SSX INDIA

RAMAIAH UNIVERSITY OF APPLIED SCIENCES | FACULTY OF PHARMACY

9th Annual Conference of the Society for the Study of Xenobiotics

BOOK OF ABSTRACTS

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ABOUT SSX INDIA

Indian Society for the Study of Xenobiotics (SSX - India) was established in 2016 as a non-profitable association, with the mission to develop and augment the knowledge of DMPK/ADMET science to the Indian scientific community. We conduct annual conferences, workshops and DMPK related short term courses.

Our conference is one of the premiere conferences organized in India specifically in the area of drug discovery and development. We have successfully conducted eight Annual International Conferences and one Asia-Pacific conference of the ISSX covering the areas of drug discovery and development. Eminent scientists from both academia & industry and students actively take part in our scientific deliberations. In addition to the annual conferences, SSX also take initiatives with the help of academic institutions to augment capabilities of academics and students in our discipline. SSX is on a mission to take the annual conferences to different parts of our country to reach out to broader scientific community.

ABOUT DMPK Course

Certificate Course in Drug Metabolism and Pharmacokinetics - (Virtual mode)

The Society for the Study of Xenobiotics, India (SSX-India) offers a 40-hour online certificate course designed to build strong foundational and applied knowledge in drug metabolism and pharmacokinetics. Delivered over five months via live Zoom sessions, this program provides flexibility for participants across India and abroad.

The curriculum covers essential ADME principles, PK parameters, metabolic pathways, clearance and volume concepts, transporter biology, species differences, and tools for preclinical-to-clinical translation. Learners also explore drug–drug interactions, pharmacogenomics, PK/PD modeling, bioanalysis strategies, and case-based applications used in discovery and development workflows.

Expert trainers from global pharmaceutical organizations, premier universities and leading research centers share practical insights aligned with current industry needs. The course is ideal for master's and PhD students, academicians, young researchers and industry professionals aiming to strengthen their DMPK expertise. Upon completion, participants receive a recognized certificate from SSX-India.

COURSE HIGHLIGHTS:

1. Live interactive sessions
2. Global speakers with expertise in the relevant areas
3. Periodical Assessment
4. Awarded with credit points
5. Access to study material
6. Six batches (above 1000 participants) have completed

At the end of the course, students are expected to:

- Understand the basics of pharmacokinetics with an emphasis on drug metabolism and gain an ability to apply these principles in research and industry scenarios
- Gain clear understanding about DMPK study concepts and techniques with a focus on industry applications
- Learn about application of DMPK in preclinical to clinical translation
- Understand the impact of various physiological variables and pharmacogenomics on pharmacokinetics.

Duration: A total of 40 hours of course spread over 5 months (August — December every year).

9th Annual Conference of Society for the Study of Xenobiotics

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Message from the Chief Patron

It is a matter of great pride that the Faculty of Pharmacy, Ramaiah University of Applied Sciences in association with the Society for the Study of Xenobiotics - India is organizing the 9th Annual Conference of the Society for the Study of Xenobiotics (SSX-2026), from 20th to 22nd February 2026.

The chosen theme *"New Approaches to Navigate Complexities in Drug Discovery and Development"* is both timely and significant. In an era where scientific innovation is rapidly transforming healthcare, it is imperative that researchers, academicians and industry professionals come together to deliberate on emerging methodologies and collaborative strategies that can accelerate safe and effective drug development. This conference will provide an invaluable platform for intellectual exchange, interdisciplinary dialogue and the nurturing of young scientific minds.

I commend the organizing committee for their dedicated efforts in hosting this prestigious event and for fostering a culture of research excellence and academic collaboration. I am confident that the deliberations and discussions during this conference will contribute meaningfully to advancements in xenobiotic research and pharmaceutical sciences.

I extend my best wishes for the grand success of SSX-2026 and trust that the conference will inspire innovative thinking and impactful research for the betterment of global healthcare.

Dr. M.R. Jayaram
Chancellor
M.S. Ramaiah University of Applied Sciences

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Message from the Patron

It gives us immense pleasure to announce that the **9th Annual Conference of the Society for the Study of Xenobiotics (SSX-2026)** is being organized in association with the Society for the Study of Xenobiotics, India and the Faculty of Pharmacy, RUAS. Centered on the compelling theme ***"New Approaches to Navigate Complexities in Drug Discovery and Development"***, this reflects the need to embrace innovative strategies and interdisciplinary collaboration in addressing the evolving challenges of modern therapeutics.

This conference aspires to serve as a catalyst for transformative thought and scientific advancement in an era defined by rapid innovation and unprecedented challenges in the pharmaceutical world.

Drug discovery and development are becoming increasingly complex, demanding integration of advanced technologies, translational research, regulatory insights and collaborative scientific efforts. This conference aims to provide a wider platform for researchers, academicians, industry professionals, regulatory experts, young scientists, and research scholars to deliberate on emerging trends, novel methodologies and transformative approaches that are shaping the future of pharmaceutical sciences.

The conference will feature keynote lectures by eminent scientists, scientific panel discussions and poster presentations. Through these interactions, we aspire to foster meaningful partnerships and stimulate innovative thinking that contributes to safer, more effective therapeutic solutions.

As we stand at the crossroads of discovery and development, SSX-2026 seeks not merely to discuss challenges but to redefine possibilities. Together, we shall explore visionary strategies that accelerate therapeutic innovation, enhance safety and efficacy, ultimately contributing to the advancement of global healthcare.

We cordially invite you all to participate in SSX-2026 and contribute to this significant scientific gathering.

We look forward to your presence and participation.

Prof. K.K. Raina
Vice Chancellor

From the President's Desk

On behalf of the Organizing Committee, it is my absolute pleasure to welcome all of you to the 9th Annual Conference of the Society for the Study of Xenobiotics – India (SSX-India).

This year's theme, "New Approaches to Navigate Complexities in Drug Discovery and Development," reflects the rapidly evolving landscape of pharmaceutical sciences. We have thoughtfully expanded our scientific program to include DMPK considerations beyond small molecules, encompassing biologics, RNA therapeutics, and emerging AI-driven approaches. In addition, this conference will explore components beyond ADMET to include components of Chemistry, Manufacturing and Controls (CMC), thereby offering a comprehensive perspective on drug development.

