluent (50ppb-5ppm) Sample preparation: 0.5g sample was digested using 10ml of 0.1 N HCl with 5ml of nitric acid on hot-plate at 100°C for 1 hour and allowed it to cool and diluted with purified water up-to 50 ml. (for Cobalt, chromium & Phosphorous) Further stock solution diluted 100 μ l to 50ml using purified water. (For iron) 0.5 ml stock solution was diluted to 50 ml using purified water. (For Calcium, Magnesium, Aluminium, Copper, Manganese, Potassium & Zinc). Linearity, method precision, intermediate precision, robustness, accuracy parameters were performed.

Results and Conclusion: linear regression was achieved by plotting concentration versus intensity of the element without any interference of other elements. Method precision, intermediate precision, accuracy, Robustness parameters were performed and found within the limit. Based on validated parameters, it was found that calcium 3.59 %w/w, magnesium 3.92%w/w, potassium 1.59 %w/w, manganese 0.12 %w/w, iron 10.98 %w/w, chromium 0.03%w/w, zinc 0.16 %w/w, aluminum 5.78 %w/w, phosphorus 0.13 %w/w, cobalt 0.22 %w/w and copper 0.45%w/w were present.

Keywords: Abhrak Bhasma, ICPOES, method validation, Ayurveda.

HTO002

Formulation and Evaluation of Polyherbal Cream Containing *Albizia Lebbeck, Glycyrrhiza Glabra* L and *Trigonella Foenum Graecum* Exctracts for Atopic Dermatitis [Eczema]

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Introduction: Atopic dermatitis is a complex illness characterized by immune response dysregulation, which results in changes to skin barrier integrity and cutaneous hyper reactivity. This formulation consists of ethanolic extract of leaves and bark of *Albizia lebbeck* [Sirish], aqueous extract of roots of *Glycyrrhiza glabra* and methanolic extract of seeds of *Trigonella foenum graecum* as the active pharmaceutical ingredients. The leaves and bark of *Albizia lebbeck* have significant immunomodulatory and anti-inflammatory properties respectively. Glycyrrhizin from *Glycyrrhiza glabra* roots is a calceneurin inhibitor that works as an immunosuppressant, whereas l-histidine from *Trigonella foenum graecum* is required for the formation of filaggrin, which is responsible for locking moisture in the skin. Phytoconstituents, such as polyphenols, resveratrol, catechin, quercetin, and flavonoids, which have been revealed as having an immense immunomodulatory effect, have been detected in the bark and leaves of *Albizia lebbeck* in ideal amounts whereas the flavanol glycosides in the bark have shown anti-inflammatory effect. An optimum immunosuppressant activity is necessary as there is an increase in the amount of IL-33, IL-25 and TSLP in Atopic Dermatitis.

Methods: The extracts of standardized APIs were formulated into a polyherbal cream which was prepared by fusion method.

Results: The cream passed all necessary evaluation parameters like spreadability, grittiness, pH. and patch test and was tested out for stability testing.





Conclusion: Not only does this cream have a high potential for reducing the systemic side effects of topical corticosteroids and tacrolimus ointment, but it is also less expensive than phototherapy and has a better penetration power than available marketed formulations like topical corticosteroids and tacrolimus ointment.

Keywords: Atopic dermatitis, immunomodulator, anti-inflammatory, filaggrin.





ABSTRACT- POSTER PRESENTATIONS

(Pharmaceutical Formulation, Biotechnology & Nanotechnology)





PTP001

Stimuli sensitive chitosan nanoparticles laden contact lenses for managing glaucoma

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Introduction: Glaucoma is a chronic eye disease and leading cause of blindness globally. is often managed with eye drop solutions, which suffer from poor bioavailability due to rapid elimination from the ocular surface. Drug-eluting contact lenses offer an alternative, but challenges such as drug leaching during manufacture, storage, and sterilization limit their commercial application. To address these issues, stimuli-sensitive chitosan nanoparticles (Cht-NPs) were developed for controlled ocular drug delivery.

Methods: Nanoparticles were prepared by ionic gelation and characterized by TEM, X-ray diffraction, DSC, and FTIR. The nanoparticle laden contact lenses were fabricated using a free radical polymerization method and evaluated using in vitro and in vivo methods.

Results: In the drug release study, conventional-soaked contact lenses (SM-TM-CL) showed high-burst release, while with direct drug-only laden contact lenses (DL-TM-CL) the drug was lost during extraction and sterilization, as well as having poor swelling and optical properties. The nanoparticle-laden contact lenses (TM-Cht-NPs) showed controlled release of timolol for 120 h in the presence of lysozyme, with acceptable opto-physical properties. In the shelf-life study, the TM-Cht-NPs contact lenses showed no leaching or alteration in the drug release pattern. In vivo studies, revealed high drug concentrations in rabbit tear fluid and helped maintain a low intraocular pressure for 120 h.

Conclusion: In conclusion, the chitosan nanoparticle-laden contact lenses demonstrated the potential application to treat glaucoma with acceptable opto-physical properties and addressed the issues of drug-leaching during sterilization and storage.

Keywords: Chitosan nanoparticles, Timolol maleate, Contact lens, Glaucoma, Controlled drug delivery.

PTP002

Development of Lidocaine Hydrochloride Hard Candy Lozenges for the Treatment of Ventricular Arrhythmia

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Introduction: Lidocaine hydrochloride is a local anesthetic and class 1b antiarrhythmic drug. It is used intravenously for the treatment of ventricular arrhythmia. however intravenous route is an invasive route of administration which results in poor patient compliance. The oral bioavailability of lidocaine hydrochloride is 35 % due to extensive hepatic first-pass metabolism. The aim of the present work was to develop lidocaine hydrochloride hard candy lozenges.

Method: The lozenges were prepared by heating and congealing method. The lozenges were prepared using sucrose, isomalt, hydroxy propyl methyl cellulose E5, polyethylene glycol 4000 and citric acid. Central composite design was used as an optimization design. The independent variables used in the design were amount of sucrose (X_1) and amount of hydroxy propyl methyl cellulose E5 (X_2) and the dependent variable was *in vitro* drug release (Y_1) . Lozenges were evaluated for appearances, weight variation, diameter, thickness, hardness, friability, *in vitro* mouth dissolving time, assay and *in vitro* drug release study.

Results and Conclusion: The optimized formulation showed, appearance of gold yellow color heart shaped and without any physical defect. Thickness and diameter of lozenges were found to be 0.61 ± 0.06 cm and 2.13 ± 0.06 cm respectively. Specific value of hardness was not found as the lozenges did not break upon applying force. Friability of lozenges was found to be 0% which passes the test as per Pharmacopeial specification. As per results of assay, percentage of lidocaine hydrochloride in lozenges was found to be 98.73% ± 1.56 %. *In vitro* release at 5 minutes from lozenges was found to be 97.31 ± 1.25 %. The predicted response of the optimized batch was in good correlation with the observed response which indicated the reliability of the model.





QRS interval of ECG pattern in rats of control group was noted down. Arrhythmia was induced in the rats of treatment group and anti-arrhythmic effect of the formulation was confirmed by normalization of QRS interval in ECG pattern. The current research can be expanded for an extensive in vivo study, a stability study, and a feasibility for large-scale production.

Keywords: Lozenges, lidocaine hydrochloride, ventricular arrhythmia, heating and congealing, central composite design.

PTP003

Electrospun Nanofiber Dressings Loaded with Tofacitinib for Effective Management of Atopic Dermatitis

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Introduction: Atopic dermatitis (AD) is a common chronic skin inflammatory disorder also known as atopic eczema. It happens when skin's barrier function is damaged. AD is a chronic and heterogeneous condition and does not have any fixed set of clinical symptoms. The severity of condition depends on the type of diet, environmental and genetic factors. Conventional treatments include use of topical steroids, immunomodulators and calcineurin inhibitors, but have several challenges such as side effects and poor drug delivery.

Method: In order to overcome the side effects of conventional products, nanofiber mats are produced using electrospinning process. Biocompatible and biodegradable polymer-based nanofiber mats were engineered to encapsulate tofacitinib. Various process parameters such as concentration of polymers, viscosity of solution, needle tip-to-collector distance, type of collector, voltage power supply etc. were optimized to obtain the optimized batch.

Results: Electrospun nanofiber mats of polyvinyl alcohol loaded with tofacitinib were successfully developed presenting drug content of 93%. The viscosity of polymer solution before electrospinning was 2828 mPa·s. Nanofiber mats were evaluated for physicochemical parameters such as ATR-FTIR, thickness, pH, folding endurance etc. Thickness and folding endurance of nanofiber mats was 0.076 mm and 304 folds, respectively. These parameters make the nanofiber mats durable and ideal candidate for sustained drug delivery.

Conclusion: Nanofibers with their structural and functional properties make them a promising approach towards sustained delivery of actives in the management of AD. In the given research, an attempt was made to develop tofacitinib-loaded electrospun nanofiber dressings for the management of AD.

Keywords: Atopic dermatitis, Nanofibers, JAK inhibitor, Electrospinning, Tofacitinib.

PTP004

Capsule Endoscopy: A Breakthrough in Gastrointestinal Diagnostic

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Introduction: A Study Shows that approximately 1.4 million individuals in India suffer from Gastrointestinal (GI) diseases. Traditional Endoscopy, the technology currently being used for diagnostic purposes, while effective, has limitations such as its invasive nature, restricted reach in convoluted parts of the small intestine, High dependency on the operator, and certain high risks for patients. Here, the need for betterment is felt, which is provided by Capsule Endoscopy.

Method: Capsule Endoscopy involves a device that is composed of Biocompatible materials that are safe for the body. The Capsule is initially stored in a case equipped with a magnet that prevents its activation. Upon removal from the case, the LED begins to flash, and the capsule commences image capture. The Capsule is subsequently swallowed orally. The Capsule contains a power source, a light source and a camera which collectively enables its operation for 8-12 hours, provide illumination for the area being examined and capture images, respectively.





As the capsule progress through the digestive tract, it captures 2-6 images per second. Once the battery is depleted, the capsule ceases to operate. Typically, Within, 24-72 hours, the capsule is exerted through Rectum route.

Result: Aids in the diagnosis of conditions such as Crohn's disease, Ulcerative colitis, celiac disease, GI bleeding, colon polyps, colon and rectal cancer, and small bowel tumors.

Conclusion: This discussion has examined the methodology, research findings, benefits, and conclusions related to Capsule Endoscopy.

Keywords: Diagnosis, Capsule Endoscopy, GI Disease, GI Endoscopy, GI tract.

PTP005

Electroceutical: A brief overview of Bioelectrical CNS Implant for Parkinson's Disease

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Introduction: Bioelectronic medicines, or electroceuticals, represent an innovative intersection of molecular medicine, neuroscience, and engineering, targeting neurological disorders such as Parkinson's disease (PD). It aims to target neural pathway of cranial nerve and help in treatment with aid of electrical impulses.

Methodology: These devices leverage electrical impulses to modulate specific neural circuits, offering a therapeutic alternative to pharmacological interventions. Parkinson's, characterized by motor dysfunction and dopamine deficits, has seen promising advancements through deep brain stimulation (DBS), a form of electroceutical therapy. DBS delivers targeted electrical stimulation to subthalamic nuclei or the globus pallidus, alleviating tremors and rigidity while improving motor control. Recent technological advances, including miniaturized, biocompatible devices with enhanced signal precision, have broadened the application spectrum of electroceuticals. By engaging the vagus nerve and central neural circuits, these devices can restore physiological functions with fewer systemic side effects.

Result: The data from multiple sources helps to conclude that the method of bioelectric implantation has opened a new way to control and cure disease which are chronic in state. It enhances the potential to stimulate memory, eyesight and even strengthen gait. It is also regarded as a safer alternative to traditional drug method as it directly involves electrical impulses and action potential

Conclusion: The integration of real-time monitoring and adaptive modulation further enhances treatment efficacy. As bioelectronic medicine progresses, its potential to transform Parkinson's disease management underscores the importance of continued interdisciplinary research and clinical trials.

Keywords: Electroceutical, Parkinson's Disease, Implant.

PTP006

A Review of Alginate-Based Hydrogels: Innovations in Cancer Treatment, Drug Delivery, and 3D Bioprinting Applications

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Introduction: Alginate-based hydrogels, derived from natural polysaccharides, have gained attention for their biocompatibility, biodegradability, and structural similarity to natural tissues. Their hydrophilic, three-dimensional (3D) networks retain high water content, making them ideal for biomedical applications such as drug delivery, tissue engineering, and wound healing. Recent advancements in crosslinking and functionalization have enhanced their mechanical and biological properties, expanding their therapeutic potential.





Methods: Various fabrication techniques, including ionic crosslinking, covalent bonding, and physical gelation, have been used to optimize alginate hydrogels. Thermally responsive hydrogels (TRGs) incorporating photothermal therapy (PTT) and immunotherapy have been developed for targeted cancer treatment. Additionally, 3D bioprinting has enabled the precise design of alginate scaffolds with tunable properties for personalized medicine applications.

Results: Preclinical studies have demonstrated that alginate hydrogels effectively deliver chemotherapeutic and immunotherapeutic agents, enhancing tumor targeting while minimizing toxicity. TRGs combining PTT with immunotherapy have successfully eliminated primary tumors and reduced metastasis. Moreover, 3D bioprinted alginate scaffolds have shown promise in tissue regeneration and controlled drug release, with nanoparticles further enhancing their functionality.

Conclusion: Alginate hydrogels offer a versatile platform for biomedical applications, particularly in cancer therapy. Their ability to support targeted drug delivery, combined with advancements in fabrication and 3D bioprinting, strengthens their potential for clinical translation. Ongoing research will be crucial in optimizing these hydrogels for personalized healthcare and regenerative medicine.

Keywords: Alginate Hydrogels, Cancer Immunotherapy, Drug Delivery Systems, Photothermal Therapy, 3D Bioprinting.

PTP007

A Review: Development of Lotus Leaf-Based Silver Nanoparticle Dermal Patches for Enhanced Wound Healing

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Introduction: Deep wound healing remains a critical challenge in medical science due to infections and delayed tissue regeneration. Lotus (*Lotus lalambensis*) bioactive, rich in flavonoids, alkaloids, and phenolics, synergize with silver nanoparticles (AgNPs) to enhance antimicrobial and anti-inflammatory effects. This study explores the potential of lotus leaf- derived AgNPs (L-AgNPs) in forming biodegradable, biocompatible dermal patches for wound healing.

Methods: Hydrogel-Based Patches are formulated by extracting lotus bioactives and synthesizing AgNPs through modified green methods. Encapsulating nanoparticles within chitosan-alginate hydrogels for sustained release and enhanced penetration. Incorporating adhesives to improve patch adherence, with zeta potential analysis for nanoparticle stability.

Results: Encapsulating L-AgNPs in hydrogels provides a controlled release system that enhances skin penetration. Hydrogel patches demonstrated effective adhesion, sustained antimicrobial activity, and prolonged wound site contact. Additionally, the bioactives from lotus and AgNPs synergistically inhibited bacterial growth and promoted tissue regeneration.

Conclusion: Lotus-based AgNP formulations hydrogel patches, could revolutionize wound care by providing a safe, effective, and eco-friendly alternative to conventional treatments.

Keywords: Lotus leaf, Silver nanoparticles, Hydrogels, Wound healing.

PTP008

State-of-art Nano-Systems for Amelioration of Candidiasis

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Introduction-Candida species, especially C. albicans, are opportunistic fungal pathogens responsible for causing candidiasis, a major global health issue that affects millions of people. Conventional antifungal treatments like azoles and echinocandins come with drawbacks such as drug resistance, toxicity, and limited





effectiveness against Candida biofilms. This review highlights how nanotechnology can help overcome these obstacles.

Method- NanoSystems offer a promising platform for improved drug delivery. These systems include metallic nanoparticles (MNPs), polymeric nanoparticles (PNPs), and Lipid nanoparticles (LNPs). Among these, polymeric nanoparticles stand out due to their flexible design, biocompatibility, and customizable drug release profiles.

Results-The review covers the benefits of polymeric nanoparticles, such as enhanced drug solubility, stability, and targeted delivery to fungal cells while reducing systemic toxicity. The review compiles the outcomes of significant research that have been explored so far for the treatment of Candidiasis using polymeric NanoSystems.

Conclusion-The review addresses the current state and limitations of NanoSystems and discusses future prospects. It emphasizes the need for further research to tackle challenges like optimizing nanoparticle design and ensuring biocompatibility and safety.

Keywords: Anti-fungal Nanoformulations, biodegradable, polymeric nanoparticles, targeted delivery.

PTP009

Topical Nanoantibiotics: Bridging Nanotechnology and Medicine to Combat Antimicrobial Resistance

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Introduction: The escalating prevalence of antibiotic-resistant bacterial infections poses a significant global health challenge, necessitating innovative therapeutic strategies. Traditional antibiotics are becoming less effective due to the rapid evolution of resistant strains among various bacterial groups, including *staphylococci*, *enterococci* etc. This leads to treatment failures and prolonged infections. Topical nanoantibiotics have emerged as a promising solution to address this issue. These nanoscale formulations enhance drug delivery and efficacy, offering potential to overcome microbial resistance mechanisms.

Methods: Various nanocarriers have been developed for topical application, including lipid-based nanocarriers, metallic nanoparticles, mesoporous silica nanoparticles, nanostructured lipid carriers, nanobiotics, and nanocrystals. These systems can disrupt bacterial biofilms, enhance drug penetration, and circumvent traditional resistance mechanisms, also precise targeting and interaction with microbial cells, potentially overcoming resistance mechanisms.

Results: Studies have demonstrated that these topical nanoformulations can effectively combat resistant bacteria. For example, mesoporous silica nanoparticles carrying multiple antibiotics have shown enhanced synergistic effects and improved biocompatibility, effectively disrupted biofilms and reducing bacterial viability. Nanostructured lipid carriers have been utilized to improve topical administration of natural substances with anti-inflammatory properties, enhancing drug penetration and efficacy. Silver, gold, and zinc oxide nanoparticles exhibit inherent antimicrobial properties. They can disrupt bacterial cell walls, Additionally, nanobiotics have been explored as a promising alternative strategy for overcoming antibacterial resistance, offering new avenues for treatment.

Conclusion: Topical nanoantibiotics represent an emerging and effective approach to combat antibioticresistant bacterial infections. By leveraging various nanocarriers, these formulations can enhance topical drug delivery, disrupt biofilms, and overcome traditional resistance mechanisms, offering a promising solution to this pressing global health challenge.

Keywords: Nanoantibiotics, Nanocarriers, Resistance, Biofilms, Topical drug delivery.

PTP010

Aspasomes as Novel Nanocarriers for Antioxidant Therapy: Improving Skin Penetration and Targeted Delivery for Skin





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Introduction: Aspasomes, composed of ascorbyl palmitate, cholesterol, and negatively charged lipid, have emerged as advanced nanocarriers for antioxidant therapy in topical drug delivery. Their unique structural properties enhance antioxidant stability and improve skin permeation. Aspasomes are effective in penetrating the skin barrier and delivering antioxidants to deeper layers, ensuring targeted delivery with prolonged therapeutic action and minimal systemic side effects.

Methods: Aspasomes are typically prepared using techniques such as thin-film hydration, solvent evaporation, reverse phase evaporation, or sonication. These methods ensure the formation of stable vesicles with high encapsulation efficiency, suitable for hydrophilic and lipophilic antioxidants. The choice of preparation method influences vesicle size, stability, and drug release profiles. Aspasomes were characterized using dynamic light scattering particle size and zeta potential analysis, transmission electron microscopy for morphology, and encapsulation efficiency.

Results: Aspasomes enhance the penetration of ascorbyl palmitate into deeper skin layers due to their nanometric size and lipid composition, ensuring targeted delivery. Ascorbyl palmitate acts as an antioxidant by neutralizing free radicals, preventing oxidative damage to skin cells, and promoting collagen synthesis for healthier, more resilient skin, also it effectively treats hyperpigmentation, skin aging, acne, and inflammation caused by oxidative stress, making aspasomes suitable for both cosmetic and therapeutic applications.

Conclusion: Aspasomes are a promising approach for antioxidant therapy in topical drug delivery. Their structure improves antioxidant stability, skin penetration, and targeted delivery with minimal side effects. Aspasomes show great potential in treating oxidative stress-related skin issues, offering an innovative platform for advancing skin health treatments.

Keywords: Aspasomes, Ascorbyl palmitate, Antioxidant, Topical drug delivery.

PTP011

Characterization of Nanovesicular Carriers of Sertaconazole in Film-forming systems to optimize Topical Antifungal Therapy

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Introduction: Sertaconazole is an effective antifungal agent in the treatment of topical fungal infections, but demonstrates a limited aqueous solubility thereby affecting absorption which brings us to the primary objective of this study to enhance the absorption. The subsequent objective was to improve the residual time for topical delivery of sertaconazole and improve patient compliance. Sertacoazole was incorporated into nano-vesicle, called spanlastics to improve permeability and subsequently incorporated into films for topical delivery. The spanlastics are elastic in nature by which they exhibit enhanced skin penetration resulting in increased absorption.

Methods: The sertacoazole spanlastics were formulated using the ethanol-injection approach, using edge activator (Tweens), non-ionic surfactant (Spans) which were optimised based on drug entrapment efficiency. Sertaconazole spanlastics were incorporated into *in-situ* film formulations developed using polymers HPMC-K100 and HPMC-E50. The formulations were evaluated for physical, rheological and release properties.

Results: Morphological characterizations (SEM and TEM) revealed that the observed particles were spherical and non-aggregated in nature. The films formulations exhibited smooth textured surface without any surface cracking or inconsistency. No residual, intact crystals of sertaconazole, particulate aggregation, and/or adsorption onto the film surfaces were observed. Furthermoreth e antifungal activity studies demonstrated that the *in-situ* films formulations incorporated with sertaconazole loaded spanlastics had reasonable activity when compared to the marketed formulations of sertaconazole.

Conclusion: Thus, the spanlastics based films of sertaconazole have promising scope for further development leading into meaningful outcome.





Keywords: Topical antifungals, sertaconazole, spanlastics, *in-situ* topical films.

PTP012

Sustainable Nanotechnology: Green Synthesis and Antimicrobial Applications of Copper Nanoparticles Using *Catharanthus roseus* Leaf Extract

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Introduction: The growing demand for metal nanoparticles in various fields, including medicine and environmental sciences, has emphasized the need for sustainable and environmentally friendly synthesis methods. This study investigates the green synthesis of copper nanoparticles (CuNPs) using *Catharanthus roseus* leaf extract, which acts as a natural reducing and stabilizing agent.

Methods: Copper nanoparticles (CuNPs) were synthesized using a cost-effective, environmentally friendly method that avoids hazardous chemicals. The synthesis process was optimized by varying parameters such as temperature, time, and concentration. Characterization of the CuNPs was carried out using Dynamic Light Scattering (DLS), Transmission Electron Microscopy (TEM), and UV-Vis Spectroscopy.

Results: Synthesized CuNPs exhibited anisotropic nanoparticles with a size of 45 nm and a zeta potential of +30 mV. TEM analysis revealed polydisperse morphology. Antimicrobial activity was assessed against *Escherichia coli* (ATCC 25922 and DH5 α) and *Aspergillus flavus* using disc diffusion and well diffusion methods. CuNPs showed significant antibacterial and antifungal effects, with enhanced activity observed when conjugated with ciprofloxacin, resulting in larger inhibition zones compared to CuNPs or ciprofloxacin alone.

Conclusion: This study demonstrates the potential of CuNPs as effective antimicrobial agents, particularly against multidrug-resistant microorganisms. It also advocates the adoption of green synthesis methods for nanoparticle production, offering a sustainable approach to conventional chemical synthesis, with reduced environmental impact. This study encourages further investigation into functionalized nanoparticles to advance therapeutic outcomes.

Keywords: Copper nanoparticles, Green synthesis, Antimicrobial activity, *Catharanthus roseus*, Functionalized nanoparticles.

PTP013

Engineering 3D and 4D Hydrogel Networks for Topical Drug Delivery: Challenges and Future Directions

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Introduction: Hydrogels are 3D polymers with remarkable water retention properties and have come out as a versatile platform in drug delivery, especially in topical delivery, Hydrogels offer remarkable advantages such as biocompatibility, and controlled drug delivery. Hydrogel has been further enhanced by the development of advanced 3D and 4D hydrogel systems, which have expanded their potential by introducing dynamic stimulibased responses. This study summarizes the engineering of 3D and 4D hydrogel networks tailored for topical drug delivery, focusing on the selection of material and fabrication technique and performance evaluation.

Methods: This review includes a structured investigation of synthetic and natural polymer-based hydrogels evaluated to determine their appropriateness for topical application and explores the fabrication of 3D complex hydrogel networks using various techniques, such as additive manufacturing (3D printer), polymerization, 4D hydrogel by 4D bioprinting, an innovative technique that constructs 3D biological matrices using hydrogel-based inks.



Results: The review highlights significant 3D and 4D hydrogel advancements in dynamic drug delivery systems, driven by their stimuli-responsive properties. Emerging techniques such as 3D printing and self-assembly methods are expected to enable the creation of sophisticated hydrogel structures with improved functionality. Still, various challenges such as regulatory compliance, scalability, and affordability are expected to be barriers to their application.

Conclusion: This review emphasizes the transformative leap of 3D and 4D printing hydrogel in topical drug delivery systems. By enabling precise and accurate hydrogel manufacturing and creating spatial design, future innovations in 4D hydrogels will enhance smart, responsive systems for improved patient care.

Keywords: Hydrogels,3D printing,4D printing, polymer, Topical drug delivery.

PTP014

Predictive AI in Co-crystal and Polymorphic system formulation: A State-of-Art review

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Introduction: Artificial intelligence (AI) is a transformative technology that simulates intelligent human behaviour using computer software and hardware. AI can profoundly reduce the economic burden in research through accelerated drug discovery, high throughput screening and predictive modelling. These advantages make AI invaluable for addressing the complexities of polymorphism and cocrystal prediction, which are crucial for determining the stability, solubility, and functionality of materials in pharmaceuticals and material science. This study investigates machine learning (ML) techniques, including graph neural networks and hybrid models, for analyzing molecular descriptors and crystallographic data.

Methods: A high-quality dataset of polymorphic and cocrystal structures derived from high-throughput experiments was used to train and validate AI models. Advanced ML approaches such as graph neural networks and hybrid models combining AI with first-principles calculations were employed to enhance predictive performance.

Results: The AI models achieved an accuracy of 85% for polymorph stability prediction and 80% for cocrystal formation, surpassing traditional methods. Hybrid models demonstrated better generalizability for underrepresented systems.

Conclusion: AI-based methodologies provide a robust framework for polymorphism and cocrystal prediction. Future advancements in dataset enrichment, model interpretability, and integration with experimental techniques will further enhance prediction accuracy and practical applications.

Keywords: Machine learning, AI, Polymorphism, Cocrystal, Neural networks, Computational algorithms.

PTP015

Artificial Intelligence in Pharmaceutical Development and Revolutionizing Drug Delivery

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Introduction: Artificial intelligence (AI) has emerged as a powerful tool that harnesses anthropomorphic knowledge and provides expedited solutions to complex challenges. Remarkable advancements in AI technology and machine learning present a transformative opportunity in the drug discovery, formulation, and testing of pharmaceutical dosage forms. By utilizing AI algorithms that analyze extensive biological data, including genomics and proteomics, researchers can identify disease-associated targets and predict their interactions with potential drug candidates. This enables a more efficient and targeted approach to drug discovery, thereby increasing the likelihood of successful drug approvals. Personalized medicine approaches can





be facilitated through AI algorithms that analyze real-world patient data, leading to more effective treatment outcomes and improved patient adherence.

Method: This review is based on a comprehensive analysis of current literature, including peer-reviewed articles, clinical studies, patents, and recent technological advancements. The review focuses on AI-driven approaches to drug discovery, formulation optimization, process development, pharmacokinetic (PK) and pharmacodynamic (PD) modeling, and toxicity prediction. We examined the use of AI in personalized medicine, the prioritization of lead compounds, and the reduction of animal testing through predictive models. Additionally, the integration of AI in designing drug delivery systems and optimizing dosage forms was explored.

Result: This comprehensive review explores the wide-ranging applications of AI in drug discovery, drug delivery dosage form designs, process optimization, testing, and pharmacokinetics/pharmacodynamics (PK/PD) studies. This review provides an overview of various AI-based approaches utilized in pharmaceutical technology, highlighting their benefits and drawbacks. Nevertheless, the continued investment in and exploration of AI in the pharmaceutical industry offer exciting prospects for enhancing drug development processes and patient care.

Conclusion: Al is revolutionizing drug delivery by enabling targeted, personalized, and adaptive therapies. Alpowered methods enhance drug efficacy, minimize side effects, and improve patient outcomes by optimizing drug dosage, administration routes, and formulations. Computational pharmaceutics, driven by AI and big data, streamlines the drug delivery process, making it more efficient, cost-effective, and data-driven. This integration of Al technologies promises to accelerate drug development, improve patient outcomes, and usher the pharmaceutical industry into a new era of innovation.

Keywords: Artificial intelligence (AI); Machine learning; drug discovery; formulation; dosage form testing.

PTP016

Lipid Nanoparticle Synthesis: A review on Conventional and Advanced approaches

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Introduction: Lipid nanoparticles (LNPs) are advanced drug delivery systems with key advantages such as biocompatibility, biodegradability, high drug loading capacity for both hydrophilic and lipophilic drugs, and excellent formulation stability. Although LNPs have great potential, their large-scale production with reproducible physicochemical properties and solvent-free production remains a major challenge. In this review we compile the conventional formulation techniques and compare them novel ones while discussing their advantages and limitations.

Methods: This review categorizes LNP production techniques into high-energy (top-down) and low-energy (bottom-up) approaches and some novel techniques. High-energy methods include high-pressure homogenization (HPH), high-shear homogenization, microfluidics, and ultrasonication, which break down lipid phases to form nanoparticles. Low-energy techniques that have been discussed include the microemulsion-based synthesis, solvent-based methods, membrane contactors, and coacervation which rely on nanoparticle formation from homogeneous systems. Additionally, novel methods such as supercritical fluid-based synthesis (SCF), electrospraying, 3D printing, bio-inspired approaches (enzyme-assisted and cell membrane mimetic synthesis) have also been discussed.

Results: The comparison of methods highlight the strengths and limitations of each method, emphasizing the trade-offs between particle size control, formulation stability, scalability, and reproducibility. While conventional methods are widely used, novel and bio-inspired techniques show promise for improving scalability and reproducibility while reducing environmental impact.

Conclusion: Improvements in LNP manufacturing procedures are crucial to achieve scalable, repeatable, and environmentally friendly production. Future studies should focus on optimizing novel and bio-inspired approaches to overcome present restrictions, allowing large- scale manufacture of LNPs for varied drug delivery applications.

Keywords: Bio-inspired nanoparticle synthesis, Electro spraying, Supercritical fluid (SCF)-synthesis, 3D printing.



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PTP017

Design, Development, Evaluation and Optimization of Novel Combinatorial Drug Delivery System for the Management of Psoriasis

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Introduction: Psoriasis is a chronic autoimmune skin disorder which is characterized by rapid build-up of skin cells, leading to the formation of thick, itchy, and red patches on the skin. While healthcare professionals have prescribed various conventional treatments, including topical, systemic, and hormonal therapies, these approaches often suffer from limitations such as instability, inadequate skin penetration, and a broad spectrum of side effects. Our research project aimed to formulate and evaluate a novel topical drug delivery strategy for treating Psoriasis, with an objective to enhance the solubility, permeability, and efficacy of the drugs. This innovative approach combines a potent glucocorticoid steroid, Fluocinonide, with a commonly employed keratolytic agent, Salicylic Acid, in an Emulgel formulation, offering dual benefits.

Methods: Eight Emulgel batches were formulated, each varying in the concentration of novel permeation enhancers, and emulsifying agents. The developed batches were evaluated for its pH, spread-ability, viscosity, extrudability, washability, globule size analysis, texture analysis, drug content, in vitro and ex vivo diffusion studies. A one-month stability study as per ICH Q1A(R2) guidelines was also conducted on the optimized batch.

Results: The in vitro release comparison of the optimized batch demonstrated a release of 58.79% of Fluocinonide and 96.75% of Salicylic Acid with an increase of 53.14% compared with marketed product Zitcare-S \mathbb{R} . The ex-vivo release studies of the optimized batch showcased a release of 21.08% of Fluocinonide and 30.56% of Salicylic Acid with an increase of 3.14% compared with marketed product Zitcare-S \mathbb{R} .

Conclusion: These promising research findings underscore the potential of formulations incorporating Fluocinonide and Salicylic Acid for managing Psoriasis. However further detailed pre-clinical investigation needs to be performed to confirm our proof of concept.

Keywords: Psoriasis, Topical Drug Delivery, Emulgel, Glucocorticoid Steroid, Keratolytic Agent.

PTP018

Development and Optimization of Film Forming Spray for Efficient Delivery for Treatment of Neuropathic Pain

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Introduction: The research study focused on develop an innovative film-forming topical spray containing Duloxetine using the film formation method, ensuring that the film exhibits uniform drug distribution and achieves sustained drug release in a controlled manner. The formulation was specifically designed to address neuropathic pain through a transdermal drug delivery approach.

Method: The experimental work began with selecting a suitable solvent to serve as a vehicle, which was determined by conducting solubility tests on various types of polymers. A solvent ratio with water was then established. To ensure optimal film formation, different grades of Eudragit and Hydroxy Propyl Methyl Cellulose (HPMC) were evaluated for their suitability. A Box Behnken Design was used for formulation optimization, and the film forming polymer, permeation enhancer and the amount of HPMC E5 were designated as independent variables. The time required for 85% drug release, viscosity, and solvent evaporation time were all dependent variables.

Results: Evaluation of the Topical Film Forming Spray encompassed various parameters such as viscosity, evaporation time, tackiness of the film after solvent evaporation, drug content, pH, in vitro drug release, skin irritation, stability, spray angle, spray pattern, average weight per dose, and leak test. All parameters are within the limit.





Conclusion: The findings of the optimized Duloxetine topical film-forming solution were satisfactory, it was compatible with human skin, and depicted sustained drug release that suggests promising applicability in facilitated topical Neuropathic pain treatments.

Keywords: Duloxetine, Film forming topical spray, box behnken design, Transdermal drug delivery system, Sustained drug release.

PTP019

Harnessing the Potential of Mesoporous Silica Nanoparticles for Targeted Breast Cancer Therapy

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Introduction: Breast cancer is the second leading cause of cancer-related death worldwide, and current conventional treatment strategies show limitations such as systemic toxicity and resistance to existing therapies. Nanocarriers like polymeric, dendritic, lipid-based, and metallic nanoparticles, have been investigated as potential vehicles for cancer therapy, but a persistent challenge is achieving controlled drug release, particularly for oral administration, to prevent degradation before reaching the tumor site without side effects. Mesoporous Silica Nanoparticles (MSNs) have unique structural and physicochemical properties like high surface area, modulable pore size, and surface functionalization, enable high cargo loading capacities allowing controlled release of various drugs, including chemotherapeutics, immunotherapies, and RNA-based drugs.

Methods: Literature review indicates that MSNs can be synthesized using sol-gel, liquid crystal template, chemical etching, and microwave-assisted techniques.

Results: Surveyed literature show significant advancements in drug targeting have been achieved through functionalization strategies, involving conjugation of targeting ligands to breast cancer biomarkers. Stimuli-responsive systems, like pH, redox, enzyme, and heat-responsive drug release, facilitate tumor microenvironment-specific delivery have been developed. Preclinical and *in vivo* study results show potential, improving tumor accumulation and reducing off-target toxicity, but challenges like biocompatibility, scalability, and immunogenicity must be addressed before commercialization.

Conclusion: This review summarizes the current status of MSN-based strategies used to improve targeted drug delivery with better efficacy and devoid of side effects. Its transformative potential and future avenues to overcome existing hurdles to achieve clinical efficacy for breast cancer therapeutics are also discussed.

Keywords: Breast cancer, Mesoporous silica nanoparticles, Targeted drug delivery, Chemotherapy.

PTP020

Nano Micelles: A Novel Platform for Enhanced Drug Delivery in the Oral Cavity

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Introduction: Nano micelles are nanoscale drug delivery systems formed by the self-assembly of amphiphilic molecules in aqueous environments. With their ability to encapsulate hydrophobic drugs in a core-shell structure, nano micelles improve drug solubility, stability, and bioavailability. These features make them a versatile platform for various biomedical applications, including cancer therapy, gene delivery, and antimicrobial treatments.

Methods: Nano micelles were synthesized using a thin-film hydration method, where amphiphilic polymers were dissolved in an organic solvent and subjected to evaporation. The resulting thin film was hydrated with an aqueous medium, forming micelles. The formulation was optimized for size, encapsulation efficiency, and drug





release profile. Techniques such as dynamic light scattering (DLS) and transmission electron microscopy (TEM) were used to characterize size and morphology, while in vitro release studies evaluated drug release patterns. **Results:** This review shows Nano micelles significantly improved the efficacy of various drugs, including antibiotics, antihypertensives, and other therapeutic agents. They enhanced drug solubility, and bioavailability leading to better therapeutic outcomes. Antibiotics showed increased antimicrobial activity, while antihypertensive drugs provided improved blood pressure control. Nano micelles also demonstrated enhanced drug delivery for anticancer and antifungal treatments. Overall, nano micelles improved drug efficacy and patient compliance by offering controlled, targeted delivery with reduced dosing frequency.

Conclusion: Nano micelles offer significant advancements in drug delivery, addressing limitations of traditional systems. Their ability to improve drug solubility, provide controlled release, and enable targeted therapy makes them a promising tool in modern medicine.

Keywords: Nano micelles, amphiphilic molecules, drug delivery, solubility enhancement, targeted therapy.

PTP021

Artificial Intelligence (AI) -Driven Innovation in Skin Kinetics for Transdermal Drug Delivery: Overcoming Barriers and Enhancing Precision

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Introduction: Transdermal drug delivery systems (TDDS) offer a high bioavailability and fewer systemic side effects than traditional oral and injectable medication administration because they circumvent gastrointestinal absorption and liver metabolism. Because of issues like the stratum corneum's and the skin's barrier function, the widespread use of TDDS has been restricted and formulations have not been refined.

Method: This is a developing area of the recently created artificial intelligence-based technique that integrates predictive modeling with customized medicine approach to address the issues associated with the development of TDDS. Predicting skin permeability and selecting efficacious medication candidates are made easier by machine learning algorithms applied to extensive molecular datasets. Models such as Deep Neural Networks (DNN), Artificial Neural Networks (ANN), BioSIM, COMSOL, K-Nearest Neighbors (KNN), and Set Covering Machine (SVM) are reviewed under this article.

Result: An AI-powered formulation optimization utilizing penetration enhancers and cutting-edge delivery systems like microneedles and liposomes possesses both safety and efficacy and acts as a prominent drug delivery system with accompanied ease of utilization.

Conclusion: Personalized TDDS design tailors drug delivery to individual patient profiles, enhancing therapeutic precision and proves to be a successful venture under AI inspired drug delivery systems that efficiently overcomes hurdles faced early on.

Keywords: Drug Delivery Systems, Bioavailability, AI Algorithms, Molecular Datasets, Penetration Enhancer.

PTP022

Intelligent Vascularized 3D/4D/5D/6D-Printed Tissue

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Introduction: Reconstruction of the tissue has become one of the eye catching phenomenon now a days. It involves blood vessels which contributes majorly for the vascularization of the tissue.

Methods: 3D printing technology, or additive manufacturing, is the construction of a three-dimensional object from a digital model by stacking layer by layer using adhesive materials. Scaffolding with the use of 3D printing is mainly used in the bone engineering techniques. Introducing bioactive groups is an effective way to impart the inert surface with desirable biological properties to address this issue has been possible with this technique.



Results: The application of additive manufacturing-technology in vascular tissue engineering, cardiovascular system, skeletal muscle, soft tissue (adipose tissue and skin), tissue metabolism, surgery and cancer has been observed due to its various advantages.

Conclusion: Even though many successful cases of vascularized additive manufacturing-scaffolds have been reported, there are still several challenges that need to be focused on and overcome.

Keywords: Vascularization, 3D printing, scaffolding, additive manufacturing, bone engineering.

PTP023

AI -Driven Nanorobotics: A Transformative Approach to Multiple-Disease Diagnosis and Treatment

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Introduction: Nanorobots containing nano-sized active pharmaceutical ingredients offer promising therapeutic advancements through precise, Artificial intelligence -driven control. Current treatments such as chemotherapy, immunotherapy, and radiotherapy for cancer and organ damage face major drawbacks, including life-threatening side effects, destruction of healthy cells, and immune rejection in organ transplants. These challenges can potentially be overcome with Nanorobotics.

Method: Nanorobots are composed of payloads, micro-cameras, electrodes, lasers, ultrasonic signal generators, and swimming tails, and are fabricated using advanced methods such as 3D printing such as Stereo-lithography and approaches like top-down or bottom-up manufacturing. AI is used to control their movement via real-time feedback, adaptive algorithms, path optimization, and integration with external magnetic or electric fields.

Results: Equipped with biosensors and biochips, nanorobots detect minute changes in pH, metabolites, or cancer signals, while onboard cameras provide real-time visualization. Electrochemical sensors utilize biological elements for diagnostics and electrodes for transduction. Nanorobots can be programmed to target and destroy malignant cells, with specific DNA aptamers decoding cancer cell DNA. Specialized nanorobots like Respirocytes mimic red blood cells, delivering oxygen and carbon dioxide in the bloodstream. Respirocyte supply 236 times more oxygen to the tissue per unit volume then cell. Clottocytes function as mechanical platelets, achieving haemostasis in under one second. Additionally, nanorobots can penetrate the blood-brain barrier to deliver drugs for neurodegenerative diseases such as Alzheimer's, Parkinson's, and multiple sclerosis. **Conclusion:** Nanorobot represents a transformative approach to addressing limitations of conventional therapies, providing targeted, efficient, and minimally invasive treatments for complex medical conditions.

Keywords: 3D printing, Stereo-lithography, Adaptive control algorithm, Clottocyte, Respirocyte.

PTP024

Systematic Development and In Vitro Evaluation of a Newer Combination for the Treatment of Shizophrenia

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Introduction: This study focuses on developing a bi-layer tablet combining Quetiapine fumarate, an atypical antipsychotic, with Bacopa monnieri extract standardized to Bacosides A, a herbal supplement, to enhance schizophrenia treatment. Schizophrenia management often requires long-term use of antipsychotics, which can cause significant adverse effects. This research aims to reduce these side effects by lowering the antipsychotic





dose while improving efficacy through Bacopa monnieri's therapeutic properties. This innovative combination strategy offers a synergistic approach to managing schizophrenia effectively.

Methods: The method development for Quetiapine fumarate and Bacopa monnieri was conducted using UV spectroscopy with the simultaneous equation method. The bi-layer tablet, designed as an IR-SR system, underwent excipient screening to ensure stability and compatibility. In-vitro dissolution and disintegration tests, along with pre- and post-compression evaluations, were performed. Bacopa monnieri's antioxidant properties were assessed using the DPPH assay, and an in-vitro bioassay evaluated the formulation's effects. Stability studies followed ICH guidelines. Optimization was done using Design of Experiment (DoE) and Quality by Design (QbD). Three optimized batches were finalized and evaluated.

Results: Stability was validated using DSC and FTIR analyses, showing no significant drug-excipient interactions. The optimized batch achieved over 90% cumulative drug release (CDR) in 8 minutes for the IR layer and 80% CDR for the SR layer in 7–8 hours. All parameters met standard requirements. The DoE and QbD approaches ensured scalability and reproducibility by identifying optimal process conditions.

Conclusion: This combination addresses schizophrenia management by reducing antipsychotic side effects. Bacopa monnieri provides antioxidant effects, reduces symptoms by stimulating dopamine and serotonin, and avoids long-term side effects. The bi-layer design enhances stability, and the novel formulation shows promising results, offering a stable and effective treatment for schizophrenia.

Keywords: Quetiapine fumarate, Bacopa monnieri, Bacosides A, Bi-layers formulation, QbD Approach, schizophrenia.

PTP026

Theranostic Mesoporous Silica Nanoparticles: A Nanomedicine-Based Strategy for Targeted Drug Delivery and Imaging in Bacterial Infections

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Introduction: Bacterial infections, worsened by antimicrobial resistance (AMR), represent a significant global health threat, causing approximately 700,000 deaths annually. Projections indicate an increasing mortality rate by 2050, with biofilm-related infections further complicating treatment. The issue is particularly concerning in developing countries due to antibiotic overuse, which limits treatment options and increases mortality. Conventional treatments face challenges such as poor targeting, side effects, and resistance development. Nanomedicine presents a promising alternative, with mesoporous silica nanoparticles (MSNs) emerging as a key solution due to their unique structure, high surface area, chemical versatility, and biocompatibility.

Method: This review explores advancements in theranostic MSNs for bacterial infections, emphasizing their role in targeted drug delivery, stimuli-responsive mechanisms, and diagnostic applications. MSNs allow for controlled drug release, enhance targeted therapy, and modulate immune responses by delivering cytokines or bacterial antigens. Additionally, MSNs help disrupt biofilms and combat resistance through enzyme-functionalized designs.

Result: Theranostic MSNs demonstrate significant potential in overcoming AMR by integrating drug delivery with diagnostic capabilities. Their ability to incorporate imaging agents like fluorescent dyes or quantum dots facilitates diagnosis, while stimuli-responsive drug release enhances therapeutic precision. The multifunctionality of MSNs positions them as a transformative tool in combating bacterial infections.

Conclusion: The dual capability of MSNs for diagnosis and therapy makes them a promising strategy for managing bacterial infections, contributing to more effective and precise treatments. Continued research is essential for translating theranostic MSNs into clinical applications.

Keywords: Theranostics, Mesoporous Silica Nanoparticles, Bacterial Infections, Antimicrobial Resistance, Nanomedicine.

PTP027





Formulation Development of Hydroxyzine Hydrochloride Sustained Release Tablets

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Introduction: Hydroxyzine, an FDA-approved antihistamine, alleviates anxiety and allergy symptoms by inhibiting the H1 receptor. This study investigates the role of different polymers and their concentrations in drug release to develop sustained-release matrix tablets comparable to reference formulation.