Over the past nine years, this conference has established itself as one of India's premier scientific forums in drug discovery and development. The growing participation from both industry professionals and academic researchers underscores its scientific excellence, impact, and ongoing relevance.

The success of this conference is built upon several key contributions. Foremost is the leadership and support of Prof. Bharath Srinivasan, along with his dedicated team from the Faculty of Pharmacy, M.S.Ramaiah University of Applied Sciences, whose meticulous planning and commitment have ensured the seamless organization of this event. Equally important is the presence of our distinguished speakers, together with the invaluable contributions of the CMC team, whose expertise and thoughtful curation have significantly enriched the scientific depth, scope, and relevance of this conference. The continued partnership of our sponsors and collaborators further strengthens this platform for scientific exchange and innovation.

Finally, the foundation of this conference lies in the unwavering dedication of the Council Members of SSX-India, whose vision and commitment continue to guide the Society forward.

Once again, I thank all of you for your continued support and enthusiastic participation. I hope this conference provides you with a truly enriching and immersive scientific experience.

Welcome to SSX-2026!

Anandi Karumbati
President SSX-India

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Message from the Organizing Chair

It is with immense pride and privilege I extend a warm welcome to all delegates, speakers, participants and sponsors to the 9th Annual Conference of the Society for the Study of Xenobiotics (SSX-2026), being organized from February 20th - 22nd, 2026 at the Ramaiah University of Applied Sciences in association with the Society for the Study of Xenobiotics - India.

We sincerely express our gratitude to the Society for the Study of Xenobiotics, India for entrusting Ramaiah University of Applied Sciences (RUAS) with the responsibility of hosting this prestigious SSX-2026 conference. We deeply value the confidence and trust placed in us and are committed to making it a successful and impactful scientific gathering.

The theme of this year's conference, "New Approaches to Navigate Complexities in Drug Discovery and Development," reflects the pressing need to embrace innovation and interdisciplinary collaboration in the rapidly evolving pharmaceutical landscape. As drug discovery and development become increasingly intricate, integrating advanced technologies, translational research, academia-industrial collaborative strategies have become essential to ensure safe, effective and timely therapeutic solutions. I am confident that the scientific deliberations and interactions during SSX-2026 will inspire innovative thinking, strengthen collaborations and contribute significantly to advancements in global healthcare.

As an Organizing Chair, I sincerely thank RUAS management for their constant support and encouragement. Their valuable advice and institutional commitment have played a pivotal role in the successful organization of SSX-2026. I also extend my sincere appreciation to the council members of SSX-India and my organizing team including student volunteers for their devoted support in meticulous planning and execution throughout this conference.

I look forward to welcoming you all to an enriching and memorable occasion.

Dr. S. Bharath
Dean-Faculty of Pharmacy
M.S. Ramaiah University of Applied Sciences

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34 Ms.Deeya Jain
35 Ms. Manasa VS

SSX-2026 Conference Agenda		
20th February 2026		
Time	**Venue : RMC Auditorium, 3rd Floor**	
08:00 - 08:45	**Registration and breakfast**	
08:45 - 09:15	**Inauguration** Chief Guest: Sri S Ashok Rao, Registrar, M S Ramaiah University	1. Dr. Bharath S, Dean FPH, RUAS 2. Dr. Anandi Karumbati, Team Lead, Centre for Chemical Biology and Therapeutics, inStem
	Speaker	**Co-Chairs**
09:15 - 10:05	**Keynote 1:** Prof. Ashok Venkitaraman, Distinguished Professor of Medicine, NUS, Chief Scientist, A-Star, Singapore	Dr. Anandi Karumbati, Team Lead, Centre for Chemical Biology and Therapeutics, inStem
Session 1: ADME considerations for drug discovery and development		
10:05 - 10:40	Dr. Raju Subramanian, Executive Director, Gilead Sciences, USA *Innovative Approaches for DMPK Problems in Drug Discovery: Assessment of Hydrogen/Deuterium Exchange for In Vitro Chiral Stability of Pharmacophores and Use of Encequidar to Delineate In Vivo Disposition Pathways*	1. Dr. Geetha T, CEO, Diponed Research International Pvt Ltd, An Evexia Group Company, Bangalore 2. Prof. Krishna Iyer, Former Professor, Bombay College of Pharmacy
10:40 - 10:55	**Group Photo**	
10:55 - 11:10	**Tea Break**	
11:10 - 11:30	Sponsor talk - Eurofins *New Approaches for Assessing Drug-Drug Interactions- CRISPR Modified MDCKII Cell Lines for Transporters and Proteomics Analysis for CYP Induction*	
11:30 - 11:50	Sponsor talk - Krishgen *Emerging opportunities in ADME research: A perspective based on researchers requirements for biospecimens.*	
11:50 - 12:25	Dr. Upendra Argikar, DMPK Leader, Gates Medical Research Institute, USA *DMPK insights in the development of sutezolid, a Mycobacterium tuberculosis inhibitor*	
12:25 - 13:00	Dr. Devang Shah, Director, Bristol Myers Squibb, Bangalore *Advancing PD-L1 Macrocyclic Peptides to the Clinic: A Story of Resilience*	
13:00 - 15:30	**Lunch, Poster & Exhibitor Session**	
15.30 - 16.05	Special session on "Resilience Decoded" by Dr. Sujata Shetty	1. Dr. Gouri Nair 2. Dr. Manasa Deepa

Sessions 2 and 3 are Parallel Sessions		
Session 2: AI/ML considerations in drug discovery and Development **Venue: Dhanvantri Hall, 2nd Floor**		
16:15- 16.50	Dr. Shridhar Narayanan, Founder Peptris/ FNDR, Bangalore *Engineering the Future Drugs-Innovating in India for the World*	1. Dr. Vishwottam Kandikere, VP and Head – DMPK, Aragen 2. Dr. Judy Jays, Associate Professor, FPH, RUAS
16:50 - 17.25	Dr. Priyaranjan Pattanaik, Vice President, Syngene International Limited, Bangalore *AI-Enabled Innovation across the Antibody–Drug Conjugate (ADC) Development Pipeline*	
17.25 - 18.00	Prof. Ramanathan Sowdhamini , Senior Professor, National Center for Biological Sciences, Bangalore *Recognition of small molecule inhibitors for toll- like receptor 4 through integrated approaches*	
Session 3: Advancements in Understanding Solid state of Pharmaceuticals **Venue: Charaka Hall, 2nd Floor**		
16:15- 16.50	Prof. Arvind K Bansal, Professor, Department of Pharmaceutics NIPER, Mohali *Crystal Structure–Guided Insights into Milling Behaviour of Pharmaceutical Solids*	1. Dr. Amol G D, Assistant Professor, NIPER, Hyderabad 2. Dr. Basavaraj B. V., Professor and Head, FPH, RUAS
16:50 - 17.25	Dr.Ramanaiah Chennuru, Director and Head, COE-Polymorphism and Crystallization, Cipla Ltd. *Solid-State Strategies in Generic Pharmaceuticals: From Polymorphs to Co crystals*	
17.25 - 18.00	Dr. Sharmistha Paldatta, Scientist & Lead, Solid State Screening Group, Dr. Reddy's Laboratories, Hyderabad *Advancements in understanding of solid state of Pharmaceuticals*	
Venue: RMC Auditorium, 3rd Floor		
18:10 - 19:30	**Cultural Program**	1. Dr. Gouri Nair, Assistant Professor, FPH RUAS 2. Dr. Manasa Deepa, Professor and Head, East West College of Pharmacy
19:30 - 20:30	**Networking and Dinner at Ramaiah University**	

21st February 2026		
Time		
08:00 - 08:30	**Breakfast**	
Venue: RMC Auditorium, 3rd Floor		
	Speaker	**Co-Chairs**
08:30 - 09:20	**Keynote 2**: Dr. Stephan Bromacher, Novartis *Necessity is the mother of Invention: the challenges of novel pharmaceutical entities and the analytics they inspire*	Dr. Hemant Bhutani, Site Head, Novartis
Session 4: Technological Innovations in Drug Discovery and Development		
09:20 - 09:55	Dr Manoj Kumar Singh, Senior Vice President, Analytical Research and Development, Microlabs *A QBD approach of Analytical method development*	1. Dr. Lakshmikant Bajpai, Director and Head, Analytical Research BMS 2. Dr. Srinivas Seekallu, Head-Preclinical Reseacrh, Anthem Biosciences Ltd
09:55 - 10:30	Dr. Sajesh Thomas, Associate Professor, IIT, Delhi *Advanced Tools in Pharmaceutical Crystal Engineering: Beyond Conventional Crystallography*	
10:30 - 11:05	Dr. Sunil Kumar Panigrahi, Associate Vice President, Aurigene Pharmaceutical Services Ltd. *Accelerating Drug Discovery with AI, ML and Physics-Based Simulations*	
11:05 - 11:20	**Tea Break**	
11:20 - 11:40	Sponsor talk – Corning *3-D Cell Culture: A New Paradigm in Xenobiotic Research Past Lessons, Future Opportunities*	Dr. Shashyendra Singh Gautam, Senior Principal Scientist, BBRC
11:40 - 12:00	Sponsor talk – Aragen *Evaluation of potential endogenous biomarkers for Oat 1/3 in mice*	
12:05 - 12:20	Felicitation of sponsors	
12:20 - 13:30	***Student talks*** 1. Salman K, Department of Pharmaceutics, College of Pharmaceutical Sciences, Dayananda Sagar University *Preparation and Characterization of Brain-Targeted Delivery of Venlafaxine using Serum Albumin Nanoparticles* 2. Shailesh D. Dadge, Pharmaceutics and Pharmacokinetics Division, CSIR-Central Drug Research Institute, Lucknow *Enhancing Target-Site Exposure of Formononetin in Bone Marrow via Bioenhancer-Assisted Phospholipid Complexation*	1. Dr. Amol Raje, Director-DMPK, Syngene International 2. Dr. R Deveswaran, Professor, FPH, RUAS

	3. Sathi Sarkar, Department of Natural Products, National Institute of Pharmaceutical Education & Research (NIPER) Kolkata *Integrative Pharmacokinetic and Transcriptomic Assessment of Herb-Drug Interactions between a Dietary Supplement and a Conventional Antidiabetic Drug* 4. Shriya V A, Department of Pharmaceutical Quality Assurance, Manipal College of Pharmaceutical Sciences, Manipal *Mechanistic PBPK Modeling to Explain Atazanavir Dose Nonlinearity and Guide Bioavailability-Enhancing Formulation Strategies* 5. Shantaveer Thakka, East West College of Pharmacy, Bengaluru *In Vitro Investigation on Smart Drug Delivery Using Polymeric Micellar Systems for Skin Cancer Treatment* 6. Rutushree, Department of Pharmacognosy, Faculty of Pharmacy, M. S. Ramaiah University of applied Sciences *Exploring the Ameliorating Potential of Thymoquinone Loaded Copper Nano Particle against DMBA Induced Breast Cancer in Rodents*	
13:30 - 16:00	**Lunch, Poster & Exhibitor Session**	
Sessions 5 and 6 are Parallel Sessions		
Session 5: Next Generation Therapeutics **Venue: Dhanvantri Hall, 2nd Floor**		
16:00 - 16:35	Dr. Maloy Ghosh CSO, Zumutor Biologics *INABLR®, a proprietary, integrated antibody discovery and engineering platform*	1. Prof. Rajkapoor B, Professor, Karpagam Academy of Higher Education 2. Dr. Swaminathan Sethu, Scientist, Narayana Netralaya Foundation
16:35 - 17:10	Dr. Arati Ramesh, Principal Scientist, Tata Institute of Genomics and Society *Re-imagining antimicrobials: Antisense oligomer-based therapeutics against infectious disease*	
17:10 - 17:45	Dr. Narmada B C , Lead Scientist, Vantage *Metabolize this! A QSP story in the fight against Obesity and Diabetes*	