Methods: Sustained-release tablets were formulated using Carbopol 971P and hydroxypropyl methylcellulose (HPMC K4M, K15M, and K100) in varying intragranular and extragranular concentrations. Formulations were prepared using high shear wet granulation and film-coating to mimic the reference tablet. Tablets were evaluated for thickness, crushing strength, diameter, weight variation, and in-vitro drug release over 6 hours in 900 mL water at $37 \pm 0.5^{\circ}$ C. Release mechanisms were analyzed using kinetic modeling.

Results: HPMC K4M showed higher drug release than the reference, while HPMC K100 exhibited lower drug release with hard granules during milling. Formulation F9, incorporating HPMC K15M (10 mg intragranular, 8 mg extragranular), achieved sustained drug release for 6 hours and followed Higuchi's non-Fickian diffusion. The dissolution profile showed an acceptable similarity factor ($f2 \ge 50$) compared to the reference. F9 demonstrated a similarity factor of nearly 90, indicating optimal alignment with the reference tablet.

Conclusion: Among the polymers tested, HPMC K15M at optimized concentrations provided the best sustained-release profile, closely matching the reference formulation. This approach offers a promising method for formulating hydroxyzine hydrochloride sustained-release tablets.

Keywords: Hydroxyzine hydrochloride, sustained-release tablets, release kinetics, high shear wet granulation, HPMC.

PTP028

Formulation and Evaluation of PLGA Nanoparticles of Ribociclib

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Introduction: Ribociclib, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is an effective therapeutic drug in the treatment of hormone receptor-positive breast cancer. As a BCS Class IV drug, it faces challenges due to its low aqueous solubility and poor permeability. PLGA Poly (lactic-co-glycolic acid) nanoparticles offers a promising solution to increase its solubility and allow controlled and sustained drug release, which could significantly improve its efficacy in cancer therapy.

Methods: PLGA nanoparticles were prepared using a solvent evaporation method in the presence of polyvinyl alcohol as the stabilizer. Critical process parameters, such as PLGA concentration, PVA concentration, and sonication time, were optimized using an augmented central composite design. The nanoparticles were characterized for particle size, zeta potential, polydispersity index (PDI), drug entrapment efficiency, and in vitro drug release. The functional integrity of ribociclib in the nanoparticles was confirmed using Fourier-transform infrared spectroscopy (FTIR).

Results: The optimized nanoparticles had a mean particle size of 138.5 ± 2.3 nm, zeta potential of -24.7 ± 0.6 mV, and PDI of 0.112 ± 0.015 . Drug entrapment efficiency was $71.92\% \pm 1.45\%$, indicating efficient encapsulation. In vitro drug release studies showed a sustained release pattern, with $78.4\% \pm 2.6\%$ drug released over 48 hours. FTIR studies showed that ribociclib showed proper encapsulation within the nanoparticle matrix. **Conclusion:** The formulated PLGA nanoparticles of ribociclib demonstrated optimal physicochemical properties and sustained release of the drug, which can enhance the therapeutic effectiveness of ribociclib in breast cancer treatment.

Keywords: Ribociclib, PLGA nanoparticles, breast cancer, sustained release, cyclin-dependent kinase inhibitor.



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Nanocrystal-Enhanced Antifungal Formulations: Improving Skin Penetration and Therapeutic Outcomes

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Introduction: Nanocrystal technology has emerged as a promising approach to enhance the efficacy of topical antifungal treatments. By reducing antifungal agents to the nanoscale, this technology significantly increases their surface area and solubility, which improves skin penetration and enhances therapeutic outcomes. Fungal infections, from superficial skin conditions to severe systemic diseases, present significant health challenges. Traditional antifungal therapies often struggle with poor skin penetration, reduced efficacy, and potential side effects. However, nanocrystal technology overcomes these limitations by developing nanosized drug particles that optimize drug delivery, ultimately improving the effectiveness of antifungal treatments.

Method: The preparation of antifungal nanocrystals involves techniques like high-pressure homogenization or solvent evaporation to reduce the drug particles to nanoscale dimensions. These nanocrystals are then incorporated into topical formulations such as creams, gels, or ointments. The nanosized particles facilitate deeper skin penetration and sustained release of the active ingredient.

Results: Antifungal nanocrystal formulations demonstrate enhanced effectiveness compared to traditional treatments by improving solubility, skin absorption, and therapeutic outcomes. They effectively penetrate fungal biofilms and deeper skin layers, making them suitable for treating chronic conditions like onychomycosis. Nanocrystals allow for targeted delivery to affected areas, minimizing systemic side effects, and can be combined with synergistic agents to address resistant fungal strains.

Conclusion: Additionally, nanocrystals can be used in intravenous formulations for systemic fungal infections and incorporated into wound dressings for prolonged antifungal activity. Overall, nanocrystal technology represents a promising advancement in antifungal therapy, offering a more efficient and safer alternative to conventional treatments.

Keywords: Nanocrystal, Antifungal drug, Topical drug delivery system.

PTP030

Effect of Cushioning Excipient Characteristics on Multiple Unit Pellet System of Omeprazole; Impact on Mechanical Strength, Release Characteristics and Processibility

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Introduction: Multiple unit pellet system (MUPS) of omeprazole is available as capsule and tablet dosage forms offering various advantages like variability in gastric residence time, greater flexibility in formulation design, reduce risk of dose dumping and local mucosal damage. However, the process of compression presents some challenges like mass and content uniformity issue, inadequate mechanical strength, change in pellet structural integrity and functionality etc. These challenges could be minimized with the help of cushioning excipients. The objective of the study was to explore the role of commonly used cushioning excipients on the processibility, mechanical strength and release characteristics of the developed MUPS based tablets.

Methods: Commercially available omeprazole loaded pellets (model drug) were compressed with lactose and MCC101 at different levels to obtain MUPS based tablet. The developed MUPS were subjected to microscopic analysis, hardness, disintegration time, friability, and dissolution to assess the impact of cushioning excipient levels on performance of product.

Results and Discussion: The results of dissolution studies revealed that using MCC 101 and lactose at 1:0.5, 1:1 and 1: 1.5 ratios with respect to omeprazole pellets, when incorporated in the form of granules or dry state were insufficient to provide necessary mechanical strength to the MUPS based tablet. Further in ratios 1:0.5 and 1:1 during compression process, the pellets tend to move to the surface resulting in rupturing of the coats and drug release. However, with higher ratios of cushioning excipient this problem was circumvented, albeit with increase in tablet weight.





Conclusion: The findings indicate that elastic, plastic, and brittle tendency of cushioning excipient and its ratio plays a significant role in maintaining the integrity of omeprazole pellets. It would be interesting to observe how combination of excipient and use of artificial neural network could be used in combination to better predict the performance of MUPS formulations for controlled drug release in future.

Keywords: Multiple unit pellet system, omeprazole, MCC101, cushioning excipient.

PTP031

Current Therapeutic Approaches for Rheumatoid Arthritis: Exploring Immunotherapy and Novel Strategies

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Introduction: Rheumatoid arthritis (RA) is a chronic, systemic autoimmune condition that mostly affects the synovial joints. If left untreated, it can cause severe pain, joint destruction, and functional disability. As per the literature survey, the main contributing component to the genesis of RA is the autoimmune inflammatory response, which attacks the joints and results in tissue destruction, joint abnormalities, and chronic inflammation.

Methods: Currently, RA is treated with synthetic disease-modifying anti-rheumatic drugs (cDMARDs), biological DMARDs (bDMARDs), nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and cell-based therapy, but there are challenges in providing effective treatment as the current therapeutic methods are significantly hindered by several shortcomings, including considerable systemic side effects, nonspecific targeting, frequent and chronic administration routines, and the development of tolerance toward these treatments.

Results: Immunotherapy is a method that focuses on the molecular pathological microenvironment of rheumatoid arthritis to improve therapeutic outcomes, potentially leading to significant advancements in the treatment of RA.

Conclusion: The present review outlines the molecular mechanisms involved in the pathology of RA, current therapeutic approaches, and explores novel strategies aimed at targeting and regulating the immune response, providing insights on future targeted therapeutic options that may significantly reduce the side effects observed with systemically applied therapies.

Keywords: Rheumatoid arthritis (RA); Disease-modifying anti-rheumatic drugs (DMARDs); Nonsteroidal antiinflammatory drugs (NSAIDs); Immunotherapy; Novel strategies.

PTP032

"Cancer treatment in using the Nanotechnology"- a review

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Introduction: Cancer are spread in all over the world. In the cancer, rapid growth of abnormal cell surrounding tissue and organ. Now treatment of cancer like chemotherapy and immune therapy often they can cause drug resistance, side effect and it are limited. So, using nanotechnology decreases side effect and drug resistance too. NPs are breakdown the target tumors and improve drug delivery and enhance the imaging techniques. The NPs have reduced the side effect and overcome drug resistance and give the therapeutic effectiveness. Additionally





play role in detection of the cancer. The review is how nanotechnology enhance the cancer cell and support the immune system.

Method: In this metallic NPs are used such as gold, silver, cobalt oxide, iron oxide, aluminum oxide. The method is decomposing large molecules into small molecules. The NPs indirectly target cancer cell and breakdown the tumors. NPs are also used in deliver the gene fragment.

Result: NPs are reducing the drug resistance, side effect, of treatment of cancer. It can improve cancer treatment by drug delivering to tumor and improve the therapeutic effect of drug. It can identify easily cancer related biomarkers.

Conclusion: Nanotechnology gives significant in advancing cancer diagnosis and treatment. It gives benefit for imaging and therapy due to target tumors and enhance drug delivery by decreases side effect and overcome drug resistance. It also plays important role in detection and identify cancer that are difficult with traditional method. It is also developing the nano medicine, their use in cancer.

Keywords: Nanotechnology, Cancer, Chemotherapy, Nanoparticles, Breakdown.

PTP033

Formulation, Development and Evaluation of Mouth Dissolving Film of Edoxaban Tosylate Monohydrate

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Introduction: His study aims to develop a mouth-dissolving film of Edoxaban Tosylate Monohydrate for treating non-valvular atrial fibrillation (NVAF). The formulation addresses Edoxaban poor solubility and limited bioavailability (62%) to improve solubility, permeability, and patient adherence, offering a more efficient alternative to traditional oral dosage forms.

Methods: The inclusion complex of Edoxaban Tosylate Monohydrate with β -cyclodextrin was prepared by solvent evaporation. The complex was characterized using phase solubility studies, FT-IR, DSC, and XRD. Saturation solubility was assessed in various buffers and water. The complex was incorporated into a mouth-dissolving film, with the formulation optimized using Design of Experiment (DoE) and Quality by Design (QbD). After optimization, all parameters of the final batches were thoroughly evaluated.

Results: A 1:1 molar ratio of Edoxaban Tosylate Monohydrate and β -cyclodextrin increased solubility by 29.164-fold, with saturation solubility at 0.9391 mg/mL. The optimized batch showed over 90% drug release and disintegration in under 30 seconds. Key parameters like thickness, drug uniformity, folding endurance, pH, and tensile strength met standards. Optimization with QbD and DoE ensured scalability and stable formulation.

Conclusion: In conclusion, the 1:1 inclusion complex of Edoxaban with β -cyclodextrin enhanced solubility, and the mouth-dissolving film demonstrated rapid disintegration and over 90% drug release, offering a promising alternative for treating NVAF.

Keywords: Non-valvular atrial fibrillation, Edoxaban Tosylate Monohydrate, Inclusion Complex, Mouth Dissolving Film, QbD Approach.

PTP034

Overview of emerging future potentials for the treatment of idiopathic pulmonary fibrosis

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Introduction: The review compromises of brief and systematic information about introduction and therapeutic strategies in the current landscape as well as throws light on the emerging future potentials for the treatment of idiopathic pulmonary fibrosis (IPF). It initiates with the introduction and elaborates on IPF as a rapidly progressive, inevitable, and lethal age-related respiratory disease of unknown cause characterized by sequential acute lung injury with subsequent scarring and end-stage lung disease.





Methods: The current conventional therapies involving tablets and capsules of Pirfenidone and Nintedanib are still behind the time in the aspect of improved condition of IPF patients with increased survival rates. Recent advancement has led to a number of novel formulations that hold promise for therapeutic efficacy for IPF.

Results: A numerous drug delivery technique such as liposomes, nanoparticles, dendrimers, and microparticles are blooming trends in the therapy of IPF. The most widely implemented lipid-based drug carrier are liposomes, which have one or more lipid bilayer membranes that range in size from 50 to 500 nm.

Conclusion: In comparison to alternative formulations liposomes provide numerous benefits for the lungs, such as the ability to maintain their size, carry a pharmacological payload, and get abolished from macrophage uptake.

Keywords: Idiopathic Pulmonary fibrosis, liposomes, dendrimers, nanoparticles.

PTP035

Design and Characterization of Voriconazole Loaded Nanocarrier for Oral Drug Delivery System

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Introduction: This research focuses on the development, optimization, and characterization of Voriconazoleloaded Self-Nanomicellizing Solid Dispersion (SNMSD) for an enhanced oral drug delivery system. Voriconazole, a triazole antifungal agent, is used to treat severe fungal infections, including invasive pulmonary aspergillosis, esophageal candidiasis, and candidemia. Voriconazole is classified as a BCS Class II (Biopharmaceutical Classification System) drug which has limited aqueous solubility. Oral administration is a convenient and frequently employed method for the delivery of drugs. Nevertheless, significant challenges arising in the development of an oral formulation of drugs are their poor solubility, due to up to 50 % of approved drugs being classified as BCS Classes. The Self-Nanomicellizing Solid Dispersion (SNMSD) approach aims to address these challenges by enhancing solubility and bioavailability.

Method: The Self–Nanomicellizing Solid Dispersion (SNMSD) of Voriconazole was developed using the Solvent Evaporation method employing D- α -Tocopherol polyethylene glycol 1000 succinate (Vitamin E-TPGS) and Poloxamer P - 407 as key carriers. The formulation was characterized by different parameters such as % Drug Entrapment, % Drug Loading, Particle Size, Zeta Potential, PDI (Polydispersity Index), CMC (Critical Micelles Concentration), Cloud Point, and pH. Further Drug Loaded SNMSD Loaded in Capsule. Capsule formulation was formulated using D- α -Tocopherol polyethylene glycol 1000 succinate (Vitamin E-TPGS) and Poloxamer P – 407. Optimized Formulation was also evaluated for their weight variation test, content uniformity test, In-Vitro drug release, and stability study. It was optimized using the Design of Experiment (DoE).

Results: FTIR and DSC analyses confirmed the absence of significant interaction between the drugs and the excipients. The ratio of Vitamin E-TPGS and Poloxamer 407 was found to significantly influence % Entrapment Efficiency, % Drug Loading, Particle Size, and Zeta Potential. The Optimized Showed evaluation parameters such as % Drug Entrapment, % Drug Loading, Particle Size, Zeta Potential, PDI (Polydispersity Index), CMC (Critical Micelles Concentration), Cloud Point, pH. The optimization process, guided by Design of Experiment (DoE), led to a formulation with favorable characteristics, including an optimal drug release profile. The capsule formulation exhibited satisfactory results in weight variation, content uniformity, and stability, demonstrating the effectiveness of the SNMSD approach in improving Voriconazole's oral delivery.

Conclusion: It was concluded that Voriconazole–Loaded Self–Nanomicellizing Solid Dispersion (SNMSD) containing capsule formulation using D- α -Tocopherol polyethylene glycol 1000 succinate (Vitamin E-TPGS) and Poloxamer P – 407. The optimization process, guided by the Design of Experiment (DoE) and Quality by Design (QbD) approaches, resulted in a formulation with favorable characteristics, including appropriate particle size, zeta potential, and drug release profile. The absence of interactions between the drug and excipients was confirmed by FTIR and DSC analysis. The capsule formulation showed satisfactory weight variation, content uniformity, and stability, indicating the effectiveness of the SNMSD approach for improving the oral delivery of Voriconazole.





Keywords: Voriconazole, SNMSD, TPGS, Poloxamer 407, Capsule.

PTP036

Applications of Nanotechnology in Pharmaceutical Formulation Development: Enhancing Drug Delivery and Therapeutic Efficacy

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Introduction: Nanotechnology, the manipulation and application of materials at the nanoscale (1-100 nm), has emerged as a transformative tool in pharmaceutical formulation development. The unique properties of nanoparticles, such as high surface area-to-volume ratio, improved solubility, targeted delivery, and controlled release profiles, have made them indispensable in addressing the limitations of conventional drug delivery systems. These advancements have the potential to improve bioavailability, reduce drug toxicity, and enhance therapeutic outcomes. The integration of nanotechnology into drug formulation is particularly relevant for overcoming challenges such as poor solubility of hydrophobic drugs, instability of biologics, and inefficient crossing of biological barriers like the blood-brain barrier. Various nanocarrier systems, including liposomes, dendrimers, polymeric nanoparticles, and nanosuspensions, are being developed to optimize the delivery of active pharmaceutical ingredients.

Methods: Nanotechnology has emerged as a revolutionary tool in pharmaceutical formulation development, offering innovative solutions for enhancing drug delivery and therapeutic efficacy. The unique physicochemical properties of nanoparticles, such as their small size, large surface area, and ability to modify surface characteristics, enable precise drug targeting, controlled release, and improved bioavailability. The various applications of nanotechnology in drug delivery systems, focusing on nanocarriers such as liposomes, dendrimers, polymeric nanoparticles, solid lipid nanoparticles (SLNs), and nanoemulsions. These systems can encapsulate both hydrophilic and hydrophobic drugs, overcome biological barriers, and ensure targeted delivery to specific tissues or cells.

Results: Nanotechnology has revolutionized pharmaceutical formulation development by enhancing drug delivery systems and therapeutic efficacy.

Conclusion: Nanotechnology has emerged as a transformative tool in pharmaceutical formulation development, offering innovative solutions to overcome traditional drug delivery challenges. By utilizing nanostructures such as nanoparticles, liposomes, dendrimers, and nanogels, researchers have enhanced the solubility, stability, bioavailability, and targeted delivery of therapeutic agents. These advancements not only improve the therapeutic efficacy of drugs but also reduce systemic toxicity and adverse effects, paving the way for more personalized and effective treatments.

Keywords: Nanotechnology, Pharmaceutical formulation, Drug delivery systems, Nanoparticles.

PTP037

Recent Trends in Phytoconstituent Based Nanoformulation for the Treatment of Oral Cancer

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Introduction: Oral cancer poses a significant global health challenge due to its high morbidity and mortality rates. Conventional therapies like chemotherapy, surgery and radiotherapy pose several challenges like severe side effects, drug resistance, and collateral damage to healthy tissues, demanding the need for innovative therapeutic approaches. Nanotechnologies, like nanoparticles, liposomes, micelles, and nanogels, address these challenges by enhancing the stability, solubility, and targeted delivery of these compounds to tumor sites.

Methods: Phytoconstituent-based nanoformulations have emerged as a promising alternative, harnessing the bioactive properties of plant-derived compounds for targeted cancer therapy. Phytochemicals like curcumin, resveratrol, quercetin, and epigallocatechin gallate (EGCG) exhibit potent anticancer activities, including





induction of apoptosis, inhibition of angiogenesis, and modulation of critical cancer progression pathways. However, their therapeutic potential is hindered by issues such as poor water solubility, rapid metabolism, and low bioavailability.

Results: The integration of phytoconstituents into nanocarriers provides several advantages, such as controlled drug release, reduced systemic toxicity, and improved therapeutic efficacy. These formulations also overcome multidrug resistance by enabling selective accumulation of active compounds in cancer cells while sparing normal tissues. Preclinical studies have shown promising results in enhancing anticancer activity and minimizing adverse effects, making these nanoformulations a viable option for clinical translation.

Conclusion: The potential of phytoconstituent-based nanoformulations as an efficient, focused, and less harmful therapeutic strategy for oral cancer is highlighted in this review. To confirm their effectiveness and create uniform treatment procedures, more investigation and clinical studies are essential.

Keywords: phytoconstituent, Nano formulation, oral cancer.

PTP038

In-Situ Gels for Ophthalmic Applications: Comprehensive Innovations and Future Directions

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Introduction: Blindness and vision impairment are major global health concerns with significant socioeconomic impacts. The eye's unique anatomy and protective barriers limit drug bioavailability to less than 5% with conventional delivery methods, necessitating advanced drug delivery systems. Ocular in-situ gel systems, which transition into gels upon administration via stimuli such as temperature, pH, or ions, have emerged as promising alternatives due to their prolonged residence time, enhanced bioavailability, and controlled drug release.

Methods: This review explores recent advancements in ocular in-situ gel systems, emphasizing thermosensitive (Poloxamer-based), pH-responsive (Carbopol-based), and ion-activated (gellan gum-based) systems. It also examines the integration of nanocarriers like liposomes, nanoparticles, and solid lipid nanoparticles to improve drug stability, permeability, and targeted delivery.

Results: Thermosensitive Pluronic F127-based gels demonstrated superior therapeutic outcomes for antiinflammatory drugs by enhancing bioavailability and prolonging drug release. pH-responsive systems showed efficacy in glaucoma treatment, ensuring controlled delivery. Hybrid systems incorporating mucoadhesive polymers or bioactive nanoparticles have been effective in treating anterior and posterior segment disorders, including bacterial keratitis, diabetic retinopathy, and glaucoma. These systems optimized drug delivery, reduced dosing frequency, and improved patient compliance.

Conclusion: Ocular in-situ gel systems offer a transformative approach to ophthalmic drug delivery by addressing limitations of conventional methods. Their ability to enhance drug stability and therapeutic outcomes makes them valuable for managing ocular disorders. Further research and clinical validation are essential to expand their clinical applications.

Keywords: ocular drug delivery system, bioavailability, In-situgel, Nanocarriers, Anterior and posterior disorders.

PTP039

Design and Optimization of In Situ Depot Forming Implant for Long Term Intervention of Alzheimer's Disease

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Introduction: In-situ forming implants (ISFI) are innovative drug delivery systems that combine controlled drug release with minimal invasiveness and ease of administration. This study focuses on developing a biodegradable ISFI using poly (lactic-co-glycolic acid) (PLGA) for the subcutaneous delivery of an acetylcholinesterase inhibitor. The aim is to treat Alzheimer's disease while minimizing bio-variability-associated side effects and ensuring sustained drug release.

Methods: The ISFI was prepared using a solvent exchange technique that allows for gel formation upon injection. A validated UV-spectrophotometric method was used to determine drug content. Initial drug loading was optimized using poly (lactic acid) (PLA) polymers, followed by in-vitro drug release studies of two formulations (F1: 25.92% drug loading; F2: 7% drug loading). Various grades of PLA and PLGA polymers were screened to identify the optimal polymer for sustained drug release. The release profile was further optimized using Design of Experiments (DoE).

Results: Drug release studies revealed that the F1 formulation sustained drug release for 7 days, while the F2 formulation extended release up to 27 days. Polymer screening identified PLGA (75:25) as providing the most favorable release profile. DoE optimization further refined the release characteristics, demonstrating the potential of this system for sustained and controlled drug delivery.

Conclusion: The developed PLGA-based ISFI shows promise for subcutaneous delivery of acetylcholinesterase inhibitors, offering controlled and sustained release with reduced side effects. This system represents a novel approach to improving the treatment of Alzheimer's disease through ease of administration and consistent therapeutic outcomes.

Keywords: In-situ forming implants (ISFI), Poly (lactic-co-glycolic acid) (PLGA), Alzheimer's disease, Sustained drug release, Acetylcholinesterase inhibitor.

PTP040

Formulation, Optimization and Invitro Evaluation of Delayed Release Dosage from for the Treatment of Epilepsy

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Introduction: The research study focuses on developing a delayed-release tablet using a reservoir-based formulation to improve patient compliance in the treatment of epilepsy with brivaracetam. This approach aims to align the drug's release with early morning seizure peaks in focal epilepsy, providing better circadian targeting.

Methods: A reservoir-based formulation approach was employed to improve the drug release pattern. Comprehensive excipient selection and screening were conducted to ensure compatibility and stability. The formulation was prepared using a compression coating technique, and preliminary assessments were carried out through subsequent analyses. The formulation process was optimized using the Design of Experiments (DoE). After obtaining the final optimized batches, all parameters were thoroughly evaluated

Results: Drug-excipient interactions were validated through thermal (DSC) and spectroscopic (FTIR) investigations. Using glyceryl behenate as a polymer, the optimized batch demonstrated greater than 90% cumulative drug release (CDR) over 8–10 hours. These results highlight the effectiveness of the optimization process in achieving the desired product characteristics. All experimental runs were conducted using a Design of Experiments (DoE) approach, which identified the best combinations of reservoir-forming substances to achieve optimal product quality.

Conclusion: The development of the brivaracetam delayed-release tablet with a novel pulsatile release formulation represents a significant advancement in the treatment of epilepsy. By aligning drug release with the circadian patterns of seizure susceptibility, particularly during early morning or nocturnal hours, this formulation enhances patient adherence and treatment outcomes. The optimized tablet also demonstrates improved stability compared to existing drugs, offering a promising solution to the challenges of effectively managing epilepsy. Overall, this approach provides a more personalized and efficient method for controlling seizures, thereby enhancing the quality of life for patients with epilepsy.

Keywords: Brivaracetam, Delayed Release, Compression Coating Formulation, Epilepsy.



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PTP041

Formulation and Optimization of Dry Suspension of Lamotrigine for the Treatment of Epilepsy

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Introduction: The study focuses on developing an extended-release dry suspension using a matrix-based formulation to enhance patient compliance in epilepsy treatment with lamotrigine. This approach addresses challenges such as poor adherence, frequent dosing, and the unpleasant taste of the drug, aiming to provide a patient-friendly oral dosage form.

Methods: A matrix-based formulation was employed with the solid dispersion technique to enhance the solubility and dissolution rate of lamotrigine. Careful selection and screening of excipients ensured formulation stability and compatibility. Alternatives to commonly used excipients like xanthan gum and citric acid monohydrate were explored to mitigate stability issues. Key evaluations included in-vitro dissolution studies, redispersibility testing, sedimentation volume analysis, viscosity measurement, pH evaluation, and tastemasking efficiency. The formulation process was systematically optimized using Design of Experiment (DoE) and Quality by Design (QbD) approaches. After optimization, three final batches were evaluated for all critical parameters.

Results: Thermal (DSC) and spectroscopic (FTIR) studies confirmed no significant drug-excipient interactions, ensuring formulation stability. The optimized batch achieved over 90% cumulative drug release within 8–10 hours, a sedimentation volume of 0.98, and other desirable micrometric properties. Parameters like redispersibility, viscosity, and pH met standard criteria, demonstrating the formulation's suitability. The QbD-based optimization process facilitated scalability and reproducibility, with DoE identifying optimal matrix concentrations and mixing speeds for product quality.

Conclusion: The extended-release dry suspension of lamotrigine improves treatment outcomes in epilepsy by enhancing adherence and addressing formulation challenges. This novel approach shows significant promise for broader applications in innovative dosage forms.

Keywords: Lamotrigine, Dry Suspension, Matrix Formulation, QbD Approach, Epilepsy.

PTP042

Non-Invasive Protein-Based Nose-to-Brain Drug Delivery Systems for The Treatment of Alzheimer's Disease

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Introduction: Alzheimer's disease (AD) is a chronic neurological condition characterized by gradual and irrevocable neuronal apoptosis and synaptic degeneration, resulting in significant loss of neurons, culminating in dementia. Current therapeutic strategies predominantly provide symptomatic relief and do not modify disease progression due to restrictive nature of the Blood Brain Barrier (BBB). Nose-to-brain delivery offers a non-invasive approach for circumventing BBB, enabling the administration of protein-based therapies like insulin, directly to the brain. Insulin has shown considerable potential due to its neuroprotective properties, synaptic enhancement effect and modulation of glucose metabolism. The aim of this review is to outline the potential of Non-invasive protein-based nose-to-brain drug delivery systems for AD.

Methods: In this review, the literature search of work done by various researchers was done to explore the mechanisms, therapeutic benefits and potential of insulin-based intranasal delivery for AD, addressing formulation challenges, delivery methodologies and strategies to optimize this advanced therapeutic approach.

Results: This review emphasizes the potential of insulin-based nose-to-brain delivery for AD, providing neuroprotective effects and glucose regulation. Bypassing BBB, it enables direct brain targeting with minimal systemic exposure. Advances in formulation, including nano-formulations and mucoadhesive systems, enhance insulin stability and bioavailability. Despite progress, challenges in dosage, consistency and patient variability remain, requiring further research and clinical trials to optimize this therapy.





Conclusion: Insulin-based intranasal delivery provides a non-invasive AD treatment with neuroprotective and glucose-regulating effects, bypassing BBB. Ongoing research and clinical studies are needed to refine this treatment modality and establish its efficacy in AD management.

Keywords: Alzheimer's Disease, Insulin, Nose-to-brain Delivery, Blood brain Barrier, Neuroprotective Effects.

PTP043

Formulation and Development of Immediate-Release Tablets Using Solid Dispersion Technique for the Treatment of Chronic Lymphocytic Leukemia

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Introduction: Chronic Lymphocytic Leukemia (CLL), driven by genetic mutations such as chromosomal deletions and trisomy 12, often requires effective drug delivery solutions for treatment. This study aims to formulate and develop immediate-release (IR) tablets of a poorly soluble drug using the solid dispersion technique, ensuring enhanced solubility and bioavailability.

Methodology: IR tablets were formulated via the Hot-Melt Extrusion technique. Solid dispersions were prepared with various ratios of the drug and carrier (Plasdone S-630) and subsequently compressed into tablets with extragranular ingredients including Poloxamer 407, HPC-SSL-SFP (Nisso), dicalcium phosphate dihydrate, magnesium stearate, and Aerosil 200. The tablets were film-coated and subjected to physicochemical evaluations such as weight variation, hardness, thickness, friability, disintegration time, and in-vitro drug release. Drug release was assessed over 4 hours using USP Apparatus III (Reciprocating Cylinder) in 250 mL phosphate buffer (pH 6.8) with 0.4% SDS at 20 DPM.

Results: The formulation incorporating Poloxamer 407 demonstrated superior drug release compared to formulations without it. Among the tested formulations, optimized formula—comprising Plasdone S-630, HPC-SSL-SFP (Nisso), Poloxamer 407, and magnesium stearate—exhibited optimal physical and chemical properties. Its drug release profile achieved an acceptable similarity factor relative to the reference product.

Conclusion: The study successfully developed immediate-release tablets of a poorly soluble drug using the solid dispersion technique. The optimized formula with Plasdone S-630 and Poloxamer 407, displayed promising results with drug release comparable to the RLD, providing a potential strategy for enhancing the therapeutic efficacy of treatments for CLL.

Keywords: Chronic Lymphocytic Leukemia, Solid Dispersion, Hot-Melt Extrusion, Immediate-Release Tablets, Plasdone S-630.

PTP044

Incorporation of Machine Learning in Additive Manufacturing and Microfluidics for development of advanced Drug Delivery Systems

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Introduction: Additive Manufacturing (AM) also referred to as 3D printing is a manufacturing process to create layer-by-layer, pharmaceuticals and novel dosage forms with complex geometries, superseding conventional manufacturing processes. Microfluidics is the science and technology of manipulation and control of extremely small volumes of fluids (nanolitres to picolitres) within channels that have dimensions ranging from tens to hundreds of micrometers, improving drug formulation, mixing efficiency and particle size distribution, resulting in improved product quality and reduced waste.

Methods: Online scientific resources, mainly Web of Science and Pubmed National Library of Medicine were accessed with keyword search "Artificial Intelligence & Additive Manufacturing" and results obtained were further analysed specifically, and literature reviewed thoroughly.





Results: ML is applied in the fields of AM, such as Fused Deposition Modelling using 'M3DISEEN' software dependent on regression analysis, Digital Light Processing printing using Artificial Neural Networks (ANNs) and Self Organizing Maps (SOMs), material jetting printing using algorithm dependent on 'Bayesian optimization', embedded printing, and in-situ 3D printing and 4D printing. In the field of microfluidics, ML is being utilized in computational fluid dynamics for assessment of fluid flow following Navier-Stokes equation and flow cytometry data analysis via applying Convolutional Neural Network (CNN) viz foundation of all image based Deep Learning (DL).

Conclusion: ML has significantly influenced the technological advancements of AM and MFs, enabling the development of NextGen systems that predict variables and identify errors. With the help of ML, efficacy of digital-based learning is enhanced through real-time monitoring and data analytics.

Keywords: Artificial Intelligence (AI), Machine Learning (ML), Additive Manufacturing (AM), Microfluidics (MFs), Artificial Neural Networks (ANNs).

PTP045

Cutting-Edge Strategies for Brain Drug Delivery via nasal route

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Introduction: Nose-to-brain drug delivery has emerged as a promising alternative to traditional methods for treating central nervous system (CNS) disorders. This approach capitalizes on the unique anatomy and physiology of the nasal cavity, offering direct access to the brain via the olfactory and trigeminal pathways, bypassing the blood-brain barrier (BBB). This review explores the structural and functional aspects of the nasal cavity that facilitate drug transport and highlights the challenges associated with traditional CNS drug delivery.

Methods: Mechanisms of drug transport, including paracellular, transcellular, and endocytosis pathways, are detailed alongside key factors influencing delivery efficiency. Effective formulation criteria, such as physicochemical drug properties, mucoadhesive agents, permeation enhancers, and compatibility with nasal mucosa, are discussed. Advances in nasal delivery devices, including targeted delivery systems, are examined for their role in enhancing therapeutic outcomes. The formulation strategies section focuses on innovative approaches, including solubility enhancement, nanoparticles, liposomes, and biodegradable polymers, that improve drug stability and transport efficiency. Techniques, such as permeability and mucoadhesion testing, imaging methodologies, and *in vitro/in vivo* models, are outlined for evaluating formulation performance.

Results: Regulatory considerations and FDA guidelines are reviewed, emphasizing the requirements for clinical trials, bioequivalence, and safety of excipients. A review of marketed nose-to-brain products and case studies illustrates the clinical efficacy and patient compliance achieved by current formulations. The discussion highlights ongoing challenges, including patient variability, ethical concerns, and sustainability in device and formulation design, while exploring future prospects like hybrid delivery systems.

Conclusion: It emphasizes the potential of nose-to-brain delivery to revolutionize CNS treatment, with a call for further research to overcome existing limitations and optimize this transformative approach.

Key words: Nose-to-brain, Central nervous system, Blood-brain barrier.

PTP046

Advancements in Self-Nanoemulsifying Drug Delivery Systems (SNEDDS): Enhancing Bioavailability of Poorly Soluble Drugs

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Introduction: Self-Nanoemulsifying Drug Delivery Systems (SNEDDS) are innovative formulations that aim to increase the bioavailability of poorly water-soluble drugs. These systems are made up of a blend of oils, surfactants, co-surfactants, and solvents that spontaneously create nanoscale emulsion when they come into contact with aqueous fluids. This review explores the composition, advantages, and applications of SNEDDS in modern drug formulation, emphasizing their role in enhancing the bioavailability and clinical efficacy of poorly soluble drugs.

Methods: SNEDDS were prepared using various oils (e.g., Capryol 90), surfactants (e.g. Tween 80), and cosurfactants (e.g., PEG-400) in different concentrations. The optimal formulation was identified through ternary phase diagrams, followed by characterization techniques including particle size analysis, polydispersity index (PDI), zeta potential, and in vitro drug release studies.

Results: The nanoscale size of the emulsion droplets ensures better drug absorption through the lymphatic system or directly into the bloodstream, minimizing the first-pass metabolism. This technology is especially beneficial for oral drug delivery, although it can also be adapted for other routes like parenteral delivery. SNEDDS offer several key benefits, including the ability to improve drug stability, offer controlled release profiles, and provide target-specific delivery.

Conclusion: SNEDDS demonstrate substantial potential for improving the bioavailability of poorly soluble drugs. The developed system showed excellent stability, nanoscale particle size, and enhanced drug release, making it a promising strategy for enhancing therapeutic efficacy. These findings underline the versatility and effectiveness of SNEDDS in drug delivery applications, particularly for oral administration of hydrophobic drugs.

Keywords: Self-Nanoemulsifying Drug Delivery Systems (SNEDDS), Oral Bioavailability, Poorly Soluble Drugs, Drug Absorption.

PTP047

Depot Drug Delivery: An Overview from Formulation to Regulatory Requirements for Hormonal Replacement Therapy

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Introduction: A sterile pharmaceutical preparation intended for injection through one or more layers of the skin or mucous membrane is referred to as parenteral. One such type is a depot drug delivery system. They are advanced parenteral dosage form that offers drug release for extended time- period. Several endocrine disorders require the use of hormonal treatments. However, frequent dosing is often necessary for conventional formulations, which results in poor patient compliance and reduced therapeutic efficacy.

Method: Depot formulations are developed including implants, intramuscular, and subcutaneous injections, combined with biodegradable polymers, lipids, and other materials to encapsulate hormones, providing a sustained release profile. Examples include FDA-approved medications like leuprolide acetate, triptorelin pamoate, and medroxyprogesterone acetate, known for their efficacy and safety.

Result: Depot formulations have been effectively used in a number of hormonal therapies, such as menopause treatment, contraception, and hormone-sensitive malignancies. One of the examples in postmenopausal women is Gynodian® Depot, a combination of estrogen and androgen, which has a more significant effect on sexuality and psychological issues than with the estrogen estradiol valerate alone. Another example is testosterone cypionate for hypogonadism in male ensuring prolong delivery of androgen.

Conclusion: Depot formulation can provide consistent hormone levels over extended period of time improving therapeutic outcomes and patient compliance. Further research is needed to optimize depot formulations and expand their applications in hormonal therapy which could address issues such as osteoporosis in postmenopausal women. This review highlights the significance, challenges, and advancements in depot drug delivery systems for hormonal replacement therapy.

Keywords: Depot drug delivery systems, Hormonal disorders, Biodegradable polymers, Controlled drug release, Regulatory compliance.

PTP048



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Targeted Drug Delivery for Diabetic Retinopathy: Combining Nanoparticles with Dissolvable Microneedles

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Introduction: This review discovers the potential of a novel ocular drug delivery system merging polymeric nanoparticles and dissolvable microneedles for the treatment of diabetic retinopathy. Diabetic retinopathy is a primary cause of eye weakening and blindness among diabetic patients, which presents serious health issues for the entire world. Currently marketed formulations such as eye drops and intravitreal injections face limitations like; poor drug permeation, low bioavailability, invasiveness, and low patient compliance.

Method: Biocompatible polymers like PCL and PLGA are used to synthesize the polymeric nanoparticles, which have the properties of sustained and controlled drug release, increasing the stability and enhancing the bioavailability of the drugs. Loading these nanoparticles into the dissolvable microneedles confirms the targeted delivery of the drugs at the specific area of the retina, overcoming structural barriers, and systemic exposure is reduced.

Result: Compared to conventional formulations, the microneedle-based approach is less invasive, easier to use, and able to deliver drugs precisely while minimizing side effects. While intravitreal injections can lead to patient pain and possible problems, and currently available solutions such as eye drops have poor corneal permeability. Nanoparticle-loaded microneedles, on the other hand, overcome these drawbacks and serve as a viable substitute.

Conclusion: The structure, functioning, and benefits of nanoparticle-microneedle systems are reviewed in this paper along with a comparison to traditional treatments. Their potential to revolutionize ocular drug delivery for diabetic retinopathy and offer a safer, more efficient, and more patient-friendly therapy option is highlighted by concluding insights. For this cutting-edge technology to be optimized and commercialized, more study and clinical trials are necessary.

Keywords: Diabetic Retinopathy, Polymeric Nanoparticles, Dissolvable Microneedles, Targeted Delivery, Improve Bioavailability.

PTP049

Fabrication and Optimization of an Easy-To Swallow Dosage Form for Geriatric Patients

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Introduction: This study introduces a novel Entacapone formulation for Parkinson's disease, combining instant jelly powder with sustained-release pellets. The formulation aims to enhance solubility, improve bioavailability, and reduce dosing frequency, addressing challenges such as swallowing difficulties and complex regimens. It simplifies administration, enhances patient compliance, and offers a more effective solution for managing Parkinson's disease.

Methods: Entacapone, a BCS Class IV drug, was sourced from a certified supplier, with β -Cyclodextrin used for solubility enhancement. Dissolution studies were conducted using 0.1 N HCl and phosphate buffers (pH 5.5, pH 6.8). Excipients for pellets and jelly premix included polymers, solubility enhancers, sweeteners, and stabilizers. FTIR, DSC, and XRD were used to characterize the Entacapone- β -Cyclodextrin complex. In vivo studies and taste assessments were carried out with a BATA model setup, and packaging materials were selected for compatibility and patient compliance.

Result: Solid dispersion with hydroxypropyl beta-cyclodextrin (HP β -CD) significantly enhanced Entacapone's solubility. Instant jelly powder formulations used sodium alginate as the gelling agent and calcium ions as the activator, while pellets incorporated MCC 101, lactose monohydrate, and PVP. The dissolution studies showed peak solubility of 2394.59 µg/mL in pH 6.8.





Conclusion: The study successfully enhanced Entacapone's solubility and bioavailability, improving patient compliance and addressing challenges in Parkinson's disease treatment.

Keywords: Entacapone, Solubility enhancement, Patient compliance, Instant jelly powder, Sustained-release pellets.

PTP050

Targeted Nanotherapeutics for Vaginal Drug Delivery: A New Frontier in Polycystic Ovary Syndrome Management

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Introduction: Polycystic Ovary Syndrome (PCOS) is an endocrine disorder characterized by ovarian cysts, irregular ovulation, and hormonal fluctuations in women. Common complications include infertility, pelvic pain, hyperandrogenism, and insulin resistance. While there is no definitive cure for PCOS, conventional treatments such as metformin, clomiphene, letrozole, progestin therapy, and anti-androgens are commonly employed. However, these treatments often rely on oral routes, leading to dose-related side effects due to non-specific targeting.

Methods: To address the challenges associated with conventional treatments for PCOS, the development of advanced nanoformulations for targeted drug delivery through vaginal route can be employed. Utilizing nanotechnology, these nanoscale formulations aim to improve drug bioavailability while minimizing systemic side effects. Biodegradable polymers can be used due to their biocompatibility and ability to control drug release profiles.

Results: As per the Literature review, preclinical and clinical studies indicate that these nanoformulations can achieve controlled drug release, allowing for sustained therapeutic effects while reducing the frequency of administration and also the enhanced targeting capabilities are expected to improve the overall therapeutic outcomes in PCOS treatment.

Conclusion: If successfully developed and evaluated, these nanoformulations could offer a non-invasive alternative to existing PCOS treatments, improving patient compliance and contributing to better management of PCOS and its associated complications.

Keywords: Biodegradable polymers, Nanotechnology, Targeted drug delivery, Vaginal delivery.

PTP051

From Diagnosis to Targeted Therapy: The Role of Microneedles in Melanoma Management

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Introduction: Melanoma is an aggressive skin cancer originating from melanocytes, associated with high mortality due to its metastatic potential, drug resistance, and invasiveness. Current therapeutic approaches, such as surgery, chemotherapy, immunotherapy, and radiation therapy, face substantial limitations. These include suboptimal anti-cancer efficacy due to premature drug degradation, systemic adverse effects, and inadequate drug concentrations at the tumor site. Additionally, conventional diagnostic techniques often involve invasive sample collection and are prone to misdiagnosis or delayed diagnosis, emphasizing the urgent need for innovative strategies.

Methods: Microneedles (MNs) were evaluated as a novel platform for melanoma treatment and diagnosis. Key parameters such as formulation considerations, therapeutic potential, and advancements in MN applications for both therapeutic and diagnostic purposes were analysed.

Results: MNs offer significant advantages over conventional therapies by penetrating the skin's stratum corneum and forming transient microchannels, allowing precise drug delivery to melanoma sites. This localized delivery minimizes systemic exposure, reduces drug leakage, and enhances drug accumulation at the tumor site,





thereby mitigating adverse effects. Moreover, MNs provide a versatile platform to integrate novel and conventional therapies, enabling the co-delivery of multiple therapeutic agents within a single matrix. For diagnostic purposes, MNs can extract skin interstitial fluid (ISF), facilitating biomarker detection with minimal biological samples and patient discomfort.

Conclusion: MNs hold immense promise for overcoming the challenges in melanoma treatment and diagnosis. By ensuring localized drug delivery, minimizing systemic side effects, and enabling minimally invasive diagnostics, MNs offer a transformative approach to improved therapeutic outcomes and patient care.

Keywords: Biomarker, Controlled release, Localized drug delivery, Skin interstitial fluid (ISF), Targeted therapy.

PTP052

Microneedles: A Revolutionary Approach for Non-Invasive Diagnosis and Treatment of Breast Cancer

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Introduction: Breast cancer (BC) remains a significant global health concern. According to GLOBOCAN 2022 estimates, there were approximately 2.3 million new cases of BC worldwide, accounting for 11.6% of all cancer diagnosis. Despite advancements in diagnostic and therapeutic strategies, conventional approaches such as biopsies, chemotherapy, and radiotherapy often involve invasive procedures that can lead to significant discomfort and adverse side effects.

Method: Microneedles offer a minimally invasive approach for BC diagnosis and treatment. These microstructures can bypass gastrointestinal and metabolic barriers, enabling targeted drug delivery directly to BC tissues while reducing systemic toxicity. Various types of microneedles, including solid, coated, dissolving, hollow, and hydrogel-forming, have been explored for their unique drug delivery mechanisms and capabilities in biomarker detection. Fabrication techniques for microneedles include micromolding, photolithography, laser cutting, 3D printing, and etching. These methods allow the development of microneedles with precise geometries, sizes, and material compositions. Innovations in microneedle materials, including polymers, ceramics, metals, and other biocompatible compounds, have further improved their safety and effectiveness.

Results: Preclinical studies have demonstrated the efficacy of microneedles in BC management, particularly in immunotherapy, chemotherapy, photothermal therapy, and photodynamic therapy. These studies reported significant tumor reduction, improved survival rates, and fewer side effects than conventional approaches.

Conclusion: Microneedles represent a significant advancement in BC diagnosis and treatment. Their ability to deliver non-invasive, accurate, and effective drugs, along with their role in precise biomarker identification, positions them as a promising substitute for traditional therapies. Ongoing research and clinical studies will enhance their effectiveness, leading to better patient outcomes and overall well-being.

Keywords: Biomarkers, Chemotherapy, Geometry, Lithography, Micromolding.

PTP053

Revolutionizing Drug Delivery: The Cutting-Edge Potential of Microsponge Technology

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Introduction: Microsponges are tiny, porous polymer spheres measuring between 5 to 300 micrometers. which have shown considerable promise in drug delivery applications. They are utilized in various biomedical fields, including targeted drug delivery, transdermal applications, anticancer therapies, and as bone substitutes. This study focuses on reviewing the manufacturing methods and evaluation parameters associated with the Microsponge Delivery System (MDS). Microsponges trap active ingredients within their porous framework,



enabling a controlled and prolonged release to targeted areas while minimizing side effects. They are available in multiple dosage forms, such as a cream, gels, lotions, ointments, powder, tablet, capsules.

Methods: This review investigates online scientific databases like PubMed, ScienceDirect, and Google Scholar. Searches using specific keywords, including "microsponges" and "targeted drug delivery," yielded substantial results. The findings were then refined for in-depth review of relevant literature.

Results: The review provided a comprehensive analysis and comparison of different manufacturing techniques for microsponges. These methods included quasi-emulsion solvent diffusion, liquid-liquid suspension polymerization, oil-in-oil emulsion solvent diffusion, water-in-oil-in-water (w/o/w) emulsion solvent diffusion, lyophilization, vibrating orifice aerosol generator, porogen addition, ultrasound-assisted microsponge, & electrohydrodynamic atomization technique. Additionally, the review assessed critical evaluation parameters for microsponges, such as molecule size, porosity, drug entrapment efficiency, percentage loading efficiency, formulation yield, resiliency, and the drug release profile.

Conclusion: Microsponges hold great promise for future scientist & study on drug delivery, offering controlled, targeted release to enhance treatment and reduce side effects, with potential for transformative applications through advanced research.

Key words: Microsponge, liquid-liquid suspension polymerization, Quasi-emulsion solvent diffusion, Resiliency.

PTP054

Nanocarriers for Crossing the Blood Brain Barrier: A Frontier for Neurological Disorder

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Introduction: The delivery of therapeutic drugs to the brain is severely hampered by the blood-brain barrier (BBB), which restricts the range of treatments available for neurological conditions like Parkinson's, Alzheimer's, and brain cancers.

Method: Drug transport across the barrier is made possible by receptor-mediated nanocarriers, which use ligands like transferrin to target specific receptors on BBB endothelial cells. This technique involves loading medicinal drugs into transferrin-functionalized nanoparticles and testing their BBB permeability. Transferrin-functionalized nanoparticles effectively breach the BBB and deliver higher concentrations of medication to the brain compared to unmodified nanoparticles, according to in vitro studies using human endothelial cell models and in vivo studies utilizing mouse models.

Result: An important development in nanotechnology, the receptor-mediated nanocarrier approach offers a precise and efficient means to transport drugs to the brain and may pave the way for safer, more effective treatments for neurological conditions.

Conclusion: This method improves the safety profile of therapies by reducing systemic toxicity and increasing therapeutic efficacy. Despite its potential, further research is required to address challenges such as scalability, biocompatibility, and regulatory compliance.

Keywords: Blood-Brain Barrier (BBB), Nanocarriers, Receptor-Mediated Transport, Neurological Disorders, Transferrin-Functionalized Nanoparticles.

PTP055

Nanomaterials in Inflammatory Bowel Disease: Innovative Therapeutic Strategies for Targeted Drug Delivery

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Introduction: Inflammatory Bowel Disease (IBD), including Crohn's disease and ulcerative colitis, is a chronic inflammatory disorder of the gastrointestinal tract with no definitive cure. Despite existing treatments, challenges like systemic side effects and incomplete efficacy persist. Recent advancements in nanotechnology offer promising solutions, leveraging unique nanomaterials for targeted drug delivery and enhanced therapeutic effects.

Methods: This review summarizes emerging nanomaterial-based therapeutic strategies for IBD, focusing on their antioxidant, anti-inflammatory, and microbiome-regulating properties. Various nanoparticle fabrication methods, such as emulsion solvent evaporation, nanoprecipitation, spray drying, and ionic gelation are utilized. Additionally, functionalization techniques like surface ligand conjugation and encapsulation of bioactive agents are employed to enhance targeting and therapeutic efficacy.

Results: Nanomaterials demonstrate significant promise in IBD treatment by improving drug stability, targeting inflamed tissues, and minimizing systemic toxicity. Nanozyme-based therapies, antioxidant nanoparticles, and nanocarriers for controlled drug release have shown enhanced therapeutic outcomes in preclinical models. Additionally, strategies targeting oxidative stress and modulating the gut microbiome have yielded favorable results, showcasing their potential for broader applications.

Conclusion: Nanotechnology-based approaches represent a paradigm shift in IBD management, addressing the limitations of conventional therapies. Future research should focus on clinical translation, optimizing biocompatibility, and scalability, and paving the way for advanced, patient-centric treatments.

Keywords: targeted therapy, anti-inflammatory, nanocarriers, ulcerative colitis, liposomes.

PTP056

Revolutionizing Psoriatic Research: A Vision for Tomorrow's Treatments

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Introduction: Psoriatic Arthritis (PsA) is a specific progressive disease associated with psoriasis, that is often described as chronic inflammatory arthropathy affecting distal joints of the hands, feet and spine which is difficult to manage. The aim of this review is to summarize what is known currently while outlining potential future paths, which could ultimately make a huge difference in PsA management.

Method: A critical examination of research published between 2019 and 2024 identifies trends, problems, and future prospects for improving PsA care and patient outcomes. Reviewed literature shows trends in PsA therapy that mainly focuses on current therapies using nonsteroidal anti-inflammatory medications (NSAIDs), and disease-modifying antirheumatic drugs (DMARDs), and emphasizes on pharmacological breakthroughs, innovative drug delivery technologies, and AI-tailored therapies.

Result: Surveyed literature shows that PsA treatments have evolved from traditional therapies to sophisticated biologics, with targeted IL-23 and ROR γ t inhibitors demonstrating improved efficacy. Emerging advances, such as nanotechnology-based drug delivery and microneedles show promising results, along with Artificial Intelligence (AI) and Machine Learning (ML) are aiming towards building predictive models for therapy responses and personalized medical strategies for patients.

Conclusion: This review highlights recent advances in psoriatic arthritis management including innovative medicines, biomarker integration, and AI-driven customization. These techniques offer better treatment precision and safety. Collaborative efforts are yet very critical for overcoming obstacles, meeting unmet needs, and improving quality of life.

Keywords: Psoriatic Arthritis (PsA), Comorbidities, IL-23 Inhibitors, RORyt Inhibitors, Novel Drug Delivery Techniques.

PTP057



6" NATIONAL CONFERENCE OF INSTITUE OF PHARMACY 2025 Harnessing Artificial Intelligence / Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges



Wound Healing Reimagined: Lessons from the Past, Achievements of the Present, and Future Possibilities

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Introduction: Wound healing is one of the most complicated dynamics of biological processes essential in repairing the structural and functional integrity of damaged tissues. Complex interactions between molecular signaling pathways and cellular responses that dynamically act to coordinate the successive stages of hemostasis, inflammation, proliferation, and remodeling are examined in this review. Local factors such as infection, tissue oxygenation, and extrinsic factors such as age, nutrition, and comorbidities also affect the course of recovery. In addition, to the increased interest in herbal medicines, and essential oils, which promise therapeutic benefits, the review looks at traditional wound care principles such as enhanced dressings, bandages, and surgical procedures.

Methods: Surveyed literature focuses on diagnostic innovations in real-time wound progression monitoring including biomarker profiling and imaging technology. Innovative novel techniques have the potential to transform wound care which includes biotechnology-driven treatments, stem cell-based interventions, and medication delivery systems boosted by nanotechnology. Additionally, the application of digital health technologies focusing on wound assessment covers, 3D bioprinting for customized skin regeneration, and artificial intelligence is investigated serving effective and personalized treatment plans.

Result: The review demonstrates fusing cutting-edge innovations with conventional techniques to improve patient outcomes globally and enhance the science of wound healing.

Conclusion: This review highlights the current approaches and the need for multiple methods to overcome the management difficulties of both acute and chronic wounds, concluding by identifying knowledge gaps and suggests areas for future study.

Keywords: Wound healing, Herbal remedies, Essential oils, Nanotechnology, 3D Bioprinting.

PTP058

Development and Characterization of Functional Drug Delivery System of Caesalpinia Pulcherrima for Urolithiasis

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Introduction: The research developed a novel Herbal tablet dosage form using Caesalpinia Pulcherrima extract of red-orange variant species having high proportion of Terpenes using Liquisolid technique, optimized with Central Composite Design demonstrating effective in-vitro Anti-Urolithiatic activity showing rapid drug release and effective therapeutic efficacy.

Method: Terpenoids were extracted using Soxhlet device and adsorbed onto silica. Liquisolid technique was used to prepare liquisolid compact involving liquid or semisolid drug solutions into freely-flowing, compressible powder by blending with carriers such as MCC and coating material as Aerosil. Moreover, SSG as a super disintegrant was utilized to ensure rapid action and quick release. This technique enhances drug solubility, dissolution rate and bioavailability. The tablet was evaluated with all parameters and critical parameters such as in-vitro dissolution and disintegration time were performed.

Result: The compressed tablets prepared exhibit good hardness, friability, uniform drug content and good disintegrating property.

Conclusion: The C. pulcherrima extract was used to formulate a novel herbal tablet formulation that showed improved therapeutic efficacy, increased patient compliance, and decreased side effects and toxic effects of the current treatment.

Keywords: Caesalpinia Pulcherrima, Caryophyllene, Liquisolid compact, Anti- Urolithiatic activity, CCD.



6th NATIONAL CONFERENCE OF INSTITUE OF PHARMACY 2025 Harnessing Artificial Intelligence / Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges



Development and Characterization of Microemulsion based Topical Dosage Form for the treatment of Diabetic Foot Ulcer

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Introduction: Diabetic foot ulcers (DFUs) are a severe complication of diabetes, linked to increased risks of lower limb amputation and mortality. These ulcers result from multifaceted pathogenesis involving peripheral neuropathy, arterial disease, and infections. Despite advances in treatments such as wound debridement, topical dressings, and glucose management, the healing process remains complex and challenging. Vitamin C, known for its antioxidant and collagen-synthesis properties, shows potential in enhancing wound healing but suffers from limited skin permeation.

Methods: This research focuses on formulating a novel topical dosage form using a microemulsion system to improve Vitamin C delivery. Multiple trials evaluated different surfactant and oil combinations, with successful formulations incorporating PEG-40 hydrogenated castor oil and PEG-400.

Results: Two optimal batches demonstrated clear and stable microemulsions, achieving particle sizes of 12–12.9 nm. Future research includes optimizing these formulations using the design of experiments (DOE), evaluating characteristics like pH and viscosity, and conducting in vitro drug release studies.

Conclusion: This study focuses on to establish microemulsions as effective carriers, enhancing Vitamin C's therapeutic potential in DFU management.

Keywords: Diabetic Foot Ulcer, Wound Debridement, Multifaceted Pathogenesis, Topical Dressings, Skin Permeation.

PTP060

Approaches and challenges in Prodrug based drug delivery system

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Introduction: The document discusses the development of prodrug-based drug delivery systems, which aim to enhance the therapeutic efficacy and safety profile of drugs. The challenges in drug discovery, including safety, long development timelines, and limited bioavailability, have led to advancements like prodrugs. Prodrugs are inactive derivatives that are bio-reversible and release the active drug upon enzymatic or chemical transformation. This approach is particularly promising for targeting cancer cells due to the unique tumor microenvironment, such as varying pH, enzyme levels, and oxidative stress.

Methods: The review covers design principles and strategies used for prodrug development. Rational Design: Enhancing solubility, permeability, and bioavailability by attaching hydrophilic or lipophilic moieties. Targeting Strategies: Utilizing enzyme-specific or transport-specific activation mechanisms. Controlled Release: Employing nanocarriers or other matrix systems to achieve sustained drug release. Masking Functional Groups: Modifying functional groups to enhance therapeutic properties while maintaining controlled activation.

Results: The study highlights successful applications of prodrugs in cancer therapy, central nervous system (CNS) disorders, and infectious diseases. Cancer Therapy: Prodrugs selectively activate in tumor environments, minimizing off-target effects. Examples include enzyme-activatable prodrugs and ROS-responsive systems for enhanced targeting. CNS Disorders: Lipophilic prodrugs and strategies to bypass the blood-brain barrier show improved drug delivery for neurological conditions. Infectious Diseases: Prodrugs offer better targeting and reduced resistance, especially in fungal and bacterial infections.

Conclusion: The prodrug-based drug delivery approach has demonstrated immense potential for enhancing drug efficacy, pharmacokinetics, and safety. However, challenges remain in terms of stability, selectivity, and toxicity. Future research should focus on rational design, innovative linkers, targeting ligands, and interdisciplinary collaboration to overcome these hurdles. Emerging technologies like nanotechnology and microfluidics offer promising solutions for advancing prodrug systems toward clinical applications.





Keywords: Prodrug, Pargeting, Release, Cancer therapy, Nanocarrier.

PTP061

Advancing Pharmaceutical Manufacturing: Machine Learning Applications in Hot-Melt Extrusion Monitoring and Control

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Introduction: Now a days, the Hot-melt extrusion (HME) has become a pivotal industrial approach in large scale manufacturing of pellets and tablets. HME offers several merits including enhanced drug solubility, scalability, and solvent-free processing. A complex integration of multiple process variables like extrusion temperature, screw speed, screw configuration, etc. in product development by HME offers unique opportunity to employ innovative AI tools. The aim of present review is to explore application of novel AI tools in HME.

Methods: Online scientific resources, namely Web of Science and Pubmed National Library of Medicine, were searched using the keyword search "Hot melt extrusion & Machine Learning" and the results acquired were further fine-tuned to narrow down database for precisely focused targeted literature search.

Results: By integrating machine learning (ML) with process analytical technology (PAT), real-time monitoring and optimization of critical quality attributes are made possible for implementing QbD. ML models demonstrated high accuracy in monitoring and predicting critical process parameters. For example, Partial least square (PLS) regression achieved minimal error, while Principal component analysis (PCA) effectively identified process variations. Advanced non-linear methods, including artificial neural networks (ANN) and Non-linear ML algorithms further optimized process conditions. Challenges such as model transferability and data preprocessing were identified but successfully mitigated through advanced algorithmic approaches.

Conclusion: Integrating ML with PAT enhances real-time process monitoring, improving pharmaceutical product quality and process efficiency. These advancements underscore the transformative potential of ML in pharmaceutical manufacturing. Future work should focus on improving model robustness and generalizability for broader industrial applications.

Keywords: Hot-Melt Extrusion, Machine Learning, Process Analytical Technology, Pharmaceutical Optimization, Real Time Monitoring.

PTP062

Development and Optimization of Drug Layering on Pellets by Wurster Coating Technique Employing QbD Approach

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Introduction: Currently, the Wurster technique is one of the most widely explored industrial approach for drug layering, barrier layering, and Enteric coating. QbD methodologies includes the setting up a 'Quality Target Product Profile' (QTPP), categorizing of 'Critical Quality Attributes' (CQAs), guided by the systematic way to optimize the process related parameters using 'Design of Experiments' (DoE). This research focuses on leveraging the Wurster technique for coating and drug layering, underpinned by Quality by Design (QbD) principles.

Methods: Drug X served as a model drug to optimize process parameters and evaluate the scalability and adaptability of drug layering on pellet formulations. Preliminary, a full factorial DoE employed to optimize the critical process parameters such as spray rate (10–30 mL/min) and atomization air pressure (1–2 bar). Additionally, a Central Composite Design (CCD) was applied to optimize the excipient composition of functional layering. Responses for both designs included 24-hour dissolution data to evaluate controlled drug release and coating uniformity. QbD principles guided the establishment of a QTPP and identification of CQAs, such as dissolution rate and coating thickness.





Results: Spray rate and air pressure emerged as key parameters affecting coating uniformity and dissolution profiles. CCD analysis indicated that the excipient composition significantly influenced the functional coating's release kinetics. The optimized formulation achieved consistent controlled drug release over 24 hours, as well as, it had demonstrated scalability.

Conclusion: This study effectively engineered a scalable platform technology that integrated Wurster technique with QbD principles to tackle formulation challenges of drug layering on pellets.

Keywords: Wurster technique, Quality by Design, Dissolution profile, Platform technology.

PTP063

Formulation and Development of Injectable In-Situ Forming Depot of an Antipsychotic Drug

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Introduction: A novel depot formulation of risperidone has been developed utilizing Atrigel® technology to achieve sustained drug release. Atrigel® technology utilizes a biodegradable polymer dissolved in a biocompatible solvent to facilitate the formation of an in-situ depot upon subcutaneous administration. It offers significant advantages over microsphere-based formulations, including a simple manufacturing process and cost-effectiveness.

Methods: In situ implants were developed using PLGA 50:50 and PLGA 75:25 in N-Methyl-Pyrrolidone (NMP) as a solvent and benzyl alcohol as a co-solvent for drug incorporation. The formulations were prepared by mixing the polymer and drug solutions, followed by evaluation of burst release at 3 and 24 hours and cumulative drug release over time. Optimization was conducted using a Box-Behnken design.

Results: The in-situ depot formulation demonstrated varying drug release profiles depending on the polymer used. PLGA 50:50 exhibited faster drug release due to its lower molecular weight (7K-17K), leading to rapid polymer degradation. In contrast, PLGA 75:25 achieved prolonged drug release, attributed to its higher molecular weight (75K-115K) and slower degradation. Initial burst release was observed due to rapid solvent dissipation. The optimization of formulation parameters effectively minimized the initial burst release and achieved sustained drug release.

Conclusion: This study focused on formulating and optimizing an injectable in-situ depot system for schizophrenia treatment, with an emphasis on minimizing burst release and achieving sustained drug delivery. The use of different polymers significantly influenced the drug release profile and the optimized formulation, based on a Box-Behnken design, achieves the desired release characteristics.

Keywords: Atrigel® Technology, In-Situ Depot, Burst release, Box-Behnken design.

PTP064

Design of Colon Targeted Delivery of Oral Glucocorticoid Drug for The Treatment of Crohn's Disease

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Introduction: The formulation of budesonide delayed-release capsules has been investigated as a therapeutic approach for the management of Crohn's disease. The objective of this study is to enhance the pharmacological efficacy of budesonide through the optimization of formulation parameters that govern drug release.

Methods: The characterization of the drug was performed using Differential Scanning Calorimetry and Fourier Transform Infrared Spectroscopy. A systematic evaluation was conducted focusing on three critical formulation





variables: binder concentration, sustained release polymer concentration, and delayed release polymer concentration. Pellets were manufactured utilizing the Wurster coating process.

Results: The results indicated that the optimal binder concentration was established at 25%, which effectively mitigated lump formation and prevented clogging during the spray coating process. A 10% concentration of SR polymer significantly improved drug release kinetics, facilitating effective targeting of the affected intestinal regions. Conversely, a 38% concentration of DR polymer successfully restricted drug release in the gastric environment, maintaining a release threshold of no more than 10%. Following the coating process, the pellets were filled into size "1" capsules after lubrication was performed using manual capsule filling machinery. Furthermore, additional parameters like disintegration time, bulk density, and tapped density were evaluated to ensure the pellets met the desired specifications for formulation performance and stability.

Conclusion: This study elucidates the potential for the development of tailored budesonide delayed-release formulations that can enhance therapeutic outcomes in Crohn's disease management. By optimizing formulation variables, these capsules may ensure improved patient adherence and directed drug delivery to inflamed intestinal sites, thereby increasing treatment efficacy.

Keywords: Budesonide, Crohn's disease, Wurster coating process, Targeted delivery.

PTP065

Exploring the Impact of Surfactant and Conditioning Polymer in Developing Shampoo Formulation for Curly Hair

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Introduction: Shampoo formulation generally contains anionic surfactant and cationic conditioning polymer, which upon water dilution forms coacervates, which helps in active ingredients deposition on hair. The anionic polymer acts as a thickening agent, and it affects coacervation charge due to its negative charge causing screening effect. Damage on curly hair leads to higher negative charge, and use of anionic polymer may offer a competition with anionic surfactant.

Methods: The present study investigates the ingredients within shampoo formulation that generates coacervation and other sensory attributes in these formulations devoid of the presence of anionic polymers. The impact of various types and concentration of primary anionic surfactant, different primary and secondary cationic polymers and secondary surfactants on coacervation has been studied in detail. Different batches of shampoo were formulated and evaluated on the basis of change in smoothness using Diastron instrument, softness using UTM, and moisture retention & sensory parameters by 'hair swatches'.

Results: It has been observed that minor variation in surfactant and the cationic polymers significantly affects coacervation process in curly hair. The optimized shampoo resulted in improved smoothness (1.16 times), softness (1.78 times) and preserve more moisture (2.13 times) compared to other compositions.

Conclusion: Shampoo formulated by combination of primary cationic polymer exhibited higher acceptance in qualitative and quantitative parameters compared to other formulations. This research ultimately supports the development of innovative hair care products tailored to meet the unique needs of individuals with curly hair, providing them with improved hair manageability, softness and hydration.

Keywords: Hair Conditioning, Coacervation, Curly hair, Cationic Polymers, Anionic Surfactants.

PTP066

Formulation and Development of Dexamethasone Ophthalmic Emulsion

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Introduction: The physiological and anatomical characteristics of the eye present significant challenges for effective drug delivery. Systemic administration of ocular drugs often requires large dosages to achieve therapeutic concentrations in ocular tissues, leading to potential systemic side effects. Direct administration into the outer eye sac offers convenience; however, it is limited by poor corneal penetration and short residence time. Dexamethasone is commonly used as a topical anti-inflammatory treatment for steroid-responsive inflammation affecting the cornea and conjunctiva, but its insolubility in water necessitates formulation as a microfine suspension. Such suspensions are often unstable and prone to variability in dosage among patients.

Methods: This study aimed to develop a nanoemulsion formulation of dexamethasone to address the limitations associated with traditional eye drops and suspensions. Solubility tests were conducted using a vortex mixer to identify optimal oil and surfactant combinations for the nanoemulsion preparation. A calibration curve for dexamethasone was established in both buffer and methanol media. Phase separation trials were performed to assess the stability of the formulation.

Results: The formulation was found to be stable following phase separation trials. The selected oil and surfactant combinations of castor oil and tween 80, propylene glycol, koliphor HS 15 demonstrated enhanced solubility of dexamethasone, indicating a potential improvement over conventional delivery system. The thermogram exhibits a distinctive endothermic peak at 260°C, indicating the drug's purity. Design of experiment was used to optimize the formulation. The average globule size of the optimized batch of nanoemulsion was 16 nm, and its polydispersity index was 0.30 using zeta sizer.

Conclusion: The development of a dexamethasone nanoemulsion for ocular drug delivery represents a promising strategy to enhance therapeutic efficacy while minimizing side effects associated with traditional formulations.

Keywords: Ocular drug delivery, dexamethasone, nanoemulsion, topical anti-inflammatory.

PTP067

Preliminary studies in development of Ectoine Microemulsion Based Gel Cream for the Management of Atopic Dermatitis

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Introduction: Atopic dermatitis is a very relapsing, chronic, itchy, and inflammatory topical disease that generally affects infants and small children as well as adults. The main symptoms of dermatitis are red itchy skin and general inflammation which turns into eczema. The main triggers of dermatitis are allergens, infection, stress, heat, and sweating. Generally, topical corticosteroids and topical calcineurin inhibitors are used for the treatment of atopic dermatitis. However, it shows side effects like skin atrophy, and temporary application site burning, which in turn causes discontinuation of the treatment. Ectoine is a natural active constituent that is obtained from bacteria and it is a natural stress-protecting molecule that is used in atopic dermatitis. It forms a protective hydration shield around protein and other biomolecules. It has been associated with skin barrier improvement, reduction in trans epidermal water loss, and better skin elasticity. It does not show any side effects like other steroids. The present study aimed to develop a microemulsion based cream of ectoine to increase the drug penetration as well as permeation.

Methods: The microemulsion was developed using Spontaneous emulsification method. Olive oil was selected as oil phase as it is a natural moisturizer that is used to soften the skin. The selection of PEG 40 Hydrogenated Castor oil as surfactant and propylene glycol as co-surfactant was done by OFAT approach. The drug was characterized using UV spectroscopy, DSC, FTIR and preformulation studies.

Results: The formulation was found to be stable following phase separation trials. Microemulsion based formulation shows better drug loading and better skin penetration.

Conclusion: The development of a microemulsion based cream containing ectoine will offer a promising alternative for management of atopic dermatitis, addressing the limitations of traditional treatments. Future work





will focus on optimizing the formulation and evaluating various parameters to establish the effectiveness and safety.

Keywords: Atopic dermatitis, Ectoine, microemulsion, transepidermal water loss, skin barrier.

PTP068

Drug Delivery by Gold Nanoparticles for Cancer

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Introduction: Nanotechnology provides innovative solutions for cancer treatment by improving drug delivery. Gold nanoparticles (GNPs) are widely studied for their ability to deliver drugs directly to tumors. These nanoparticles can carry anticancer drugs and release them specifically at the tumor site, reducing side effects.

Methods: Gold nanoparticles were synthesized using the citrate reduction method. The nanoparticles were loaded with the chemotherapy drug cisplatin. Their size, stability, and drug release profile were analysed. The effectiveness of the drug-loaded GNPs was tested on lung cancer cells in vitro.

Results: The gold nanoparticles had a size of 50 nm and showed excellent stability. Drug release studies indicated that cisplatin was released more rapidly in the acidic environment of tumors compared to normal conditions. In vitro experiments showed that cisplatin-loaded GNPs reduced lung cancer cell viability by 65%, which was higher than free cisplatin.

Conclusion: Gold nanoparticles improve drug targeting to cancer cells and reduce side effects on healthy tissues. This method has great potential for future cancer treatments. They offer safe and efficient way to deliver anticancer drugs like cisplatin. Keywords: Nanotechnology, Gold nanoparticles (GNPs), Cisplatin, Drug Delivery and Cancer Treatment.

PTP069

Leveraging AI-Driven Approaches for Optimizing Solid Dispersion Techniques in Drug Formulation

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Introduction: Recent trends reveals that application of solid dispersion technique has been significantly explored in the pharma field by enhancing the solubility and bioavailability of poorly water-soluble drugs. Despite several advancements, the challenges related to predicting physical stability and optimizing formulation processes remain complex task for formulation scientist. Novel tools like Artificial intelligence (AI) as well as Machine learning (ML) provide innovative approaches to address such issues, offering precise predictive capabilities and streamlining formulation processes.

Methods: A systematic search was conducted on scientific databases such as Web of Science and PubMed National Library of Medicine using the keyword combination "Solid Dispersion & Machine learning". The outcomes were further refined to create a focused database, emphasizing studies that explore the application of AI and ML in solid dispersion formulation and optimization.

Results: The reviewed studies illustrate several scientists have explore the AI based methodologies in designing solid dispersions as transformative research. Studies revealed that ML algorithms may enable predictions of physical stability of formulations, improving the efficiency and reliability of the development process. One group of scientists have developed online platform 'PharmSD' utilizing advanced computational tools to integrate diverse data sources, providing valuable insights for formulation design. These technologies improve reproducibility, reduce development timelines, and enhance decision making through-out the formulation process.

Conclusion: AI/ML emerging as game changing technologies in the realm of solid dispersion formulation, providing enhanced stability predictions with efficient process design. By leveraging these tools, the pharmaceutical industry can accelerate innovation and overcome traditional formulation challenges.



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Keywords: Solid dispersion, Machine Learning, Pharmaceutical Optimization, Drug Formulation, Stability Prediction.

PTP070

AI-Powered Design of Liposomal and Polymeric Drug Delivery Systems

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Introduction: The integration of artificial intelligence (AI) in the design of liposomal and polymeric drug delivery systems is transforming pharmaceutical development. These advanced systems enhance drug solubility, stability, and targeted delivery, significantly improving therapeutic outcomes.

Methods: This review explains recent advancements in AI applications for optimizing liposomal and polymeric drug delivery systems. A systematic literature review was conducted on machine learning algorithms which were employed to analyse extensive datasets, focusing on parameters such as formulation composition, physicochemical properties, and release kinetics. A literature review was also conducted on various AI techniques, including predictive modelling and simulations, which were evaluated for their effectiveness in enhancing formulation design.

Results: AI-driven approaches have led to the development of novel formulations that exhibit improved drug encapsulation efficiency and stability. For instance, machine learning models successfully predicted optimal lipid-polymer interactions, resulting in hybrid systems with enhanced controlled release profiles. Furthermore, AI has facilitated personalized medicine by identifying patient-specific biomarkers that inform tailored drug delivery strategies.

Conclusion: The application of AI in the design of liposomal and polymeric drug delivery systems represents a significant advancement in pharmaceutical technology. By leveraging machine learning and data analytics, researchers can create more effective and personalized therapeutic interventions. The ongoing exploration of AI's potential in this field promises to address existing challenges in drug delivery, ultimately leading to improved patient care and outcomes.

Keywords: Artificial intelligence, liposomal drug delivery, polymeric systems, machine learning, personalized medicine.

PTP071

Crystallo Co Agglomeration: For Better Dissolution and Micromeritics Properties of Drug

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Introduction: Direct compression is the preferred method for tablet manufacturing due to the simplicity in processing and its cost effectiveness. However, for applying direct compression in tablet manufacturing, the drug used should have good flow properties and compaction characteristics. Many drugs are lacking these properties and so it is not possible to compress them directly into tablets. Crystallo co agglomeration (CCA) is an innovative technique developed with intends to provide the drugs with good micromeritic and mechanical characteristics.

Method: The process of CCA involves crystallisation followed by simultaneous agglomeration of the drug with the aid of a good solvent and /or a bridging liquid and a bad solvent. It is also possible to incorporate other drugs (to get a combination tablet), excipients (e.g. disintegrants for fast dissolving tablets) and different polymer combinations (to modify the drug release properties). In the recent years, attempts were made to produce Crystallo co agglomerates of various drugs, which were briefly discussed in this article.





Conclusion: Even though large-scale applications of CCA is not yet made possible, this technique gives a new line of opportunities to the tablet manufacturing process, ensuring low cost, single stepped production of particles with good micromeritic and mechanical characters which can be directly compressed.

Keywords: Crystallo co agglomeration, good solvent, bridging liquid, bad solvent, direct compression.

PTP072

Mesoporous Silica Nanoparticles as a Promising Nanoplatform for Ocular Disease Treatment

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Introduction: Ocular diseases, including glaucoma, macular degeneration, and diabetic retinopathy, can significantly impair vision and lead to blindness, severely affecting daily life. Traditional treatments often fail to effectively deliver drugs across the blood-retinal barrier, highlighting the need for innovative solutions. Recent advancements in nanotechnology have positioned mesoporous silica nanoparticles (MSNs) as promising carriers for ocular drug delivery due to their unique properties, including small size, large surface area, and porous structure.

Methods: MSNs are commonly synthesized using the sol-gel method, Stöber Method, Microemulsion Method, Evaporation-Induced Self-Assembly (EISA) Method by adjusting synthesis parameters such as pH, reaction time, and temperature, researchers can tailor particle size, pore diameter, and surface functionality to optimize drug loading and release.

Results: MSNs have demonstrated the ability to penetrate ocular barriers effectively, enhancing the bioavailability of therapeutic agents. Their porous structure facilitates high drug loading, while surface modifications enable targeted and stimuli-responsive delivery. These properties have shown potential in treating various ocular conditions, improving therapeutic outcomes, and reducing systemic side effects.

Conclusion: Despite their significant advantages, including adaptability and improved drug delivery efficiency, concerns regarding the biosafety and toxicity of MSNs must be addressed. Further studies are required to optimize MSN properties, ensure scalability for mass production, and validate their safety in clinical applications. Overall, MSNs represent a promising nanotechnology platform with the potential to revolutionize the treatment of ocular diseases and improve patient outcomes.

Keywords: Mesoporous Silica Nanoparticles, Ocular Drug Delivery, Blood-Retinal Barrier, Targeted Delivery.

PTP073

Qbd Approach for Azelaic Acid Nano Cochleates

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Introduction: Quality By Design (QBD) is a systematic approach used in development of pharmaceutical products. Azelaic acid is widely used for acne and but has stability issues and causes skin irritation. Nano cochleates is a delivery system that has shown to improve entrapment efficiency and stability of drugs. Thus, Azelaic Acid (AZA) nano cochleates are optimized with the maximum entrapment efficacy and the smallest particle size using QbD apprach.

Methods: To optimize the formulation Box Behnken Design was employed with 17 runs. By identifying critical quality attributes (CQA) like particle size and entrapment efficiency with Critical Process Parameters (CPPs; probe sonication time) and critical material attribute (cholesterol concentration, and volume added of zinc), the best formulation was optimized.

Results: The results indicated, 10mg cholesterol,1ml of cation, probe of 3min would be the best optimized batch with entrapment efficiency of 85.10% and particle size of 338.03nm. FTIR was conducted for the optimized batch.





Conclusion: The QBD approach using Box- Behnken Design demonstrated that from the 17 experimental runs, a optimized formulation with the highest entrapment and lowest particle size.

Keywords: Azelaic Acid, Nano cochleates, Box Behnken.

PTP074

AI and Computational Modelling in Pharmaceutical Product development

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Introduction: Computational modelling and innovative AI-tools are foreseen as an obligatory tool for sustainable and resource-effective pharmaceutical product development. Several AI algorithms and computational modelling have now been explored for analyzing and modeling of various drug delivery systems at molecular, microscopic and macroscopic levels. The market of AI is expected to grow at a CAGR of 42.68% from 2024 to 2029. AI tools are now extensively improving predictability of drug properties, formulation optimization of nano-medicines, API-excipient interactions, drug release kinetics, and effect of physiological factors on the formulation characteristics, stability profiling, pharmacokinetic parameter estimation, drug bio-distribution kinetics, IVIVC etc.

Methods: Genetic Algorithms, Artificial Neural Networks (ANNs), Support Vector Machines (SVMs), Particle Swarm Optimization (PSOs), AI-based expert systems, Monte Carlo Simulation, Computational Fluid dynamics (CFD), ANN-Genetic Algorithm etc. are some of the computational AI-based models used extensively for the Pharmaceutical Product development.

Results: The use of AI and computational tools have markedly reduced the efforts and have briefed the timelines of formulation development. Utilization of appropriate AI-based tools can help identify and mitigate the potential risks associated with the drug performance aiding in QbD concept on a ground level proactively.

Conclusion: The use of AI and computational modeling in pharmaceutical product development is gradually getting a regulatory back-up and is anticipated to leverage the sustainable pharmaceutical production to an unpredictable venture soon.

Keywords: Support-Vector Machine, AI-driven QbD, Computational Fluid Dynamics, Computational-Modelling.

PTP075

From Static to Dynamic: 4D Printing Transforming Drug Delivery and Personalized Medicine

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Introduction: 4D printing, an evolution of 3D printing, incorporates time as a dynamic element, enabling printed objects to alter their shape, function, or properties in response to environmental stimuli. This transformative technology holds immense potential in the healthcare sector, particularly in advancing personalized medicine and drug delivery systems. By integrating smart materials with adaptive functionalities, 4D printing facilitates the creation of dynamic, patient-specific healthcare solutions, redefining traditional therapeutic approaches.

Method: This review investigates the applications of 4D printing in personalized healthcare, with a focus on advanced drug delivery systems. Smart materials, including shape-memory polymers (SMPs), hydrogels, and other stimuli-responsive substances, were analyzed for their potential in creating programmable and targeted drug delivery solutions. These materials, responsive to triggers such as temperature, pH, and other biological stimuli, were also evaluated for applications in customized implants and tissue scaffolds, reinforcing their versatility in patient-specific care.





Result: 4D-printed drug delivery systems demonstrated unprecedented precision in controlled, localized drug release. For instance, pH-sensitive systems exhibited superior efficacy in delivering therapeutic agents to targeted sites, minimizing systemic side effects. Similarly, temperature-responsive carriers enabled the timed release of drugs, aligning treatment with individual patient needs. These findings underscore the transformative potential of 4D printing in personalizing drug therapies and addressing specific healthcare challenges.

Conclusion: By enabling the creation of adaptive, patient-specific drug delivery systems and therapeutic devices, 4D printing is set to revolutionize healthcare. This review highlights key advancements, current challenges, and future opportunities in leveraging 4D printing for personalized medicine, emphasizing its pivotal role in improving therapeutic outcomes and patient care.

Keywords: 4D printing, Drug delivery systems, Personalized medicine, Smart materials.

PTP076

Studies on Formulation Development of Glucocorticoid oral Solution for the Treatment of Rheumatoid Arthritis

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Introduction: To investigate and develop a glucocorticoid oral solution for the effective treatment of rheumatoid arthritis, with a focus on formulation optimization, pharmacokinetic evaluation, stability studies, and patient compliance.

Methods: The formulation includes glucocorticoid as the active ingredient and excipients such as ethanol, propylene glycol, glycerine, EDTA, anhydrous citric acid, saccharin sodium, sucrose, benzoic acid, FDC Red No. 40, and purified water. The solution was prepared using the stirring method to ensure uniform mixing. The final formulation(F1-F7) displayed a slightly pinkish-red color, a pH range of 3.5–4.0, and a density between 1.15–1.25 g/mL.

Results: Stability studies were conducted following ICH Q1A(R2) guidelines under accelerated ($40^{\circ}C \pm 2^{\circ}C$, 75% RH \pm 5%) and long-term ($25^{\circ}C \pm 2^{\circ}C$, 60% RH \pm 5%) conditions over 6,12 months. The F4 formulation remained stable, with no significant changes in appearance, pH, density, or active ingredient content. Additionally, no microbial contamination or degradation was detected during the study.

Conclusion: In conclusion, the oral glucocorticoid solution demonstrated compliance with ICH stability standards, ensuring its physical and chemical stability. Its patient-friendly properties and ease of use make it a promising therapeutic option for rheumatoid arthritis. Further clinical studies are necessary to validate its safety and efficacy.

Keywords: Glucocorticoid, Oral solution, Rheumatoid arthritis, ICH stability studies, Solubility.

PTP077

Development and Optimisation of Glutathione Niosomes to Improve Oral Bioavailability for Non-Alcoholic Fatty Liver Disease

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Introduction: Non-alcoholic fatty liver disease (NAFLD) is a progressive liver condition affecting nearly 25–30% of the global population. Oxidative stress plays a critical role in its pathogenesis. Glutathione (GSH), a potent antioxidant, is effective in countering oxidative damage but suffers from poor oral bioavailability due to degradation in the gastrointestinal tract.

Methods: This study aimed to formulate and optimise GSH-loaded niosomes using the thin-film hydration method. A design of experiments (DOE) approach was employed to optimise the surfactant-to-cholesterol ratio,





sonication time, and hydration time. The niosomes were characterised by particle size, polydispersity index (PDI), zeta potential, encapsulation efficiency, and in vitro drug release.

Results: Optimised GSH-loaded niosomes demonstrated a particle size of 270.8 ± 18.7 nm with a PDI of 0.433 \pm .26 and a zeta potential of -54.3 \pm 3.6 mV, confirming stability and uniformity. Encapsulation efficiency was $85.4\% \pm 3.6$. In vitro release studies showed a sustained release of up to $92.8 \pm 3\%$ over 24 hours.

Conclusion: These findings highlight the potential of niosomal drug delivery systems to overcome the challenges associated with oral GSH administration, such as enzymatic degradation and poor absorption. By improving the stability and release profile of GSH, this formulation could pave the way for more effective antioxidant therapies for chronic liver conditions like NAFLD.

Keywords: Glutathione, Niosomes, NAFLD, Oral bioavailability, Antioxidant.





ABSTRACT- POSTER PRESENTATIONS

(Pharmacology, Clinical Pharmacy, Pharmacovigilance & Pharmacy Practice)





PLP001

A Prospective Interventional Study to Assess the Fall Risk and Knowledge of Fall Prevention Strategies in Osteoporotic Patients

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Introduction: Osteoporosis is characterized by reduced bone mass density leading to bone fractures and falls. A number of risk factors contribute significantly to fall risk irrelevant of gender. Therefore, assessment of the associated risks and effective knowledge on preventive strategies assist in improving bone health and minimizing fall risk.

Method: The prospective interventional study was conducted among the known cases of osteoporosis of either gender above 30 years of age, excluding the pregnant and immobilised patients of 2 different hospital in Ahmedabad and Gandhinagar. Demographic details such as age & gender was collected. Fall risks were assessed using Berg Balance Scale and knowledge was assessed by self-designed pre validated questionnaire consist of 13 questions, each question was rated 1 or 0 mark. The Adherence to Refills and Medications Scale (ARMS) scale was used to measure adherence and fall related questionnaire to identify the risk factors. Patient counselling was provided at baseline. Patient were followed up at the interval of 1 month. Suitable descriptive and inferential statistics were applied to the outcome.

Result: Of the 135 enrolled patients, female were 74 and 61 were males. The fall risk assessment mean score of fall risk at base line was 27.26 with 10.78SD and at follow up mean score was 34.88 with 11.39SD, P value 8.57. ARMS baseline mean 18.3 with 6.37SD and at follow up mean score was 16 with 5.4SD. The knowledge of subjects as increased at follow up compered to base line

Conclusion: Educational intervention observed effective in improving medication adherence, knowledge on fall risk and associated risk factors including FRIDs, comorbidities, age, gender and prevention measures minimize fall risk, improve bone health. Adherence significantly affected by age and poly pharmacy. The fall risk assessment showed significant difference despite of gender and age

Keywords: Fall risk, fall prevention, FRIDs, Adherence to Refills and Medications Scale, Medication adherence, Berg Balance Scale, Comorbidities.

PLP002

Nanotech Innovations: Shaping the Future of Alzheimer's Diagnosis and Treatment

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Introduction: Alzheimer's disease (AD) is a major global health issue characterised by amyloid plaques and neurofibrillary tangles. Current therapies have limitations, underscoring the need for novel approaches. Nanotechnology, with its potential to modify matter at the atomic and molecular levels, could revolutionise medicine, especially in addressing Alzheimer's. This review investigates nanotechnology's potential in AD for drug delivery, diagnostics, and therapeutic interventions.

Methods: A comprehensive literature review summarised key findings from scientific publications on nanotechnology's use in Alzheimer's. The review focused on studies involving nanoparticles for therapeutic modulation, drug delivery, and diagnostics. We examined nanoparticle types, mechanisms of action, and their effects on neuroinflammation, amyloid plaque and tau protein targeting, and blood-brain barrier (BBB) penetration. Developments in nanotechnology for microRNA (miRNA) modification and clinical trial data were analysed, along with ethical and safety concerns.

Results: Nanoparticles improve medication transport across the BBB and enable precise targeting of tau proteins and amyloid plaques. Nanotechnology has shown promise in early diagnosis through highly sensitive imaging agents and biomarker detection. Therapeutic approaches involving antioxidant delivery by





nanoparticles and regulation of neuroinflammation are promising. Targeted delivery of miRNAs via nanoparticles is emerging as a potent disease-modifying strategy. Multifunctional nanomedicines combining diagnosis and treatment (theragnostic) are actively researched but require further validation.

Conclusion: Nanotechnology offers promising approaches to combat Alzheimer's, including improved drug delivery, early diagnosis, and therapeutic interventions. Targeted medication, miRNA delivery via nanoparticles, and advancements in imaging and biomarkers are evolving for AD management. Safety and ethical concerns must be addressed, with future research focusing on personalised strategies and technological advancements to improve patient outcomes. Successful clinical integration will depend on regulatory compliance and long-term safety evidence.

Keywords: Nanotechnology, Alzheimer's disease, Drug delivery, Diagnostics, Therapeutic interventions.

PLP003

Evaluate Herbal Combination for the Treatment of Rheumatoid Arthritis

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Introduction: Rheumatoid arthritis (RA) is a systemic autoimmune disorder causing chronic inflammation, predominantly in synovial joints. It affects approximately 1% of the global population, with a higher prevalence in females and developing nations. The pathogenesis involves a complex interaction of genetic, environmental and immune-mediated factors, prominently driven by Toll-like Receptors (TLR4) and the NLRP3 inflammasome. These pathways amplify inflammatory cytokine production, leading to tissue damage. While NSAIDs are effective for symptom relief, their prolonged use is linked to adverse effects, necessitating safer alternatives.

Methods: Phytochemical investigations were conducted on methanolic extracts of *Cichorium intybus* roots, *Kigelia pinnata* fruits and *Cedrus deodara* wood oil. These were analyzed for their bioactive phenolic and terpenoid content, with antioxidant assays confirming their radical scavenging activities. A 2⁵ factorial design was employed to evaluate the anti-inflammatory efficacy of extract combinations in CFA-induced arthritis models. Rats received doses of 30 mg/kg, 100 mg/kg, and 300 mg/kg over 28 days.

Results: The 300mg/kg dose exhibited pronounced anti-inflammatory effects by lowering proinflammatory cytokines, enhancing haematological markers, and mitigating oxidative stress. Histopathological results indicated reduced inflammatory infiltration and connective tissue damage, suggesting TLR4 modulation and suppression of cytokine transcription.

Conclusion: Phytochemicals demonstrated significant therapeutic potential in modulating inflammatory pathways in RA, meriting further investigation for clinical application.

Keywords: Rheumatoid arthritis, TLR4, NLRP3, phytochemicals, anti-inflammatory.

PLP004

AI Based Probabilistic Approach to Ovarian Cancer Diagnostics Through Metabolomics

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Introduction: Ovarian cancer, arising primarily due to mutations in the ovarian epithelium, has the highest mortality rate among gynecological cancers. Its non-specific signs and symptoms often lead to late-stage diagnoses, earning it the designation of a "silent killer." This review focuses on a study by Ban et al., which developed a machine learning-based diagnostic tool utilizing serum metabolomic profiles to identify ovarian cancer.

Methods: The study analyzed serum samples from 431 ovarian cancer patients and 133 healthy individuals collected across four geographic locations. Serum metabolomic profiles were generated using ultra-performance liquid chromatography-tandem mass spectrometry (UPLC-MS/MS). Key metabolites were identified using





recursive feature elimination and cross-validation techniques. A consensus classifier was developed by integrating multiple machine learning models, including K-Nearest Neighbors (KNN), Logistic Regression Classifier (LRC), Support Vector Classifier (SVC), Adaptive Boosting Classifier (ADA), and Random Forest Classifier (RFC). The model assigned probabilities to classify samples as cancerous or normal, enabling the development of a probabilistic diagnostic tool.

Results: The consensus classifier demonstrated high accuracy in distinguishing ovarian cancer patients from healthy individuals. By identifying critical serum metabolites and integrating machine learning techniques, the study successfully developed a personalized diagnostic tool capable of estimating the likelihood of ovarian cancer in individual samples.