Session 6: Intricacies in the Development of Next Generation Therapeutics **Venue: Charaka Hall, 2nd Floor**		
16:00 - 16:35	Dr. Ravi Shah, Professor & Head, Department of Pharmaceutical Analysis, NIPER, Ahmedabad *Unlocking Complexity of Oligo Therapeutics: LC-HRMS as the Indispensable Analytical Armory for Next Generation Therapeutics*	1. Dr. R K Shakthi Devan, Head, Veterinary Sciences, Syngene International 2. Dr. J. Anbu, Professor and Head, FPH, RUAS
16:35 - 17:10	Dr. M. V. Narendra Kumar Talluri, Director, Daicel Chiral Technologies *Modern Approaches to Chiral and Complex Peptide Therapeutics Impurity Profiling: Evolving Analytical Tools for Pharmaceutical Precision*	
17:10 - 17:45	Dr. Manikandan R, Senior Vice President, Analytical Research and Development, Granules India *Challenges in Chemistry, Manufacturing, and Controls (CMC) for Next Generation Therapeutics*	
Venue: RMC Auditorium, 3rd Floor		
17:45 - 18:30	**Panel Discussion: Fireside chat with Pathbreakers** 1. Dr. Chandrashekaran Siddamadappa, Vipragen 2. Dr. Vijay Ivaturi, Pumas AI 3. Dr. Janani Venkataraman, Biomoneta 4. Dr. Gopi Kadiyala, Kyntox Biotech	Dr. T. Thanga Mariappan, Director, Head, Pharmaceutical Candidate Optimization, BBRC
22nd February 2026		
Time		
08:00 - 08:30	**Breakfast**	
Venue: RMC Auditorium, 3rd Floor		
	Speaker	**Co-Chairs**
Session 7: Advances in Clinical Pharmacology		
08:30 - 09:05	Prof. Hiroyuki Kusuhara, University of Tokyo, President of JSSX *Application of Intestinal Stem Cell–Derived In Vitro Models for ADME and Toxicity Assessment in Drug Development*	1. Dr. Premkumar N, Professor, Krupanidhi College of Pharmacy 2. Dr. Ashoka Babu V L, Associate Professor and Head, FPH, RUAS
09:05 - 09:40	Dr. Rama Sivasubramanian, Head of R&D – India, Teva Pharmaceuticals *Emerging Trends in Drug–Drug Interaction Evaluation: From Mechanistic Models to AI-Driven Predictions*	

09:40 - 10:15	Dr. Sahadev Shankarappa, Professor, Ramaiah University of Applied Sciences *Designing Nanoparticles to Navigate Axonal Routes for Targeted Neural Drug Delivery*	
10:15 -10:30	Tea Break	
Session 8: Case studies in Drug Discovery and Development		
10:30 - 11:05	Dr. Kumar Nemmani, Associate Vice President, Sun Pharma *Integrating DMPK Principles to Engineer Next-Generation Antibody–Drug Conjugate Immunotherapies for Cancer*	1. Dr. Surulivel Rajan, Professor, Manipal College of Pharmaceutical Sciences 2. Dr. Manasa Deepa, Professor, East West College of Pharmacy, Bangalore
11:05 - 11:40	Mr. Prasad Chodavarupu, Founder and Managing Director, Aganitha Cognitive Sciences *Lessons from a year of applying Agentic AI in Biopharma R&D*	
11:40 - 12:15	Dr. Vijay Kulkarni, Co-Founder & Director, Swalava Enterprises Private Ltd. *Hot melt extrusion- a new approach to enhance drug capability*	
12:15 - 12:45	Awards ceremony	1. Dr. Amol Raje, Director-DMPK, Syngene International 2. Dr. R Deveswaran, Professsor, FPH, RUAS
12:45 - 13:00	Vote of Thanks	Dr. Arti Thakkar, Senior Associate Director, PUMAS- AI
13:00 - 14:00	Lunch	

ABOUT THE SPEAKERS

Prof. Ashok Venkitaraman
Distinguished Professor of Medicine,
NUS, Chief Scientist, A-Star, Singapore

Ashok Venkitaraman is a Distinguished Professor of Medicine at the National University of Singapore, the Director of the Cancer Science Institute of Singapore, and Chief Scientist for biomedical research at the Agency for Science, Technology & Research (A*STAR). Ashok previously held the Ursula Zoellner Professorship of Cancer Research at the University of Cambridge from 1998-2020. He was the Director of the Medical Research Council (MRC) Cancer Unit in Cambridge from 2006-2019.

Ashok's research has contributed fundamentally to our understanding of how human cancer is suppressed by genes that maintain the integrity of the genome. To translate his work to clinical impact, Ashok has pioneered new technologies that enable the precise identification and validation of therapeutic targets, leading to the serial spin-out by Cambridge University of biotechnology firms based on his research.

Ashok's work has been recognized by international awards, and appointments to the advisory boards of leading academic organizations and pharma companies, including Astex Therapeutics, Cambridge Antibody Technology and Chugai Pharmaceuticals (Roche Group). He was inducted as a Fellow of the Academy of Medical Sciences, London in 2001, a member of the EMBO academy, Heidelberg, in 2004, a Member of Academia Europaea, in 2025, and a Fellow of the Academy of the American Association for Cancer Research, in 2025.

Abstract
Approaches for therapeutics development are rapidly evolving to overcome challenges that restrict the repertoire of drug discovery, and further development towards clinical impact. I will briefly summarise these emerging approaches, including examples from my laboratory's work.

ABOUT THE SPEAKERS

Dr. Raju Subramanian
Executive Director, Gilead Sciences, USA

Dr. Raju Subramanian is an Executive Director in the department of Drug Metabolism and Pharmacokinetics (DMPK). He received his Ph. D. in Physical Chemistry from State University of New York at Stony Brook (1994). He completed two postdoctoral stints thereafter – 1st one at Department of Physics, College of William and Mary followed by a 2nd one at Beckman Institute, University of Illinois Urbana-Champaign. He has 25+ years of pharmaceutical industry experience – Stints at Merck (5 years), Amgen (11 year) and currently at Gilead since Jun'2016. He is currently a nonclinical sciences team leader wherein he is a mentor and contributor proactively supporting cross-functional discovery and development teams. Projects (past and present) include cardiovascular, virology, inflammation, metabolic disorders, nephrology, neuroscience, and oncology therapeutic areas. He is a (co)author of 90+ publications. He has made meaningful contributions to at least four new drug approvals - etelcalcetide (Parsabiv), bictegravir/emtricitabine/ tenofovir alefanamide (Biktarvy), remdesivir (Veklury), and lenacapavir (Sunlenca, Yeztugo).