Conclusion: The reviewed study underscores the potential of serum metabolomic profiling and machine learning integration in advancing ovarian cancer diagnostics. This innovative approach offers significant promise for early detection and improved clinical outcomes for this challenging disease.

Keywords: Ovarian cancer, metabolomics, machine learning, consensus classifier, personalized diagnostics.

PLP005

Vagus stimulation: A new approach to treat Rheumatoid Arthritis

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Introduction: There has been a marked improvement in the treatment of rheumatoid arthritis (RA), but most patients do not achieve disease remission. Neuromodulation can be used as a novel anti-inflammatory approach. Neuromodulation can be done with either chemical or electrical stimulus. For RA, scientists are looking into using electrical currents. In neuromodulation a device is used to disrupt nerve messages, and thus fight inflammation, in your body. Vagus nerve stimulation delivered with an implanted device has been shown to improve rheumatoid arthritis severity.

Method: Electrical stimulation of the parasympathetic vagus nerve leads to activation of the sympathetic splenic nerve which produces norepinephrine in close proximity to choline acetyltransferase positive (CHATb) T-cells.

Result: The CHAT^b T-cells are able to produce the anti-inflammatory mediator acetylcholine, which can bind to the nicotinergic acetylcholine receptor type 7 (a7nAChR) and reduces cytokine production. This results in reduced inflammation in the joints.

Conclusion: If successful, the advantage of this approach could be that it is a safe, and well-tolerated therapy, appealing to patients as it aims to restore the natural balance by targeting an intrinsic anti-inflammatory pathway. VNS therapy should not lead to immunosuppression and can therefore be combined with both sDMARDs and bDMARDs, nor does it have the problem of causing development of anti-drug antibodies. The long life-span (7-10 years) of the VNS pulse generator will make this approach cost-effective, if there is a prolonged therapeutic effect.

Keywords: Rheumatoid arthritis, neuromodulation, vagus nerve stimulation, immunosuppression, DMARDs.

PLP006

Targeting EphB2 and EphA4 Receptors for Alzheimer's Disease

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Introduction: A complicated neurodegenerative disease, Alzheimer's disease (AD) is typified by synaptic disruption and progressive cognitive impairment. Recent research has shown that the Eph receptor tyrosine kinases—in particular, EphB2 and EphA4—are important regulators of the brain's neuronal circuitry and synaptic plasticity. The pathophysiology of AD has been linked to the dysregulation of these receptors and their ephrin ligands, which are essential for preserving synaptic function. Hence, it is worth to investigate the role of EphB2 and EphA4 receptors for Alzheimer's Disease modulation.





Methods: The dual axis of EphB2 and EphA4 will be discussed, with particular attention paid to their functions in synaptic signalling, relationships with disease hallmarks and downstream pathways that affect axonal guidance, neuroinflammation and cell survival.

Results: While EphA4 hyperactivation exacerbates synaptic loss and neurodegeneration through processes involving amyloid-beta (A β) and tau pathology, EphB2 loss contributes to poor long-term potentiation (LTP) and memory impairments. Knowing the complex EphB2 and EphA4 network highlights their potential as viable therapeutic targets and provides new insights into the pathogenesis of AD.

Conclusion: We open the door for novel approaches to address synaptic dysfunction and cognitive decline in Alzheimer's disease by clarifying this axis.

Keywords: Alzheimer's disease, EphB2, EphA4, Targets, Therapeutics, amyloid-beta.

PLP007

Mitochondrial Vulnerability: A Key Factor in Neurodegeneration Induced by Environmental Toxins

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Introduction: Mitochondria are crucial for energy production, and playing a vital role in neuronal health. Alterations in mitochondrial integrity dysfunction are central to neurodegenerative diseases, including Alzheimer's, Parkinson's. Environmental toxicants such as heavy metals (lead, mercury, arsenic, cadmium) and pesticides exacerbate mitochondrial impairments, disrupting bioenergetics and increasing oxidative stress, which accelerates neuronal damage. This study recapitulates mitochondria as an important target in governing the pathogenesis of environmental toxicant induced alteration in neurodegenerative disorders such as Alzheimer's and Parkinson's disease.

Method: This review examines the impact of various environmental toxicants on mitochondrial integrity and their role in neurodegenerative diseases. A wide plethora of published articles were assessed to summarize mitochondria as the target for the environmental toxicants induced neurodegenerative disorders. Mechanistic pathways, including oxidative stress, mitochondrial dynamics disruption, and apoptosis, were summarized using broad review search.

Results: Environmental toxicants including Heavy metals, pesticides, solvents compromise altered mitochondrial bioenergetics, disturb mitochondrial dynamics and more by disrupting the electron transport chain, leading to elevated production of reactive oxygen species (ROS) causing the compromised damaged in neurodegenerative disorders, Arsenic, mercury, and cadmium amplify oxidative stress and mitochondrial fragmentation, impairing calcium homeostasis and mitophagy. Pesticides such as organophosphates and organochlorines inhibit mitochondrial enzymes, disrupt energy production, and promote protein aggregation.

Conclusion: Environmental toxicants profoundly impact mitochondrial health, linking them to neurodegenerative diseases. Strategies to enhance mitochondrial function, such as boosting antioxidant defenses, improving mitophagy, and minimizing toxicant exposure, hold promise for mitigating disease progression. The review highlights the importance of targeting mitochondrial resilience to counteract the harmful effects of environmental toxicants and improve outcomes in neurodegenerative conditions.

Keywords: Neurodegenerative Disorders, Mitochondrial Dysfunction, Environmental Toxicants, Heavy metals.

PLP008

Protective Potential of Polyherbal Formulation in Streptozotocin Induced Diabetic Model

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Introduction: Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia, which leads to various complications. Current therapies have limitations, prompting the exploration of natural remedies. The present study investigates the anti-diabetic potential of a polyherbal formulation composed of *Piper longum, Centratherum anthelminiticum*, and *Holarrhena antidysenterica*. The formulation's effects on blood glucose regulation, oxidative stress, and steroid-induced hyperglycemia were evaluated using an experimental model.

Methods: Powdered plant materials were authenticated and processed into hydroalcoholic and aqueous extracts using maceration. The polyherbal formulation was tested on 24 Wistar albino rats (200–250 g), divided into five groups (n=6). Group I served as the normal control and received saline. Group II was the diseased control with diabetes induced by streptozotocin (STZ). Group III received STZ and the polyherbal formulation. Group IV was treated with STZ and metformin. Doses of the polyherbal formulation (low, medium, and high) were administered for 14 days. Parameters such as food and water intake, body weight, and blood glucose levels were monitored, and oxidative stress was assessed via malondialdehyde (MDA) levels.

Results: The polyherbal formulation significantly reduced blood glucose levels compare to STZ-induced group, and also to STZ with metformin group. The formulation also reduced MDA levels, indicating antioxidant activity of formulation. No toxic activity and no animal death were observed during the study.

Conclusion: The results of present study indicate that polyherbal formulation containing *Piper longum*, *Centratherum anthelminiticum*, and *Holarrhena antidysenterica* having a significant anti-diabetic and antioxidant potential. Its efficacy in modifying hyperglycemia and oxidative stress exhibits its therapeutic promise in managing diabetes.

Keywords: Streptozotocin, malondialdehyde, diabetes, antioxidant, polyherbal formulation.

PLP009

Beyond Hormones: Oxidative Stress as a Key Player in PCOS

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Introduction: Polycystic Ovary Syndrome (PCOS) is a prevalent hormonal disorder characterised by elevated androgen levels, irregular ovulation, and multiple ovarian cysts. Oxidative stress – an imbalance between reactive oxygen species (ROS) production and antioxidant defences – plays a crucial role in PCOS development. Both obese and non-obese PCOS patients exhibit increased oxidative stress markers and decreased antioxidant levels, which are linked to hyperinsulinemia, hypertension, and dyslipidaemia. Mitochondrial dysfunction in granulosa cells exacerbates oxidative stress, impairing ovarian function and ovulation.

Methods: A systematic literature review was conducted using PubMed, Web of Science, and Scopus, focusing on oxidative stress in PCOS.

Results: The Keap1/Nrf2 pathway, a key antioxidant defence regulator, is dysregulated in PCOS, with chronic oxidative stress reducing levels of the protective enzyme heme oxygenase-1 (HO-1). Emerging evidence suggests that oxidative stress-targeted therapies, such as melatonin supplementation, humanin analogs, and miR-873-5p suppression, may enhance insulin sensitivity and overall metabolic and reproductive health in PCOS patients.

Conclusion: This review explores the complex relationship between PCOS and oxidative stress, highlighting underlying mechanisms, clinical implications, and potential therapeutic interventions targeting oxidative stress to manage PCOS.

Keywords: Polycystic Ovary Syndrome (PCOS), Oxidative Stress, Mitochondrial Dysfunction, Antioxidant Therapy, Insulin Sensitivity.

PLP010

Study on Prevalence of Maternal Anemia and its Association with Neonatal Health Outcomes

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Introduction: Maternal anemia is a global health issue, particularly in low- and middle-income countries, with high prevalence among pregnant women. Defined by reduced hemoglobin levels, it is linked to adverse outcomes such as preterm birth, low birth weight, and neonatal morbidity and mortality. Despite interventions like iron and folic acid supplementation, maternal anemia remains a major threat to maternal and neonatal health. This prospective study examines the prevalence of maternal anemia and its association with neonatal health outcomes, offering insights to address its burden and improve maternal care.

Method: A comprehensive group of 450 pregnant women from LG Hospital, Ahmedabad, were selected for the study using a multistage sampling technique. The participants were closely monitored and followed up until one week after delivery.

Results: Approximately 17.89% of the women experienced maternal or fetal morbidity. Anemia emerged as the most prevalent pregnancy-related complication (69.56%), followed by hypertension (8.22%), hypothyroidism (4.88%), and abortions or stillbirths (3.5%). Fetal complications included low birth weight (28.5%), premature delivery (3.57%), fetal tachycardia, and neonatal death (1.78%)

Conclusion: The study emphasizes the importance of addressing maternal anemia to improve neonatal outcomes and maternal health, highlighting how proactive management and interventions can positively influence the well-being of both mothers and their babies.

Keywords: Maternal anemia, Neonatal outcomes, prevalence, pregnancy complications.

PLP012

Impact of Counseling on Hemoglobin Levels in Anemic Pregnant Women

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Introduction: Maternal anemia, remains a prevalent public health issue globally. It poses significant risks to both maternal and fetal health. As a personalized and interactive approach, counseling has emerged as a promising intervention to address these challenges. By providing tailored nutritional guidance, enhancing awareness about anemia, and fostering behavioral change, counseling can empower pregnant women to adopt healthier practices, improve adherence to supplementation, and mitigate the adverse effects of anemia.

Methodology: Counseling was provided to a sample of 115 patients, who were followed up for approximately one month. Leaflets in Hindi and Gujarati were used to enhance patient understanding and communication. The differences in results were analyzed using a paired t-test.

Result: The counseling intervention led to a significant improvement in hemoglobin levels among anemic pregnant women. The proportion of women in the lowest hemoglobin range (<7 g/dl) decreased from 7% to 0%, while those in the 7.1–8.9 g/dl range declined from 38% to 23%, and those in the highest range (9.0–10.9 g/dl) rose from 55% to 75% post-counseling. These results highlight the effectiveness of counseling in improving hemoglobin levels and reducing severe anemia among pregnant women.

Conclusion: Post-counselling assessments revealed that most women experienced improvements in their hemoglobin levels, demonstrating the potential effectiveness of the counseling provided.

Keywords: pregnancy, maternal anemia, counseling, hemoglobin levels.

PLP013

Targating Epilepsy Through the Gut-Brain-Axis: Therapeutic Potential of Canabinnoids in Leaky Gut-Associated Seizures

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Introduction: Epilepsy, a neurological disorder characterized by recurrent seizures, has been increasingly linked to gut-brain axis dysfunction, particularly in cases associated with intestinal barrier disruption or "leaky gut" which is characterised by release of lipopolysaccharides (LPS) in systemic circulation. There are two possible pathways associated with Leaky Gut which includes the upward and the downward pathways where the Vagus nerve connects the gut to the brain.

Methods: The literature search was conducted using Pubmed and Google Scholar to retrieve information on Cannabinoids which are a class of chemical compounds that interact with the endocannabinoid system (ECS) in the human body.

Results: Cannabinoids can mitigate gut inflammation, enhance intestinal barrier integrity, and modulate gut microbiota composition, thereby influencing systemic immune responses and reducing neuroinflammation. A literature search was performed to review the effect of Cannabidiol (CBD) in leaky gut associated LPS and its effect on mast cell and macrophage activation and epilepsy which proposed mechanism of CBD in the management of leaky gut and reduction of seizures by three potential targets- Transient Receptor Potential Vanilloid-1 (TRPV1), the orphan G protein-coupled receptor-55 (GPR55) and the Equilibrative Nucleoside Transporter 1 (ENT-1). Thus, by targeting these molecular pathways, cannabinoids show potential to mitigate gut associated seizures.

Conclusion: The integration of cannabinoids into epilepsy treatment can pave the way for novel, personalized therapeutic approaches, offering hope to patients who are unresponsive to conventional therapies.

PLP014

Comparative Efficacy of *Mucuna pruriens vs* Conventional Levodopa Therapy in Parkinson's Disease

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Introduction: Parkinson's Disease is a progressive neurodegenerative disorder characterized by motor and nonmotor symptoms. Conventional treatment primarily involves levodopa, which can lead to long-term complications. *Mucuna pruriens*, a natural source of L-DOPA, has been suggested as a potential alternative or adjunct therapy. This study aims to compare the efficacy of *Mucuna pruriens* with conventional levodopa in managing PD symptoms.

Methods: A systematic review and meta-analysis of randomized controlled trials focused on studies comparing *Mucuna pruriens* to levodopa. Databases such as PubMed, Cochrane Library and Scopus were searched for relevant articles published till date. Data on motor function, quality of life and side effects were extracted and analyzed using standard statistical methods.

Result: *Mucuna pruriens* shows comparable efficacy to conventional levodopa therapy, offering a faster onset and longer "on" time without worsening dyskinesias. It effectively improves motor symptoms and reduces dyskinesia and other side effects, leading to a better quality of life for patients. Further studies are needed to assess its long-term effects and potential as a standard treatment option.

Conclusion: *Mucuna pruriens* demonstrates comparable efficacy to conventional levodopa therapy in managing Parkinson's Disease symptoms with advantages.

Keywords: Parkinson's Disease, Mucuna Pruriens, Levodopa, Motor Symptoms, Meta-analysis.

PLP015

The KatG Gene and its Role in Combatting Isoniazid Resistance in Multidrug-Resistant Tuberculosis

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Introduction: MDR-TB is condition where Mycobacterium tuberculosis develops resistance to key drugs such as isoniazid (INH) and rifampicin (RMP). INH needs to be activated by the enzyme catalase-peroxidase, which





is encoded by the KatG gene. Mutations at codon 315 in the KatG gene impair the function of the enzyme, resulting in resistance. RNA interference (RNAi), a natural gene-silencing mechanism, provides a potential strategy to counteract resistance by targeting specific genes.

Methods: RNAi molecules, including siRNA and miRNA, were designed to target and silence mutated KatG gene sequences. These molecules were tested in vitro on MDR-TB strains with known KatG mutations. Polymer-based drug delivery systems were used to enhance the stability, bioavailability, and targeted delivery of RNAi formulations. The efficacy of gene silencing was assessed using real-time PCR and Western blot analysis, while drug susceptibility tests evaluated the restored sensitivity to INH.

Results: KatG mRNA and protein were significantly reduced by RNAi therapy in MDR-TB strains. Real-time PCR and Western blot analyses confirmed gene silencing efficiency, and MIC values were restored in treated strains, which exhibited susceptibility to INH. RNAi stability and targeted action of polymer-based delivery systems minimized off-target effects.

Conclusion: The approaches based on RNAi, employing siRNA and miRNA to silence the KatG gene, show promise for overcoming INH resistance in MDR-TB. The research shows that RNAi is capable of reducing expression of genes responsible for resistance and restoring drug sensitivity. Although optimization of delivery still poses a problem, polymer-based technological advancements are on the right track.

Keywords: Tuberculosis, Genetic polymorphism, Mycobacterium, Isoniazide, Rifampacin, Multidrug resistance etc.

PLP016

Harnessing AI and Molecular Insights to Decipher L-Arginine's Role in Pancreatic Inflammation

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Introduction: Pancreatitis, marked by acute or chronic pancreatic inflammation, is a critical global health issue with limited treatment options. L-arginine, a semi-essential amino acid, plays a dual role in this condition. While essential for nitric oxide production and immune regulation, elevated L-arginine levels trigger oxidative stress, mitochondrial dysfunction, and NF- κ B-mediated inflammatory signalling, contributing to pancreatic acinar cell damage.

Methods: Preclinical studies and computational approaches, including artificial intelligence and machine learning, were employed to analyze L-arginine's role in pancreatitis. These tools facilitated molecular simulations to identify therapeutic targets, multi-omics integration to discover biomarkers for early disease progression, and predictive modelling to establish toxicity thresholds.

Results: L-arginine-induced toxicity was found to exacerbate pancreatic inflammation and acinar cell damage. Computational models identified critical biomarkers and safe toxicity limits, aiding in drug discovery and refining preclinical and clinical trial designs. These insights support the potential of L-arginine modulation in therapeutic strategies.

Conclusion: This study highlights L-arginine's dual role in pancreatitis pathogenesis and the transformative potential of computational technologies in understanding its mechanisms. Combining biological and computational approaches accelerates precision medicine development, offering hope for effective therapies for inflammatory diseases like pancreatitis.

Keywords: L-arginine, toxicity, inflammatory signalling, Artificial Intelligence, biomarkers.

PLP017

Exploring NOGO Receptor Modulation: Bridging the Gap in Parkinson's Disease Therapy

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Introduction: Parkinson's disease (PD) is a neurodegenerative disorder characterized by the progressive loss of dopaminergic neurons in the substantia nigra, leading to motor impairments such as tremor, rigidity, and bradykinesia. Recent evidence suggests that the inhibitory signalling pathways involving NOGO-A and its receptor, NOGO-A receptor 1 (NgR1), are critical in the progression of PD. The study aims to investigates the pathophysiological role of NOGO-A and NgR1 in PD through various mechanisms.

Methods: A detailed literature survey including research articles, review articles and meta-analysis from various scientific database like Pubmed, Elsevier, Sciencedirect etc has been done using the mentioned keywords.

Results: Inhibition of NOGO-A/NgR1 signalling has been associated with several mechanisms *viz*. Inhibition of Axonal Regeneration: NOGO-A prevents axonal sprouting and limits neuronal repair; Neuroinflammation: NgR1 activation triggers inflammatory pathways, exacerbating neuronal damage; Apoptosis and Neurodegeneration: NOGO-A/NgR1 signalling activates apoptotic pathways in dopaminergic neurons and Synaptic Dysfunction: Impairment in synaptic plasticity affects motor function and cognitive processes. Recent studies have shown increased expression of NOGO-A in both animal models and human postmortem tissue, indicating its role in disease progression. Various strategies such as pharmacological inhibitors, monoclonal antibodies, or gene therapy targeting NOGO-A or NgR1 have shown promise in enhancing neuroplasticity and neuronal survival.

Conclusion: The NOGO-A/NgR1 axis plays a significant role in the pathophysiology of PD. Targeting this pathway may offer novel therapeutic strategies to slow disease progression and improve outcomes for patients with Parkinson's disease. Further research is essential to fully understand the potential of these interventions as disease-modifying therapies.

Keywords: Parkinson's disease, NOGO-A receptor (NgR1), neurodegeneration, axonal regeneration.

PLP018

Parents or Caregivers Perception versus Conception Towards OTC Medicines in Paediatric Patients

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Introduction and Objective: Parental knowledge and awareness are vital for safe paediatric drug use, especially with OTC medications in children under 16. This study evaluates parental and caregiver knowledge of OTC medications in paediatric care, comparing knowledge with actual practices and validating the study's questionnaire through expert review.

Methodology: A prospective observational study was conducted from October 2023 to March 2024 at two primary care hospitals in Gandhinagar, with 376 participants. The study used a pre-defined questionnaire with four parts: Part-1 (demographic details), Part-2 (knowledge-based questions assessing understanding of paediatric medicines), Part-3 (practice-based questions evaluating medicine management practices), and Part-4 (perception-based questions on medicine effectiveness, size, cost, and colour). Data were analysed using MS Excel and chi-square analysis.

Result: Of 376 respondents, 220 were mothers and 145 were fathers. Most parents (92.8%) defined medicines as treatments for diseases, with antipyretics/analgesics, particularly paracetamol, being the most commonly used. Many preferred syrups for paediatric medicines, and most followed (84.04%) and checked (85.10%) the prescribed dosage. For practice-based questions, 67.55% stored medicines in a box, and 88.56% discarded them if they changed in appearance. OTC medicines were mostly used for fever, cough, and cold.

Conclusion: Parents showed good knowledge of common OTC medications like paracetamol but lacked awareness of other options, appropriate usage, storage, and side effects. This underscores the need for targeted educational efforts to enhance parental understanding of OTC medications.

Keywords: Over-the-counter medicines, paediatric medication, parental knowledge, health literacy, medication practices.





PLP019

Mitragyna Speciosa and its Dual Impact: Neurocognitive Alterations and Hepatic Implications

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Introduction: "Kratom" refers to a plant species formally known as *Mitragyna speciosa*. is native to tropical and subtropical regions of Southeast Asia and Africa. The plant, which is valued for its medicinal and recreational qualities, is known by a number of names, including "Ketum" in Malaysia and "Kratom" in Thailand. Because to their high content of active chemicals, its leaves can be used as a natural treatment for a variety of ailments, including chronic pain, tiredness, and opium addiction. Kratom has sleepy, morphine-like effects at larger dosages and stimulant-like effects at lower dosages. It is often ingested by crushing the leaves into a powder or making a tea or decoction.

Methods: In this review, the literature search was conducted using PubMed, Google Scholar, to retrieve information about consumption, phytochemistry, phytoconstituent, toxicology, pharmacokinetics, and pharmacological effects of kratom using like Sedative activity, Stimulant activity, Anxiolytic effect, cognitive activity and anti-depressant. There is conflicting evidence that kratom causes hepatotoxicity, which is backed by research on humans and animals.

Results: Findings at lower dosages, kratom demonstrates stimulant qualities and opioid-like sedative and painrelieving effects. It may have antidepressant, anxiolytic, and cognitive properties. Hepatotoxicity, dependence, and addiction are among the negative effects, Kratom has the ability to cure pain and psychological disorders, but it also has safety dangers like addiction and liver toxicity.

Conclusion: Kratom has great potential for treating pain and mood disorders, but it also has serious safety dangers, such as liver damage and addiction.

Keywords: Stimulant effect, Sedative effect, Cognitive effect, Hepatotoxicity, Addiction and Dependence.

PLP020

The Multifaceted Role of Interleukin-1 Receptor-Associated Kinase 4 in Myddosome Formation and Toll-Like Receptors Signaling

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Introduction: Interleukin-1 receptor-associated kinase 4 (IRAK4) is a crucial mediator in the innate immune response, playing a crucial role in Toll-like receptor (TLR) and interleukin-1 receptor (IL-1R) signaling pathways. Upon stimulation by microbial or endogenous ligands, IRAK4 initiates key molecular cascades that drive inflammatory and immune responses. This kinase's dual functionality in myddosome formation and downstream signaling underscores its critical importance in maintaining immune homeostasis. Given its central role, dysregulation of IRAK4 has been linked to various inflammatory diseases, autoimmune disorders, and cancer, making it an attractive target for therapeutic intervention.

Methods: A systematic review of existing literature was conducted to understand the functional mechanisms of IRAK4 in immune signaling pathways. The review focused on the assembly and role of the myddosome complex involving myeloid differentiation primary response gene 88 (MyD88), IRAK1, and IRAK4, along with downstream effectors such as TRAF6. Structural studies examining the kinase activity of IRAK4 and its phosphorylation targets, including IRAK1, were analyzed. Additionally, recent advancements in therapeutic approaches targeting IRAK4 were explored to provide insights into its regulatory mechanisms and potential inhibitors.

Results: The review revealed that IRAK4 plays a dual role in immune signaling. Firstly, it facilitates the formation of the myddosome complex, acting as a core signaling unit in the TLR and IL-1R pathways. This





complex formation is essential for the recruitment and activation of downstream effectors like TRAF6, which subsequently leads to the activation of nuclear factor- κ B (NF- κ B) and mitogen-activated protein kinases (MAPKs). Secondly, IRAK4's kinase activity directly phosphorylates IRAK1 and other substrates, amplifying the immune response by promoting cytokine production and antimicrobial peptide expression. The dysregulation of these processes has been implicated in the pathogenesis of several inflammatory and autoimmune diseases, as well as cancer.

Conclusion: IRAK4 serves as a critical mediator in innate immune signaling pathways, with its dual role in myddosome formation and kinase activity being central to immune responses. Dysregulation of IRAK4 can lead to excessive or deficient immune responses, contributing to various diseases. Understanding the structure-function relationships and regulatory mechanisms of IRAK4 provides valuable insights for developing targeted therapies. Recent studies on potential inhibitors highlight the therapeutic promise of modulating IRAK4 activity to treat inflammatory and autoimmune disorders.

Key Words: Neuroinflammation, IRAK4, MAPKs, nuclear factor-κB (NF-κB).

PLP021

AMPK Activation: Molecular Target in Metabolic and Hormonal Pathway of Polycystic Ovary Syndrome

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Introduction: Polycystic ovary syndrome (PCOS) is a complex endocrine disorder that affects patient's reproductive system and is often diagnosed during the reproductive age in women. Polycystic ovary syndrome is chiefly characterized by hyperandrogenemia, hyperinsulinemia, abnormal ovulation and polycystic ovaries. In this disorder there are many hormonal and metabolic changes occurring at molecular level.

Methods: This paper reviews the latest research and advancements in treatment of PCOS. Various scientific database like Scopus, PubMed etc were searched for data compilation.

Results: Due to insulin resistance in polycystic ovary syndrome, the activity of glucose uptake and glycogen synthesis is reduced along with manifestation of steroidogenic effect in ovaries. The metabolic actions of insulin take place in its target organs skeletal muscles, fibroblasts, adipose tissue. AMPK plays a major role with its varying action in different tissues. Glucose uptake, which is mediated by AMPK, is altered during polycystic ovary syndrome and activation of AMPK may result in a different outcome. Its activation may lead to the positive actions of insulin like glucose uptake, targeting the hyperinsulinemia of polycystic ovary syndrome. AMPK through its signaling also regulates steroidogenesis in gonads by mainly regulating adrenal steroidogenesis and androgen production. This can be beneficial to control the insulin and androgen levels and we can get more ameliorating action in this disorder.

Conclusion: Thus, AMPK activation can be a beneficial target in the treatment of polycystic ovary syndrome.

Keywords: Hyperandrogenemia, Hyperinsulinemia, Steroidogenesis, Polycystic Ovary.

PLP022

AI-Driven Innovations in Alzheimer's Diagnosis and Treatment Jenil Joshi, Prachi Belani, Soni Jalpa

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Introduction: Alzheimer's disease (AD) is a brain disorder that slowly destroys memory and thinking skills and, eventually, the ability to carry out the simplest tasks, changes in behavior and personality. Alzheimer's disease is affecting more than 50 million people around the world. About 8.8 million Indians older than 60 living with dementia. There's no cure for Alzheimer's disease, but treatment can help to slow its progression and manage symptoms. The drug which are used in the treatment of AD is donepezil, galantamine, rivastigmine (cholinergic activator) and many more.





Methods: Use of AI in combination with these drugs can produce more specific and targeted therapy for the treatment of AD. According to the Current research on galantamine, implementation of AI technology in galantamine treatment can produce MutComputeX system that identifies how to mutate proteins inside the bacteria. AI machine learning is used to improve the design of the enzyme which can be used to synthesize MutComputex. Galantamine with nanotechnology will enhance its bioavailability and efficiency. In this system, galantamine will be used in combination with SLNS [solid liquid nanopartical] loaded with galantamine hydrobromide.

Result: AI and Nanotechnology with galantamine enhance its bioavailability and improve memory.

Conclusion: The integration of AI and nanotechnology with galantamine-based therapies shows promise in creating more targeted and effective treatments for Alzheimer's disease.

Key words: Galantamine, Mutcomputex, Ai machine learning, Neno particals, Solid Liquide Nanoparticals [SINs] coating.

PLP023

Prediction of New Indication of Approved Drugs by Applying Artificial Intelligence on Pharmacovigilance Reports

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Introduction: Drug repurposing is a method that is used to search new therapeutic uses of existing drugs that are already licensed for other uses. It effectively reduces the time and cost of developing a new drug and have higher success rates in regulatory approvals when compared to *De Novo* drug discovery. Pharmacovigilance (PV) reports contain information about the patient, the drug and the adverse drug reactions (ADR) which serves as phenotypic biomarkers and helps in understanding the correlation between drugs having different approved indications. It is believed that the drugs which we use for a particular indication usually have more than one binding sites in our body, due to which it displays different other reactions either unfavourable or beneficial, along with the intended outcome.

Methods: A systematic literature review was performed utilizing Google Scholar, Science Direct and PubMed to locate peer-reviewed journals published until January 2025. The keywords used were 'Artificial Intelligence/Machine Learning in PV' and 'Drug repurposing using PV and/or ADRs'.

Results: Literature review revealed that researchers use different methods such as construction of drug network using ADRs, searching similar ADRs in between drugs approved for different indications, searching ADRs opposite to the disease's mechanism, searching inverse signals to predict new indications. PV reports consist of large volumes of data which is very difficult for humans to manually analyse as it requires lots of time and resources also such data are prone to inconsistencies due to human error. Researchers have found that use of Artificial Intelligence (AI) tools such Recurrent Neural Networks, Long Short-Term Memory, Bayesian Confidence Propagation Neural Networks etc., on PV data can process volumes of data simultaneously, recognize patterns and provide rapid signal detection. However, human expertise is required for contextual judgment.

Conclusion: Predicting new indications of drugs through AI holds a large scope in addressing global health challenges.

Keywords: Drug repurposing, Pharmacovigilance, Adverse Drug Reactions, Artificial Intelligence, Machine Learning.

PLP024

Advancing Bone Health with AI and ML: A New Era in Research and Management

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Introduction: Osteoporosis is a common disorder that often remains undetected, causing millions of fractures annually and imposing considerable strain on healthcare systems. Although dual-energy X-ray absorptiometry (DXA) is the established diagnostic method, its high costs, radiation exposure, and restricted availability underscore the necessity for new alternatives. Recent progress in artificial intelligence (AI) and machine learning (ML) presents promising technologies that could enhance the care of bone health.

Methods: A comprehensive systematic review was conducted utilizing PubMed, Scopus, and Google Scholar to locate peer-reviewed research published until January 2025. The search utilized terms such as "AI in bone health," "ML in osteoporosis detection," and "non-invasive bone diagnostics." The selection of articles was based on their relevance, methodological soundness, and emphasis on innovative, clinically applicable strategies for the management of bone health.

Results: Recent advancements in AI/ML technologies have introduced innovative, non-invasive, and radiationfree alternatives to DXA for bone health diagnostics. Key developments include the Osentia Test using Raman spectroscopy for fracture risk assessment, Radiofrequency Echographic Multi-Spectrometry (REMS) leveraging ultrasound for precise bone density measurement, Quantitative Ultrasound (QUS) for portable screening, AIbased analysis of dental radiographs for early detection, and microwave technology for bone health evaluation. These advancements enhance accessibility, improve early detection, and reduce healthcare costs.

Conclusion: AI and ML innovations in bone health diagnostics offer accessible, cost-effective, and radiation-free alternatives to DXA, enabling early detection and improved management. Their integration into clinical practice could significantly reduce the burden of osteoporosis.

Keywords: Artificial Intelligence, Machine Learning, Bone Health, Osteoporosis, DXA.

PLP025

Smart Healthcare Solutions: Use of AI-ML to Bridge the Gap Between Self-Medication and Patient Safety

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Introduction: Self-medication is becoming more popular, which has advantages like rapid relief and less healthcare costs, but it also has drawbacks including safety issues, incorrect diagnoses, and inappropriate drug use. In order to overcome these obstacles, this work presents an AI-ML-based system that enhances the effectiveness and safety of self-medication. The system prioritizes precise symptom analysis, medication identification, and customized risk assessments while maintaining patient safety and accessibility.

Methodology: Three key technologies are integrated within the methodology: machine learning (ML), computer vision, and natural language processing (NLP). While computer vision recognizes and authenticates drugs, natural language processing (NLP) examines user-reported symptoms to offer accurate counsel. ML algorithms take into account variables like medication interactions and medical history when determining a person's risk. The most recent medical research and guidelines are updated in a dynamic knowledge base to guarantee relevancy. For a more efficient experience, the system's mobile application interface links users with pharmacists and medical professionals.

Result: The outcomes show how effective the system is. Computer vision verified the legitimacy of the medication, the NLP module decreased the likelihood of misdiagnosis, and machine learning algorithms identified possible drug interactions with tailored suggestions. Real-time access to pharmaceutical information and medical assistance was made possible by mobile integration. Additionally, the system demonstrated potential wearable technology integration and flexibility to accommodate regional healthcare practices.

Conclusion: In summary, the AI-ML framework improves safety and informed decision-making, bridging the gap between professional healthcare and self-medication. It is a flexible solution that opens the door to a safer and more efficient self-medication ecosystem because of its scalability, adaptability, and capacity to change in tandem with medical breakthroughs.

Keywords: Artificial Intelligence, Machine Learning, Self-medication, Patient Safety, Healthcare Technology, Digital Health, Preventive Healthcare, NPL (natural language processing).





PLP026

Exploring Potential Targets of *Acanthopanax trifoliatus* for Alzheimer's Disease Through Network Pharmacology

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Introduction: Alzheimer's disease (AD), a progressive neurodegenerative disorder characterized by senile dementia presents significant challenge in healthcare, urging exploration of novel therapeutic avenues. Research is underway to find novel compounds targeting exact pathogenesis in AD. *Acanthopanax trifoliatus*, a ginseng-like plant, stands out as a potential candidate due to its traditional use in managing cognitive function. The aim of the study is to utilize network pharmacology-based tactics to explore the potential of *Acanthopanax trifoliatus* as a therapeutic intervention for AD *via* finding its related active constituents, latent targets and potential molecular mechanisms.

Methods: Through active constituent pre-screening and target prediction, combined with Kyoto Encyclopedia of Genes and Genomes (KEGG) pathway enrichment analysis, this study identified potential molecular pathways and targets involved in *Acanthopanax trifoliatus* therapeutic effects. Molecular docking experiments were further conducted to validate these findings.

Results: Five main active constituents were identified—Acantrifoic acid A, Acankoreoside A, Acankoreoside D, Acantrifoside A and Impressic Acid—each exhibiting positive drug likeness, suggesting their potential suitability for therapeutic development. Subsequent network construction and gene ontology (GO) and KEGG pathway analyses unveiled key genes involved in AD metabolic pathways, including TLR4, PI3K, NF- κ B, ADAM17, CDK5, CK2 and NMDA. Molecular docking studies further revealed promising insights, with *Acanthopanax trifoliatus'* active constituents demonstrating notably lower binding energies compared to the co-crystal ligand of TLR4 is better across various target genes.

Conclusion: This study offers insights into molecular mechanisms underlying the efficacy of the plant against AD, paving the way for future therapeutic developments in neurodegenerative diseases.

Keywords: Acanthopanax trifoliatus, Docking, KEGG pathway, Network Pharmacology.

PLP0027

Integration of ImageJ and R Studio for Histopathological Study in Exploring the Osteoprotective Activity of *Bambusa arundinacea*

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Introduction: Osteoporosis, a prevalent bone condition, reduces bone mineral density and quality, thereby increasing the risk of fractures. The plant Bambusa arundinacea, which contains silica, has been recognized for its medicinal properties in traditional practices. The rationale of this study is to examine the osteoprotective efficacy of Bambusa arundinacea from a histopathological perspective using ImageJ and data analysis through R Studio.

Methods: The osteoprotective effect of Bambusa arundinacea was evaluated in an animal model of osteoporosis induced by glucocorticoids. Upon completing the study, femur bones were collected, sliced, and stained with H&E. The morphology and structure of the bones were examined using ImageJ software, emphasizing important factors such as trabecular bone, bone volume, and alterations in the marrow. Data from ImageJ were adjusted for background and statistically evaluated with R Studio to ascertain significance.

Results: The results showed a marked enhancement in histomorphometry of bone mass and architectural properties of the disease affected bones in the treatment group. Image analysis of ImageJ showed that treated





animals had increased trabecular bone volume, number, thickness, and decreased bone erosion in comparison to untreated animals. Calculations done in R Studio supported the data with reliable p- values.

Conclusion: Based from the study, Bambusa arundinacea possess osteoprotective effects which could be due to silica and other phytochemicals present on the plant. Combining ImageJ and R Studio improves the accuracy of histopathological metric and offers a stable procedure for assessing bone quality in animal models.

Keywords: Osteoporosis, Histopathology, ImageJ, R Studio, Bone health.

PLP028

Effects of Gestational Diabetes and Docosahexaenoic Acid Deficiency in Development of Autism

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Introduction: Autism Spectrum Disorder (ASD) is characterized by social interaction deficits, communication challenges, and restrictive behaviours. Research suggests that maternal hyperglycaemia during pregnancy may contribute to ASD's neurodevelopmental pathophysiology, with potential disruptions to neuronal connectivity. This review investigates the multifactorial etiology of ASD, focusing on the impact of maternal hyperglycaemia and associated metabolic disturbances.

Methods: The review explores mechanisms through which maternal hyperglycaemia, such as gestational diabetes mellitus (GDM), affects fetal brain development. Emphasis is placed on neuronal migration, oxidative stress, and the role of key nutrients like docosahexaenoic acid (DHA) in neurodevelopment. The study also discusses the effects of advanced glycation end-products (AGEs) generated by hyperglycaemia on brain function.

Results: Maternal hyperglycaemia during pregnancy may disrupt neuronal migration, particularly in the frontal lobe, through oxidative stress and reduced availability of neurotrophins. DHA transport across the placenta is compromised in cases of GDM, impairing fetal brain development. Additionally, AGEs impact neuronal migration by altering Rac1 activation, further disrupting neural connectivity. These factors may contribute to the development of ASD-related traits.

Conclusion: The findings highlight the crucial role of maternal metabolic health in fetal neurodevelopment. Disturbances in maternal nutrition, fatty acid metabolism, and oxidative stress during pregnancy can have lasting effects on brain structure and function, potentially contributing to the onset of ASD. These insights underline the importance of early intervention and maternal health management to mitigate neurodevelopmental risks in offspring.

Keywords: Autism Spectrum Disorder (ASD), Maternal Hyperglycaemia, Neurodevelopment, Oxidative Stress, Docosahexaenoic Acid (DHA).

PLP029

Mitochondria-Derived Peptides: A New Perspective on Parkinson's Disease

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Introduction: Parkinson's disease (PD), a progressive neurodegenerative disorder, is characterized by dopaminergic neuron loss and Lewy body accumulation. Mitochondrial dysfunction is a key factor in PD pathogenesis, highlighting its role in neuroprotection and energy metabolism. Mitochondria-derived peptides, such as SHLP2, have gained interest for their neuroprotective and anti-inflammatory properties. This review explores SHLP2's mechanisms and therapeutic potential in PD.

Methods: A comprehensive literature review was conducted to identify studies focusing on SHLP2, its biological roles, and its relevance to PD. Inclusion criteria included experimental studies, clinical observations,





and mechanistic investigations into SHLP2's effects on mitochondrial function, oxidative stress, inflammation, and neuronal survival. Studies focusing on PD-specific models and SHLP2's systemic effects were prioritized. **Results:** SHLP2 has shown neuroprotective effects by regulating inflammatory pathways, reducing oxidative stress, and enhancing mitochondrial bioenergetics. In Parkinson's disease models, SHLP2 improved neuronal survival and reduced dopaminergic neurodegeneration. It stabilizes mitochondrial DNA, promotes fusion over fission, and mitigates systemic neuroinflammation, offering potential therapeutic benefits in slowing PD progression.

Conclusion: SHLP2 represents a promising therapeutic target in Parkinson's disease due to its multifaceted roles in mitochondrial protection and neuroprotection. Future studies should focus on elucidating its precise molecular mechanisms, optimizing delivery methods, and exploring its potential in clinical settings. Harnessing the therapeutic potential of SHLP2 may offer new avenues for mitigating PD progression and improving patient outcomes.

Keywords: SHLP2, Mitochondria-derived peptides, Parkinson's.

PLP030

Meloxicam: A Neuroprotective Agent in STZ-Induced Alzheimer's Disease

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Introduction: Amyloid beta plaques and neurofibrillary tau protein tangles in the brain are the hall marks of Alzheimer's disease. NSAIDs, have shown neuroprotective effect by inhibiting cyclooxygenase (COX) enzymes. This study aims to evaluate the neuroprotective properties of meloxicam and to explore the possible mechanism related to AD.

Methods: The study was conducted in Sprague Dawley rats and were divided in six different groups i.e. sham control (SC), disease control (DC), donepezil treated (5mg/kg, p.o.) (DNP-5), and meloxicam treated (1mg/kg, 5mg/kg, and 7 mg/kg) (ML-1, MM-5, and MH-7). Different parameters were assessed.

Results: Treatment with DNP-5, MM-5, and MM-7 significantly improved % arm alteration in the Modified Ymaze. Escape latency in morris water maze was reduced in DNP-5 and MH-7 group. For oxidative stress parameters the levels of GSH was significantly increased in DNP-5, ML-1, MM-5, and MM-7 group. The MDA levels were found to be significantly decreased in DNP-5 and MH-7 group. SOD levels were significantly increased in DNP-5 and MH-7 group. Acetlycholinestrase activity was significantly decreased in DNP-5 and MH-7 group. SGOT levels were significantly decreased in DNP-5, ML-1, and MM-5 group. SGPT levels were significantly decreased in DNP-5, and ML-1 group. TNF-alpha levels were significantly reduced in DNP-5, ML-5, and MM-7 group. IL-6 levels were significantly reduced in DNP-5 and MM-7 group. Alzheimer specific markers: tryptophan-hydroxylase was significantly increased in DNP-5, ML-5, and MM-7 group. For Kynurenine pathway and kynurenine acid activity was significantly decrease in DNP-5, ML-1, MM-5, and MM-7 group. No effect on quinolinic acid was observed.

Conclusion: Meloxicam demonstrated neuroprotective effect and may be a potential therapeutic candidate for AD. However, its impact on hepatic function warrants careful consideration.

Keywords: Alzheimer's disease, Meloxicam, COX, NSAIDs.

PLP031

Pharmacological Evaluation of *Bacillus Subtilis* and *Bacillus Coagulans* in regulating High Fat Diet induced Obesity in Mice

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Introduction: Obesity, a global health challenge, is linked to metabolic dysfunctions and systemic inflammation. Probiotics, such as *Bacillus subtilis* and *Bacillus coagulans*, are emerging as potential therapeutic agents to prevent and reverse diet-induced obesity by modulating gut microbiota and systemic pathways.

Methods: A high-fat diet (HFD) was used to induce obesity in Balb/c mice over six weeks. Mice were divided into seven groups: normal control, disease control, orlistat-treated, and treatment groups receiving *Bacillus subtilis* and *Bacillus coagulans* in preventive and curative setups. Preventive groups were treated with probiotics from the onset of the HFD, while curative groups received probiotics two weeks post-HFD induction. Morphological, biochemical, oxidative, and histological parameters were analyzed, including body weight, food and water intake, serum lipid profile, inflammatory cytokines, oxidative stress markers, and adipose tissue morphology.

Results: Probiotic-treated groups demonstrated significant improvements in body weight, food and water intake, and survival rates compared to disease controls. Serum analysis showed reduced triglycerides, cholesterol, LDL, ALP, AST, and ALT levels, with increased HDL and adiponectin levels. Probiotics also alleviated oxidative stress by modulating LPO, SOD, GSH, and CAT levels. Inflammatory cytokines (TNF- α , IL-1 β , IL-6) and tight junction protein ZO-1 were significantly improved. Histological evaluation revealed reduced adipose tissue size and restored liver morphology. Short-chain fatty acids analysis suggested a rebalanced gut microbiota.

Conclusion: *Bacillus subtilis* and *Bacillus coagulans* demonstrated preventive and curative potential against obesity and its associated metabolic dysfunctions by modulating inflammation, oxidative stress, and gut microbial ecosystems.

Keywords: Probiotics, obesity, Bacillus subtilis, Bacillus coagulans, gut microbiota.

PLP032

Utilizing Protox 3.0 for Toxicity Prediction in Cervical Cancer Therapeutics: A Comparative Analysis of Primary Drugs and Alternatives

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Introduction: Cervical cancer is the second most common cancer among women in India, with 96,922 new cases and over 60,000 deaths annually. Although various chemotherapeutic and immunotherapeutic agents, such as paclitaxel, cisplatin, pembrolizumab, bevacizumab, veliparib, topotecan, ifosfamide, mitomycin C, etoposide, vincristine, doxorubicin, and erlotinib, have shown effectiveness in treating the disease, they are associated with significant toxicity risks like nephrotoxicity, cardiotoxicity, and carcinogenicity.

Methods: To assess the safety profiles of these therapies, the study utilized Protox 3.0, a cheminformatics-based software that predicts toxicity using machine learning algorithms. This software evaluates the molecular properties of drugs to identify potential adverse effects. The toxicity risks of primary drugs and their alternatives were compared to determine safer treatment options.

Results: The analysis revealed that primary therapies, including cisplatin, paclitaxel, veliparib, topotecan, ifosfamide, mitomycin C, etoposide, vincristine, doxorubicin, and erlotinib exhibited high toxicity, particularly in the form of nephrotoxicity, cardiotoxicity, and immunotoxicity. In comparison, alternative agents such as carboplatin, nivolumab, and olaparib displayed significantly lower toxicity risks, with reduced nephrotoxicity and immunotoxicity. Overall, alternatives showed better safety profiles with lower cumulative toxicity scores.

Conclusion: This study highlights the effectiveness of Protox 3.0 in predicting toxicity risks and optimizing therapeutic strategies for cervical cancer. Safer alternatives identified through this analysis can minimize adverse effects, improve patient outcomes, and reduce the healthcare burden of cervical cancer in India and globally.