Abstract

Innovative Approaches for DMPK Problems in Drug Discovery: Assessment of Hydrogen/Deuterium Exchange for In Vitro Chiral Stability of Pharmacophores and Use of Encequidar to Delineate In Vivo Disposition Pathways

Josh Yu Ph. D., Murali Subramanian Ph. D., and Raju Subramanian Ph. D., Drug Metabolism and Pharmacokinetics (DMPK), Gilead Sciences, Foster City, CA

1. Hydrogen/Deuterium Exchange for Chiral Stability Assessment

Acidic methine-containing compounds are a key component of pharmacophores such as glutarimides and thiazolidinediones present in molecular glues and protein degraders. The acidic methines are prone to racemization which can impact their pharmacological and toxicological profiles. This study introduces a robust hydrogen/deuterium (H/D) exchange based on high resolution mass spectrometric method for high-throughput assessment of racemization and epimerization kinetics and is exemplified with 28 compounds that contain this motif. The method quantifies chiral stability without requiring enantiopure standards or specialized chiral chromatography, enabling rapid, multiplexed analysis. Results reveal that glutarimide-based molecular glues have moderate chiral stability, while thiazolidinediones racemize more rapidly. Several protein degraders exhibit exceptional chiral stability, likely due to unique conformational features. The study also demonstrates a significant kinetic isotope effect with methine deuteration and highlights the influence of protein binding, pH, and temperature on chiral stability. This H/D exchange approach provides a powerful tool for early-stage drug discovery and the design of stereochemically stable therapeutics.

2. Encequidar as a Gut-Restricted P-gp Inhibitor for Elucidation of In Vivo Disposition Pathway

Encequidar is a gut restricted P-glycoprotein (P-gp) inhibitor that is a useful tool molecule to boost the oral bioavailability of P-glycoprotein substrates. Encequidar displays moderate to high clearance, volume of distribution, and low oral bioavailabilities (<10%) in rat, dog and monkey. We show, in vivo, the ability of encequidar to inhibit gut P-gp and boost the oral exposures of known P-gp probe substrates (paclitaxel, apixaban and talinolol) by 5 to 20-fold in nonclinical species. Additionally, we show low portal vein levels of encequidar suggesting that it is an efficient gut P-gp inhibitor but unlikely to inhibit bile canicular or systemic P-gp. We leverage this gut-restricted nature of encequidar to differentiate between intestinal excretion/secretion mediated by gut P-gp and biliary elimination mediated by canicular P-glycoprotein in bile-duct intact animal studies. We show that encequidar can inhibit intestinal secretion of known P-gp substrates in rat and dog. The reduction in amount of parent in feces, post intravenous substrate dose with oral encequidar coadministration reflects intestinal secretion whereas the remaining amount of parent in feces in presence of encequidar reflects biliary elimination in absence of enterohepatic circulation. In all cases, renal elimination was unaffected by encequidar. Overall, we demonstrate that encequidar can differentiate between the various disposition pathways- renal, biliary and intestinal in dogs and provides a quick qualitative estimate of the human disposition pathways.

ABOUT THE SPEAKERS

Dr. Upendra Argikar
DMPK Leader, Gates Medical Research Institute, USA

Dr. Upendra A. Argikar, PhD, has 20+ years of industry experience in the field of drug metabolism and pharmacokinetics (DMPK). He received a doctoral degree in Medicinal Chemistry from the laboratory of Professor Rory P. Remmel at the University of Minnesota. While at the University of Minnesota, Upendra was involved in several national and international collaborations. Thereafter Upendra joined the DMPK department at Novartis. Upendra has supported multiple discovery and development projects, across many disease areas and grew into leadership roles. Upendra later joined Gates Medical Research Institute, a non-profit organization focussed on research and development of medicines for low- and middle-income countries, where he presently serves as the Head of Drug metabolism and pharmacokinetics.

Over time, he has contributed to the discovery and/or development of >20 investigational new drugs, 4 of which are marketed for clinical use. Upendra has a keen interest in disposition mechanisms of new chemical entities and clinical drugs. Upendra has published >60 original research and review articles and has co-authored 10 book chapters. He is also a co-editor of 'Enzyme Kinetics in Drug Metabolism: Fundamentals and Applications', which is utilized as a textbook in DMPK graduate programs. Upendra serves on the editorial boards of journals including Drug Metabolism and Disposition, Xenobiotica, Current Drug Metabolism, and Drug Metabolism Letters. Upendra has served as faculty for DMPK courses at Novartis globally and he continues to serve as a guest lecturer for graduate courses at US based universities.

Abstract

DMPK insights in the development of sutezolid, aMycobacterium tuberculosis inhibitor

Sutezolid is an antimicrobial that inhibits the growth of Mycobacterium tuberculosis by blocking microbial translation and, thereby, protein synthesis. Sutezolid is currently being investigated in Phase 2 studies for the treatment of pulmonary tuberculosis. Sutezolid, is oxidized to a major active sulfoxide metabolite (M1) which then undergoes renal excretion. M1 has also been identified to be metabolized to a sulfone metabolite (M2). This presentation includes the in vitro and in vivo drug metabolism and pharmacokinetic studies conducted to support the clinical development for Sutezolid and M1, along with mechanistic ADME investigations. In vitro interactions of sutezolid with drug metabolizing enzymes and transporters are covered, along with an in vivo preclinical mass balance study. Finally, the presentation outlines the collation of this information along with available clinical data enabled construction of a robust PBPK model to support clinical development.

ABOUT THE SPEAKERS

Dr. Devang Shah
Director, Bristol Myers Squibb, Bangalore

Dr. Devang Shah earned his Ph.D. in pharmacokinetics from the Institute of Chemical Technology (formerly UDCT), Mumbai. He has over 16 years of experience in the DMPK field and currently serves as a Scientific Director at Bristol Myers Squibb in Pharmaceutical Candidate Optimization. In this role, he represents DMPK across small- and large-molecule discovery programs, guiding candidate progression through DMPK characterization and PK/PD modeling. His work supports PoC studies, human PK and dose projection. He has co-authored multiple publications in drug metabolism and pharmacokinetics.