Keywords: Cervical cancer, Protox 3.0, Toxicity.

PLP033

Using Artificial Intelligence to Help Adults with Autism Spectrum Disorder Live Better Lives





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Introduction: Autism Spectrum Disorder (ASD) poses lifelong challenges, particularly for adults, who often face barriers in healthcare access, employment, and independent living. Traditional approaches frequently overlook the unique needs of this population, leaving a critical gap in support systems. The long and subjective nature of the current traditional ASD screening procedures may be criticized due to their high item count and reliance on domain expert standards

Methods: The review utilized databases like PubMed, ScienceDirect, and Google Scholar, using keywords such as autism spectrum disorder in adults, "AI in ASD support," and "independent living challenges in ASD" with Boolean operators to refine the search. Inclusion criteria focused on studies from the last 10 years, emphasizing adults with ASD and AI/ML applications, excluding pediatric-focused papers. Critical analysis of articles highlighted gaps in healthcare, employment, and ASD screening methods, and the potential of AI/ML-driven solutions to address these challenges.

Results: AI-powered tools like wearable devices and virtual assistants can enhance independent living by monitoring stress levels, providing reminders for daily tasks, and facilitating social communication. AI also enables adaptive learning platforms to improve skill-building and job training, helping adults with ASD achieve meaningful employment. Additionally, scalable AI models can ensure accessibility in low-resource settings, bridging gaps in care for underserved populations.

Conclusion: This work highlights case studies and data showcasing AI's effectiveness in improving outcomes for adults with ASD, emphasizing the need for scalable, inclusive, and ethical AI models. By leveraging AI/ML, we can address the global health challenge of supporting neurodiverse individuals, fostering equity, and improving quality of life across diverse communities.

Keywords: Autism Spectrum Disorder, Artificial Intelligence, Machine Learning, Independent Living, Comorbidities Prediction.

PLP034

Advancing Neuroscience with AI: Understanding Brain Disorders and Animal Behaviours

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Introduction: The use of Artificial Intelligence (AI) and Machine Learning (ML) in neuroscience is growing rapidly, enabling the analysis of large, multimodel datasets and offering unbiased insights into brain functions. This progression supports earlier and more accurate detection of neurological disorders, as well as the development of effective interventions.

Methods: A multi-omics approach utilizing AI and ML was employed to analyse and integrate complex omics data. This approach enhances understanding of neurological diseases, predictive modelling, and personalized therapies.

Results: Advances in deep learning and computer vision have enabled markerless pose estimation for individual animals, although challenges remain in studying multiple animals, especially in social or natural environments. The Social LEAP Estimates Animal Poses system was developed to address these issues.

Conclusion: Social LEAP Estimates Animal Poses supports workflows for data labelling, model training, and inference on new datasets. Its comprehensive framework, featuring over 30 model architectures and real-time application capabilities, significantly enhances behavioural neuroscience research in complex environments.

Keywords: Artificial Intelligence, Machine Learning, Neuroscience, Social LEAP, Behavioural Analysis.

PLP035

The Role of Artificial Intelligence in Advancing Alzheimer's Disease Diagnosis, Prediction, and Treatment





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Introduction: Alzheimer's disease is an irreversible neurodegenerative disease that progressively destroys cognitive skills, up to the development of dementia. AI methods leverage feature extraction and classification techniques to address the complex challenges of diagnosing and managing AD effectively. AI offers powerful tools to analyse this data, surpassing human capabilities, to enhance diagnostic accuracy, predict disease progression, and enable personalized medicine.

Methods: The methods that are used are artificial intelligence, particularly machine learning and deep learning, to analyse complex data sets for Alzheimer's disease research. These approaches involve integrating data from neuroimaging, biochemical markers, clinical records, and neuropsychological tests to develop predictive models for early diagnosis, progression prediction, and patient stratification. Techniques include supervised ML for classification, unsupervised learning for clustering subtypes, and ensemble learning to enhance prediction accuracy.

Results: AI techniques, particularly deep neural networks and convolutional neural networks, have demonstrated remarkable potential in analysing neuroimaging data, such as MRI, PET, and CT scans, for early and accurate detection of AD. AI's ability to learn from raw data and perform nonlinear transformations enables it to detect subtle and intricate biomarkers, making it a powerful tool for predicting disease progression and aiding personalized treatment.

Conclusion: AI models are optimized to find relationships between different data modalities, in order to identify the patterns that predict AD diagnosis and progression and to distinguish between several sub-types of the disease. Presently, AD can be predicted using eye-tracking data, retinal images, and non-invasive near-infrared technology, offering a more accessible path to early intervention.

Keywords: Artificial intelligence, Machine learning, Alzheimer disease, Deep learning, Neuroimaging.

PLP036

Investigating Neurocognitive Profile and Hepatotoxicity of *Piper Methysticum* (Kava): A Critical Review

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Introduction: *Piper methysticum* is a perennial shrub from the Pacific Islands known for its significant cultural importance and psychotropic medicinal properties. This study aimed to systematically review the effects of kava supplementation on neurocognitive behaviours and potential liver toxicity, highlighting its anxiolytic, sedative, and anti-inflammatory effects primarily due to kavalactones.

Methods: The review utilized databases such as PubMed, Science Direct, Google Scholar to gather information on kava, focusing on its consumption, health effects, phytochemistry, toxicology, and pharmacological actions like antioxidant, anti-inflammatory, sedative, neuroprotective, and anxiolytic effects. A comprehensive literature review was conducted to include relevant human and animal studies. A total of ten pertinent articles were collected from various research papers, literature reviews, and case studies on kava.

Results: Kava has demonstrated significant benefits in reducing oxidative stress and neuroinflammation related to neurodegenerative diseases. It may enhance cognitive function by inhibiting noradrenaline reuptake in the prefrontal cortex, while increased body sway could be linked to GABA pathway modulation. Additionally, kava exhibits anti-ischemic and anticonvulsant properties by blocking sodium channels and has behavioral effects similar to anxiolytics, along with notable sedation.

Conclusion: Current evidence suggests that kava is effective for treating generalized anxiety, but more research is needed to assess its safety and efficacy concerning liver health, cognition, driving, and sexual effects. While it can alleviate anxiety and tension, there are potential risks of severe liver toxicity. Given its increasing use, further studies are essential to understand kava's toxic effects on the liver and its long-term cognitive impacts.

Keywords: Piper methysticum, Anxiolytic, Psychoactive, Hepatotoxicity, Neurocognitive.





PLP037

A Review on Mechanism of Immune Mediated-DILI (Drug Induced Liver-Injury)

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Introduction: DILI or acute liver failure which occurs due to toxicity or metabolic products of drug. The metabolic product of drug when covalently binds to macromolecules of liver cells leads to mitochondrial failure, and the depletion of cellular antioxidants, also results in loss of protein and increase in ROS level.

Methods: Drug toxicity can trigger an inflammation with activation of innate immune cells through release of damage-associated molecular patterns (DAMPs). An excess of ROS levels results in inflammation, causing the release of pro-inflammatory mediators (TNF- α and IFN-Y). im-DILI which starts from ROS formation in the liver leads to release of DAMPs associated with infections. Excess of ROS lead to oxidative stress in macromolecules of cell, which can damage the cells and tissues.

Result: im-DILI occurs due to drug toxicity leads to release in DAMPs because of excess of release of ROS in liver inducing oxidative stress. Symptoms for im-DILI are Jaundice, pale stool and pruritus, additive to rash and arthralgia (immune- mediated).

Conclusion: The cells which are damaged by ROS activate DAMPs leads to the production of inflammatory cytokines and the secretion of chemokines. This results in inflammation and the recruitment of immune cells.

Keywords: Immune mediated-DILI, Reactive oxygen species (ROS), DAMPs, Inflammation.

PLP038

Androgenic Anabolic Steroid (AAS) Abuse: A Global Crisis Emphasizing on Prevalence, Public Health Consequences and Regulatory Gaps in India

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Introduction: Androgenic Anabolic Steroids (AAS) are synthetic derivatives of testosterone having approved and non-approved indications. They are used to treat hypogonadism, delayed puberty and HPA axis dysfunction. Recently, the nonmedical use of AAS has proliferated worldwide among men seeking performance enhancement and muscular aesthetic appearance. It's a major public health challenge in India where the regulatory framework is debilitated.

Methods: A meta-analysis and meta-regression analysis using data gathered from PsycINFO, PubMed, ISI Web of Science, including original data of prevalence rates was performed. Anabolic abuse, initially limited to professional athletes and bodybuilders, has penetrated the common population, aiming a muscular physique. Misuse of steroids is fuelled by internet resources. In India, due to lack of strict laws and awareness, only a small fraction of AAS users seek medical support.

Result: Long term abuse of AAS has detrimental consequences on cardiovascular, hepatic, dermatological, renal, and psychological systems like hypertension, myocardial infarction, acne, liver failure, or psychiatric disorders. These risks are exacerbated by limited access to Post-Cycle Therapy (PCT), leading to prolonged usage cycles.

Conclusion: A multifaceted approach is imperative to address AAS abuse including awareness programs, psychoeducation campaigns and gender distinct prevention strategies. Physicians need specialized training to tackle AAS abuse and its complications. Proper regulatory control policies must be framed to monitor and control AAS accessibility. Considering the global increase in AAS abuse, we need a composite approach from physicians, regulatory agencies, and the communities. Stringent regulations, education, and tailored interventions can alleviate AAS abuse and improve public health outcomes.

Keywords: Androgenic anabolic steroids, steroid abuse, athletes, post-cycle therapy, public health.





Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis – An Overview

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Introduction: Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) are severe, lifethreatening cutaneous adverse drug reactions characterised by an abnormal immune response. They represent a spectrum of disease severity, with SJS affecting less than 10% of the body surface area and TEN affecting more than 30%. SJS/TEN-overlap syndrome occurs when 10-30% of the body surface area is involved. Pathophysiology primarily involves cytotoxic T-cell activation and granulysin release, which are influenced by genetic factors, particularly HLA alleles. Clinical manifestations include fever, flu-like symptoms, a painful rash progressing to blistering and skin peeling, and mucosal involvement.

Methods: This review article examines the existing literature on SJS and TEN, encompassing epidemiology, pathophysiology, management, and novel therapeutic approaches.

Results: SJS and TEN are rare but potentially fatal conditions. Treatment focuses on immediate withdrawal of the offending medication, supportive care to manage fluid loss, electrolyte imbalances, and pain, and the use of immunosuppressive therapies in severe cases. Early diagnosis and prompt intervention are crucial for improving patient outcomes.

Conclusions: SJS and TEN are serious adverse drug reactions with significant morbidity and mortality. Ongoing research aims to enhance our understanding of the underlying mechanisms, identify individuals at higher risk, and develop more effective and targeted therapies to improve patient outcomes.

Keywords: Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Therapies, Pathogenesis, Epidemiology.

PLP041

Dichotomy of Phytochemicals: Friends and Foes in Bone Health

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Introduction: Phytochemicals are bioactive compounds produced by plants that offer various health benefits, particularly concerning bone health. These compounds, found in fruits, vegetables, legumes, and whole grains, include polyphenols, flavonoids, isoflavones, lignans, and alkaloids. Their effects on bone health can be dichotomous; they may act as both beneficial agents and potential adversaries depending on the type and dosage consumed.

Methods: The review utilized databases such as PubMed, Science Direct, Google Scholar to gather information on phytochemicals that exhibit certain effects on bone health if not taken in optimum quantities. A comprehensive review of the literature was conducted, encompassing human and animal studies from research papers, literature review, and case studies, to explore the roles of phytochemicals as either friend or foe.

Results: Review indicates that certain phytochemicals can enhance bone density and decrease osteoporosis risk when consumed in moderation. Lignans and isoflavones are identified as "friends" for their protective effects on bone remodeling, while some flavonoids may act as "foes" by disrupting hormone signaling and negatively affecting bone mineral density. Excessive intake of alkaloids can lead to toxicity or impaired calcium absorption.

Conclusion: While phytochemicals present both advantages and risks for bone health, moderate consumption is associated with positive outcomes. Future research should focus on determining safe dosage ranges and understanding the variables influencing the efficacy of these compounds in promoting bone health.

Keywords: Phytochemicals, Bone Health, Osteoporosis, Polyphenols, Phytochemical Sources.

PLP042





Ameliorating Potential of Flavonoids Against Heavy Metal Induced Oxidative Stress: A Review

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Introduction: Flavonoids, a class of phytochemicals, are the most important candidates for heavy metal scavenging due to their strong chelating and antioxidant activities. Compounds like quercetin, luteolin, catechin, and rutin have, therefore, been extensively investigated on account of their potentiality to complex and neutralize heavy metals like lead, cadmium, and mercury.

Method: Their chelating activity may arise from the presence of hydroxyl groups in their structure, forming stable complexes with metal ions, thus reducing their availability and toxicities. Thus, for example, quercetin forms a very stable compound with cadmium, tending to scavenge ROS, hence alleviating oxidative stress and other forms of cellular damage. Luteolin exhibits comparable activity, inhibiting metal-induced lipid peroxidation and DNA damage. The catechins present in green tea are remarkable for their ability to reduce mercury toxicity by increasing the excretion of mercury complexes. These flavonoids also upregulate detoxifying proteins such as metallothioneins and glutathione, further aiding in metal sequestration and neutralization.

Conclusion: Flavonoids have an extended role in environmental remediation, wherein flavonoid-rich plant extracts can immobilize heavy metals in soil and water, reducing environmental contamination.

Result: Their dual role in chelation and antioxidation suggests that flavonoids are great natural, cheap alternatives to synthetic chelators for the treatment of heavy metal toxicity in biological and ecological systems.

Key words: Flavonoids, Chelation, Antioxidant, Heavy metals, Detoxification.

PLP043

From Blood Sugar to Breathlessness: How Diabetes Alter the Lung Health

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Introduction: Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycaemia, resulting from disturbances in carbohydrate metabolism due to defects in insulin secretion and action. This inefficiency in glucose utilization leads to its overproduction and has far-reaching effects on various organ systems. Patients with diabetes often experience debilitating complications, including chronic renal failure, hepatic insufficiency, obesity, peripheral neuropathy, and retinopathy. Recent studies have raised concerns about the lungs as a potential "target organ" for diabetes-related complications, prompting further investigation into the impact of chronic hyperglycaemia on lung function.

Methods: To explore this issue, a comprehensive literature review was conducted using research articles, review articles, and meta-analyses sourced from scientific databases such as PubMed, Elsevier, and Science Direct. Keywords related to diabetes and lung function were employed to identify relevant studies.

Results: The collected information informs that lung dysfunction in diabetic patients may result from biochemical changes in connective tissue components of the lungs, particularly collagen and elastin. Additionally, microangiopathy caused by non-enzymatic glycosylation of proteins due to chronic hyperglycaemia contributes to these alterations. These changes lead to thickening of the alveolar epithelial basal lamina, which impairs the lungs' ability to effectively diffuse gases like carbon monoxide.

Conclusion: This review confirms that diabetes adversely affects lung structure and function, supporting the concept of the "diabetic lung". Impaired lung function may arise from systemic inflammation, oxidative stress, and microvascular complications associated with diabetes. These findings highlight the importance of monitoring pulmonary health in diabetic patients and emphasize the need for further research into targeted interventions to mitigate lung complications in this population.

Keywords: Diabetes mellitus, Lung Dysfunction, Hyperglycaemia, Oxidative Stress, alveolar-capillary.





Unravelling the Gut-Brain Axis: TurmiZn as a Novel Treatment Approach for Gut Health associated Cognitive Impairment

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Introduction: The two-way communication system between gastrointestinal tract and brain is called as gutbrain axis. Dysregulation of the axis is related to various conditions including depression, anxiety, cognition decline and Alzheimer's disease. TurmiZn, a novel compound combining curcumin, zinc and tetrahydrocurcumin, exhibits potent anti-inflammatory and anti-oxidant properties. The research aims to investigate the neuroprotective and pharmacological effect of TurmiZn on cognitive impairment induced by chronic heat stress.

Methods: Wistar rats were randomized into seven experimental groups: normal control (NC), TurmiZn-treated control (CT), disease control (DC), curcumin-treated (STD-50mg/kg), and TurmiZn treated (LD-10mg/kg; MD-25mg/kg; HD-50mg/kg). Chronic heat stress was used to induce disease. Different parameters were assessed.

Results: Hematological analysis showed a significant reduction in WBC and RBC count in LD-10, MD-25, and HD-50 groups when compared to DC group (p<0.05). The behaviour assessments, in elevated plus maze, % time spent in closed arm, there was significant increase in STD-50, LD-10, MD-25, and MD-50 group when compare with DC group (p<0.05). However, no significant difference was found in morris water maze and modified Y-maze. Brain oxidative markers i.e., MDA, and GSH showed no significant changes. In colon, MDA levels were significantly decreased in MD-25, and MD-50 group when compared to DC group (p<0.05). However, acetylcholinesterase activity remains unchanged. Levels of IL-6, IL-1 β , TNF- α , were significantly decreased in STD-50, LD-10, MD-25, and HD-50 group compared with DC group (p<0.05) in colon but not in brain.

Conclusion: Chronic exposure to heat stress induced altered colon permeability however brain functions were unaltered. TurmiZn pre-treatment of 25mg/kg and 50 mg/kg shows protective effect in colon against heat stress induced model.

Keywords: TurmiZn, Gut-Brain Axis, Cognition, Leaky gut, Heat stress.

PLP045

Pharmacological Chaperone Therapy for Fabry Disease

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Introduction: Deficient α -galactosidase A activity is cause of Fabry disease, a hereditary lysosomal storage disorder. A lot of missense mutations in Fabry disease result in misfolded gene products, which quality control system keeps in endoplasmic reticulum until endoplasmic reticulum-associated degradation takes them out. In mammalian cells, we found that 1-deoxygalactonojirimycin, a strong α -galactosidase A inhibitor, functions as a pharmacological chaperone to help mutant enzyme fold by attaching to its active site. This enhances enzyme's stability and lysosome trafficking.

Method: A transgenic mouse (TgM) was created to investigate safety and effectiveness of DGJ. TgM and KO mice were bred to create a transgenic animal. A rise in α -Gal A activity was seen in all of main organs after DGJ was added to drinking water of TgM mice for two weeks after they were given it orally at varying dosages. α -Gal A activity increased in heart, kidney, liver, muscle. heart and kidney are majorly affected, so examined immunohistochemically. They showed granular immunostaining throughout their cardiomyocyte cell matrix.

Results: These data indicated that DGJ is easily delivered to cardiomyocytes and distal convoluted tubules, where decomposition of Gb3 is hard to achieve by enzyme replacement therapy.

Conclusion: it involves using a competitive inhibitor to increase intracellular activity of a mutant enzyme. This inhibitor facilitates proper folding of mutant enzymes in ER, resulting in maturation of protein and its transport to lysosomes.





Keywords: pharmacological chaperone, Fabry disease, α-galactosidase A, misfolded gene, transgenic mouse.

PLP046

Leveraging Artificial Intelligence and Machine Learning Techniques in Pharmacovigilance to tackle Global Health Issues

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Introduction: Artificial intelligence (AI) and machine learning (ML) have emerged as powerful tools to enhance pharmacovigilance and address global health issues. These technologies offer significant benefits, including increased efficiency and accuracy, earlier detection of safety signals, and more comprehensive data analysis.

Methods: A systematic literature search was conducted utilizing the key terms "artificial intelligence", "machine learning", and "pharmacovigilance" in the PubMed database to explore the AI and ML applications in pharmacovigilance. These applications include automated adverse event detection and processing, predictive modelling for drug safety, natural language processing for literature mining, real-time signal detection and prioritization, and personalized risk assessment.

Results: Case studies demonstrate the potential of AI-powered adverse event detection systems and ML models for predicting drug-drug interactions. However, the implementation of AI and ML in pharmacovigilance also presents challenges, such as data privacy and security concerns, algorithmic bias and fairness issues, regulatory acceptance, and the need for human oversight. Addressing global health challenges requires multifaceted approaches, including improving safety monitoring in low-resource settings, enhancing the detection of safety issues in diverse populations, accelerating responses to emerging health threats, and facilitating global data integration and analysis.

Conclusion: Future directions for AI and ML in pharmacovigilance include integration with other emerging technologies such as blockchain, continuous learning systems, and global collaboration and data sharing. While challenges remain, the potential impact of AI and ML on global health outcomes is significant, and continued research, development, and collaboration among stakeholders are essential for realizing the full benefits of these technologies in pharmacovigilance.

Keyword: - Pharmacovigilance, Artificial Intelligence, Machine Learning.

PLP047

Algorithms to Electrodes: Artificial Intelligence in Deep Brain Stimulation for Parkinson's Disease

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Introduction: Parkinson's Disease (PD) is a progressive neurodegenerative disorder marked by motor and nonmotor symptoms that significantly impact patients' quality of life. Deep Brain Stimulation (DBS) has emerged as an effective therapeutic approach for managing motor symptoms in advanced PD cases. Recently, Artificial Intelligence (AI) and Machine Learning (ML) techniques have revolutionised the understanding and implementation of DBS by enabling real-time adaptation and optimised therapy. This review compiles and analyses recent findings on the synergistic role of AI/ML and DBS in improving the management of PD.

Methods: A systematic review of peer-reviewed articles was conducted using databases such as PubMed and Google Scholar. Studies that examined the combined application of AI/ML and DBS in PD were included.

Results: AI-driven methods have enhanced DBS precision, particularly in target localisation, thereby improving therapeutic outcomes. Studies have shown that ML algorithms facilitate real-time adjustment of stimulation parameters in adaptive DBS systems, leading to significant reductions in motor symptoms and enhanced patient





outcomes. Moreover, the integration of AI with neuroimaging has enabled the identification of biomarkers and the prediction of treatment efficacy, fostering personalised therapeutic strategies.

Conclusion: The convergence of AI/ML with DBS represents a transformative shift in the management of PD. By enabling personalised and adaptive interventions, this approach holds promise for improving patient outcomes and advancing clinical practices. Future research should aim to address current limitations, such as data heterogeneity and ethical considerations, to maximise the potential of these technologies in PD therapy.

Keywords: Parkinson's Disease, Artificial Intelligence, Machine Learning, Deep Brain Stimulation, Personalised Medicine.

PLP048

AI and ML in Nanoneurotherapeutics for Alzheimer's Disease

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Introduction: Alzheimer's disease (AD) is a progressive neurodegenerative disorder affecting millions worldwide. Current treatments face challenges such as crossing the blood-brain barrier (BBB) and targeting pathological proteins like amyloid-beta and tau. Nanoneurotherapeutics, combined with Artificial Intelligence (AI) and Machine Learning (ML), offer transformative potential in addressing these challenges by optimizing nanoparticle design, accelerating drug discovery, and enhancing diagnostics and therapeutic monitoring.

Methods: This review systematically analyses studies integrating AI/ML into nanoneurotherapeutics for AD. AI models were investigated for optimizing nanoparticle properties such as size, charge, and drug release profiles. ML algorithms for drug discovery, including target identification and predicting drug-nanoparticle compatibility, were reviewed. AI applications in diagnostics and therapeutic monitoring, including biosensors and imaging tools, were also explored.

Result and Conclusion: The integration of AI/ML into nanoneurotherapeutics represents a paradigm shift in AD management. By addressing challenges in BBB penetration, drug delivery optimization, and early diagnostics, AI/ML empower the development of precise, personalized therapeutic strategies. Future efforts must focus on interdisciplinary collaboration to ensure effective clinical translation.

Keywords: Alzheimer's disease, nanoneurotherapeutics, artificial intelligence, machine learning, precision.

PLP050

Adverse Drug Reaction in Paediatric Population in Gandhinagar

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Introduction: Adverse Drug Reactions (ADRs) are unintended, harmful responses to medications used at therapeutic doses. Paediatric patients are vulnerable due to distinct physiological characteristics affecting drug pharmacokinetics and pharmacodynamics. ADRs in children can cause hospitalization, disability, or death. Risk factors include multiple drugs, off-label or unlicensed drug use, and complex illnesses. Drug-Related Problems (DRPs) challenge clinicians, increasing healthcare costs. Clinical pharmacy is crucial in mitigating DRPs and optimizing medication safety.

Methods: This prospective observational study included paediatric patients from inpatient, outpatient, and neonatal intensive care units. Data were recorded in Case Record Forms, with In-patient department patients monitored daily and Out-patient department patients instructed to report adverse effects. ADRs were assessed





for causality, severity, and classified using ATC-WHO and SOC-WHO guidelines. DRPs were analysed and categorized.

Result: Of 1482 screened patients, 1412 met inclusion criteria. Thirteen patients reported 16 ADRs, and 7 reported 18 vaccine-related adverse events. Antibiotics were the most implicated drug class, with diarrhoea and localized swelling being the most frequent ADR and adverse event, respectively. Overdosing was the most prevalent DRP. The average cost of management of ADR is Rs. 226.8.

Conclusion: Efficient healthcare management minimized ADR incidence and severity, with no fatalities or long-term effects. However, ADR-related costs burden caregivers and healthcare providers, necessitating strategies to reduce expenses. Accurate dosing is critical to paediatric safety.

Keywords: Adverse Drug Reaction, Pharmacovigilance, Paediatric, Vaccine-related adverse events, Drug-Related Problems.

PLP051

Assessment of Risk Factors, Medication Adherence and Depression amongst Stroke Survivors: A Prospective Observational Study

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Introduction: Stroke, often termed a "brain attack," results from disrupted cerebral blood flow due to vessel blockage or rupture. Types include ischemic stroke, haemorrhagic stroke, and transient ischemic attack (TIA). Key modifiable risk factors for recurrence include hypertension, diabetes mellitus, dyslipidaemia, cardiac conditions, smoking, alcohol use, and obesity. This study aims to evaluate these risk factors, medication adherence, and depression among stroke survivors. It further investigates brain involvement, clinical findings, dietary habits, sociodemographic factors, stroke-related myths, and the correlation between depression and non-adherence.

Methodology: This observational study enrolled 70 participants, with 69 completing follow-up. Eligible participants provided informed consent, and data on demographics, clinical diagnoses, brain involvement, risk factors, and lifestyle habits were recorded. Depression was assessed using the PHQ-9 questionnaire, and medication adherence via the ARMS scale. Educational leaflets on risk factors and stroke myths were distributed at baseline.

Results: Of 69 participants, 60.86% were male and 39.13% female, primarily aged 61-80 years. Ischemic strokes accounted for 91.3% of cases. Hypertension (15.9%) was the most common risk factor, followed by combined hypertension and diabetes (11.5%). Obesity was observed in 36.2%. Depression and medication adherence scores showed a positive direct correlation.

Conclusion: The study highlights modifiable risk factors such as hypertension, obesity, and diabetes, advocating improved medication adherence, mental health support, and lifestyle changes for better recovery and prevention.

Keywords: Stroke survivors, Ischemic stroke, Haemorrhagic stroke, Medication adherence, Depression.





ABSTRACT- POSTER PRESENTATIONS

(*Computer Aided Drug Design & Medicinal Chemistry***)**





CHP001

Artificial Intelligence in Drug Discovery: Present Status and Future Prospects

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Introduction: Artificial Intelligence (AI) is transforming drug discovery by redefining traditional methodologies. With its ability to analyse vast datasets and model complex biochemical pathways, AI accelerates the identification of therapeutic candidates, minimizes costs, and enhances precision. The global AI-driven drug discovery market was valued at \$1.7 billion in 2023 and is projected to reach \$12 billion by 2033, with significant contributions from North America, Europe, and Asia Pacific.

Methodology: AI is applied across the drug discovery pipeline, including target identification, lead optimization, toxicity prediction, and clinical trial design. Techniques such as machine learning, generative chemistry, and quantitative structure-activity relationship (QSAR) modelling are used to explore molecular interactions and optimize drug properties. AI also enables drug repurposing and simulates clinical trials, providing insights into patient responses and efficacy.

Results: AI has led to the development of over 20 AI-designed drug candidates currently in clinical trials, ranging from Phase I to Phase III. Notable innovations include knowledge graphs for target validation and AI-driven prediction of adverse drug reactions. Despite these advances, challenges such as data quality, biological complexity, and regulatory hurdles persist.

Conclusion: AI is poised to revolutionize drug discovery, enabling unprecedented breakthroughs in personalized medicine and complex disease treatment. Addressing challenges in data standardization, interpretability, and regulatory frameworks is critical for unlocking its full potential. Collaboration across disciplines will be key to overcoming barriers and realizing the promise of AI-driven pharmaceutical innovation.

Keywords: Artificial Intelligence, Drug Discovery, Machine Learning, Clinical Trials, Personalized Medicine.

CHP002

Liquid Crystal Schiff's base esters of Isoniazid with 4-*n* -Alkoxy benzoic acids derivatives: Antituberculosis Drug

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Introduction: Isoniazid liquid crystal derivative is a synthetic antimicrobial and one of the most important firstline drugs used in the treatment of tuberculosis. Since it was introduced in the therapy from 1952, the drug remains at the front line of the antituberculosis treatment mainly due to its power and high selectivity against Mycobacterium tuberculosis. Pharmaceutical analysis and therapeutic drug monitoring of isoniazid in both, pharmaceuticals and biological samples, plays an important role to comprehend aspects reference to bioavailability, bioequivalence and therapeutic monitoring during patients following-up.

Where, $\mathbf{R} = -\mathbf{C}_{n}\mathbf{H}_{2n+1}$, n = 1 to 8,10,12,14,16

Methods: One new mesogenic homologous series of isoniazid with Schiff's base ester having Alkyl 4-[(E)-{4-[(pyridin-4-ylcarbonyl)hydrazono]methyl}phenoxy]benzoate the above general formula have been synthesized. The molecular structures of the synthesized isoniazid Schiff's base ester compounds were characterized by the standard spectroscopic methods and elemental analysis. Isoniazid Schiff's base ester prepared by condensing 4-





n alkoxy benzoyloxy benzaldehyde [A] with isoniazid [B] by Schiff's base method [B] synthesized by condensing in the presence of an alcoholic acidic medium.

Results: The mesomorphic behaviour of these new INH ester was mainly investigated with the help of optical polarizing microscope. For some representative compounds investigated by IR, NMR and differential scanning calorimetric study was carried out to support the optical observation of transition temperatures and associated enthalpies.

Conclusion: All members in series are exhibiting nematic-mesophase.

Key words: Isoniazid (INH), Liquid Crystal Schiff base ester, Antituberculosis, Nematic phase, mesogenic.

CHP003

Molecular Recognition of Poly (ADP-Ribose) Polymerase1 (PARP1) Inhibitors: Drug Design Perspective

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Introduction: PARP1 (Poly (ADP-ribose) polymerase 1) is a critical enzyme involved in the repair of DNA single-strand breaks through the base excision repair pathway. PARP1 inhibitors have emerged as a promising therapeutic approach, particularly in treating cancers with defective DNA repair mechanisms, such as those with BRCA1 or BRCA2 mutations. These inhibitors function by preventing PARP1 from repairing DNA damage, leading to the accumulation of DNA breaks, which can induce cell death, especially in cancer cells with compromised repair pathways. The effectiveness of PARP1 inhibitors has been most notably observed in the treatment of ovarian, breast, prostate, and pancreatic cancers. Clinical trials have demonstrated that PARP1 inhibitors, such as olaparib, rucaparib and niraparib, can significantly improve progression-free survival in patients with specific genetic mutations. Despite promising results, challenges remain regarding resistance mechanisms, toxicity profiles, and the identification of optimal patient populations.

Methods & Results: This review investigates the literature on current marketed PARP1 in the treatment of cancer. It presents an update on PARP1 inhibitors along with their structural design techniques. Pre-clinical molecules were also reviewed and have been categorized into two primary chemical classes: NAD analogues and non-NAD analogues. To comprehend the structural characteristics necessary for the in-silico design of next-generation PARP1 inhibitors, we also detailed the crucial amino acid interactions of these inhibitors at the target region.

Conclusion: Overall, present work discusses the molecular recognition of marketed PARP1 inhibitors with specific emphasis on strategy to design next generation inhibitors with better efficacy and selectivity over PARP2.

Keywords: PARP1, Molecular recognition, BRCA1/2, PARP2.

CHP004

Design of Novel Heterocyclic Compounds for Spike Protein Inhibitors

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Introduction: COVID-19, caused by SARS-CoV-2, emerged in December 2019 and is genetically similar to SARS-CoV. The Spike glycoprotein (S protein) on the virus facilitates entry into host cells by interacting with the ACE2 receptor. Given its critical role, the S protein is a potential target for antiviral therapies. This study aims to develop a pharmacophore hypothesis to identify compounds that could inhibit SARS-CoV-2 infection. **Methods:** A 5-point pharmacophore hypothesis was created using the structure of the Spike protein (PDB ID: 1D6MOJ) via Phase software. This model represented key features of the Spike-ACE2 interaction. After





validating the pharmacophore, a database screening of the ChEMBL library was conducted to identify active compounds that could bind to the Spike protein. Additionally, new compounds were designed based on screening results and literature review.

Results: The database screening identified several active compounds with potential to inhibit the Spike-ACE2 interaction. These compounds were further analyzed for binding affinity and compatibility with the pharmacophore model. A set of new compounds was also designed to improve efficacy.

Conclusion: A pharmacophore model was successfully developed to identify potential inhibitors of SARS-CoV-2 infection. Screening led to the identification of promising compounds, and new compounds were designed for further testing. Synthesis and biological studies are needed to validate their effectiveness as antiviral agents. Against SARS-CoV-2.

Keywords: SARS-CoV-2, COVID-19, Spike Glycoprotein, Pharmacophore, Molecular Docking.

CHP005

Cocrystal software through artificial intelligence

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Introduction-: Cocrystal software is a computational tool designed to aid in the discovery, design, and optimization of cocrystals in pharmaceutical and material science application By leveraging advanced algorithms and artificial intelligence, the software predicts cocrystal formation, stability, and properties based on molecular interactions and crystal engineering principles increasing interest in cocrystals is driven by their ability to improve the physicochemical properties of pharmaceutical compounds. Traditional methods of cocrystal discovery are often resource-intensive Advanced computational tools leveraging artificial intelligence provide a promising alternative.

Methods: Molecular docking - Predicts binding affinity and interactions between potential coformers and the target compound. lattice energy calculation-Evaluates cocrystal stability. solubility Guides coformer selection for improved bioavailability database -Facilitates efficient coformer search and data access Results-The software successfully predicted cocrystal formations validated experimentally, with stability and solubility predictions aligning well with experimental data. The database and user interface were praised for their ease of use and efficiency.

Conclusion-This AI-driven cocrystal software accelerates cocrystal discovery and optimization, reducing reliance on experimental methods. Its predictive capabilities have significant implications for pharmaceutical and material science applications. Future developments may refine algorithms and expand the database to include more compounds and coformers.

Keywords: molecular docking, bioavailability, cocrystal software, algorithms, stability.

CHP006

Targeting Multidrug-Resistant Organisms with Quinazolin-4(3H)-one Derivative: Insights from Molecular Docking, and Dynamics Simulations

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Introduction: The rise of multidrug-resistant organisms (MDROs) poses a significant global health threat, underscoring the urgent need for novel antimicrobial agents. Quinazolin-4(3H)-one and isatin moieties are crucial due to their significant biological importance.

Methods: This study evaluates the antibacterial potential of newly synthesized quinazolinone derivatives using molecular docking and molecular dynamics (MD) simulations. Docking studies were performed against





Staphylococcus aureus (PDB ID: 4CJN) and *Bacillus cereus* (PDB ID: 2GX8) employing the co-crystal ligand QZN and Norfloxacin as reference standards.

Results: Molecular docking revealed that compounds IVa and IVe displayed robust interactions, forming stable hydrogen bonds with key residues in both bacterial targets. Compound IVa achieved a docking score of -4.183 kcal/mol against *B. cereus*, while IVe achieved a score of -3.919 kcal/mol against *S. aureus*, indicating strong dual-target efficacy. The stability of these interactions was corroborated by 100-ns MD simulations. The *S. aureus*-IVa complex demonstrated consistent protein-ligand interactions and maintained exceptional structural stability, with an RMSD of 3.5 Å.

Conclusion: These results indicate that compounds IVa and IVe are promising candidates for the treatment of multidrug-resistant bacterial infections and merit further investigation.

Keywords: Quinazolinone, Antibacterial, Molecular Docking, Molecular Dynamics Simulations.

CHP007

Development of Ai Driven 3d-Printing for Personalized Medicine

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Introduction: The integration of Artificial Intelligence (AI) and 3D printing is paving the way for ground breaking advancements in personalized medicine. This technology has emerged as a transformative tool in the pharmaceutical industry, the ability to create customized drug delivery systems tailored to individual patient needs. This method also facilitates the production of multi-drug combinations in a single dosage form, improving patient compliance. It permits rapid manufacturing, design, and bioprinting. The use of 3D printing for on-demand drug manufacturing, reducing the need for large-scale production and inventory, thus improving drug accessibility and reducing waste.

Methods: The main methods of 3D Printing used in personalized medicines- 1. fused Deposition Modelling (FDM). 2.Stereolithography (SLA). 3.Selective Laser Sintering (SLS). 4.Inkjet Printing.

Result: AI driven 3D printing for personalized medicine yielded unique outcomes demonstrating the capabilities to produce drug delivery system tailored to the precise needs of individual patients. It promises enhanced patient outcomes and also provides a blue print for the future of drug development and delivery.

Conclusion: The successful combination of AI and 3D printing opens up for future research and clinical application within the potential to redefine how pharmaceuticals are created and delivered. However, it is expected that in the next decade, 3D printing changes the path of personalized medicines.

Keywords: Tailored drugs, personalized medicine, drug designing, AI driven 3D printing.





ABSTRACT- POSTER PRESENTATIONS

(Pharmaceutical Analysis, Regulatory Affairs & Quality Assurance)



6th NATIONAL CONFERENCE OF INSTITUE OF PHARMACY 2025 Harnessing Artificial Intelligence / Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges



PAP001

AI-Enhanced Medical Devices: Navigating US Regulatory Approvals

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Introduction: Healthcare is being revolutionized by the incorporation of artificial intelligence (AI) into medical equipment, which makes it possible for more accurate diagnosis, individualized treatment plans, and better patient care. Nevertheless, the novel character of these technologies presents noteworthy obstacles within the regulatory structure of the United States. The FDA in the United States has set up thorough procedures for assessing and approving AI-powered medical devices, guaranteeing their dependability, efficacy, and safety.

Methods: The FDA's Good Machine Learning Practices architecture and recommendations, which prioritize openness, interpretability of algorithms, and the assessment of adaptive systems, are reviewed in this paper. In addition to case studies of AI-enhanced devices like IDx-DR (diabetic retinopathy) and VIZ.ai (stroke detection), important regulatory procedures were examined.

Results: According to the report, the FDA's regulatory structure is ideally adapted to handle the difficulties presented by medical devices with AI enhancements. The potential of AI in meeting important healthcare demands is demonstrated by the successful approval of devices like VIZ.ai and IDx-DR. While VIZ.ai uses AI to quickly diagnose strokes from imaging scans, IDx-DR uses AI algorithms to identify diabetic retinopathy from retinal pictures. These gadgets demonstrate how the FDA can accommodate cutting-edge AI technology while upholding strict safety regulations.

Conclusion: Healthcare delivery is being revolutionized by the incorporation of AI into medical devices; nevertheless, navigating the regulatory environment in the United States necessitates strict adherence to existing standards. Innovation has been successfully promoted while maintaining patient safety thanks to the FDA's Good Machine Learning Practices and strong review processes. Examples from the real world, including VIZ.ai and IDx-DR, demonstrate how AI may enhance diagnosis and treatment results. In order to handle new issues like algorithm bias and cybersecurity threats, regulators, developers, and healthcare practitioners must continue to work together as the area of AI in healthcare develops.

Keywords: AI-medical devices, Healthcare, Regulatory

PAP002

Development and Validation of RP-HPLC method for estimation of Perindopril Erbumine, Indapamide and Amlodipine besilate in Pharmaceutical Dosage Form

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Introduction: The purpose of the investigation was to develop and validate a new, simple, rapid and accurate RP-HPLC method for the analysis of Perindopril Erbumine, Indapamide and Amlodipine Besilate.

Method: The separation was achieved from a Sheisedo C18 (4.6x250mm) 5μ with a mobile phase containing mixture of Water: Acetonitrile: Methanol pH adjusted to 3 by 1% Orthophosphoric acid (40:35:25) %V/V. The sample were monitored at 220nm for detection at a flow rate of 1.0ml/min.

Results: Retention time for Perindopril Erbumine, Indapamide and Amlodipine Besilate was 2.259 min, 3.96 min and 5.07 min respectively. The calibration curve was linear over the concentration range 8-48 μ g/ml, 2.5-15 μ g/ml and 10-60 μ g/ml for Perindopril Erbumine, Indapamide and Amlodipine Besilate respectively.

Conclusion: Method was found to be rapid, specific, precise and accurate can be successfully applied for the routine analysis in bulk and combined dosage form without any interference by the excipients.

Key-word: Perindopril Erbumine, Indapamide and Amlodipine Besilate, RPHPLC, Validation



6th NATIONAL CONFERENCE OF INSTITUE OF PHARMACY 2025 Harnessing Artificial Intelligence / Machine Learning in Pharmaceutical Innovations to Address Global Health Challenges



PAP003

Revolutionizing Mass Spectrometry: AI and ML in data Analysis and Discovery

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Introduction: Mass spectrometry (MS) plays a transformative role in analytical sciences, enabling detailed characterization of complex molecular systems across diverse fields such as drug discovery, proteomics, and metabolomics. Despite its potential, conventional approaches often fail to fully utilize the intricate and high-dimensional data MS generates. Integrating artificial intelligence (AI) and machine learning (ML) offers innovative solutions, tackling issues like data analysis, pattern recognition, and predictive modeling.

Methods: This overview delves into how AI/ML integration is reshaping MS. Key advancements include improved data preprocessing techniques, such as normalization and feature extraction, which refine raw MS data for further analysis. Supervised and unsupervised learning algorithms, ranging from gradient-boosted decision trees to deep neural networks, enhance tasks like spectral annotation, peak classification, and molecular structure prediction. Combining dimensionality reduction techniques like PCA and t-SNE with clustering methods helps uncover hidden insights within high-dimensional datasets.

Results: AI/ML accelerates analytical workflows by automating the detection and interpretation of complex spectra, facilitating quicker and more accurate chemical identification. These technologies support real-time adjustments to experimental setups, minimize errors in quantitative analyses, and enhance reproducibility. Furthermore, AI/ML integrates seamlessly with existing tools, streamlining hypothesis generation and testing. Ensemble models, such as gradient boosting and neural network ensembles, significantly improve the accuracy and scalability of real-time MS data analysis.

Conclusion: These innovations reduce the need for manual interpretation, leading to the discovery of novel bioactive compounds and biomarkers, thus advancing therapeutic and chemical research. This poster outlines the workflow of integrating AI/ML into MS, emphasizing the computational breakthroughs that are driving the evolution of data-driven analytical sciences.

Keywords: Mass Spectrometry, Artificial Intelligence, Machine Learning, Data Analysis, Deep Learning.

PAP004

Navigating Pharmaceutical Regulations: The Divergence from EU Harmonization to UK Independence Post-Brexit

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Introduction: The United Kingdom's withdrawal from the European Union (EU) in 2020 caused substantial disruption to pharmaceutical regulation by dissolving the European Medicines Agency's (EMA) unified framework. This shift necessitated a reassess of compliance strategies by pharmaceutical firms and marketing authorisation holders (MAHs) to traverse the two unique regulatory regimes in the EU and UK. The Medicines and Healthcare Products Regulatory Agency (MHRA) established independent regulatory roles by introducing a unique licensing process for Great Britain (GB), whereas the Windsor Framework addressed Northern Ireland's (NI) specific challenges, ensuring trade continuity and balancing sovereignty with regulatory clarity.

Methods: A thorough comparative analysis was conducted to examine pre- and post-Brexit regulatory landscapes. The study assessed licensing pathways, reporting systems, and supply chain adaptations, focusing on the roles of the MHRA, EMA, and the operational implications of the Windsor Framework. Data sources included MHRA guidance documents, EU legislative updates, and stakeholder feedback, with an emphasis on transitional guidelines for the January 2025 deadline.





Results: Post-Brexit, stakeholders faced significant challenges adapting to a bifurcated regulatory environment. The MHRA implemented adaptive frameworks to streamline processes, promoting innovation while maintaining safety standards. The Windsor Framework addressed GB-NI trade disparities, clarifying regulatory obligations and minimizing conflicts. Stakeholders were urged to align internal systems with UK-specific requirements to capitalize on the UK's innovation-driven policies.

Conclusion: Brexit redefined pharmaceutical regulation, creating challenges and opportunities. The MHRA's adaptive pathways and the Windsor Framework have fostered a practical balance between sovereignty and regulatory coherence, ensuring robust supply chains and market access.

Keywords: Brexit, MHRA and EMA, Windsor Framework, Northern Ireland Protocol, Pharmaceutical regulation.

PAP005

Electrochemical Biosensor: Bridging the Gap from Lab to Home

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Introduction: Electrochemical biosensors represent a new generation of advanced sensing tools in the biomedical, environmental, and food industries. These compact, portable, wearable, and implantable devices convert biochemical signals into electrical signals using transducers such as thermistors and electronic systems. Categorized into amperometric, potentiometric, conductometric, and impedimetric types, each operates optimally under specific conditions and offers diverse applications.

Methods: Advances in sensor fabrication methods, scalable material synthesis, flexible electronics, and wireless communication have enabled biosensors to transition from hospital-centric systems to home-centric solutions suitable for non-experts. However, key challenges, such as scalability, material durability, power management, and environmental stress resistance, limit their widespread application. The development of third-generation biosensors has focused on improving direct electron transfer and enhancing device performance under real-world conditions.

Results: The integration of biosensors with Internet-of-Things (IoT), artificial intelligence (AI) and machine learning (ML) has demonstrated transformative potential in real-time data analysis, disease prognosis, and personalized patient care. Despite their benefits, challenges such as data security vulnerabilities, privacy concerns, and regulatory compliance must be addressed to ensure their ethical and safe deployment.

Conclusion: This review presents an in-depth analysis of the evolution of electrochemical biosensors into miniaturized, integrated platforms as biosensor. Special emphasis is placed on their application in healthcare sector.

Keywords: Electrochemical biosensors, real-time monitoring, Internet-of-Things (IoT), artificial intelligence (AI), personalized healthcare.

PAP006

Preparation of Annual Report in compliance with USFDA requirements and Comparative Interpretation of Post Approval changes of Generic Drugs in the USA, Europe and Canada

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Introduction: The global market for generic drugs has experienced consistent growth recently, largely due to their cost-effectiveness and streamlined approval processes. Generic drugs are essentially identical to branded drugs in terms of safety, strength, dosage, method of administration, intended use, and quality. As the usage of these drug products continues to rise, it's crucial to comprehend the regulatory frameworks governing them.





Methods: This study highlights the preparation of the annual report as per the USFDA requirements under the post-approval changes showing a comparative study for the regulated countries such as US, Europe and Canada which is essential to balance the product life cycle management.

Results: Post-approval changes encompass alterations to any aspect of a pharmaceutical product following approval, categorized as major, moderate, or minor based on their potential impact on the product's identity, strength, quality, purity, or potency, and how these factors may influence its safety or effectiveness. Changes in Chemistry, Manufacturing, and Controls (CMC) are inevitable due to evolving needs, new findings, and ongoing advancements.

Conclusion: Consequently, whether for investigational or commercial products, regulations mandate thorough evaluation and implementation of any changes through the appropriate regulatory channels. Applicants must provide scientific rationale for any changes to approved products, and since all changes fall under audit scrutiny, meticulous record-keeping, preferably online, is essential.

Keywords: Annual Report, Post Approval Changes, US, Europe, Canada

PAP007

Artificial Intelligence for personalized medicines in space environment

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Introduction: Space exploration presents unique challenges, particularly concerning astronaut health due to prolonged exposure to radiation and microgravity. These conditions lead to specific health issues requiring innovative solutions. Artificial Intelligence (AI) has emerged as a transformative tool for delivering tailored healthcare solutions in such environments. By addressing changes in pharmacokinetics, immune responses, and other physiological adaptations in space, AI offers a personalized approach to medical care during space missions.

Method: AI platforms leverage machine learning algorithms to analyze vast datasets from sources such as sensor-equipped devices and medical records. These systems track wellness metrics, predict health outcomes, and identify correlations in personal health data that traditional methods may overlook. Additionally, autonomous AI systems are designed to make real-time medical decisions without relying on Earth-based consultations, compensating for communication delays during deep space missions.

Results: By providing real-time monitoring and predictive modeling, AI enhances therapeutic efficacy and safety in space. Its ability to tailor treatments to individual astronauts ensures effective management of health risks. Autonomous decision-making technologies further assist medical personnel onboard spacecraft by offering rapid assessment advice and customized treatment recommendations. This dual approach ensures timely responses to health issues and improves overall mission success.

Conclusion: The integration of AI in personalized medicine for space exploration holds significant potential to enhance astronaut health and mission outcomes. By enabling efficient, data-driven, and autonomous healthcare solutions, AI can address the unique challenges of long-duration space missions. This review highlights the role of AI in predicting, preventing, and managing health issues through tailored medication strategies, paving the way for a safer and more effective space exploration era.

Keywords: Artificial Intelligence (AI), Personalized Medicine, Space Exploration, Astronaut Health, Autonomous Healthcare.

PAP008

Market Analysis and Regulatory Framework for Pharmaceutical Products in Saudi Arabia

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Introduction: The pharmaceutical market in Saudi Arabia has seen substantial growth in recent years, by increasing health demands and government initiatives promoting domestic drug production, alongside rigorous regulatory compliance. Like many industries, this study examines the current legal environment surrounding product registration, licensing, and distribution, as well as the market dynamics and opportunities available to both domestic and international investors. This analysis is crucial because the regulatory actions affecting competition interact with the market forces that shape the sector.

Method: A combination of qualitative and quantitative research approaches was utilized. The primary source of data was the official guidelines from the Saudi Food and Drug Authority (SFDA) regarding the certification of electrical medical equipment. Additionally, secondary industry reports and market analyses were reviewed. Historical data and experiences were also considered to develop long-term business strategies for lobbying and addressing emerging regulatory challenges.

Results: The research reveals significant potential for growth in Saudi Arabia's pharmaceutical industry, primarily due to government policies that encourage domestic production and a more open regulatory environment. The regulatory framework is progressively aligning with international standards, enhancing accessibility for foreign investors. The rising demand for advanced products and healthcare services further fuels growth opportunities, raising critical questions about compliance and collaboration.

Conclusion: The findings of this study underscore the importance of seeking synergy between business strategies and the existing rules and regulations that currently define the Saudi Arabian pharmaceutical market. Companies that can adeptly navigate these complexities and operate within the established regulatory framework are likely to emerge as leaders and maintain competitiveness in the future.

Keywords: Saudi Arabia, Market dynamics, Pharmaceutical product registration, Licensing and Distribution, Emerging Market Opportunities.

PAP009

Regulatory Approaches and Market Insights for Generic Medicines in Malaysia and Singapore

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Introduction: The Malaysian and Singaporean pharmaceutical markets are influenced by demographic, economic, and regulatory factors. Malaysia's growth is driven by increasing healthcare needs, an aging population, and government initiatives to boost accessibility and domestic manufacturing. Singapore, on the other hand, focuses on innovation and precision in pharmaceutical development and distribution.

Methods: Key market dynamics, population trends, healthcare infrastructure, growth drivers such as patent expirations, affordable generics, and supportive government policies were analyzed. Major challenges, including regulatory requirements and intellectual property (IP) issues, were discussed. A comprehensive comparison of the National Pharmaceutical Regulatory Agency of Malaysia and the Health Sciences Authority of Singapore was conducted, outlining differences in submission timelines, approval processes, and documentation. Emphasis was placed on the ASEAN Common Technical Dossier (ACTD) for harmonization of regulatory submissions, particularly regarding quality, safety, and efficacy documentation.

Results: To succeed in the oncology and over-the-counter (OTC) markets, pharmaceutical companies must have a deep understanding of the regulatory frameworks and ACTD guidelines. The insights provided help companies navigate regulatory landscapes and leverage growth opportunities, particularly in oncology and OTC markets, despite challenges such as workforce shortages and rising healthcare costs.

Conclusion: The analysis concludes that mastering regulatory nuances and ACTD processes is crucial for successful market entry and sustainability in Malaysia and Singapore. These strategic insights empower stakeholders to address regulatory hurdles, ensure compliance, and foster growth in the dynamic pharmaceutical sectors of both countries.

Keywords: Pharmaceutical markets, Market dynamics, Healthcare infrastructure, pricing dynamics





PAP010

Enhancing Access to Safe and Effective Medical Products Across The East African Community: Optimizing Regulatory Convergence Through Modules 2 And 3 in Ethiopia, Kenya, Rwanda, & Uganda

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Introduction: This study investigates the potential of regulatory convergence in the East African Community (EAC) by utilizing Modules 2 and 3 of the Common Technical Document (CTD) to enhance access to safer and more effective pharmaceutical products. The initiative aims to harmonize product approval requirements, thereby facilitating a streamlined and efficient approval process across member states.

Methods: A comprehensive analysis of the current regulatory landscapes in Ethiopia, Kenya, Rwanda, and Uganda was conducted. The study identifies and addresses common challenges such as inconsistent regulatory requirements, limited resources, and capacity-building needs. The approach includes qualitative and quantitative assessments of how a unified adoption of Modules 2 and 3 can improve regulatory processes.

Results: The findings reveal that Modules 2 and 3, which consist of quality summaries, overviews, and detailed quality documentation, are critical for ensuring compliance with safety and efficacy standards. The analysis highlights issues such as regulatory inconsistencies and resource limitations. A harmonized approach, facilitated by these modules, could reduce redundancies, streamline regulatory processes, and promote mutual recognition among regulatory authorities. This, in turn, enhances coordination and collaboration across the region.

Conclusion: The study concludes that regulatory convergence through Modules 2 and 3 of the CTD is essential for improving access to safe and effective medical products in the EAC. Streamlining the approval process not only expedites access to necessary medicines but also contributes significantly to public health outcomes by ensuring the availability of high-quality pharmaceutical products.

Keywords: Regulatory convergence, East African Community, harmonized regulatory frameworks, Quality documentation, pharmaceutical approvals.

PAP011

From Data to Discovery: AI in Drug-Excipient Compatibility Assessment

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Introduction: Preformulation requires thorough drug-excipient compatibility studies to ensure the stability, safety, and effectiveness of pharmaceutical formulations. Excipients play a significant role in influencing overall product performance and therapeutic effectiveness through chemical interactions, physical modifications, and the presence of impurities. Despite their importance, no guidelines are available. Traditional methods like isothermal stress testing, chromatographic and spectroscopic techniques are commonly used but requires more time and researchers' experience. Artificial intelligence has emerged as a transformative tool in pharmaceuticals, particularly in predicting drug-excipient incompatibilities.

Methods: This innovative application has led to the development of advanced systems like PharmDE, an expert system. Using substructure searches and logical reasoning, it categorises interaction risks based on molecular structures. Another system, DE-Interact, is based on a machine learning using artificial neural networks model, thereby accelerating the formulation process.

Results: PharmDE demonstrated a risk prediction accuracy of 78.5%. DE-Interact predicted incompatibilities, achieving 99.3% training accuracy and 91.61% validation accuracy.

Conclusion: These AI-driven tools streamline compatibility assessments, ensuring formulation stability while reducing time and reliance on traditional trial-and-error methods.





Keywords: Drug Compatibility, AI in Pharma, Preformulation, ML in Drug Formulation, Incompatibility Prediction Systems.

PAP012

A Comprehensive Review of Analytical and Bioanalytical Techniques for PARP Inhibitors across Various Matrices

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Introduction: Poly (ADP-ribose) polymerases (PARPs) are a family of enzymes that catalyze the transfer of ADP-ribose to target proteins. PARPs play a fundamental role in DNA repair and many other cellular processes, including transcription and modulation of chromatin structure. Olaparib was the first PARP inhibitor approved by the US FDA in 2014. Since then, drugs like Rucaparib, Niraparib, Talazoparib, and Mefuparib have been approved by the USFDA, while drugs like Fluzoparib and Pamiparib have been approved by China as PARP inhibitors. A few drugs like Veliparib, Simmiparib, and Venadaparib are currently under clinical trial at various phases.

Method: The present review covers different analytical and bioanalytical techniques to estimate quantitatively the marketed and non-marketed PARP inhibitors in various matrices like bulk drugs, dosage forms, plasma, etc. using techniques such as UV-visible, RP-HPLC, LC-MS/MS, and UPLC-MS/MS.

Result: Along with the methods(chromatographic parameters) their validation parameters have also been discussed and compared wherever applicable.

Conclusion: The review also gives insights into the future scope around the analytical/ bioanalytical method development for novel dosage forms containing PARP inhibitors either alone or in conjugation with other agents.

Keywords: PARP inhibitors, Olaparib, Analytical methods, Bioanalytical methods, HPLC.

PAP013

A Strategic Approach to minimize Screening Deficiencies

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Introduction: Screening deficiencies in regulatory submissions lead to delays and increased costs in the pharmaceutical industry. A strategic approach is required to optimize submission processes, enhance compliance, and achieve timely regulatory approvals by addressing these deficiencies effectively.

Method: The strategy emphasizes proactive pre-submission reviews to identify gaps, stringent quality control to ensure consistency, and aligning dossiers with regional guidelines. Using standardized templates, digital tools for document management, and automated validation checks further improves accuracy and efficiency. Collaboration among regulatory, clinical, and quality assurance teams enhances coordination, while regular training programs keep teams updated on evolving regulatory requirements.

Results: Implementing these strategies results in reduced screening deficiencies, improved submission accuracy, and faster regulatory approvals. Quality control measures and digital innovation minimize manual errors, ensuring better compliance. Cross-functional collaboration strengthens submission quality, and training increases readiness for managing complex applications.

Conclusion: A comprehensive approach incorporating planning, documentation, collaboration, and technology effectively mitigates screening deficiencies. It enhances submission quality, reduces delays, and lowers costs. Continuous process improvement through post-submission feedback refines future submissions, promoting regulatory compliance, operational efficiency, and successful market access.



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Key words: Screening deficiencies, regulatory submissions, quality control, compliance, dossier preparation, continuous improvement, regulatory approval.

PAP014

RP-HPLC Based Related Substance & Assay Method Development for Neurotransmitter Drug for Injection

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Introduction: A novel, automated, simple, sensitive, specific, accurate and precise HPLC based method has been developed for determination of related substance in Neurotransmitter drug for injection.

Methods: Among many trials conducted, this method proved to be the most suitable, offering high resolution and better separation under the specified condition. The separation was carried out on Xselect CSH C18 (100mmx4.6 mm, 3.5μ m) column. The mobile phase consisted of 990:10mL mixture of phosphate buffer (pH 2.0) and methanol at flow rate of 1.5 mL/min with gradient. The separation was carried out at 25°C and quantification was achieved at 280 nm. Force degradation condition applied including acid, base, oxidative, thermal and humidity.

Results: The developed method was validated according to the current ICH guideline for accuracy, precision, limit of detection, limit of quantification, linearity and robustness. Method was found linear in the range of 0.0049 - 0.0728 ppm with correlation coefficient of 0.9982. Limit of detection and limit of quantification were 0.0049 and 0.0016 ppm, respectively. % Recovery of known impurity was in the range of 93.6 - 103.6% with %RSD less than 5%. The forced degradation study of drug showed that the drug degraded in acid and Thermal condition.

Conclusion: Validation of the developed HPLC method confirmed the system suitability, precision, linearity, accuracy, FD. All validation criteria were within the acceptable limits.

Keywords: Neurotransmitter, Forced degradation, Method development, RP-HPLC, Validation.

PAP015

An overview of the packaging systems used for protein-based products to maintain their quality and stability by applying various analytical techniques

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Introduction: Protein-based products, including biopharmaceuticals such as (monoclonal antibodies, vaccines, etc.) require specialized packaging systems to ensure their quality and stability throughout their shelf life. A thorough understanding of the physicochemical properties of proteins is essential for selecting appropriate packaging. This review emphasizes the use of various packaging systems for protein-based products, such as glass containers (e.g., pre-filled syringes, vials, ampoules), plastic containers (e.g., bottles), and metal containers (e.g., metal tins, stainless steel), and their significance in preserving product quality. Furthermore, the compatibility and efficacy of these packaging systems are evaluated using advanced analytical techniques. **Methods:** Analytical techniques including UV-visible spectroscopy and chromatography techniques like Size exclusion chromatography (SEC), Ion exchange chromatography (IEC), and Reverse-phase chromatography (RP-HPLC).

(RP-HPLC), were employed. These techniques were used to detect degradation pathways, such as protein adsorption, deamination, and aggregation, and to evaluate the compatibility of packaging materials with protein formulations.





Result: The findings indicate that glass packaging, particularly pre-filled syringes, vials, and ampoules, is most suitable for protein-based products. Glass materials showed a reduced risk of protein degradation, aggregation, and deamination, offering effective protection throughout the product's shelf life.

Conclusion: The investigation concluded that glass materials are highly suitable for packaging protein-based products. Proteins do not adhere to glass surfaces, helping to maintain product quality and stability, which makes glass an ideal material for such applications.

Keywords: Protein products, Packaging system, Quality, Stability, Analytical techniques

PAP016

An Overview of Registration Pathway of Iron Complex Products for Brazil

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Introduction: Iron complex products, such as ferric carboxymaltose, are essential for treating iron deficiency anemia, a condition with significant public health implications. The Brazilian regulatory framework, governed by ANVISA, establishes rigorous requirements for registering these pharmaceutical products. This research examines the registration pathway in Brazil, emphasizing the need for compliance with safety, efficacy, and quality standards, alongside adherence to Good Manufacturing Practices (GMP). The study also explores the complexities of manufacturing iron complex products, including the controlled release of iron and the role of the carbohydrate shell in product performance, while comparing regulatory approaches in Brazil, the USA, and the European Union.

Methods: This study reviewed the Brazilian regulatory framework and guidelines issued by ANVISA for registering iron complex products. It analyzed requirements for pre-clinical and clinical studies, manufacturing processes, and quality assessments. Comparative analysis with regulatory frameworks in the USA and the European Union was conducted to identify similarities and differences in the approval pathways. The research also incorporated case studies of registered products to illustrate practical applications of the regulatory process.

Results: The findings revealed that registering iron complex products in Brazil requires demonstrating safety, efficacy, and quality attributes through rigorous studies and specialized analytical methods. These methods must address the unique characteristics of iron complex products, such as controlled iron release and the carbohydrate shell's impact on product performance. Additionally, strict adherence to GMP is essential throughout manufacturing and quality control. The comparative analysis showed that while Brazil's regulatory pathway shares similarities with the USA and the European Union, key differences exist, particularly in documentation and process timelines.

Conclusion: Navigating the Brazilian regulatory framework for iron complex products requires a thorough understanding of ANVISA's requirements and effective compliance strategies. Pharmaceutical companies that meet these stringent standards can ensure timely access to essential medications for patients with iron deficiency anemia. This research enhances understanding of Brazil's regulatory landscape, offering insights to support informed decision-making in the pharmaceutical industry and contributing to improved patient care and public health outcomes.

Keywords: Iron Complex Products, Registration Pathway, Brazil, USA, Europe

PAP017

FDA's Vision for AI/ML in Pharmaceuticals: Bridging Global Health Disparities

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Introduction: The integration of Artificial Intelligence (AI) and Machine Learning (ML) is transforming drug development, from discovery to post-market safety surveillance, with a focus on optimizing processes, enhancing public health, and advancing manufacturing. AI/ML also plays a crucial role in Software as a Medical Device (SaMD), enabling dynamic adaptations and expanding its use in clinical and regulatory workflows. As the pharmaceutical industry embraces Industry 4.0, AI/ML frameworks, regulatory advancements, and digital health technologies (DHTs) drive innovation, efficiency, and compliance.

Method: In this review, a systematic analysis of AI/ML applications was conducted in five areas: drug discovery, nonclinical research, clinical research, post-market surveillance, and pharmaceutical manufacturing. Regulatory frameworks, including the FDA's ISTAND and MIDD pilot programs, SaMD guidelines, and industry advancements like digital twins, advanced process controls (APC), and data governance practices were reviewed. Attention was given to Good Machine Learning Practices (GMLP) and international standards ensuring data integrity and transparency. However, FDA seeks the assistance from stakeholders for the same as challenges regarding data quality, bias, and transparency persist.

Result: AI/ML showed significant benefits across the drug development lifecycle; accelerated target identification, compound screening, and drug repurposing in drug discovery; while SaMD and DHTs improved patient outcomes with real-time monitoring, adaptive algorithms, and better safety signal detection. Clinical research saw improvements in trial design, participant recruitment, dosing optimization, and adherence monitoring in pharmaceutical manufacturing, AI/ML optimized processes, predictive maintenance, and compliance with Industry 4.0 standards. Post-market surveillance was enhanced through automated adverse event evaluations and real-time pharmacovigilance systems.

Conclusion: This review offers transformative potential of AI/ML in drug development, driving innovation and operational efficiency. Future efforts should focus on enhancing transparency, improving data representativeness, addressing ethical concerns, and fostering collaboration between stakeholders to fully realize AI/ML's potential in the pharmaceutical sectors.

Keywords: Artificial Intelligence (AI), Machine Learning (ML), Pharmaceutical Innovations, FDA Regulations, Software as a Medical Device (SaMD)

PAP018

Nitrosamine Impurities – An Overview in different Regulatory Markets U.S., E.U. and Canada

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Introduction: Nitrosamine impurities, known for their potent genotoxic and carcinogenic properties, have become a significant focus in pharmaceutical regulatory oversight following contamination incidents in widely used medications. These impurities can form during manufacturing or storage, posing serious risks to drug safety and public health. This study aims to provide a comprehensive overview of nitrosamine impurities by examining their sources, formation pathways, and toxicological impacts. It also seeks to compare the regulatory approaches of the United States (U.S.), European Union (E.U.), and Canada, highlighting their risk assessment frameworks, control strategies, and compliance requirements.

Methods: A detailed literature review and analysis of regulatory guidelines, scientific publications, and case studies were conducted to explore the regulatory landscapes in the U.S., E.U., and Canada. Comparative analysis methods were used to identify convergences and divergences in regulatory requirements. Industry best practices and global harmonization efforts were reviewed, with a focus on advanced analytical testing methodologies and supply chain management strategies.

Results: The analysis revealed shared priorities among the U.S., E.U., and Canada, including stringent risk assessment protocols, adoption of advanced analytical techniques, and mandatory reporting of nitrosamine impurities. However, significant regional differences in enforcement actions, permissible limits, and timelines for compliance were observed. Key case studies illustrated the impact of regulatory decisions on drug manufacturers and patient safety. Emerging challenges, such as managing complex global supply chains and the need for harmonized approaches, were identified as critical areas for future focus.



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Conclusion: This study underscores the importance of a harmonized global approach to managing nitrosamine impurities to ensure the safety, efficacy, and quality of pharmaceuticals. While significant progress has been made, challenges remain in analytical testing, supply chain oversight, and international regulatory alignment. By addressing these issues through collaborative efforts, the pharmaceutical industry and regulatory agencies can enhance public health outcomes and foster greater confidence in the safety of medicines worldwide.

Keywords: Nitrosamine Impurities, U.S, E.U, CANADA, Carcinogenic

PAP019

A Comprehensive Review on: Regulatory considerations on Artificial Intelligence for Health as per WHO

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Introduction: The World Health Organization (WHO) aims to enhance health outcomes globally through the adoption of artificial intelligence (AI) in health care. AI offers transformative potential in diagnostics, treatment, and public health, but its rapid deployment raises safety and ethical challenges. This document, produced by WHO in which outlines regulatory considerations for AI in health, emphasizing transparency, risk management, validation, data quality, privacy, and stakeholder engagement.

Method: The WHO Focus Group on AI for Health, comprising multidisciplinary experts, identified six key regulatory considerations: documentation and transparency, risk management across the AI lifecycle, intended use and validation, data quality, privacy and protection, and stakeholder collaboration. These areas were developed through consultations with global and regional stakeholders.

Result: The document outlines best practices and principles for regulatory frameworks, emphasizing the importance of lifecycle documentation, robust validation techniques, high-quality data usage, adherence to privacy regulations, and fostering collaboration. Key challenges include addressing biases, ensuring equitable deployment, and aligning with diverse regulatory environments.

Conclusion: The report provides recommendations for stakeholders to harmonize regulatory practices, ensuring the safe, ethical, and effective use of AI in health care. As AI technologies evolve, adaptive regulatory frameworks and continuous engagement are essential for maximizing their potential while safeguarding public health.

Keywords: Artificial intelligence, documentation, data protection, risk management. Validation.

PAP020

A Review on Indispensable Role of Multi-Angle Light Scattering in Pharmaceutical Science

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Introduction: Conventional analytical techniques for measuring molecular weight are laborious, yield data based on relative standards, are unable to characterize aggregates with very high molecular weights and have certain other limitations. Accurate determination of the size, molecular weight or molecular weight distribution as well as aggregation is necessary for ensuring stability and quality standards. Among the techniques that is frequently used to examine the physical properties of molecules is light scattering.

Methods: This review highlights the principle of static light scattering, various advancements in MALS, and its integration with other methodologies such as Size Exclusion Chromatography (SEC), Ion-exchange Chromatography (IEX), and different Flow Field Fractionation techniques.

Results: MALS have been particularly beneficial for characterizing complex substances such as proteins, polymers, monoclonal antibodies (mAbs), and nanoparticles since it provides a precise assessment of molecular weight, size as well as conformation. It has been useful in detecting aggregation, an important quality trait for biopharmaceuticals.





Conclusion: In pharmaceutical science, multiangle light scattering (MALS) has become a vital analytical tool that has shown exceptional accuracy in determining the absolute molecular weights and therefore offers important insights into the molecular characteristics of many pharmaceuticals.

Keywords: MALS, SEC, IEX, Flow Field Fractionation

PAP021

Enhancing Pharmaceutical Supply Chain Efficiency with AI Powered Predictive Analytics

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Introduction: The pharmaceutical supply chain is a multifaceted system that encounters distinct challenges, such as varying demand, strict regulatory standards and logistical constraints. This paper examines how AI driven - predictive analytics can improve the management of pharmaceutical supply chains by offering a conceptual framework that helps companies utilize advanced data analytics for better decision making, risk mitigation and operational effectiveness.

Methods: It involves the use of key AI methods such as machine learning, data mining, and predictive demand forecasting which serve as a solution to critical supply chain problems like inventory management, demand fluctuations and compliance with regulatory requirements. It also suggests future research avenues, focusing on the need for flexible predictive models and ethical considerations of AI in the pharmaceutical sector.

Results: By showcasing the transformative power of data analytics, this paper presents practical recommendations for pharmaceutical industries aiming to create more resilient and adaptive supply chains.

Conclusion: The given AI method in the paper helps in improving drug supply chain management by ensuring security, reducing costs, enhancing efficiency and safety of drug management.

Keywords: Pharmaceutical Supply Chain, AI driven predictive analytics, Machine Learning, Demand Forecasting, Regulatory Compliance.

PAP022

How to improve efficiency & global harmonization in regulatory submissions by using AI/ML

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Introduction: The integration of Artificial Intelligence (AI) and Machine Learning (ML) technologies into regulatory reporting and e-submissions has revolutionized the way organizations handle compliance and risk management. These advancements enhance precision, efficiency, and adherence to evolving regulations, providing significant benefits across various industries.

Method: AI and ML technologies streamline regulatory processes by automating complex tasks, including data collection, analysis, and submission. Techniques such as real-time monitoring, predictive analytics, and natural language processing (NLP) enable proactive risk management and dynamic compliance with global standards. AI tools standardize data reporting formats and facilitate seamless collaboration among international regulatory bodies while addressing jurisdiction-specific mandates.

Results: The implementation of AI-driven tools reduces manual workloads, mitigates human error, and ensures accuracy in regulatory reporting. Organizations benefit from optimized resource allocation, enhanced reporting precision, and improved global harmonization. Additionally, AI supports dynamic regulatory adaptation and promotes a consistent compliance framework across jurisdictions.

Conclusion: Despite its transformative potential, the successful implementation of AI in regulatory compliance requires addressing challenges such as algorithm transparency, data bias, and ethical concerns. Human oversight and ethical judgment remain vital in validating AI-driven outcomes and aligning them with global frameworks.





By adopting AI-enabled e-submissions, organizations can achieve greater accuracy, efficiency, and collaboration, paving the way for a more harmonized global regulatory environment.

Keywords: Artificial Intelligence (AI), Machine Learning (ML), Regulatory reporting, Natural Language Processing (NLP).

PAP023

Navigating the Complexities of Regenerative Medicine: Insights from India, USA, EU, and Japan

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Introduction: Regenerative medicine, which includes innovations such as stem cell and gene therapies, represents a transformative approach to treating chronic and life-threatening conditions by leveraging the regenerative capabilities of cells and genes. The field faces significant ethical, financial, and safety challenges despite its promise. Each country has developed distinct regulatory frameworks to address these challenges, reflecting varying stages of adoption and innovation.

Methods: The review was conducted by collecting and analyzing references from various academic publications, regulatory documents, and expert opinions. A comparative analysis approach was employed to identify key similarities and differences in the regulatory frameworks of the USA, EU, Japan, and India.

Results: In the United States, the Regenerative Medicine Advanced Therapy (RMAT) designation facilitates the expedited approval of groundbreaking treatments. The European Union's Priority Medicines (PRIME) initiative supports medical innovation while maintaining strict safety standards. Japan's Sakigake project and risk-based regulatory approaches aim to accelerate market approval and clinical advancement. Conversely, India's regenerative medicine sector is still in its early phases, with regulatory frameworks gradually evolving to balance innovation with safety concerns. Additionally, this review discusses the broader implications of these regulatory differences, including their impact on global collaboration, ethical considerations, and the emerging issue of stem cell tourism.

Conclusion: The review concludes that while significant strides have been made globally in the regulation of regenerative medicine, ongoing challenges remain. Robust regulatory frameworks and international coordination are essential to effectively navigate the complexities of this rapidly evolving field, ensuring both innovation and safety are prioritized.

Keywords: Regenerative Medicine, Stem Cell Therapy, Gene Therapy, Regulatory Frameworks, Ethical Challenges.

PAP024

Bioanalytical methodologies for Quantification and monitoring of second-generation antipsychotics in biological matrices

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Introduction: A severe and long-lasting mental illness, schizophrenia affects a person's ideas, feelings, and behaviors. It frequently shows itself as delusions, hallucinations, disordered thinking, and a diminished capacity for emotional expression. Second-generation antipsychotics (SGAs), also known as atypical antipsychotics, form the cornerstone of schizophrenia treatment, offering enhanced efficacy and fewer adverse effects compared to first-generation antipsychotics. SGAs, such as risperidone, olanzapine, quetiapine, aripiprazole, and clozapine are widely prescribed not only for schizophrenia but also for managing severe depression, anxiety, and bipolar disorder. Despite their therapeutic benefits, potential life-threatening side effects and the need for rigorous monitoring highlight the importance of precise pharmacokinetic studies for these drugs.



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Methods: This review provides a comprehensive evaluation of bioanalytical methods utilized for quantifying SGAs in biological matrices, emphasizing the role of therapeutic drug monitoring (TDM) in optimizing efficacy and minimizing adverse effects. The sensitivity, specificity, and clinical applicability of advanced analytical techniques, such as high-performance liquid chromatography (HPLC), gas chromatography (GC), gas chromatography-mass spectrometry (GC-MS), liquid chromatography-tandem mass spectrometry (LC-MS/MS), capillary electrophoresis-mass spectrometry (CE-MS) are critically evaluated. In order to improve analytical performance, novel sample preparation methods are also investigated, such as solid-phase extraction and microextraction by packed sorbent.

Results: The review also addresses challenges such as interindividual variability, low analyte concentrations, and matrix effects, proposing emerging strategies to overcome these limitations.

Conclusion: By synthesizing current advancements, this work aims to guide researchers and clinicians in selecting optimal bioanalytical methods for therapeutic drug monitoring of SGAs ultimately contributing to improved therapeutic outcomes in schizophrenia management.

Keywords: Schizophrenia, Atypical antipsychotics (SGAs), Therapeutic drug monitoring (TDM), Bioanalytical methods.

PAP025

Simultaneous estimation of Dapagliflozin and Linagliptin by First-Order Derivative Method using UV Spectroscopy

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Introduction: This research aimed to develop a simple, accurate, and precise first-order ratio derivative UV-spectrophotometric method for the analysis of Dapagliflozin (DAPA) and Linagliptin (LINA). It is rapid, cost-effective, and does not require complex instrumentation or separation procedures. This method improves accuracy and precision while being applicable even in complex formulations, ensuring efficient analysis in pharmaceutical quality control. The ratio derivative method simplifies the simultaneous estimation of two drugs by eliminating spectral overlap in UV spectrophotometry.

Methods: The methods were designed using a phosphate buffer at pH 6.8, an optimal condition for the analysis of this formulation. In the first-order ratio derivative UV-spectroscopic method, DAPA is quantified at a detection wavelength of 225 nm, while LINA is measured at 293 nm. For the first-order derivative method, the zero-crossing points (ZCPs) for DAPA were found to overlap the spectra of both drugs and then the best point that has zero effect on the other drug spectra was selected as the "ZCP."

Results: The methods were validated following ICH Q2 guidelines to ensure accuracy, precision, and reliability. The ZCP of LINA was found to be 226 nm, and for DAPA, it was 274 nm. After validation, the method was found to be accurate, precise, and repeatable.

Conclusion: These developed methods are suitable for quantifying DAPA and LINA in the novel formulation and for evaluating their drug release profiles. By using these approaches, the simultaneous analysis of DAPA and LINA can be efficiently carried out in the developed formulation, offering a reliable means of quality control and ensuring the accurate measurement of both compounds in pharmaceutical applications. The proposed methods also provide a foundation for future research in formulations containing combinations of these active ingredients.

Keywords: Simultaneous Estimation, DAPA, LINA, UV, ZCP

PAP026

Leveraging Real-World Evidence for Medical Device Regulation: A Comparative Study of Global Frameworks

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Introduction: This study explores the growing significance of Real-World Evidence (RWE) in medical device regulation, focusing on data derived from diverse sources, including electronic health records, claims databases, registries, and patient-generated inputs. The research examines the regulatory frameworks of four key jurisdictions: the United States, the European Union, Japan, and India, providing a comparative analysis of their approaches to RWE integration.

Method: A systematic review of regulatory guidance documents, agency publications, case studies, and peerreviewed literature was conducted to identify the extent of RWE application within these jurisdictions. Data were critically analysed to compare the types of RWE utilized, the scope of their regulatory applications, and the degree of alignment between the frameworks.

Results: Findings indicate significant variation in RWE adoption. The U.S. FDA has issued detailed guidance promoting RWE use, particularly in premarket submissions and post-market surveillance. Similarly, the European Medicines Agency (EMA) integrates RWE for purposes such as safety monitoring and label modifications. Japan and India are gradually incorporating RWE into their regulatory paradigms, although their frameworks remain less developed relative to the U.S. and EU.

Conclusion: The study underscores RWE's transformative potential in enhancing regulatory decision-making by providing insights into real-world device performance and patient outcomes. However, challenges persist, including issues related to data quality, standardization, privacy concerns, and the need for methodological advancements. Addressing these challenges is imperative to fully realize RWE's utility in global medical device regulation.

Keywords: Real-world evidence, Medical device regulation, Comparative analysis, Data quality, Regulatory frameworks.

PAP027

Review on Critical Quality Attributes in Process Development Studies for Monoclonal Antibodies

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Introduction: Monoclonal antibodies (mAbs) are critical biologics used for therapeutic applications due to their specificity and targeted action. Ensuring product consistency, safety, and efficacy requires rigorous quality control. Critical Quality Attributes (CQAs), including glycosylation profiles, charge variants, aggregation levels, and impurities such as host cell proteins (HCP) and residual DNA, are vital to their safety and effectiveness.

Methods: Advanced analytical techniques, such as chromatographic and spectroscopic methods, evaluate structural and functional CQAs. Ligand-binding assays and bio-assays measure binding affinity and potency, while ELISA and qPCR quantify impurities. Stability and compatibility studies assess the impact of storage, freeze-thaw cycles, and material interactions on mAb integrity. Process development studies address freeze-thaw stress, mixing, shear stress, tubing compatibility, hold time, and filter adsorption to optimize manufacturing conditions.

Results and Discussion: Glycosylation and charge heterogeneity significantly influence mAb activity, while aggregation increases immunogenicity risks. Controlled freeze-thaw studies revealed that temperature fluctuations lead to protein denaturation. Mixing and shear stress assessments showed that excessive mechanical forces cause degradation. Tubing compatibility studies ensured selected materials did not contribute impurities. Hold time and filter adsorption evaluations minimized product loss and preserved stability. Optimized purification processes reduced HCP and residual DNA. Analytical techniques like HPLC and mass spectrometry ensured robust manufacturing and compliance.

Conclusion: Monitoring and optimizing CQAs are crucial for producing high-quality mAb therapeutics. Advanced analytical methods and process development strategies address challenges like glycosylation heterogeneity, aggregation, and impurities, ensuring regulatory compliance and therapeutic success. Continuous innovation in technology will further enhance mAb manufacturing.





Keywords: Monoclonal Antibodies, Critical Quality Attributes, Freeze-Thaw Stress, Shear Stress, Process Optimization.

PAP028

Development & validation of a mass compatible stability-indicating UPLC method for the determination of Posaconazole tablets

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Introduction: Posaconazole, a second-generation triazole antifungal, is primarily used for the prevention and treatment of invasive fungal infections in immunocompromised patients. It is effective against resistant fungal pathogens, including Aspergillus and Candida species, and is crucial in managing refractory oropharyngeal candidiasis and infections caused by Fusarium and Zygomycetes. A simple, novel, rapid, and reliable Ultra-High-Performance Liquid Chromatography (UHPLC) method was developed and validated for the quantification of Posaconazole in tablet dosage forms.

Methods: The method employed an Acquity UPLC BEH C18 column (50 mm \times 2.1 mm, 1.7 µm particle size) and a mobile phase consisting of methanol and 10 mM ammonium bicarbonate buffer (70:30, v/v) at a flow rate of 0.3 mL/min. The separation was performed at a column temperature of 40°C, with an injection volume of 5 µL. Quantification was achieved using UV detection at 260 nm.

Results: Method was found linear over the range of 25-225 μ g/mL with correlation coefficient of 0.999. %Recovery was found between 98.7-100.6% with maximum %RSD of 0.4%. %RSD for precision study was 0.2%. The method demonstrated robust stability-indicating capabilities through forced degradation studies, including exposure to acid, base, oxidative, thermal, and photolytic stress conditions. Degradation was observed predominantly under acid and oxidative conditions, Posaconazole was stable under alkali hydrolysis, thermal, photolytic condition.

Conclusion: This mass-compatible method, validated per ICH guidelines, exhibits excellent specificity, linearity, precision, and sensitivity. It is suitable for routine quality control and stability testing of Posaconazole formulations in pharmaceutical settings.

Keywords: UHPLC, Mass-compitable, Posaconazole, Stability-indicating, Forced degradation.

PAP029

Development and validation of stability-indicating HPLC method for the quantitative analysis of Hemostatic agent

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Introduction: An accurate, resilient, and novel High-Performance Liquid Chromatography (HPLC) method was developed to assay a hemostatic agent active pharmaceutical ingredient (API) used in wound care and surgical procedures.

Methods: The technique was designed as a stability-indicating procedure and effectively evaluates the API under forced degradation conditions, including acid and base hydrolysis, oxidation, photolysis, thermal stress, and humidity. The separation was carried out on a Sapphirus silica HP Classic C18 column (250 mm \times 4.6 mm), 5 µm particle size column with an isocratic elution program. The mobile phase consisted of phosphate buffer





(pH 3.0) and acetonitrile at a flow rate of 1 mL/min. The analysis was conducted at 25°C with an injection volume of 15 μ L, and quantification was carried out at 205 nm.

Results: The method was validated according to current ICH guidelines, demonstrating excellent linearity over the concentration range of 250–1500 ppm, with a correlation coefficient greater than 0.999. The method exhibited recovery rates of 98–102% and low relative standard deviations, ensuring high precision and accuracy. **Conclusion:** Several key chromatographic factors, were evaluated in order to optimize the detection of all potentially relevant degradants. The present review discusses the stability-indicating assay methods(SIAM) and approaches for the development of SIAM as per the current regulatory requirements. This validated HPLC assay method is robust, sensitive, and suitable for routine quality control and stability testing of the hemostatic agent API.

Keywords: RP-HPLC, Hemostatic agent, Stability indicating method, Regulatory guidelines, force degradation.

PAP030

Stability indicating RP-HPLC method development and validation for determination of related substance in combination of Propranolol hydrochloride and Flunarizine tablet dosage form

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Introduction: A simple, novel, rapid, reproducible and sensitive RP-HPLC method is developed for determination of related substance in combination of Propranolol hydrochloride and Flunarizine tablet dosage form.

Methods: Among 8-9 trials conducted, this method proved to be the most suitable, offering high resolution and better separation under the specified condition. The separation was carried out on X-bridge C18 (250mm \times 4.6mm), 5µm or equivalent column. The mobile phase consisted of 20mM phosphate buffer (pH 5.0) and acetonitrile at flow rate of 1 mL/min with gradient elution program. The separation was carried out at 25°C and injection volume was 25 µL. Quantification was achieved at 240 nm. Force degradation condition applied including acid, base, oxidative, photolytic, thermal and humidity. The developed method was validated according to the current ICH guideline for accuracy, precision, limit of detection, limit of quantification, linearity and robustness.

Results: The described method was linear over the range of $0.4 - 6.0 \ \mu\text{g/mL}$ and $0.1 - 1.5 \ \mu\text{g/mL}$ for Propranolol hydrochloride and Flunarizine, respectively with correlation coefficient greater than 0.990. Limit of detection for Propranolol hydrochloride and Flunarizine were found 0.132 and 0.033 $\mu\text{g/mL}$, respectively and the limit of quantification for Propranolol hydrochloride and Flunarizine was 0.4 $\mu\text{g/mL}$ and 0.1 $\mu\text{g/mL}$, respectively.

Conclusion: Chromatographic peak purity data of both drugs and unknown impurities indicated no co-eluting peaks with the other peaks which demonstrated the specificity of related substance method for their estimation in presence of degradation products.

Keywords: HPLC, Propranolol hydrochloride, Flunarizine, Related substance, Force degradation.

PAP031

Estimation of Ticagrelor and its Related Substances by RP-HPLC Method

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Introduction: Ticagrelor is an antiplatelet drug that prevents platelets from sticking together and decreases your body's ability to form blood clots. The objective of the study was to develop and validate a new rapid, sensitive,





Reverse-Phase High-Performance Liquid Chromatography technique for the estimation of Ticagrelor and its related substances(Impurities). Ticagrelor is a generic product, hence, there are many methods available for the estimation of ticagrelor and its related substances but in the case of different excipients used in formulation (Tablet) or ticagrelor (API) purchased from different vendors, it must be necessary to develop or validate impurity analysis method.

Method: Chromatographic separation was achieved on an Agilent Zorbax SB C-18 (150 x 4.6mm, 1.8 μ) with a buffer of Sodium Dihydrogen Phosphate 1.3 M [pH – 3 was adjusted by ortho-phosphoric acid] and the ratio of mobile phase A [Buffer: Water: Acetonitrile (10:890:100)] and for mobile phase B [Buffer: Water: Acetonitrile (10:290:700)] with gradient flow. The temperature of the column was maintained at 15^oC and detection was made at 242nm. The run time was as short as 40.0 min The developed method was validated according to the International Conference of Harmonization (ICH) guidelines with respect to linearity, accuracy, precision, and specificity.

Result: The developed method was linear for Ticagrelor and its impurity from $0.05 - 1.3 \mu g/ml$ and the linear regression obtained was found to be 0.999 for ticagrelor and its all impurity. The limit of detection and limit of quantification is carried out by its signal-to-noise ratio (S/N) and reporting threshold value.

Conclusion: The conclusion suggests that the developed RP-HPLC method is reproducible and reliable.

Keywords: Ticagrelor impurity analysis, RP-HPLC, Validation.

PAP032

Overview of Antibiotic Residue Contamination in Water Bodies: Impacts on Resistance and Public Health

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Introduction: The escalating contamination of water bodies with pharmaceuticals has raised global concerns due to potential health repercussions. The need to analyze the accumulation of antibiotic residues is of significant importance as it increases antibiotic resistance in waterborne organisms. The excessive consumption of antibiotics has led to the increase in antibiotic resistant bacteria (ARB), which along with environmental antibiotic residues (EARs) contribute to global antimicrobial resistant (AMR).

Methods: The water samples were collected from various water bodies such as river, lakes and sewage. The samples are screened for identification of antibiotic residues. Priority screening of antibiotics is performed. The quantitative analysis of samples is performed by HPLC-MS/MS technique where ESI is the ionization source. Kinetex Column is used for separation. The pattern of occurrence of antibiotic residues is observed regionally and seasonally to understand and estimate the pattern of consumption of antibiotics by humans. Risk assessment is performed by including the following parameters, ecological risk assessment, human risk assessment including risk quotient (RQ), and screening for antibiotic resistant bacteria (ARB).

Result: The results obtained from the priority screening of antibiotics indicate the detection limits of various antibiotics exceeding the higher limit. This indicates excessive use of antibiotics by humans and rise of antibiotic-resistant bacteria (ARB).

Conclusion: The results obtained indicate the conclusion that the antibiotic concentrations in water bodies are positively correlated with population density and economic development. If left unchecked, the presence of antibiotic residues in water bodies threatens to reverse gains made in ensuring universal access to clean water.

Keywords: Antibiotic residues, Antibiotic resistance, HPLC-MS/MS, Risk assessment, Water contamination.

PAP033

Comprehensive study for comparative analysis on regulations of Herbal medicinal products by US and EU

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Introduction: Herbal medicinal products, also known as phytotherapy or phytomedicine, are a significant component of complementary and alternative medicine, utilizing natural plant-derived products for therapeutic purposes, the growing popularity of herbal products for their medicinal use globally has led to increased regulations and scrutiny for them.

Methods: This study of herbal medicinal products reviews the regulatory aspects such as the historical context of herbs, various types, applications, and associated safety considerations. The study also provides a comparative analysis of regulatory guidelines for herbal medicines established by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

Results: Further more the comparison in this study focuses on critical regulatory aspects such as quality assurance, safety, efficacy, and labeling requirements, for the herbal medicinal products, highlighting the key differences and similarities between the regulatory guidance provided by both respective regulatory bodies.

Conclusion: By studying these regulatory frameworks and guidelines, this study aims to offer a comprehensive understanding of the global landscape for herbal medicine regulation, thereby explaining the implications for manufacturers, healthcare providers, and consumers.

Keywords : Herbal formulations, FDA, EMA, Regulatory aspects, Comparative analysis.

PAP034

A Review of Analytical and Bioanalytical Techniques for Determination of Organophosphorus Pesticide Residues in Various Fruits and Vegetables

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Introduction: Organophosphate (OP) pesticides, such as malathion, chlorpyrifos, parathion, profenofos, and diazinon, are widely used in agricultural and household applications due to their low bioaccumulation, rapid biodegradation, high toxicity, and broad-spectrum activity. These esters of phosphoric acid have been in use for nearly 50 years, helping to control pests and improve crop yields. However, their extensive application poses significant risks to human health and the environment, contaminating fruits, vegetables, and processed foods. Prolonged exposure to OP pesticides has been linked to severe health issues, including neurological and developmental disorders, necessitating stringent monitoring to ensure food safety.

Methods: Monitoring pesticide residues in agricultural produce is essential to ensure compliance with the maximum residue limits (MRLs) set by regulatory bodies such as the Codex Alimentarius Commission and the European Union. Traditional analytical methods, including gas chromatography–mass spectrometry (GC–MS), liquid chromatography–tandem mass spectrometry (LC–MS/MS), ultraviolet-visible spectroscopy, and high-performance liquid chromatography (HPLC), offer high accuracy but require extensive sample preparation and skilled operation. In contrast, modern detection techniques, such as biosensors, provide rapid, sensitive, and on-site analysis. Electrochemical, optical, and piezoelectric biosensors have demonstrated significant potential for real-time pesticide detection.

Results: Traditional methods offer reliable and precise results, while modern biosensors provide quicker and more convenient detection with comparable sensitivity and specificity.