Abstract

Advancing PD-L1 Macrocyclic Peptides to the Clinic: A Story of Resilience

Although there are numerous examples of monoclonal antibodies which inhibit programmed death ligand 1 (PD-L1), to date there have been more limited examples of successful engagement of this target using other modalities. This presentation will focus on the journey that resulted in the advancement an orally dosed, potent PD-L1 macrocyclic peptide, BMS-986238. Initial studies focused on the discovery and characterization of BMS-986189, a first generation macrocyclic peptide for which target engagement was determined using ex-vivo receptor occupancy studies in cynomolgus monkeys and positron-emission tomography (PET) in tumor-bearing mice. Early clinical data for BMS-986189 validated this pre-clinical approach. Subsequent studies focused on a next generation peptide with pharmacokinetics optimized to ensure target coverage while also maintaining the feasibility of oral administration. These studies resulted in the discovery of BMS-986238.

ABOUT THE SPEAKERS

Dr. Shridhar Narayanan
Co-founder of Peptris Technologies Pvt. Ltd

A passionate drug hunter with more than 20 years of drug discovery and development experience in Indian pharmaceutical industry in various therapeutic areas. Shridhar holds a basic degree in Pharmaceutical Sciences from University of Mumbai, a PhD in Pharmacology from The Ohio State University and has post-doctoral experience in Neuropharmacology at the University of California, Los Angeles. Shridhar, a serial entrepreneur, is currently Founder Director, Chairman and Chief Executive Officer of Foundation for Neglected Disease Research (FNDR), a not-for-profit company established in 2014 with a mission to discover and develop drugs for diseases of the developing world.

Shridhar is also the co-founder of Peptris Technologies Pvt. Ltd., an AI/ML company working towards the discovery and development of new drugs in rare diseases, oncology and inflammation. Prior to this, Shridhar was appointed Vice President and Head of Innovative Science for the Infection Innovative Medicines group at AstraZeneca, India and was responsible for the discovery and development of potential clinical candidates in TB and malaria. Throughout his career, Shridhar has overseen the Discovery and Development of 1 drug, Enmetazobactam, TBA-7371, ZY-19489 and 15 other clinical candidates in the areas of infection, oncology, diabetes, inflammation and respiratory diseases. He has also executed out-licensing deals with major pharma as well as in-licensing of candidates (NCE/NBE) which are in active development. This has generated up-front revenues in excess of 180 million USD. As part of FNDR, Shridhar has managed to raise donations worth 2.7 million USD from AstraZeneca, more than 2 million USD in grant money from the funding agencies and around 30 million USD in investment into preclinical and clinical asset development by partners over the last 8 years. Shridhar is a mentor to several start-ups, member of advisory boards, joint research committees, academic and industry collaborations and has served as a Ph.D. guide. Shridhar has more than 50 publications and 25 patents to his credit. Shridhar and his organizations, FNDR and Peptris, have been the recipient of several awards at the National and International level including the Jack Beal Award for Outstanding Alumnus, Lifetime Achievement Award from Indian Society for Clinical Research, The Longitude Prize Award and the Smart Bio Award to name a few.

Abstract

Engineering the Future Drugs-Innovating in India for the World

The talk will cover recent advances in AI/ML related to drug discovery and development. Specific case studies of the use of AI/ML for the discovery of a novel and a repurposed molecule for Duchenne muscular dystrophy will be covered.

ABOUT THE SPEAKERS

Dr. Priyaranjan Pattanaik
Vice President and Head,
Discovery Biology and Biotherapeutics.
Syngene International Limited, Bangalore

Dr. Priyaranjan's scientific journey spans advanced discovery biology and complex biotherapeutic platforms, including monoclonal antibodies, bispecific antibodies, antibody–drug conjugates (ADCs), and other bioconjugates. He completed his PhD at JNCASR, Bangalore, followed by postdoctoral research at Case Western Reserve University. Trained as a structural biologist, he has been deeply involved in structure-based drug discovery throughout his career. Priyaranjan has authored several peer-reviewed publications and has successfully led multiple large-molecule discovery programs from concept to clinic.

Abstract

AI-Enabled Innovation across the Antibody–Drug Conjugate (ADC) Development Pipeline

Artificial intelligence (AI) is reshaping the development of antibody–drug conjugates (ADCs) by providing a more predictive and mechanistic framework for designing targeted cancer therapeutics. Historically, ADC optimization has relied on empirical screening, limited structural insight, and low-throughput experimental cycles. The integration of AI now enables a shift toward data-driven, closed-loop engineering across discovery, design, and clinical development.

In target identification, AI models that combine multi-omics data with graph-based biological networks enhance the prioritization of tumor-selective and internalizing antigens. For antibody engineering, deep learning tools facilitate structure prediction, developability assessment, and the rational identification of conjugation sites that maintain binding while improving stability and drug-to-antibody ratio control. Generative and multi-objective optimization algorithms further expand sequence exploration for affinity maturation and scaffold tuning.

AI is also transforming linker–payload design by integrating chemical features, structural attributes, and molecular dynamics simulations to support balanced optimization of potency, stability, release kinetics, and safety. In parallel, advanced ADMET prediction frameworks, response-modelling platforms, and emerging digital-twin simulations improve pharmacokinetic forecasting, toxicity assessment, and patient stratification.

While challenges remain—including data sparsity, interpretability, and regulatory alignment—AI-enabled platforms are accelerating iterative ADC optimization and paving the way for more rational, scalable, and personalized next-generation therapeutics.

ABOUT THE SPEAKERS

Prof. Ramanathan Sowdhamini
Senior Professor, National Centre for Biological Sciences

Sowdhamini is a Senior Professor in National Centre for Biological Sciences since 1998. She received her basic degree and Masters in Chemistry. Her PhD thesis was on the modeling and analysis of disulphide bonds in proteins. She worked on fold prediction and protein domains during her postdoctoral tenure in Prof Tom Blundell's laboratory initially in Birkbeck College (London) and later in University of Cambridge.