Conclusion: This review highlights the need for effective residue monitoring to ensure food safety and public health. Advanced detection technologies complement traditional methods, playing a crucial role in mitigating health risks and ensuring sustainable agricultural practices.

Keywords: Organophosphorus pesticides, Fruit and vegetable crops, Analytical methods, Biosensors.



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PAP035

AI/ML assisted Pharmaceutical Analytical Techniques for Efficient Separation and Detection of Compounds

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Introduction: The areas of artificial intelligence (AI) and machine learning (ML) have transformed the landscape, particularly in pharmaceutical research and development (R&D). Although machine learning (ML) enables systems to learn and enhance from data without direct programming, artificial intelligence (AI) employs algorithms that mimic human decision-making processes. These technologies have progressed significantly in the past few years due to improvements in data management and processing capabilities. Their application in pharmaceutical analytical techniques has been crucial in addressing longstanding problems related to efficiency, cost, and time.

Method: Various review and research articles published in reputable journals and databases like Google Scholar, Elsevier, Science direct, PubMed, were thoroughly reviewed to gather insights into AIML-assisted advanced pharmaceutical analytical techniques. The articles focusing on the importance of AI and ML in drug discovery and analysis were reviewed for their findings and compiled.

Result: High-throughput virtual screening, gas chromatography, liquid chromatography (LC), and various chromatographic techniques are some of the analytical methods that extensively employ AI/ML. AI/ML systems forecast complex behaviours, enhance chromatographic parameters, and accelerate method development through the analysis of extensive datasets. Examples of specific applications include high-throughput virtual screening, pharmacophore modelling, de novo drug design, and Quantitative Structure-Activity Relationship (QSAR) modelling. These technologies surpass traditional trial-and-error approaches regarding efficiency, precision, and scalability. The integration of AI/ML into analytical methods has demonstrated a substantial improvement in both separation effectiveness and detection precision. AI/ML, for instance, enhances separation parameters, reduces experimental errors, and decreases the time required to develop a method in liquid chromatography. AI-driven predictive models enable rapid assessment and detection of potential chemicals from extensive databases. These advancements surpass traditional methods regarding accuracy and scalability, resulting in enhanced throughput, reproducibility, and cost efficiency.

Conclusion: In summary, artificial intelligence (AI) and machine learning (ML) have revolutionized pharmaceutical analytical techniques by providing unprecedented levels of speed, precision, and efficiency in the separation of analytes. These advancements have transformed the pharmaceutical sector by addressing longstanding issues in drug discovery and technique improvement. AI/ML is set to greatly enhance R&D processes as computational progress persists, driving innovation and improving results in the pharmaceutical processes.

Keywords: artificial intelligence, machine learning, separation efficiency, detection, spectroscopy, chromatography.

PAP036

Digital Therapeutics and Software as a Medical Device: A Review of Emerging Trends and Regulatory Perspectives

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Introduction: Digital therapeutics (DTx) and Software as a Medical Device (SaMD) are transforming healthcare by offering software-driven solutions for treatment, diagnostics, and monitoring. DTx provides therapeutic interventions for preventing, managing, or treating conditions, while SaMD performs medical tasks independently of physical devices. The rise of chronic diseases, advancements in personalized healthcare, and innovations like artificial intelligence (AI) drive their rapid growth. This review explores the applications, regulatory frameworks, challenges, and future trends of DTx and SaMD.





Methods: This review analyzed peer-reviewed articles, clinical trials, regulatory guidelines, and product registries. Focus was placed on regulatory pathways established by organizations like the FDA and European Commission. Examples were assessed for therapeutic focus, regulatory approval, clinical validation, and patient impact. Products were categorized into therapeutic, diagnostic, and monitoring applications to demonstrate their diverse roles.

Results: Highlighted examples include: reSET-O (Pear Therapeutics): A mobile app delivering FDA-approved cognitive-behavioral therapy for opioid use disorder. Omada Health: A platform addressing diabetes and hypertension through personalized coaching. IDx-DR: An FDA-cleared AI tool for autonomous diabetic retinopathy diagnosis. HeartFlow FFRct: Software analyzing coronary CT images to assess blood flow for diagnosing coronary artery disease. Challenges include regulatory complexity, data security, and patient adherence.

Conclusion: DTx and SaMD offer scalable, personalized, and non-invasive healthcare solutions. However, updated regulatory frameworks and broader acceptance are essential. Future advancements in AI, data security, and harmonized regulations will further unlock their potential to improve patient outcomes in personalized medicine.

Keywords: DTx, SaMD, Pear Therapeutics, Regulatory Frameworks.

PAP037

Analytical Methods for determination of Phytoconstituents in Polyherbal Formulation: A Review

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Introduction: Polyherbal formulations have been a cornerstone of traditional medicine, offering synergistic therapeutic benefits by combining multiple herbal constituents. The identification and quantification of phytoconstituents in these formulations are essential for ensuring quality, efficacy, and safety.

Method: A comprehensive literature search has been carried out for the analysis of *Psidium guajava*, *Calendula officinalis & Glycyrrhiza glabra* from various formulation or herbal drug. For *Psidium guajava*, methods such as GC-MS, HPLC-DAD, HPLC-TOF-ESI-MS, HPLC-DAD-QTOF-MS, and HPTLC have been employed. Analysis of *Calendula officinalis* has utilized techniques including GC-MS, UV spectrophotometry, HPTLC, and HPLC-DAD. Similarly, the phytoconstituents of *Glycyrrhiza glabra* have been studied using methods such as Capillary zone electrophoresis, GC-MS, HPTLC, liquid chromatography, UHPLC, LC-ESI/MS, and HPLC-PDA.

Results: Literature indicates that High-Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC) are the most commonly employed analytical techniques. The C_{18} column is the most widely used column in HPLC. Extraction methods predominantly include maceration, decoction, and fermentation. Ethanol, hexane, and diethyl ether are the most widely used solvents for extraction.

Conclusion: This review provides a detailed analytical method for determination of *Psidium guajava*, *Calendula officinalis & Glycyrrhiza glabra* from various matrices & it is helpful for researchers to find a suitable method.

Keywords: Polyherbal formulation, Phytoconstituents, Analytical techniques, Extraction, Formulation.

PAP038

Overview of Quality Assessment Parameters Used for the Production of Antibiotics from Streptomyces Species

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Introduction: The *Actinomycetes* family of bacteria, particularly the *Streptomyces* species, has served as a significant source of the majority of antibiotics currently in use. It is essential to not only attain the required chemical compound from the microorganism adequately but also to evaluate its physico-chemical, therapeutic, and other quality-centric parameters to ensure that the chemical entity as well as the extraction and isolation methods, are effective and safe for the intended purpose.

Method: To establish the checkpoints for quality assessment, it is essential to analyze the bio-synthetic pathway of the antibiotic, which is inclusive of everything from the selection of an appropriate strain of microorganism to the final stages of antibiotic extraction and purification. Antibiotic production involves selecting and cultivating bacterial strains, followed by fermentation under optimal conditions to maximize yield. After extraction, purification is achieved using methods like TLC, HPLC, or re-crystallization. Characterization includes UV-Visible spectroscopy, Mass Spectroscopy, Nuclear Magnetic Resonance (NMR) Spectroscopy, and Infrared spectroscopy. Biological activity is assessed through bio-assays to determine Minimum Inhibitory Concentration (MIC). Stability testing evaluates shelf life under various conditions. The mechanism of action is identified, including cell wall synthesis inhibition, protein synthesis disruption, or nucleic acid interference. Target identification uses molecular techniques. Finally, examination for purity and residual solvent analysis is also a part of this study.

Results & Conclusion: The best suited formulations are developed for effective delivery and stability. This review focuses on compilation of all the necessary parameters which are taken into consideration during the production of an antibiotic from the given species of bacteria.

Keywords: Streptomyces species, Antibiotics production, Quality assessment, Production parameters, Pharmaceutical Analysis.

PAP039

Intravenous to subcutaneous injection development requirement for mAbs

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Introduction: The rising interest in therapies based on monoclonal antibodies (mAb) for chronic diseases has prompted the shift from intravenous (IV) to subcutaneous (SC) delivery; primarily due to better patient adherence and decreased healthcare expenses. In addition, while an IV treatment takes several hours for its administration, SC therapy achieves the same within a much shorter time frame. This makes SC delivery a promising and suitable alternative to IV, according to patient and healthcare providers. These benefits are particularly evident in therapies for chronic conditions such as breast cancer, asthma, and rheumatoid arthritis.

Methodology: The creation of SC formulations encounters obstacles like inconsistent and incomplete bioavailability, elevated viscosity, aggregation, and potential immunogenicity. Elements affecting the development of SC injection encompass molecular weight, volume of injection, absorption processes, and traits related to the host. Tackling these challenges is essential for enhancing mAb administration via the SC pathway. To address the challenges in creating SC injections, advancements in formulation science have focused on increasing protein concentration, enabling greater delivery volumes, and employing innovative technologies like infusion pumps and the co-administration of hyaluronidase.

Results: Recent advancements in large-volume injectables and high-concentration antibody formulations (HCAF) have significantly facilitated SC administration of mAb therapies. Recombinant human hyaluronidase (rHuPH20, Hylenex), an FDA-approved product, has demonstrated enhanced bioavailability when combined with therapeutic antibodies like trastuzumab, tocilizumab, and rituximab. Clinical applications of these combinations have received regulatory approval from the European Medicines Agency (EMA) for tumor therapy, while SC-administered tocilizumab has been approved by both the FDA and EMA for treating primary immunodeficiency (PI) and rheumatoid arthritis (RA), respectively. These advancements have broadened the use of SC formulations across multiple therapeutic areas.

Conclusion: The transition from IV to SC administration offers numerous benefits, including enhanced stability, production efficiency, and patient satisfaction. Improvements in supply chain strategies and delivery methods have further ensured the safety, effectiveness, and convenience of mAb-based treatments. While challenges related to formulation and bioavailability persist, ongoing innovations in SC delivery, such as high-concentration formulations and the use of rHuPH20, hold great promise in making SC injections a viable and efficient alternative to IV therapies.





Keywords: Monoclonal antibodies, SC injection, IV injection, Hyaluronidase, Patient Adherence.

PAP040

Comprehensive Review of USFDA Regulatory Framework for Peptide Therapeutics

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Introduction: The heightened interest and activity within the pharmaceutical industry surrounding peptide therapeutics have been major catalysts for the development and refinement of regulations in this domain. Therapeutic peptides are a distinct category of pharmaceutical agents made up of ordered amino acids, typically of molecular weights in the range of 500 to 5000 Da. Peptides have several significant clinical applications like wound repair, inflammatory chronic skin conditions, tumor targeting and molecular imaging.

Methods: A comprehensive literature search was conducted to gather information on the USFDA's regulatory framework for peptide drug products using search engines like Sci-Finder, Scopus and from the official USFDA Website.

Results: Despite the inherent challenges in discovering, developing, and delivering peptide therapeutics in a patient-friendly manner, the number of peptide drugs progressing to clinical development and reaching the market has grown significantly over the past decade. Development of peptide drug has started a new age in this millennium, with significant advancements in recombinant biologics, new synthetic, structural biology, and analytical methods accelerating this process. Since 2000, 33 non-insulin peptide drugs have been globally approved.

Conclusions: The U.S. Food and Drug Administration (FDA) regulates peptide drug products to ensure their safety, efficacy, and quality. Straddling the line between traditional small molecules and large proteins, peptides have introduced a host of regulatory challenges. The regulatory landscape for peptide therapeutics in the United States is complex and multifaceted. This comprehensive review explores the USFDA's regulatory framework for peptide drug products, highlighting key guidelines and considerations for their development and approval. This review aims to provide a thorough understanding of the regulatory pathways and challenges faced by developers of peptide-based therapies, offering valuable insights for industry professionals and researchers alike.

Keywords: Peptides, Therapeutics, Guidelines, USFDA, Regulatory framework.

PAP041

Regulatory Landscape for Radiopharmaceuticals in Australia: Navigating Safety, Compliance and Challenges

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Introduction: Radiopharmaceuticals are medications that incorporate radioactive chemical elements called radioisotopes, used for diagnosing or treating various medical conditions depending on the type of radiation they emit. The utilization of ionizing radiation in medical diagnostics and treatment is rapidly growing in Australia and globally. This review addresses the regulatory requirements and challenges for radiopharmaceuticals in Australia.

Methods: Various Australian websites, regulatory guidelines, and review articles were examined and compiled for comprehensive analysis.

Result: The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the primary authority on radiation protection and nuclear safety in Australia. ARPANSA's 2008 safety guide on Radiation Protection in Nuclear Medicine covers aspects such as justification, duties and responsibilities, occupational exposure, and





quality assurance. Manufacturing and handling must focus on preventing cross-contamination, managing short half-lives of radionuclides, and waste disposal. Australia follows EMA guidelines for the clinical evaluation of diagnostic agents and radiopharmaceuticals based on monoclonal antibodies. Applicants can apply for a source license and facility license, which are assessed by regulatory officers. The Australasian Radiopharmaceutical Trials Network (ARTnet) promotes and facilitates innovative collaborative clinical research using radiopharmaceuticals for imaging or therapy. However, the existing manufacturing and regulatory framework limits patient access to nuclear medicine procedures.

Conclusion: Radiopharmaceuticals in Australia are governed by a well-defined and stringent framework, distinct from conventional medicine. However, radiopharmaceuticals should be regarded as a separate class of "drug" when assessing registration on the ARTG to prevent transportation impediments by TGA regulations.

Keywords: Ionizing radiation, Radioisotopes, Radiopharmaceuticals.

PAP042

Stability indicating RP-HPLC Method Development and Validation for Simultaneous Estimation of Dapagliflozin and Metoprolol in synthetic mixture

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Introduction: Stability indicating RP-HPLC method was developed for Simultaneous estimation of Dapagliflozin and Metoprolol in synthetic mixture under different stability environments of acid, base, thermal, oxidation, and photolytic degradation.

Methods: Separation was achieved on Ultrasphere C18, (250 mm x 4.6 mm) 5.0 μ m column by using a mobile phase (Methanol:ACN:Phosphate buffer pH 3.0)%v/v/v (60:10:30) with isocratic flow rate of 0.8 ml/min and detection was at 223 nm.

Results: The retention time of Dapagliflozin was found to be 7.012 min and Metoprolol was found to be 3.392 min. The method was linear in the range of $1 - 50\mu$ g/ml, & $5 - 250\mu$ g/ml and correlation coefficient was found to be 0.999 for Dapagliflozin and Metoprolol.

Conclusion: The developed method was validated according to the ICH guidelines. The developed method was validated system suitability, specificity, linearity, limit of detection and quantitation, accuracy, precision and robustness. Results of each parameter meet with this acceptance criteria. Hence, the method will be useful for routine quality control analysis.

Key Words: RP-HPLC, Dapagliflozin, Metoprolol, Validation.

PAP043

Pharmacovigilance of Herbal Drugs: A Global Perspective on ADR Reporting in India, the US, and Nigeria

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Introduction: Herbal medicines are used internationally which needs the efficient pharmacovigilance system to ensure is safety and efficacy, though Adverse Drug Reaction (ADR) associated with them are unreported due to unstable pharmacovigilance framework, bounded public awareness and limited standardization. This study depicts the pharmacovigilance system in India, United States and Nigeria focusing on ADR reporting software's and Mechanisms.

Method: For ADR reporting data was analyzed from National Pharmacovigilance Programs using software and information was gathered from governmental agencies, published literature and WHO resources. India's Pharmacovigilance Programme (PvPI) uses e-Shushrut, Vigiflow Software for reporting of ADR which is linked to the WHO Uppsala Monitoring center. The United States uses MedWatch System which allows consumers to report ADRs and reporting can be done through the Mobile Application or by filling form number 3500 for





healthcare professionals and form number 3500B for consumers. Nigeria's NAFDAC (National Agency of Food and Drug Administration and Control) report ADR through MedSafety Application which is supported by WHO platform.

Result: ADR Reporting system are weak in India and Nigeria because of weak infrastructure, underreporting, limited awareness and inadequate training as compared to USA as it has the robust system for reporting. Fragmentation, limited funding and weak regulatory oversight can worsen these issues.

Conclusion: This comparative study shows the importance for strengthening Pharmacovigilance framework, public awareness universally across the countries for reporting of Adverse Drug Reaction and safe use of Herbal Medicines. Implementation of Innovative Digital tools in the Adverse Drug Reaction system can improve the quality of the software and for efficient reporting of ADR.

Keywords: Herbal Medicines - ADR Reporting, Vigiflow, e-Shushrut, MedWatch, MedSafety Applications.

PAP044

Regulatory Challenges and Strategies in the Development and Evaluation of Combination Vaccines in USA: Ensuring Safety, Efficacy, and Quality

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Introduction: Combination vaccines represent a critical innovation in immunization, enabling protection against multiple diseases with a single injection. They simplify vaccination schedules, reduce the number of required appointments, and improve compliance, particularly in regions with limited healthcare access. By addressing practical concerns such as storage and distribution, combination vaccines are instrumental in enhancing global immunization efforts.

Methods: The development of combination vaccines involves a rigorous process to ensure their safety, efficacy, and compatibility. Key factors include verifying the compatibility of vaccine components, preventing immune interference, and maintaining antigen activity. Compliance with regulatory requirements, such as the FDA's Title 21 CFR Parts 600-680, is mandatory. Extensive preclinical studies are conducted to assess the quality parameters of purity, potency, and safety for each component. Clinical trials are designed to demonstrate that the combination vaccine matches the immunogenicity and efficacy of individual monovalent vaccines. Statistical analyses ensure the validity of trial results, while regulatory pathways guide the approval process.

Results: Clinical evaluations show that combination vaccines consistently meet safety and efficacy standards. Their ability to offer the same protection as monovalent vaccines has been confirmed, while their convenience increases public acceptance of vaccination programs. Advanced technologies used in development have further improved their reliability and practicality.

Conclusion: Combination vaccines are a pivotal tool in modern immunization, offering significant benefits for public health, especially in underserved areas. Ongoing post-licensure surveillance is essential to monitor rare adverse events. Harmonizing global regulatory standards and adopting advanced technologies are key to ensuring their successful development, distribution, and sustained public trust.

Key words: Combination Vaccines, Clinical Trails, Efficacy, Immunization, Safety.

PAP045

Comprehensive Review of Analytical Techniques for Monoclonal Antibody Characterization

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Introduction: Monoclonal antibodies (mAbs) are lab-made proteins that target specific proteins in the body. They have a "Y" shape: the top part (Fab region) binds to an antigen, and the bottom part (Fc region) helps interact with immune cells. When mAbs bind to an antigen, they can trigger the immune system to destroy the target cell by direct killing or by activating the complement system, which can block cell receptors and stop





signals inside the cell. IgG1 mAbs are especially important in therapy due to their stability and specific functions.

Methods: Characterizing an IgG1 mAb using advanced analytical methods across different stages of the production process. The upstream phase includes cell culture, media and feed optimization, and fermentation, while the downstream phase involves purification and final product preparation. Various chromatographic techniques were applied like size exclusion, cation exchange, Protein-A, and HILIC (N-Glycan analysis).

Results: The results show that the upstream process preserves the antibody's structure and function, while the downstream purification improves its purity and integrity. Analytical techniques confirm the quality and consistency of the final product. Various chromatographic techniques: Protein A measured titer levels, Size Exclusion checked for aggregation, which can reduce efficacy or increase immunogenicity. Cation Exchange can monitor charge differences due to post-translational modifications or degradation. HILIC (N-Glycan) analyzed glycosylation, which affects the antibody's stability, solubility, and interaction with immune cells. **Conclusion:** This review can help to evaluate and thoroughly examine these methods, highlighting their

importance for quality control and regulatory compliance.

Keywords: Monoclonal Antibodies, Size exclusion chromatography, HILIC, IgG1.

PAP046

Streamlining Regulatory Submissions: Leveraging SDTM and ADaM for Clinical Trial Data

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Introduction: The Clinical Data Interchange Standards Consortium (CDISC) is a universal, non-profit organization which makes standards with an aim to enhance, interpretation of data and to boost medical research and healthcare. CDISC concentrating on to design and organize Study Data Tabulation Model (SDTM) domains and subsequent creation of Analysis Data Model (ADaM) datasets. Before these standards, diverse data formats were prevalent which makes troubles in analysis processes of clinical trial data. Aim of the study is to focus on the accurately improvements in regulatory submissions by leveraging standardized SDTM and ADaM datasets.

Methods: SDTM framework is generally structures clinical trial data into proper domains such as Interventions, Events, Findings, Trial design domains, etc. A set of variables like identifier variables, topic variables, qualifier variables that correspond to a row in a dataset or table can be used to characterize each observation of participants in clinical study. While ADaM converts clinical trial data analysis ready using different datasets such as ADSL (Subject Level Analysis Dataset) and BDS (Basic data structure) with different variables. It uses standardized structures and variables to ensure the data is ready for analysis, allowing for efficient and accurate statistical evaluations.

Result: SDTM and ADaM standards have been evolved to try to meet the requirements of the FDA and industry. Use of these will also be beneficial for reviewers to work with data more smoothly in very less time. **Conclusion:** By employing SDTM and ADaM datasets in clinical trials can significantly improve regulatory submissions which can streamline submission process consistency in data collection and analysis.

Key words: CDISC, SDTM, Domains, BDS, ADSL.

PAP047

Evaluating the EMA Procedures on Orphan Drug Development: Regulatory Compliance in the EU

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Introduction: The European Medicines Agency (EMA) is key in overseeing the development of orphan drugs for rare diseases in the EU, ensuring these treatments are regulated and accessible to those who need them most.





Orphan diseases often face neglect due to the profit-driven nature of the pharmaceutical industry. EMA addresses this by offering several incentives, including market exclusivity, protocol assistance, and reductions in yearly fees. These mechanisms encourage innovation and improve access to treatment options for rare diseases, even when commercial viability is limited.

Methods: The orphan designation process involves continuous interaction among the EMA, pharmaceutical companies, and patient advocacy groups. The collaborative framework including stepwise procedures to navigate scientific, clinical, and ethical hurdles and Article 5(7) of Regulation (EC) No 141/2000 for transparent appeal and review mechanisms were analyzed for this review work.

Results: The incentives provided by EMA have mitigated financial risks associated with orphan drug development, but challenges remain. The complexity of clinical trials for rare diseases can lead to delays in market access, highlighting the need for further regulatory improvements.

Conclusion: EMA's regulatory system ensures a balance among the interests of patients, pharma companies, and healthcare systems for the acceleration of orphan drug developments. However, further perfecting is required in the direction of irregular diseases. Working together within the EU regulations and fine-tuning these incentives would ensure timely and compliant drug development and adequate access to them.

Keywords: European Medicines Agency (EMA), Market exclusivity, Orphan drugs, Patient Advocacy, Rare diseases.

PAP048

Role of AI in increasing efficiency of Validation Parameters

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Introduction: Pharmaceutical analysis plays a critical role in ensuring the safety, efficacy, and quality of drugs. Validation parameters such as sensitivity, accuracy, precision, specificity, robustness, repeatability, and linearity are essential for establishing the reliability of analytical methods. The integration of Artificial Intelligence (AI) in pharmaceutical analysis has revolutionized these validation processes by enhancing efficiency, reducing errors, and improving analytical outcomes.

Method: AI techniques, including machine learning (ML), deep learning (DL), and data analytics, were applied to optimize and validate analytical methods. In this work, we reviewed and compiled existing literature on the application of Artificial Intelligence (AI) and Machine Learning (ML) in the validation of pharmaceutical analytical methods. This compilation highlights the advancements and methodologies where AI and ML have been employed to enhance the reliability, accuracy, and efficiency of validation processes in pharmaceutical analysis.

Results: The compilation revealed that AI and ML significantly improve validation parameters such as accuracy, precision, and robustness in pharmaceutical analysis by automating data processing and modeling complex variables. Additionally, these technologies streamline analytical workflows, reduce human errors, and enable predictive insights, making validation processes more efficient and reliable.

Conclusion: The application of AI and ML in pharmaceutical analysis has proven to be a transformative approach, enhancing the accuracy, efficiency, and robustness of validation processes. By integrating these advanced technologies, the pharmaceutical industry can achieve higher standards of analytical reliability, ultimately accelerating drug development and ensuring compliance with regulatory requirements.

Keywords: Artificial Intelligence, Pharmaceutical Analysis, Validation Parameters, Machine Learning.

PAP049

Environmental Monitoring: An overview for Non- Targeted Analysis of Water

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Introduction: Contaminants refers to a diverse group of synthetic or naturally occurring substances that are not yet regulated in existing control limits. Despite their lack of regulation, these substances are found in water at concentrations that may cause recognized or suspected toxic effects on the environment, ecosystems, and human health. Targeted Analysis is bound to detect and measure the presence of specific substances expected to be present while the Non-targeted Analysis (NTA) focuses on identifying and quantifying the presence of known and unknown substances without a predefined list of targets.

Method: NTA of water can be done using Liquid chromatography/ High-resolution mass spectrometry (LC/HR-MS) technique to detect various types of compounds in a single sample. Many other approaches can be used to process this data: chemo-metrics, compound databases, MS/MS libraries, and ion mobility spectrometry tools.

Result: The most widely used technique for NTA for constituents present in water is HR-MS as it gives chemical profiling and a holistic characterization of different chemicals markers.

Conclusion: NTA not only uncovers the emerging pollutants but also improves the understanding of water quality to enhance public health. As environmental monitoring demands continue to evolve, NTA plays a crucial role in ensuring more accurate, efficient and holistic assessment of water safety.

Key words: Non-targeted analysis (NTA), Liquid chromatography/high-resolution mass spectrometry (LC/HR-MS), Contaminants, Environmental monitoring.

PAP050

Comparative Analysis of Regulatory Frameworks for Custom-Made Medical Devices (CMDs) in India and Australia: Toward Global Harmonization

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Introduction: This research examines the regulatory landscapes for Custom-Made Medical Devices (CMDs) in India and Australia, identifying differences and similarities to inform harmonized global regulations. By comparing these frameworks, the study seeks to balance patient safety, innovation, and market access. India's regulatory approach, governed by the Medical Device Rules 2017, prioritizes accessibility and streamlining, offering f exclusions from clinical trials and specific licensing requirements to facilitate market entry. on the other hand, Australia's Therapeutic Goods Administration (TGA) gives a stringent framework with mandatory notifications, detailed record-keeping, annual reporting, and robust post-market surveillance.

Method: Using a relative analysis methodology, this study reviews key features of CMD regulation, including risk-based classification, quality management systems, clinical trial exemptions, post-market surveillance, mandatory reporting, and advertising controls. Primary and secondary sources, such as government regulations, expert analyses, and scholarly literature, provide insights into each system's strengths and weaknesses.

Results: Findings suggest India's flexible approach enhances accessibility and market growth but lacks various post-market surveillance. Australia's stringent regulations ensure robust oversight and patient safety but may hinder innovation and market access due to higher compliance expenses. Both countries emphasize quality management and risk-based classification, though Australia's framework is more comprehensive.

Conclusion: This study highlights the importance of a balanced approach, integrating India's flexibility and Australia's robust oversight, to develop harmonized global policies. Harmonizing regulatory standards while accommodating national priorities can advance patient safety, foster innovation, and support the growth of the CMD sector worldwide.

Keywords: Regulatory frameworks, Custom-Made Medical Devices (CMDs), India, Australia, harmonized global policies.

PAP051

Analytical Advances in Triazole Antifungal Agents and Heterocyclic Compounds: A Comprehensive Review of Chromatographic and Electrophoretic Methods

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Introduction: The accurate and reliable analysis of pharmaceutical compounds is essential for ensuring their quality, efficacy, and safety. This review focuses on the development of analytical methodologies for these compounds, particularly emphasizing chromatographic and electrophoretic techniques over recent decades. High-performance liquid chromatography (HPLC) has emerged as the predominant method for analyzing these substances due to its versatility, precision, and widespread applicability.

Method: The review focuses on analytical techniques for triazole antifungals (categorized into first- and second-generation) and heterocyclic compounds. Techniques like UV-visible spectrophotometry, electrochemical methods, and LC-MS are highlighted, with HPLC identified as the most utilized method.

Result: HPLC emerged as the leading technique for analyzing pharmaceutical formulations and biological samples due to its precision and reliability. Other methods like UV-visible spectrophotometry and LC-MS complement the analysis of triazole antifungals and heterocyclic-containing drugs.

Conclusion: Despite advancements in analytical techniques, challenges remain in achieving higher accuracy and efficiency. Further innovation in methodology is essential for improved pharmaceutical analysis, quality control, and therapeutic outcomes.

Keywords: Antifungal agents, heterocyclic compounds, HPLC, chromatographic techniques, electrophoretic techniques.

PAP052

Comprehensive review on Green analytical HPLC and HPTLC methods: Key Green Metric Tools

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Introduction: Green HPLC & HPTLC Method has gained significant attention as a sustainable solution to the environmental challenges proposed by traditional methods, which are inherently unsustainable due to their reliance on toxic organic solvents and the generation of large amounts of hazardous waste. Traditional method uses solvent such as Dichloromethane which is Carcinogenic and ozone-depleting.

Methods: The use of eco-friendly strategies, such as green solvents, solvent recycling and reuse, and system miniaturization is explored to reduce toxicity and promote sustainability. By adopting green approaches & implementing green analytical methodologies in a practical and effective manner help to establish sustainable green approach. Green metric tools Analytical GREEnness Evaluation (AGREE) & Green Analytical Procedure Index (GAPI) are applied to assess the ecological impact and environmental sustainability of HPLC & HPTLC methods & provides valuable insights into their environmental friendliness.

Results: This review provides a practical framework for implementing sustainable analytical practices and highlights the role of green metric tools AGREE & GAPI in evaluating the environmental impact of HPLC & HPTLC methods.

Conclusion: The adoption of Green HPLC & HPTLC method represents step toward achieving sustainability in analytical chemistry. By integrating eco-friendly strategies such as the use of green solvents, solvent recycling, system miniaturization, and waste reduction. Green method significantly reduces the environmental impact of traditional methods.

Keywords: Green HPLC & HPTLC method, Green Solvents, Green Metric Tools, Analytical GREEnness Evaluation (AGREE), Green Analytical Procedure Index (GAPI).

PAP053

A Review on Multi – Attributal Method for Characterization of Biologics and its Application





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Introduction: In the manufacturing of biologics, particularly monoclonal antibodies, monitoring critical quality attributes (CQAs) and process parameter is essential to ensure product consistency and safety. Traditional analytical techniques, such as ion exchange chromatography and ELISA, often face challenges in accurately detecting and quantifying specific CQAs due to overlapping peaks. To overcome these limitations, the Multi-Attribute Method (MAM), combined with high-resolution techniques like Liquid Chromatography-Mass Spectrometry (LC-MS), has been developed. MAM enables the precise measurement of post-translational modifications (PTMs) such as oxidation, deamidation, clipping, and glycosylation, ensuring better product quality control and process differentiation in biologics production.

Methods: This review highlights the principle of static multi attribute method, various advancements in MAM, and its integration with other methodologies such as Size Exclusion Chromatography (SEC), Ion-exchange Chromatography (IEX), and ELISA techniques.

Results: The result of using advanced methods like Multi-Attribute Method (MAM) and Liquid Chromatography-Mass Spectrometry (LC-MS) is improved accuracy in detecting and quantifying critical quality attributes (CQAs) and post-translational modifications (PTMs), leading to better product quality control, consistency, and safety in biologics manufacturing. These methods effectively separate overlapping peaks, enabling precise measurement of attributes such as oxidation, deamidation, clipping, and glycosylation, ensuring higher reliability during production and quality assessment.

Conclusion: In pharmaceutical science, MAM combined with LC-MS enhances the monitoring of CQAs and PTMs, ensuring improved product quality and consistency in biologics manufacturing.

Keywords: MAM, CQAs, PTMs, ELISA, LC-MS.

PAP054

Development and Validation of RP-HPLC method for determination of related substance in combination of drugs used in hypercholesterolemia

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Introduction: A simple and accurate RP-HPLC method was developed for the determination of related substance in combination of drugs used in hypercholesterolemia.

Method: The objective of the study is to separate the related substances in combined dosage forms. Successful separation of the drugs from the process-related impurities and degradation products was achieved on Inertsil ODS-3V ($250 \times 4.6 \text{ mm}$, 5 µm) column. The mobile phase-A consists of acetonitrile: water (pH adjusted to 4.0 with phosphoric acid): methanol at 15:75:10 (%v/v/v), and mobile phase-B contains acetonitrile. Water: Methanol in ratio of 30:70 %v/v was used as diluent. The separation was carried out in gradient elution mode with a flow rate of 1.0 ml/min and at 210 nm detection wavelength. The separation was carried out at 25°C and injection volume was 20 µL. The method was validated according to ICH Q2(R1) guideline for linearity, precision, limit of detection, limit of quantification, accuracy, robustness.

Result: The method was linear over the range of $0.5 - 7.5 \,\mu\text{g/mL}$ for the impurities. Limit of detection and limit of quantification were found to be $0.5 \,\mu\text{g/mL}$ and $0.15 \,\mu\text{g/mL}$ respectively.

Conclusion: Good resolution between the peaks corresponds to process-related impurities and degradation products from both drugs was observed.

Keywords: RP-HPLC, Related substance, hypercholesterolemia.

PAP055

Review on Analytical Methods for Cannabinoids: Advances in Plant Extracts, Formulations, and Commercial Products





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Introduction: The bioactive compounds known as cannabinoids, which are present in Cannabis sativa, have garnered interest due to their potential for therapeutic use and psychoactive qualities. The need for precise and reliable analytical techniques to guarantee the safety, potency, and purity of cannabinoids is growing as regulatory environments change. The techniques created for cannabinoid analysis are examined in this review, with an emphasis on plant extracts, formulations, and other commercial goods.

Methods: Review and research based articles, focusing on spectroscopic and analytical chromatographic techniques reported for high performance and ultra performance liquid chromatography, GC-MS/MS, GC-MS, UHPLC-DAD techniques analysis were reviewed. The information was collected by searching in various databases like pub made science, google-scholar.

Results: In the last ten years, liquid chromatographies based analytical techniques, such as high-performance and ultra-performance liquid chromatography, in conjunction with detectors such as mass spectrometry, photodiode array, and ultraviolet, have become dependable instruments for accurate cannabinoid analysis. Utilizing advancements like derivatization and advanced ionization techniques, gas chromatography, in particular GC-MS and advanced GC-MS/MS techniques, is also crucial. UHPLC-DAD techniques for cannabinoid analysis in cannabis biomass and supercritical fluid extraction resin have recently been validated, meeting international regulatory standards. Advanced technologies like ion-mobility Mass spectrometry and improved sample preparation methods like microextraction and QuEChERS have improved detection and quantification procedures even more.

Conclusions: Characterizing cannabinoids in plant extracts, formulations, and commercial products has been made possible in large part by the development of sophisticated analytical techniques. The safe and efficient use of cannabinoid products will be supported by ongoing innovation and method standardization, which will further improve quality control and regulatory compliance.

Keywords: Cannabinoid Analysis, Liquid Chromatography, Gas Chromatography, Mass Spectrometry, Quality Control.

PAP056

Non-Thermal Plasma—A Great Hope for Health and Environmental Sustainability, with Special Emphasis on its Potential for Treating Textile Effluents effectively

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Introduction: Water quality is a critical global challenge, profoundly impacting public health, ecosystems, and economic development. According to the report of the World Health Organisation (WHO), water pollution contributes to 3.1% of global deaths and 3.7% of disability-adjusted life years. Untreated wastewater and toxic contaminants are leading factors in this crisis. Contaminated water poses severe risks not only to aquatic life and animal health but also to human health, while conventional treatment methods are often evidenced ineffective or economically infeasible. This review investigates the feasibility of non-thermal plasma (NTP) as an advanced, sustainable technology for wastewater treatment, With an emphasis on its effectiveness in degrading textile dye effluents.

Methods: Non-thermal plasma system that exploits advanced oxidation process (AOP). These systems utilize the high oxidation potential of OH⁻ and other reactive oxygen-nitrogen species for degrading contaminants. NTP is widely utilized in healthcare, food processing, and environmental sustainability, showcasing its promise as an innovative solution for wastewater treatment.

Results: NTP treatment effectively degrades dyes and hazardous chemicals in textile effluents, achieving complete pollutant degradation in a shorter time frame under energy-efficient conditions. Additionally, NTP supports circular economy standards by enabling the reuse of treated wastewater, consequently reducing environmental impact.





Conclusion: NTP offers a sustainable and competent solution for textile effluent degradation, surpassing traditional methods without incorporating harmful chemicals. Exceeding wastewater treatment, NTP's application extends to wound healing, surface modification, food safety, disinfectants, and air purification, demonstrating its ability to handle environmental and health challenges. NTP is set to play a pivotal role in global pollution reduction and the advancement of sustainable industrial practices.

Keywords: Non-thermal plasma, Cold Plasma, AOPs, Textile effluent treatment.

PAP057

Stability-Indicating RP-HPLC Method Development and Validation for the Quantification of Related Substances in GLP-1 Analogue

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Introduction: To develop a method for the separation of three impurities that co-elute with the main peak in the USP monograph method for related substances of a GLP-1 analogue drug.

Method: The method involved the preparation of a custom buffer, coupled with optimized mobile phases consisting of buffer, acetonitrile, and tetrahydrofuran, and was performed on an Agilent Poroshell 120EC C18 (250mm × 4.6mm), 2.7µm column under a gradient elution program. The method's robustness was enhanced by incorporating a column wash procedure, ensuring consistent performance and column longevity. Validation demonstrated excellent precision (RSD: 2.3–1.3%) and linearity (R² values of 0.9988, 0.995, 0.999 for impurities C, B, and A, respectively), with relative response factors (RRF) close to unity, ensuring accurate impurity quantification. Sensitivity was validated with LOQ values of 0.066–0.077 µg/mL and LOD values of 0.013–0.031 (µg/mL). Recovery studies confirmed the method's accuracy (91.43–105.98%). Forced degradation studies showed the highest impurity (2.65%) under alkali treatment (0.1N NaOH), with minimal degradation (0.17%) under dry thermal (60°C for 28 hours) and wet thermal (60°C for 4 hours) conditions. Metal ion, peroxide, and acid treatments caused impurities ranging from 0.17% to 0.36%. These results highlight the sample's stability, particularly under thermal and acidic conditions.

Result: The developed chromatographic method effectively separated the three co-eluting impurities from the main peak of the GLP-1 analogue drug, ensuring precise detection and quantification. The incorporation of a column wash procedure enhanced method reproducibility and robustness, further supporting its reliability for routine analysis. Validation results demonstrated excellent precision, linearity, and recovery, affirming the method's suitability for impurity profiling. Forced degradation studies highlighted the drug's stability under various conditions, reinforcing the method's applicability for both quality control and stability testing, making it a comprehensive tool for GLP-1 analogue drug analysis.

Conclusion: A robust RP HPLC method was developed to separate and quantify three co-eluting impurities in a GLP-1 analogue drug. The method demonstrated excellent precision, accuracy, and stability, with effective impurity profiling under various stress conditions. Its reliability makes it ideal for routine quality control and stability testing.

Keywords: RP-HPLC, GLP-1 Analogue, Related substance, Co-eluting impurities, Force degradation.

PAP058

Quantitative Estimation of Various Janus Kinases (JAK) Inhibitors: Analytical & Bioanalytical Method Innovations and Insights





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Introduction: Janus kinases (JAK) inhibitors are one of the tyrosine kinase inhibitors and are currently being used as immunomodulators in treating cancer, inflammatory diseases like rheumatoid arthritis, various skin diseases like atopic dermatitis, psoriatic arthritis, etc.

Methods & Results: Present review covers various analytical and bioanalytical methods for the quantitative estimation of marketed JAK inhibitors in matrices like solid oral dosage forms and plasma using techniques such as UV-Visible, RP-HPLC, LC-MS/MS, and UPLC-MS/MS. Along with the methods, their validation parameters have also been discussed and compared wherever applicable.

Conclusion: The review gives insights into the future scope around the analytical/bioanalytical method development for novel dosage forms containing JAK inhibitors either as a single agent or in combination.

Keywords: JAK inhibitors, Quantitative estimation, Bioanalytical methods, Pharmacokinetic study, HPLC.

PAP059

Sustainable Green Analytical Chemistry (GAC) and Robust Analytical Quality by Design (AQbD) the combine approach for future prospective: A Review

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Introduction: Traditional chromatographic techniques rely heavily on hazardous organic solvents, rising environmental and safety concerns. Green Analytical Chemistry (GAC) and Analytical Quality by Design (AQbD) have emerged as synergistic methodologies to address these challenges. This review highlights the potential of integrating GAC and AQbD principles to develop sustainable, robust chromatographic methods. GAC emphasizes environmentally friendly practices, while AQbD provides a systematic framework to optimize method performance and ensure reliability.

Material and Methods: The principles of GAC focus on reducing environmental impacts by minimizing solvent consumption, enhancing waste management, and eliminating derivatization techniques. Tools such as AGREE, AGREEprep, GAPI, complexGAPI, HPLC-EAT, AMGS, and AMVI are employed to calculate greenness scores, assessing the environmental footprint of chromatographic methods. AQbD, in contrast, adopts a systematic approach to method development by employing tools like Design-Expert software. This facilitates statistical optimization of critical chromatographic parameters, such as mobile phase composition, flow rate, and column temperature, enhancing robustness and reproducibility. The combined application of GAC and AQbD involves leveraging their respective tools to refine chromatographic techniques sustainably and statistically rigorously.

Results and Discussion: Integrating GAC principles into chromatographic methods led to a notable reduction in solvent consumption, improved waste management, and enhanced operator safety. Methods developed using GAC tools exhibited higher greenness scores, validating their reduced environmental impact. Similarly, employing AQbD ensured improved method performance by identifying and optimizing critical method parameters, thus enhancing method robustness. The synergy of GAC and AQbD methodologies enabled the development of chromatographic techniques that were both environmentally friendly and methodologically robust.

Conclusion: The review highlights the transformative potential of integrating GAC and AQbD principles in chromatographic method development. By addressing environmental concerns and ensuring methodological robustness, the synergy of these two approaches fosters the creation of sustainable, reliable, and efficient analytical methods. This dual focus not only supports environmental responsibility but also strengthens the foundation for addressing complex analytical challenges sustainably.

Keywords: GAC (Green Analytical Chemistry), SDG's (Sustainable Development Goal's), AQbD (Analytical Quality by Design), Organic Solvents, Waste management.



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PAP060

Regulatory Framework for Positron Emission Tomography (PET) Drugs in USA

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Introduction: Positron Emission Tomography (PET) drugs are critical for molecular imaging, especially in diagnosing complex diseases like cancer and neurological disorders. These radiopharmaceuticals use radioactive isotopes such as fluorine-18 or carbon-11, which emit positrons detectable by PET scanners. This review discusses the market approval process, regulatory requirements for compliant manufacturing facilities, pre-approval inspections, ongoing monitoring for regulatory compliance and lifecycle management to ensure continuous oversight throughout the drug's lifespan.

Methodology: In the U.S.A, PET drug regulation begins with an IND application (FDA Form 1571), supported by Form FDA 1572, progressing through clinical trials and safety reporting. Approval involves submitting an NDA (FDA Form 356h) with an Environmental Assessment or Claim for Categorical Exclusion. Manufacturing must follow GMP under 21 CFR Part 212. Post-approval, lifecycle management includes PADER submissions and monitoring product changes to maintain safety and efficacy.

Results: Due to their radioactive components, PET drugs are regulated by both the FDA's CDER and CDRH. GMP for PET drugs covers manufacturing controls, quality assurance, radiation safety, labelling, documentation, and personnel training. Environmental assessments are required to manage radioactive waste, ensuring safety for patients, healthcare workers, and the environment.

Conclusion: The regulation of PET drugs is complex with challenges such as short half-lives, stringent GMP requirements and inconsistent global harmonization. This review provides valuable insights to stakeholders likes regulatory professionals, pharmaceutical companies, healthcare providers, researchers, and policymakers to navigate regulations and improve patient outcomes.

Keywords: Positron emission tomography, Current Good Manufacturing Practices, 21 CFR Part 212, Radio pharmaceutical, Molecular imaging.

PAP061

QAI - Redefining IPQC in pharmaceuticals with AI technology or Artificial intelligence

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Introduction: The QAI model automates pharmaceutical quality assurance by integrating AI with pharmacopoeial standards (IP, BP, USP). Using a user-friendly interface and the chatgpt API backend, it dynamically generates preparation methods, calculates ingredient quantities, and outlines evaluation steps. Users can input experimental results, which the model compares against benchmarks for compliance. Automating calculations and adherence checks enhances efficiency, reduces errors, and supports real-time decisions, streamlining IPQC and manufacturing processes.

Methods: The QAI model integrates ChatGPT API to automate pharmaceutical quality assurance per pharmacopoeial standards (IP, BP, USP). Users input drug details via the frontend, and the backend generates preparation methods, ingredient quantities, and evaluation steps. It compares results with benchmarks for compliance, reducing errors, enhancing efficiency, and streamlining real-time IPQC and manufacturing through coding and AI automation.

Results & Conclusion: The QAI model successfully automates drug formulation, quality evaluation, and compliance verification using pharmacopoeial standards (IP, BP, USP). By leveraging the ChatGPT API in the backend, the model generates accurate preparation methods, calculates ingredient quantities, and compares user input results with pharmacopoeial benchmarks, significantly reducing manual errors and time spent on calculations. The system proved effective in real-time quality assurance and IPQC, enhancing operational efficiency in pharmaceutical manufacturing. Ultimately, the model provides a reliable and scalable solution for ensuring drug quality, safety, and compliance, making it a valuable tool in the pharmaceutical industry.



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Keyword: Artificial intelligence, Quality assurance, In-Process Quality Control (IPQC), Pharmacopoeial Standards (IP, BP, USP), Compliance Benchmarking.

PAP062

Thermodynamics of doxorubicin - bile salt association: An investigation based on isothermal titration calorimetry

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Introduction: Doxorubicin (DOX), a potent anticancer agent, has low aqueous solubility and tends to form selfassociative aggregates ranging from dimers to polymeric chains. The aggregation behavior affects drug permeability, binding affinity, and therapeutic efficacy. Bile salts, acting as biosurfactants, have been employed to modify DOX aggregation via micellization. This study explores the thermodynamics of DOX-bile salt association under varying conditions using isothermal titration calorimetry (ITC).

Methods: DOX and bile salt solutions were prepared using deionized water and analyzed through ITC experiments conducted at different temperatures. The titration involved incremental injections of bile salts into DOX solutions, with thermodynamic parameters such as micellization enthalpy, Gibbs free energy, and critical micelle concentration (CMC) being calculated from enthalpy curves.

Results: The presence of DOX significantly reduced the CMC of bile salts, suggesting stronger hydrophobic interactions and structural water expulsion. The thermodynamic analysis revealed an increase in free energy, indicating a loss in spontaneity of micellization upon DOX incorporation. Enthalpy-entropy compensation analysis provided insights into structural rearrangements within the bile salt micelles.

Conclusion: The study concludes that DOX-bile salt interactions lead to modulation in micellization characteristics, which can influence drug solubilization and delivery. The findings suggest potential applications of bile salt micelles in improving DOX stability and therapeutic performance.

Keywords: Micellization, Hydrophobic Interactions, Electrostatic Charge, Heat Capacity, Gibbs Free Energy.

PAP063

Development and Validation of UV Spectometric Method for Metoprolol succinate, Telmisartan and Cilnidipine by Succesive Ratio Derivative Method in Tablet Dosage Form

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Introduction: A simple, precise, accurate and cost-effective spectrometric method has been developed for UV spectrometric of Metoprolol succinate, Telmisartan and Cilnidipine by employing Successive Ratio Method in methanol.

Method: The method was validated as per the international council for Harmonization (ICHQ2-R1) guidelines. The successive ratio amplitude at 224 nm (zero cross point of Metoprolol Succinate), 296 nm (zero cross point of Telmisartan) and 240 nm (zero cross point of Cilnidipine) for qualification of combination.

Result: Drugs followed the linearity in the concentration range of $2-12\mu$ g/mL of all drugs with correlation coefficient(r^2) of 0.998, 0.9982, 0.9981 for Metoprolol Succinate, Telmisartan and Cilnidipine, respectively. Intra and Inter-day precision, accuracy and assay had %RSD value of <2 and assay recovery of drug were 99.74%, 99.58% and 98.83%, respectively.

Conclusion: Thus, from the result obtained it can be concluded that proposed method is simple, rapid, specific and accurate method, utilizing Methanol as solvent.

Keywords: Metoprolol succinate, Telmisartan, Cilnidipine, UV spectrometry, Successive ratio, Beer's law, validation.





PAP064

Quantification of PI3K Inhibitors in Different Matrices: A Review of Analytical & Bioanalytical Techniques

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Introduction: Phosphatidylinositol 3-kinase (PI3K) inhibitors are a novel class of anticancer drugs approved to treat various malignancies. PI3K is a pivotal enzyme in cellular signaling pathways, and its inhibition has shown promise in treating multiple cancers. Idelalisib, a first selective PI3K δ inhibitor, approved in 2014 by USFDA, has emerged as an effective treatment for hematological malignancies. Later, Copanlisib, Duvelisib, Alpelisib and Umbralisib got approval. Many drugs are currently under clinical trials.

Method: Present review focuses on different analytical and bioanalytical techniques used for the precise quantification of commercially available PI3K inhibitors in diverse matrices, including bulk drugs, dosage forms, and plasma. The analytical methods discussed include UV-visible spectroscopy, RP-HPLC, LC-MS/MS, and UPLC-MS/MS.

Result: The outcome parameters of the applied techniques such as retention time, peak area, validation parameters etc. have been analyzed and discussed.

Conclusion: The present review envisions the future scope in developing an analytical/ bioanalytical method for quantifying novel PI3K inhibitors either alone or in combination with similar or hyphenated techniques.

Keywords: PI3K Inhibitors, Idelalisib, Analytical methods, Bioanalytical methods, HPLC.

PAP065

Recent Advancements and Developments in Investigation of Peptide Aggregation for Alzheimer's Disease Using AI Deep Generative Model, DoE Software and Spectroscopic Techniques

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Introduction: Alzheimer's is a progressive neurodegenerative disorder characterized by gradual decline in cognitive function-memory, thinking, language & problem-solving ability, associated with accumulation of Aβ-plaque and neurofibrillary tangles, composed of tau-protein in the brain, which disrupts neuronal signalling, & cause neuronal loss. Thus, understanding and mitigation of Aβ-aggregation is crucial. Addressing Aβ-aggregation requires innovative approaches that combine advanced technologies.

Method: This study focuses on AIML models including Deep Generative Models (DGMs), Variational Autoencoders (VAEs), for predicting design of possible new peptides and aggregation-resisting peptides by prediction of aggregation-prone regions (APRs) & designing novel peptides resistant to misfolding. By Principles of Design of Experiment (DoE), process parameters to generate best suitable combinations & factor selection- for formulation protocol inputs to ensure robust & scalable design is optimized. Multiple factors influence aggregation, Thus, need for real-world verification of designs prepared from AI-DoE tools is done by Spectroscopic techniques in analysis of β -sheet formation (2° structural changes), Confirmational transitions, Impurity Profiling, and understanding self-assembling behavior. This Combination bridges the gap between computational predictions & real-world validation.

Results: The study successfully demonstrated synergistic efficacy of AI tools with Spectroscopic analysis in understanding & mitigation of A β -aggregation. By Craftmanship of DoE & DGMs, structural change at specific





regions were predicted & novel therapeutic peptides were designed. Overall, it provided significant strides in peptide therapies for Alzheimer's.

Conclusion: This multidisciplinary approach offers a comprehensive solution to address $A\beta$ -aggregation. Additionally, these advancements hold promise for expanding applications to other neurodegenerative diseases.

Keywords: Alzheimer-Targeted Peptide Design, Amyloid- β Aggregation, AI-Driven Generative Models, DoE for Peptide Optimization, Advanced Spectroscopic Analysis.

PAP066

Potential of Artificial Intelligence in Development of HPLC-Based Analytical Methods

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Introduction: High-Performance Liquid Chromatography (HPLC) is a vital analytical technique employed in numerous fields. However, its traditional method development relies on trial-and-error approaches, leading to prolonged timelines. This study reviews the integration of Artificial Intelligence (AI) into HPLC workflows, exploring how technologies such as Machine Learning (ML) and Deep Learning (DL) can automate and optimise chromatographic processes.

Methods: Various AI techniques were applied, including Support Vector Machines (SVM) for predictive modelling and Convolutional Neural Networks (CNN) for peak detection. Parameters like mobile phase composition, flow rate, and gradient elution were optimised using genetic algorithms and Bayesian optimisation models.

Results: AI integration in HPLC substantially reduced development time and improved reproducibility. Automated systems enhanced peak detection even in noisy chromatograms and facilitated predictive maintenance, minimising instrument downtime and ensuring consistent analytical results.

Conclusion: The findings demonstrate that AI has transformative potential in revolutionising HPLC by automating labour-intensive tasks, reducing costs, and improving accuracy. However, addressing challenges such as data quality and model interpretability is crucial for the broader adoption of AI-driven analytical methods.

Keywords: High-performance liquid chromatography, artificial intelligence, machine learning, deep learning, optimisation



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ABSTRACT- POSTER PRESENTATIONS (Herbal Technology & Natural Products)



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HTP002

Formulation of Pastilles from Centella Asiatica Plant Extract for the Treatment of Alzheimer's

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Introduction: The Pastilles of Centella Asiatica which includes phytoconstituents like Asiatic acid, asiaticoside, madecassoside, madecassic acid. The prominent phytoconstituent is asiaticoside. These phytoconstituents helps to restoring mitochondrial dysfunction, reduces oxidative stress and prevent the formation of beta amyloid plaques and neurofibrillary tangles. Vitamin B12 deficiency is significant cause for Alzheimer's therefore, incorporation of vitaminB12 is done to treat disease efficiently.

Method: Hydrophilic excipients are used such as HPMC & PEG which used to enhance drug properties as solubility and permeability. In addition, the super disintegrant - Cross povidone is used for the rapid action. For pastille's preparation hot melting method is used. In which firstly, the excipients are melt using the double boiler method and let them cool for a while then slowly add the drug, mix it well. Then the dropping method is applied. Cool it until it solidifies. Evaluation parameters of pastilles are Disintegration time, contact angle measurement, In vitro dissolution, weight variation, content and uniformity and phase solubility.

Result: The stable, identical shaped pastilles are obtained. It has no spreadibility and stickiness. Its disintegration time is also less and dissolve smoothly through the oral cavity.

Conclusion: Pastilles are eco-friendly dosage form in which there is no usage of organic solvent. It is an industrial-friendly formulation because it has single step process. It has more patience compliance for one who face difficulty in swallowing of tablet and dose accuracy is more than that of liquid preparations. VitaminB12 deficiency is fulfil with efficient treatment. The prominent notion behind this research is to convert the old traditional system in to novel drug delivery system.

Keywords: Centella asiatica, pastilles, eco-friendly, industrial-friendly, vitaminB12.

HTP005

Formulation and Development through Natural Remedies by Formulating a Herbal Balm for Migraine using extracts of *Tanatum parthenium* L. and *Zingiber officinale*

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Introduction: Migraine, a prevalent neurological condition, is characterized by recurrent headaches lasting between 4 to 72 hours. This balm formulation has been meticulously optimized for purity, spreadability, pH balance, texture, and viscosity. It incorporates a lipophilic extract of *Tanacetum parthenium* and an ethanolic extract of *Zingiber officinale*, targeting the trigeminal nerve to reduce CGRP levels and alleviate migraine pain. The active constituent, parthenolide, aids in mitigating smooth muscle spasms, while camphor enhances transdermal penetration and exhibits anti-inflammatory and anti-histaminic properties.

Methodology: The balm was formulated by incorporating active extracts of *Tanacetum parthenium* and *Zingiber officinale* into a base of melted beeswax, olive oil, and cocoa butter, with the addition of Vitamin E to enhance therapeutic benefits. Multiple combinations of excipients were tested to achieve the desired viscosity, stability, and organoleptic properties, ensuring a refined product with optimal therapeutic attributes.

Results: The developed formulation demonstrated superior efficacy and enhanced penetration compared to existing market preparations. Stability assessments revealed robust physical integrity, consistent organoleptic properties, and durability over time. The balm exhibited excellent tolerability with minimal adverse effects, confirming its clinical viability in managing migraine symptoms.

Conclusion: Through rigorous testing and optimization, a highly stable and effective balm for migraine relief was successfully developed. Its enhanced absorption, durability, and efficacy provide a safe and rapid therapeutic alternative, positioning it as a superior option to current market formulations.

Keywords: Migraine, CGRP, trigeminal nerve, anti-histaminic, trigeminovascular system





HTP006

In-silico Investigation of Some Potential Flavonoids for Management of Alzheimer's Disease

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Introduction: Alzheimer's disease (AD) is a neurodegenerative disorder which progresses with time. It is identified through cognitive decline and memory impairment. Current therapeutic options provide limited efficacy, necessitating the exploration of novel bioactive compounds. Flavonoids, a class of polyphenolic compounds derived from natural sources, are reported to possess neuroprotective properties through various mechanisms. The present work aims to investigate the potentials of some selected flavonoids in management of AD through preliminary molecular docking studies.

Methods: An in-silico approach was employed to preliminarily evaluate the binding affinities of selected flavonoids against prominent AD targets, including tau protein kinase I (TPKI), butyryl cholinesterase (BChE), beta-secretase (BACE 1), and acetyl cholinesterase (AChE). Molecular docking was performed using GOLD (Version 5.2), CCDC and binding interactions were analyzed through Discovery Studio.

Results: Molecular docking revealed that amentoflavone, hesperidin and kaempferol demonstrated satisfactory binding scores, exhibiting strong interaction. Galangin showed the highest binding affinity with TPKI and BACE 1, while hesperidin and kaempferol effectively targeted BChE and AChE respectively.

Conclusion: The findings suggest that flavonoids, hold promise as potential therapeutic agents for Alzheimer's disease. Their dual functionality as enzyme inhibitors and antioxidants could be taken as a basis for their further exploration and evaluation.

Keywords: Flavonoids, Alzheimer's disease, in-silico study, molecular docking, neuroprotection

HTP007

A Review on Analytical Methods for Determination of Biomarkers from Polyherbal Formulation

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Introduction: Polyherbal formulations are widely used in traditional medicine, offering synergistic therapeutic effects through their complex mixtures of bioactive compounds. However, the standardization and quality assurance of such formulations require precise analytical methods to identify and quantify biomarkers accurately. This review focuses on the compilation of analytical methods for biomarkers in polyherbal formulations. The objectives are to explore current analytical techniques, address challenges in analysing complex herbal matrices, and propose strategies for improving reliability and reproducibility.

Method: The methodologies for estimation of biomarkers include various chromatographic (HPLC, GC, etc.), spectroscopic (UV, FTIR), and other advanced hyphenated techniques (LC-MS/MS, GC-MS). Validation parameters such as specificity, sensitivity, accuracy, precision, and robustness are discussed to ensure compliance with regulatory standards.

Result: This review indicates that HPLC and HPTLC are the most commonly used analytical techniques. In HPLC mainly reverse phase C18 column is used and for extraction various method like maceration, decoction and fermentation is used. From various studies it highlight the efficacy of these advanced methods in overcoming matrix interferences and achieving high analytical precision.

Conclusion: Validated analytical methods are critical for the standardization and global acceptance of polyherbal formulations, ensuring their safety, efficacy, and therapeutic consistency. This review provides a comprehensive guide for researchers and industry professionals to adopt advanced analytical strategies, enhancing the quality and credibility of herbal medicines.

Keywords: Polyherbal formulations, biomarkers, analytical method development, method validation, standardization.





HTP008

Development and Evaluation of Herbal Formulation for Management of Hyperpigmentation

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Introduction: Hyperpigmentation is a common dermatological condition characterized by the excessive accumulation of melanin, leading to uneven skin tone and dark patches. Causes of hyperpigmentation are skin inflammation, sun exposure, melasma, reactions to drug use and medical conditions. The present study focuses on the formulation and evaluation of an herbal face gel enriched with *Morus rubra* (red mulberry) and *Morinda citrifolia* (noni) extracts, known for their potent skin-lightening and antioxidant properties. *Morus rubra* may help in reducing the appearance of scars, keep the skin young and reduce age spots due to these antioxidant properties. It helps combat hyperpigmentation and has amazing anti-aging benefits. *Morinda citrifolia* Fruit mainly contains the ascorbic acid, which is effective on the skin, it enhances the glow of skin and also decrease the pigmentation.

Method: The gel base was formulated using a blend of natural polymers to ensure optimal consistency, hydration, and ease of application. The formulated gel was subjected to physicochemical characterization, including pH, viscosity, spreadability, and stability studies, to ensure its quality and efficacy. Skin irritation test was also done on a small number of human participants. Preliminary skin irritation studies revealed that the gel was safe for topical use.

Result and Discussion: The study concludes that the herbal face gel incorporating *Morus rubra* and *Morinda citrifolia* extracts have potential to offer a natural, safe, and effective solution for managing hyperpigmentation and promoting an even skin tone, paving the way for further clinical investigations.

Keywords: Hyperpigmentation, Morus rubra, Morinda citrifolia, Anti-tyrosinase activity, flavonoids

HTP009

From Nature to Nanoscale: Transforming Herbal Remedies for Management of Atopic Dermatitis

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Introduction: Atopic dermatitis (AD) is a chronic inflammatory skin condition affecting 15–20% of children and 2–10% of adults worldwide. Conventional treatments, such as corticosteroids and immunosuppressants, are often associated with significant side effects, driving the need for safer, natural alternatives. Herbal formulations, enriched with bioactive compounds, offer promising therapeutic potential for managing AD. Integrating artificial intelligence (AI) and machine learning (ML) into formulation development can revolutionize treatment efficacy and personalization.

Method: This review examines both traditional and cutting-edge herbal formulations, such as transdermal patches, oils, gels, and creams, as well as formulations based on nanoscale technology, such as liposomes, nanoemulsions, nanoparticles, and phytosomes. Evaluation parameters such as pharmacological activities, physicochemical characteristics, release and permeation studies, stability, and toxicological assessments are detailed. The role of AI/ML in optimizing formulations, predicting efficacy, and personalizing therapies is emphasized. Herbal nano/micro-formulations enhance bioavailability, stability, and targeted delivery of active compounds.

Result: The role of AI and ML is emphasized in optimizing formulations, predicting efficacy, and enabling personalized therapies. These technologies facilitate compound discovery, formulation refinement, and high-throughput screening, ensuring efficient and patient-specific treatment options. Clinical studies demonstrate significant improvements in AD symptoms, including reductions in lesions, erythema, and itching, along with better skin penetration and retention of active compounds.





Conclusion: By combining traditional knowledge with contemporary pharmaceutical advancements, herbal formulations and AI-driven technologies offer a transformative approach to AD management. Future research should prioritize clinical validation, scalability, and expanded AI applications to provide cost-effective and sustainable solutions for global health challenges.

Keywords: Atopic Dermatitis, Herbal Technology, Nano formulations, Artificial Intelligence, Machine Learning.

HTP010

Exploring the Anti-Depressive Effect of Gallic Acid on Depression Linked with Hyperglycemia

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Introduction: Diabetes Mellitus is a cluster of metabolic disorders which is characterized by hyperglycemia resulting from insulin resistance. Managing hyperglycemia causes symptoms of stress in diabetic individuals. The etiology of depression in hyperglycemic conditions like diabetes is quite complex and is still not known properly. However, environmental factors, inflammation, hypothalamic-pituitary-adrenal axis dysregulation, and insulin resistance are some of the factors responsible for the pathogenesis of depression and cognitive dysfunction in individuals with type 2 diabetes.

Methods: Oxidative stress and hyperglycemia are involved in the development of cognitive impairment. Peroxisome proliferator-activated receptor (PPAR)- α and γ play as a vital target for neuropsychiatric disorders and behavioral dysfunction. The role of (PPAR)- α and γ ligands centrally are well known for the treatment of diabetes and cardiovascular disease.

Results: The downregulation of PPAR has led to behavioral deficits and further upon administration of PPAR- α agonist, improvement in the condition has been observed. Now it plays a major role as a target for depression. Gallic acid, an antioxidative polyhydroxy phenolic compound acts on (PPAR)- α and γ , which may be useful in the treatment. It acts on this AMPK and activates it which regulates body weight and glucose homeostasis. **Conclusion:** Gallic acid has significant potential as an anti-depressive, anti-oxidative, and blood sugar-lowering compound and can be effective against depression linked with hyperglycemia.

Keywords: Gallic acid, Antioxidant, Hyperglycemia, Antidepressive effect, Diabetes Mellitus

HTP011

A review on Pharmaco-Therapeutic applications of Chandraprabha Vati as per Ancient references

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Introduction: Chandraprabha Vati is a classical Herbo- mineral preparation. It comprises of overall 37 ingredients. The preparation of this Vati is stated in the Sarangdhar Samhita with Shilajit and Guggulu present in maximum quantity. The classics have stated wide range of therapeutic applications in various diseases as metabolic disorders, urinary tract infections, abdominal disorders, skin diseases, etc. with reference to the synergistic blend of natural ingredients.

Methods: Various articles regarding the clinical research are referred. Also, research papers regarding the pharmacological activities are referred. Ayurvedic texts are also taken as reference for the review. Papers regarding the toxicity and standardization of drug are also taken into consideration.

Results: Chandraprabha vati is considered as Sarva rog Pranaashini which cures all types of disease. Its dominant actions are observed in the urinary and reproductive systems. It also influences various systems as digestive, musculoskeletal and circulatory systems. The constituents of the formulation have analgesic, anti-inflammatory, anxiolytic and other such properties making it wider in various illnesses.





Conclusion: Chandraprabha Vati is a herbo mineral ayurvedic formulation having wide range therapeutic activities. With reference of preparation from the ancient texts of Sarangdhar Samhita, the clinical practice of the formulation is mentioned in the Ayurvedic Formulary of India. Various therapeutic indications are studied as a multi organ system.

Keywords: Chandraprabha vati, Sarangdhar Samhita, Sarva rog pranaashini, multi organ system

HTP012

Review on:-"Hridayaamrit vati for vataj hridya roga"

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Introduction: Angina Pectoris is a complex feature caused by temporary myocardial ischaemia, which happens any time when there is unevenness between myocardial oxygen supply & demand. Stable angina is a state characterized by frequent occurrence of chest pain or discomfort, usually caused by physical exertion or emotional stress. Stable angina is generally caused due to atherosclerosis, coronary artery disease (CAD) or cardiac ischaemia. Symptoms which are seen under stable angina are chest pain or discomfort i.e. angina pectoris, shortness of breath, fatigue, dizziness or lightheadedness, pain in arms, back, neck, jaw or stomach. The figure of CAD is fastly rising due to malfunctioning lifestyle & nutritional habits. In ayurveda, stable angina can be match up with Vataja hridaya roga. The current study evaluates combined effect of Hridayamrita vati with Arjunaksheera paka as anupana in Vataja hridaya roga.

Method: To satisfy the purpose total 40 patients were recorded of pre-diagnosed case of stable angina & these patients were provided Hridayamrita vati 2tab BD with 40ml Arjunaksheer paka as anupana for 90 days & a meal plans.

Result: This learning appears that comprehensive outcome of treatment, 21.21% had absolute calmness, 39.4% of patients were clearly make progress, 33.33% were somewhat make progress, 6.06% were lightly improved and 00.00% of patients were continuing.

Conclusion: It was developing that given treatment have outstanding results in individual limiting factor. Medication has worldly goods i.e. Hridya, deepaniya, pachaniya, vata-kapha shamaka and tridoshashamaka.

Keywords: Hridayaamrit Vati, Vataja hridaya roga, CAD, Arjunaksheera paka.

HTP013

(Review) Crown Flower (Calotropis gigantea) as a Potential Anti-Diabetic Agent

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Introduction: Calotropis gigantea, commonly known as crown flower, is a traditional medicinal plant recognized for its wide range of pharmacological properties. Recent studies have highlighted its potential in managing diabetes mellitus, a chronic metabolic disorder characterized by persistent hyperglycaemia and associated complications.

Methods: The hypoglycemic effect of Calotropis gigantea was evaluated in normal rats using chloroform extracts of its leaves and flowers at doses of 10, 20, and 50 mg/kg, administered orally. To assess the oral glucose tolerance, non-diabetic rats were treated with the leaf and flower extracts at the same doses, along with a reference drug, glibenclamide (10 mg/kg, p.o.). Glucose (2 g/kg, p.o.) was then administered to these animals, and their serum glucose levels were measured at intervals of 0, 1.5, 3, and 5-hours post-administration. In a separate experiment, streptozotocin-induced diabetic rats were treated with the same doses of the leaf and flower extracts, while normal control rats were given either glibenclamide or 0.5 ml of 5% Tween-80 solution. The treatment lasted for 27 days, and blood samples were collected from all groups via retro-orbital puncture on days 7, 14, 21, and 27. The serum glucose levels were then estimated using a glucose assay kit to determine the effectiveness of the treatments.





Results: The *Calotropis gigantea* leaves and flowers extracts were effective in lowering serum glucose levels in normal rats. Improvement in oral glucose tolerance was also registered by treatment with Calotropis gigantean. The administration of leaf and flower extracts to streptozotocin-induced diabetic rats showed a significant reduction in serum glucose levels.

Conclusion: Calotropis gigantea shows promising anti-diabetic potential, making it a candidate for further pharmacological and clinical investigations. However, standardized extraction methods and human trials are necessary to validate its efficacy and safety for therapeutic use.

Keywords: Calotropis gigantea, Crown Flower, Anti-diabetic, Hypoglycaemic Activity, Traditional Medicine.

HTP014

Review on Sida cordifolia (Bala): An Ayurvedic Herb with Medicinal Potential

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Introduction: Bala (Sida cordifolia Linn.) from the Malvaceae family, is an important medicinal plant in the traditional healthcare systems like Ayurveda, Unani, and Siddha. It is also known as "Indian Ephedra" and is praised for its diverse therapeutic applications as immunomodulator, anti-inflammatory, and analgesic. Classical texts such as Vedas, Samhitas, and Nighantus provide its uses in addressing illnesses like fever, asthma, weight loss, and chronic bowel complaints.

Methods: Information from classical Ayurvedic literature as Samhitas and Nighantus was analysed along with modern phytochemical and pharmacological studies.

Results: Traditional formulations as decoctions, oils, and pastes of Bala were noted for their versatility in both internal and external applications. Phytochemical studies confirmed the presence of bioactive compounds as alkaloids, saponins, and tannins and hence, validate its traditional statements of therapeutic potential. Pharmacological insights suggest scope for further experimentation.

Conclusion: Bala (Sida cordifolia Linn.) is an important herb in Ayurveda, depicting versatility in its therapeutic applications. The integration of traditional and modern scientific validation highlights its potential as a natural remedy for various illnesses and suggests further exploration of its pharmacological properties.

Keywords: Bala, Ayurvedic, Phytochemical, pharmacological, Versatility

HTP015

An Overview of Resveratrol's Effect on Counteracting Muscle Atrophy in Low-Gravity: Implications for Astronauts

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Introduction: The polyphenol resveratrol, which is present in blueberries, grapes, and other foods, has antiinflammatory and anti-diabetic properties. It is unclear how it affects bone and muscle mass in low-gravity settings, such as Mars gravity.

Method: In this study, rats in normal gravity (100% body weight) and low gravity (40%, simulating Mars) are used to test the effects of resveratrol (150 mg/kg/day) on muscle health. Rats were kept under observation for 14 days after being divided into groups with or without resveratrol administration. Calf circumference and grip strength were measured every week, and at the end of the trial, muscle mass and fiber size were examined. One-way and two-way ANOVA statistical studies suggested that resveratrol might help prevent muscle atrophy in low-gravity situations.

Result: In rats subjected to low gravity (PWB40), resveratrol administration increased grip strength and inhibited muscular atrophy. In the soleus and gastrocnemius muscles, it enhanced muscle mass and partially repaired myofiber cross-sectional area (CSA).





Conclusion: To sum up, resveratrol helps reduce muscle atrophy and improve grip strength in reduced gravity. This offers potential for astronauts experiencing muscle deconditioning in space. Although its effects on full muscle recovery are limited, resveratrol could mitigate muscle loss in long-duration missions, benefiting astronaut health.

Keywords: Resveratrol, Astronaut health , Muscle Mass Preservation, Partial Gravity

HTP016

Swertiamarin an Iridoid Glycosides: a future of diabetes treatment

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Introduction: Iridoid Glycosides are a class of natural plant metabolites recognized for their pharmacological advantages in the management of various chronic diseases, including diabetes. Among them, swertiamarin is one of the glycosides found predominantly in species of Swertia and Enicostema have been reported to have anti-diabetic activity.

Method: Antidiabetic activity refers to enhancing insulin sensitivity, promoting glucose uptake in peripheral tissues, and controlling related enzymes of carbohydrate metabolism, such as glucokinase and glucose-6-phosphatase activities. Moreover, swertiamarin was reported to reduce oxidative stress and inflammation, both of which are key contributors to diabetes pathogenesis and its complications.

Conclusion: Swertiamarin, according to research, is not only effective in maintaining blood glucose levels but also protects the pancreatic β -cells from hyperglycemia and free radicals-induced damage, which in turn supports sustained insulin production. This dual action of glucose regulation and cellular protection makes it a potential natural candidate to address both symptoms and causes of diabetes.

Result: Traditional medicine use of swertiamarin and other iridoid glycosides emphasizes their therapeutic potential and opens avenues for their use in modern diabetes management strategies.

Keywords: Swertiamarin, iridoid glycoside, antidiabetic, Swertia, Enicostema

HTP017

Iron oxide nanoparticles in cancer treatment

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Introduction: In their lengthy clinical history, iron oxide nanoparticles have proven to be safe and adaptable in a wide range of applications, such as the treatment of iron deficiency anaemia (IDA), magnetic fluid hyperthermia, and cancer diagnostics. It is also used as liposomal drug delivery injectable iron therapies take advantage of innate immunological interactions.

Methods: Here is an example of such experiment using the synthesized or commercial nanoparticle coated with biocompatible materials on mice or rat for in vivo studies by giving the drug doxorubicin. Iron oxides nanoparticles are prepared via coprecipitation, thermal decomposition or sol-gel methods. Load chemotherapeutics onto iron oxides nanoparticle and evaluate tumour targeting in animal models. Injects IONPs into tumour tissue and apply an external magnetic field to induce localized heating. Use IONPs as contrast agents for MRI to monitor tumour localization.

Result: We observe that there are assess tumour regression, survival rates, and possible side effects. They may cause toxicity, stability or off target effects. Shows that iron oxide nanoparticles have unexpected immune-modulating qualities, which may lead to anti-tumour immune responses.

Conclusion: Iron oxides nanoparticle in cancer treatments through their multifunctional application, such as targeted hyperthermia, enhanced drug delivery. further optimization is required to improve clinical translatability.





Keywords: iron oxide nanoparticles, anti-tumour immune responses, targeted drug delivery system, cancer.

HTP018

AI-Enhanced Pharmaceutical Innovations: Maximizing the Potential of Finger Millet Calcium for Fibroblast Regulation in Diabetic Wounds

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Introduction: Diabetic wound healing, especially in chronic diseases like ulcers associated with diabetes, is a major issue. Fibroblasts, which are necessary for collagen formation and tissue regeneration, frequently fail in diabetes circumstances due to variables such as hyperglycemia and oxidative stress. Calcium ions (Ca^{2^+}) regulate fibroblast behaviour, including migration, proliferation, and collagen production.

Methods: Diabetes, on the other hand, interferes with calcium signalling, which slows wound healing. Finger millet, a calcium-rich grain, shows potential as a diabetic wound healer. Its calcium can boost fibroblast activity, boosting migration and the creation of extracellular matrix (ECM), both of which are essential for wound healing. Furthermore, finger millet's antioxidant capabilities may help rectify calcium dysregulation and promote cellular responses that are essential for healing.

Results: Studies have suggested that calcium supplementation can enhance collagen synthesis and fibroblast proliferation, which may promote tissue repair in diabetic wounds. Additionally, calcium may help restore the function of endothelial cells and promote angiogenesis. However, further study is needed to figure out how it impacts fibroblast activity and calcium signalling. Artificial intelligence technology might help forecast how finger millet-derived calcium interacts with biological processes, allowing for more focused therapy.

Conclusion: AI-driven drug design and personalised medicine techniques can improve these therapies by tackling calcium delivery and efficacy issues. Finger millet may give an innovative and effective alternative for improving diabetic wound healing results, allowing patients to recover and regenerate while also addressing global health challenges.

Keywords: Calcium, Finger Millet, Diabetic Wound Healing, Fibroblast

HTP019

Cultivating Mentha, Other Herbs, and Unique Vegetables in Space Environments

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Introduction: Sustaining human life during long-duration space missions necessitates the development of efficient and reliable food production systems. Growing crops in space poses challenges such as microgravity, limited natural resources, and confined environments. However, advancements in controlled-environment agriculture make it possible to cultivate a variety of crops in space. This study examines the potential for growing Mentha (mint), other herbs like basil and parsley, as well as fruits such as strawberries and vegetables like lettuce, tomatoes, and radishes. These crops were selected for their nutritional value, adaptability, and growth characteristics under extraterrestrial conditions.

Methods: A comprehensive review of space farming experiments and literature was conducted to evaluate the feasibility of growing diverse crops in microgravity. Hydroponic and aquaponic systems were analyzed as primary methods for soil-less cultivation. Studies on the impact of controlled lighting, temperature, and nutrient delivery systems on crop growth were incorporated. Specific attention was given to Mentha and other herbs for their resilience and multifunctional benefits, while fruits and vegetables like strawberries and tomatoes were evaluated for their adaptability to space environments. Advanced technologies such as hydrogels for water retention and nutrient optimization were also considered.

Results: Mentha, basil, parsley, lettuce, tomatoes, radishes, and strawberries have all shown successful growth in hydroponic and aquaponic systems under controlled conditions. Herbs demonstrated rapid growth and low





resource requirements, while vegetables like lettuce and tomatoes adapted well to microgravity with consistent yields. Fruits such as strawberries thrived in confined environments, providing high nutritional value. Hydrogels further improved water and nutrient efficiency, particularly for root stability in low gravity.

Conclusions: The cultivation of Mentha, other herbs, and a variety of fruits and vegetables in space demonstrates significant potential for supporting human missions beyond Earth. These crops can provide fresh food, improve crew well-being, and enhance sustainability in space agriculture. Future research should focus on optimizing crop combinations, understanding plant behavior under prolonged microgravity, and exploring innovative resource management strategies to maximize productivity in extraterrestrial environments.

Keywords: Space farming, Mentha cultivation, hydroponics, aquaponics, microgravity agriculture.

HTP020

Development, Optimization and Characterization of Plant-Based Hair Dye for Higher Gray Coverage

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Introduction: The shift towards sustainable and safer cosmetic solutions has increased interest in natural hair colorants as alternatives to synthetic dyes. This study explores the uses natural colors, including Natural color-1, Natural color-2, Natural color-3, and Natural color-4, delivered through oil-based and aqueous vehicles to optimize gray hair coverage and conditioning properties.

Methods: Natural colors were incorporated into oil-based and aqueous formulations and applied to gray hair swatches. Color performance was evaluated using Lightness (L*), Red/Green (a*), and Blue/Yellow (b*) parameters. The pH-responsive transitions of the natural colors were assessed, and hair conditioning properties, including smoothness, softness, and wash fastness, were measured. Additionally, the impact of enzyme inhibitors on shade development was studied to expand the achievable color range.

Results: Oil-based formulations outperformed aqueous systems in terms of color uptake, producing vibrant, uniform, and rich shades. Natural color-1 in oil-based formulations yielded deep dark brown hues with improved hair texture. The combination of Natural color-2 with enzyme inhibitors produced a distinct purple shade, while Natural color-3 and Natural color-4 exhibited pH-sensitive color transitions, enhancing the color palette at higher alkaline pH levels. Enhanced hair conditioning attributes, such as smoothness, softness, and wash fastness, were observed in oil-based systems.

Conclusion: Plant-based hair dyes, particularly in oil-based formulations, offer promising potential as alternatives to synthetic dyes. The findings demonstrate improved gray hair coverage, vibrant coloration, and superior hair conditioning properties, indicating their viability for wider application and further research into formulation scalability and stability.

Keywords: Plant-based hair dyes, Natural hair colors, Oil-based systems, Gray coverage, Hair conditioning.

HTP021

Big-leaf Mahogany (Swietenia macrophylla King): From Traditional Medicine to Modern Therapeutic Applications

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Introduction: *Swietenia macrophylla* King commonly known as big-leaf mahogany is a timber tree, that belongs to the family Meliaceae. Under the Swietenia genus, there are 3 species. All have characteristics of pharmacological activity. However, this species gained more interest for its potent antidiabetic, antiinflammatory, antioxidant, anticancer, and antimicrobial properties. It is traditionally used for abortion,





hypertension, antidiabetic, and fever. It is native to Central and South America, but also found in wet and dry tropical forests, it grows in a variety of soil types. Extensive phytochemical research confirmed that the whole plant has medicinal importance, containing limonoids, flavonoids, and phenolic acids.

Methods: The seeds of *S. macrophylla* are particularly notable for their limonoid content, which has been extensively studied for its potential in managing diabetes and related complications. Moreover, extracts from the leaves and bark have demonstrated significant efficacy in combating oxidative stress, a contributing factor in chronic diseases. The plant's ecological role, including its use in reforestation and its impact on biodiversity, further underscores its importance.

Conclusion: *S. macrophylla* holds incredible medicinal promise, however, several obstacles stand in its research studies and its commercialization. Unsustainable harvesting practices and the destruction of its natural habitat threaten its very existence, noted as an endangered plant. On the other hand, the lack of robust scientific studies makes it difficult to fully understand its healing potential. This review brings together all information related to this remarkable plant - from its chemical makeup and medicinal properties to its deep-rooted uses in traditional healing.

HTP022

Luteolin Nanodiscs: A promising approach for cancer therapy

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Introduction: Luteolin (3',4',5,7-tetrahydroxyflavone), a bioactive flavonoid found in vegetables like parsley, celery, and broccoli, has demonstrated potent anti-inflammatory, anti-hypertensive, antioxidant, and anticancer effects. It is effective against various cancers, including breast, colorectal, and lung cancers. Luteolin also mitigates the side effects of chemotherapeutic agents like Doxorubicin (DOX).

Methods: Luteolin's anticancer activity was studied in vitro and in vivo. It inhibits cellular proliferation, induces apoptosis, reduces metastasis and angiogenesis, and increases reactive oxygen species (ROS) production. Luteolin also reverses epithelial-mesenchymal transition (EMT), a key process in cancer progression. To improve its therapeutic potential, luteolin was incorporated into high-density lipoprotein (HDL) nanodiscs, complexed with apolipoprotein E3 (apoE3) and phospholipids.

Results: The HDL nanodiscs, around 17 nm in diameter, efficiently deliver luteolin to the nucleus, bypassing lysosomal degradation. This targeted delivery enhances luteolin's anticancer effects by improving its cellular uptake and bioavailability.

Conclusion: Luteolin offers significant anticancer potential, both as a direct therapeutic agent and by alleviating chemotherapy side effects. The development of HDL nanodiscs for targeted delivery represents a promising strategy for improving its therapeutic efficacy.

Keywords: Luteolin, Nanodisc, Flavonoid, Apolipoprotein E3, Reactive Oxygen Species

HTP023

RP-HPLC Method for Quantitative Analysis of Naturally Occurring Flavonoids in Dasmoola Churna

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Introduction: Flavonoids are pivotal in plant biochemistry and physiology, contributing significantly to the biological activities of plants. Reverse phase High-Performance Liquid Chromatography (RP-HPLC) is a highly effective technique for detecting and quantifying flavonoids in various plants and their derived products, making it a preferred method for quality control and standardization. This study presents a novel and rapid HPLC method for the identification and quantification of flavonoids in the ten herbal components of Dasmoola Churna.





Methods: Dried plant parts were extracted using methanol as the solvent. Flavonoid analysis was conducted using a mobile phase of acetonitrile and methanol (50:50 v/v) at a flow rate of 1 mL/min, with detection at 256 nm.

Results: The study revealed that Dasmoola Churna contains significant levels of flavonoids, specifically Rutin, which is indicative of the high antioxidant potential of its constituent plants.

Conclusion: This research highlights the health benefits of flavonoids and supports the growing interest in natural products. It also shows that HPLC is a reliable and efficient method for identifying flavonoids in complex mixtures, paving the way for further studies on their therapeutic uses.

Keywords: Dasmoola Churna, flavonoids, RP-HPLC, Rutin

HTP024

A Brief Description of the Leaf Hypericum Perforatum: Extraction Methods

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Introduction: *Hypericum perforatum*, commonly known as St. John's Wort, is a medicinal plant widely recognized for its therapeutic properties, particularly in treating depression, anxiety, and wounds. The bioactive compounds in *Hypericum perforatum*, such as hypericin, hyperforin, and flavonoids, are of significant interest for pharmaceutical applications. The efficacy of these compounds largely depends on the extraction methods employed, which can influence the yield and purity of active ingredients.

Methods: This review explores various methods of extracting bioactive compounds from the leaves of *Hypericum perforatum*, focusing on solvent-based techniques such as maceration, Soxhlet extraction, and ultrasound-assisted extraction. Maceration involves soaking the plant material in a solvent for an extended period, whereas Soxhlet extraction uses continuous solvent reflux to ensure complete extraction. Ultrasound-assisted extraction, a modern technique, utilizes ultrasonic waves to enhance the penetration of the solvent into the plant material, improving efficiency and reducing extraction time. Additionally, the effectiveness of each method in terms of time, cost, and yield of active constituents is discussed, along with comparisons of traditional versus novel extraction techniques.

Conclusion: The extraction of bioactive compounds from *Hypericum perforatum* leaves is a critical process in the preparation of therapeutic formulations. While traditional methods like maceration and Soxhlet extraction are widely used, newer techniques such as ultrasound-assisted extraction have shown promising results in improving yield and efficiency. The choice of extraction method depends on the specific application, required purity, and scalability, making it important to select the most suitable technique based on the desired outcome.

Keywords: *Hypericum perforatum*, extraction methods, bioactive compounds, Soxhlet extraction, ultrasound-assisted extraction.

HTP025

Evaluation of the Efficacy and Safety of a Polyherbal Formulations in Hemorrhoid Management

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Introduction: Hemorrhoids are a prevalent anorectal condition characterized by swelling, inflammation, bleeding, and discomfort, affecting millions worldwide. While conventional treatments such as surgical interventions and pharmacological therapies are effective, they often come with limitations, including adverse effects and recurrence. This has spurred interest in complementary and alternative therapies, particularly herbal formulations, owing to their safety, affordability, and multi-targeted therapeutic actions. This review explores the efficacy and safety of polyherbal formulations in the management of hemorrhoids. It compiles and critically



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evaluates evidence from preclinical and clinical studies on various polyherbal combinations that exhibit antiinflammatory, analgesic, hemostatic, and wound-healing properties. Key phytoconstituents such as flavonoids, tannins, alkaloids, and saponins in these formulations are discussed for their roles in reducing inflammation, improving venous tone, and accelerating tissue repair. Comparative analysis with conventional therapies highlights the potential of these formulations to offer holistic management with minimal side effects. Despite promising results, the review identifies gaps in standardization, dosage optimization, and high-quality clinical trials, which limit the generalizability of findings. The safety profiles of polyherbal formulations are largely favorable, but long-term safety data remain sparse. Furthermore, the mechanisms of action of these formulations require deeper exploration through molecular studies.

Conclusion: polyherbal formulations hold significant promise as an adjunct or standalone treatment for hemorrhoids, offering a natural, effective, and safer alternative to conventional therapies.

Keywords: Hemorrhoids, polyherbal formulation, phytoconstituents, anti-inflammatory.

HTP026

Development of Pongamia Pinnata Extract Loaded Mouth Dissolving Film for the Oral Hygiene

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Introduction: The objective of the present investigation was to develop a herbal-based mouth dissolving film utilizing *Pongamia pinnata* stem bark extract, aiming for improved patient compliance and rapid onset of action in managing oral diseases such as oral cancer, mouth ulcers, and tooth decay. Traditionally, *Pongamia pinnata* stem bark has been used as a natural toothbrush to promote oral hygiene by reducing biofilm and dental plaque formation while alleviating oral disease symptoms.

Methods: The stem bark extract was prepared using the Soxhlet extraction method, yielding a maximum recovery of 10.95%. Karanjin, a key herbal marker, was quantified using High-Performance Thin Layer Chromatography (HPTLC). Mouth dissolving films were formulated via the solvent casting method using various grades of hydroxypropyl methylcellulose (HPMC E5, E15, and E50) as film-forming polymers, while PEG 400 and propylene glycol were employed as plasticizers.

Results: The optimized batch, containing 250 mg of HPMC E5 and 0.70 mL of propylene glycol, exhibited a disintegration time of 25 ± 1 seconds, a wetting time of 18 ± 0.5 seconds, and a folding endurance of 110 ± 2 folds. Stability studies conducted at $40 \pm 2^{\circ}$ C / $75 \pm 5\%$ RH revealed no significant changes in physical characteristics, indicating the formulation's stability.

Conclusion: The prepared mouth dissolving film demonstrates promising potential as an innovative herbal approach for maintaining oral hygiene and managing related diseases.

Keywords: *Pongamia pinnata*, extraction, HPTLC, mouth dissolving film, oral hygiene.

HTP027

Solubility Enhancement of Hesperidin using Natural Deep Eutectic Solvents and its Characterization

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Introduction: Hesperidin is a bioflavonoid predominantly present in citrus fruits with extensive pharmacological benefits. Despite that, the application of hesperidin remains relatively restricted due to its poor solubility and poor absorption. Deep Eutectic Solvents (DES) are liquids, which are a combination of hydrogen bond donor (HBD) and hydrogen bond acceptor (HBA), having a freezing point lower than each of their





components. DES improves the solubility and bioavailability of the compounds and proves to tackle several major problems in pharmaceutical formulation.

Methods: DES prepared by the method of heating and stirring at 80°C. HBA used was choline chloride (ChCl). Different HBDs mainly amines, carbohydrates, alcohols, and carboxylic acids in different mole ratios were tried. The mixture having higher solubility was selected for further studies such as pH determination, kinematic viscosity, phase contrast microscopy, ATR-FT-IR and ex vivo studies.

Results: The solubility of DES with hesperidin was found to be highest in ChCl: Urea (1:2) with good solubility of 10±0.22mg/mL. Viscosity was observed at 203.1 cSt and pH was found 9. Visual observations of final DES with Hesperidin showed clear yellow liquid. The phase contrast microscopy indicated the presence of crystals in plain drug whereas DES with hesperidin was clear liquid in microscopy, demonstrating the superior solubilization. The ATR-FT-IR represented the presence of OH and CH stretching with different functional groups indicating presence of hesperidin in DES.

Conclusion: The research successfully demonstrated that DES can serve as an effective, sustainable alternative to conventional solvents for solubilizing poorly water-soluble phytochemicals like hesperidin.

Keywords: Deep eutectic solvents, Choline Chloride, Hesperidin, Urea.



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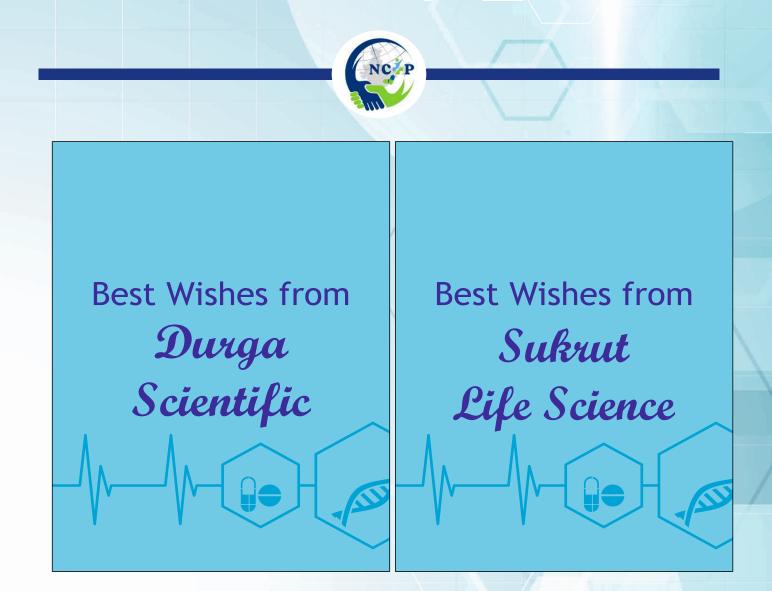
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