Broad research interests in Dr. Sowdhamini's laboratory in NCBS have been in the analysis of protein structural similarities and distant relationships amongst proteins. Their group has interests on protein-protein interactions, protein-ligand interactions and in plant genomics of medicinal plants.

Sowdhamini was a Wellcome Trust Senior Research Fellow and DBT career fellow. She is a Fellow of Indian National Science Association and Indian Academy of Sciences. She holds a JC Bose Fellowship.

Abstract

RECOGNITION OF SMALL MOLECULE INHIBITORS FOR TOLL-LIKE RECEPTOR 4 THROUGH INTEGRATED APPROACHES

Toll-like receptors (TLRs) are pattern recognition receptors present on the surface of cells playing a crucial role in innate immunity. One of the TLRs, TLR4, recognizes LPS (Lipopolysaccharide) as its ligand leading to the release of anti-inflammatory mediators as well as pro-inflammatory cytokines through signal transduction and domain recruitment. TLR4 homodimerizes at its intracellular TIR (Toll/interleukin-1 receptor) domain that helps in the recruitment of the TRAM/TICAM2 (TIR domain-containing adaptor molecule 2) molecule. TRAM also contains TIR domain which in turn, dimerizes and functions as an adapter protein to further recruit TRIF/TICAM1 (TIR domain-containing adaptor molecule 1) protein for mediating downstream signaling. Apart from LPS, TLR4 also recognizes endogenous ligands like fibrinogen, HMGB1, and hyaluronan in autoimmune conditions and sepsis. We employed computational approaches to target TRAM and recognize small molecule inhibitors from small molecules of natural origin, as contained in the Super Natural II database. Finally, cell reporter assays and NMR studies enabled the identification of promising lead compounds. Hence, this study aims to attenuate the signaling of the TLR4-TRAM-TRIF cascade in these auto-inflammatory conditions.

ABOUT THE SPEAKERS

Prof. Arvind K Bansal
Professor, Department of Pharmaceutics,
National Institute of Pharmaceutical Education
and Research (NIPER), Mohali, Punjab

Dr. Arvind Kumar Bansal is a Professor in the Department of Pharmaceutics at the National Institute of Pharmaceutical Education and Research (NIPER), SAS Nagar, Punjab, India. With a career spanning over three decades, he is a globally recognized leader in pharmaceutical research and development, renowned for bridging academic innovation with industrial application.

Dr. Bansal earned his M.Pharm. in Pharmaceutics (1988) and Ph.D. (1993) from the University of Delhi, India. Before joining NIPER in 2000, he honed his expertise as a Senior Scientist and Group Leader at JK Pharmaceuticals and Ranbaxy Research Laboratories for eight years. There, he spearheaded the conceptualization, formulation strategy, and technology transfer of novel chemical entities (NCEs) and generic drug products, laying the groundwork for his impactful academic career.

At NIPER, Dr. Bansal has pioneered advancements in pre-formulation and formulation development, with expertise in amorphous form stabilization, polymorphism, pseudo-polymorphism, particle engineering, salt form screening, oral bioavailability enhancement, compaction physics, and lyophilization. Guided by his mission to develop "science-based, industrially viable pharmaceutical technologies," his research group collaborates closely with the pharmaceutical industry to translate innovations into commercially viable products.

Dr. Bansal's contributions have earned him prestigious accolades, including being named the first India-based Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2016. His awards include the AAPS Distinguished Educator and Researcher Award, the Innocentive Award, the Organization of Pharmaceutical Producers of India (OPPI) Award, and the Indian Pharmaceutical Association (IPA)-ACG Scitech Innovation Award 2018 for Best Innovative Development of Solid Dosage Form.

His prolific research output includes over 650 industry-sponsored projects in pharmaceutical material characterization, de-formulation studies, and formulation development. Dr. Bansal holds 11 granted patents, has filed 27 additional patents, and has authored 200 research articles and 27 review articles, with a Google Scholar h-index of 60. He serves on the editorial boards of RSC Pharmaceutics, Journal of Excipients and Food Chemicals, Drug Development Research, and Pharmaceutics, and advises the editorial boards of Journal of Pharmaceutical Sciences and Molecular Pharmaceutics.

Dr. Bansal's leadership extends beyond research, fostering strong academia-industry partnerships and mentoring the next generation of pharmaceutical scientists. His visionary work continues to shape the future of drug development, making significant contributions to global healthcare.

Abstract

Crystal Structure–Guided Insights into Milling Behaviour of Pharmaceutical Solids

Milling of active pharmaceutical ingredients (APIs) is a ubiquitous unit operation in pharmaceutical manufacturing, yet the molecular-level origins of milling outcomes remain poorly understood. A structure-guided understanding of milling behavior is critical for rational control of particle size, surface properties, and ultimately product quality. Correlating crystal structure with milling response enables a mechanistic interpretation of process–property relationships beyond empirical observations.

Voriconazole, a BCS class II drug, exhibits pronounced resistance to uniform size reduction during air-jet milling, failing to reduce below a critical particle size (dcrit) despite repeated milling cycles. This phenomenon was elucidated through detailed crystal structure analysis combined with predicted indentation hardness. The results revealed that an interplay of geometric and thermodynamic (lattice energy and slip systems) factors governs the fracture behavior of voriconazole, thereby limiting further comminution.

In contrast, terbutaline sulfate demonstrated efficient size reduction, achieving a D90 of 3.46 µm after three milling cycles at 8 bar. However, the milled material exhibited pronounced electrostatic charging and fine-particle agglomeration. Specific surface area–normalized water sorption measurements, using DVS, showed a substantial increase relative to the unmilled sample. Enhanced water uptake in the milled samples was not attributable to preferential exposure of hydrophilic crystal facets. Instead, the increased sorption was linked to the generation of surface amorphous domains induced by milling.

Together, these case studies illustrate how the integrated application of experimental techniques and computational tools can unravel the molecular and solid-state origins of milling behavior in pharmaceutical powders. Such insights provide a rational framework for designing milling strategies that balance size reduction efficiency with control over surface disorder and downstream performance.

ABOUT THE SPEAKERS

Dr. Ramanaiah Chennuru
Director and Head for COE Polymorphism and Crystallization at Cipla Pharmaceutical

Doctorate in Pharmaceutical Sciences with 17+ years of experience in polymorph screening, crystallisation process development, scale-up (QbD & PAT tools), technology transfer, and pre-formulation research. Proven track record in discovering novel, stable, non-infringing solid forms for generic product development, with 12 Para IV ANDAs and 15 DMFs filed. Recognised for creating world-class facilities and driving innovation in solid-state research.

Core Expertise

- Polymorph Screening & Development: Advanced solid-state characterisation (PXRD VT/VH, DSC, TGA, Raman, NMR, Mass, Single-Crystal XRD).
- Crystallisation Process Scale-Up: Kilo/pilot/plant validations, QbD, PAT tools.
- Novel Solid Forms: Polymorphs, amorphous forms, solid dispersions, co-crystals.
- Regulatory & IP Strategy: Non-infringement evaluation, Para IV ANDAs, DMFs.
- Leadership & Facility Setup: Designed and implemented polymorphism & crystallisation labs with HTS platforms, PXRD, DSC, TGA, HPLCs, GC, KF, spray drier, dissolution systems.
- Project Management & Tech Transfer: From lab to plant scale.

Key Achievements

- 55 Patents: Including 10 granted in the USA and 20 PCT/USA publications.
- 17 Peer-Reviewed Publications: H-index: 9 | i10-index: 7 | Citations: >280.
- Industry Impact: Delivered presentations and training on polymorphism and crystallisation to leading pharma organisations.
- Leadership Development: Certified in Lean Daily Management (LDM) and Leadership Development Programme (LDP).

Specialities Polymorph screening | Solid-state characterisation | Pre-formulation | Pharmaceutical development | Generic solid-state R&D | Technology transfer | Lab design | Team building | IP strategy.

Abstract

Solid-State Strategies in Generic Pharmaceuticals: From Polymorphs to Cocrystals

Solid-state engineering is a cornerstone of modern pharmaceutical development, profoundly impacting the stability, manufacturability, and therapeutic performance of drug products. In the generic pharmaceutical industry, where innovation must coexist with intellectual property constraints and cost-effectiveness, mastering solid-state science becomes even more critical.

This talk explores the strategic role of solid-state engineering in designing robust and high-quality generic

formulations. It delves into key concepts such as polymorph screening, salt and cocrystal selection, and the development of multicomponent solid forms to optimize drug properties. Special emphasis is placed on overcoming challenges related to scalability, regulatory compliance, and patent landscapes.

Through real-world case studies, the session illustrates how crystallographic insights have resolved complex issues such as mitigating hydrate variability, reducing pill burden via cocrystal technology, and achieving breakthrough formulations using rare solid forms. Additionally, the presentation highlights the application of advanced analytical techniques, including single-crystal XRD, powder XRD, DSC, and TGA, for precise structural characterization and performance optimization

ABOUT THE SPEAKERS

Dr. Sharmistha Pal Datta
Dr. Reddys Laboratories, Hyderabad

Dr. Sharmistha Pal is leading the solid form screening team in Dr. Reddys Laboratories. She has more than 20 years' experience in the pharmaceutical industry working in area of solid form development, manufacturing and characterization. Her expertise is in the field of developing and modulating physicochemical and bulk properties of API through solid form transformations and crystallization processes to address challenges in formulation and bioavailability within regulatory framework. Prior to joining Dr. Reddys Lab, she worked in different scientific roles at leading big pharma and CROs like Eli Lilly &Co., AstraZeneca India, and Biocon Bristol Myers Squibb Research Center (BBRC). She holds Ph.D. in Pharmaceutics from University of Minnesota.

Abstract

Advancements in understanding of solid state of Pharmaceuticals

Molecular and bulk properties of API may significantly influence manufacturing, stability and characterization of drug substance and may further impact drug product manufacturing feasibility, stability and bioavailability in patients. Materials with low solubility, suboptimum density or flow behavior, and physical or chemical instability issues create significant challenges in developing pharmaceutical products that are both patient centric and economically viable. This talk will review the various approaches, both conventional, and state of the art AI based tools and techniques utilized to address above challenges by solid property modulation of API including polymorphism, crystallization and powder property control.

ABOUT THE SPEAKERS

Dr. Sujata Shetty

Dr Sujata Shetty has had over 20 years of experience in researching, writing and speaking on mind- body health. She is the published author of “99 not out – your guide to a long and healthy life”. Prior to that she wrote close to 100 columns on mind and body health for Mint Business Newspaper. Dr Shetty is a certified life coach and resilience trainer and currently consults with TCS on employee mental health. She is a trained clinical research scientist with post-doctoral experience from the National Institutes of Heath. She worked with Dr Chrousos, one of the world's foremost stress researchers. Her second book titled Resilience Decoded: What every parent should know about teen mental health and published by Penguin Random House is the subject of discussion today.

ABOUT THE SPEAKERS

Dr. Stephan Bromacher
Vice President of Analytical Research and Development, Novartis

Dr. Stephan Brombacher is a Vice President of Analytical Research and Development in Novartis with 22 years of experience in the pharmaceutical industry. He is an analytical chemist by education and specialized on analytical characterization of API and Drug Products during his career at Novartis. Having various roles in the organization from Analytical science to Site Quality Head for chemical production, he is now leading the global analytical organization in the Technical Development Department for Synthetic Drugs in Novartis.

Abstract

Necessity is the mother of Invention: the challenges of novel pharmaceutical entities and the analytics they inspire

In recent years the paradigm shifts in the discovery and development of novel pharmaceutical therapies from the intervention of conventional protein targets to those previously considered “undruggable” has created significant challenges in analytical and separation science. This pushed the classical analytical toolbox beyond what is needed for traditional small molecules. New chemical modalities including RNA therapeutics, radioligands and peptides have matured, demonstrating clinical success and are now considered key targets for appraisal. In this viewpoint, we highlight challenges and recent progress in the field of the analysis and separation of oligonucleotide-conjugates and the need for orthogonal techniques and modes, and different method development strategies. Among these, diastereomer fingerprinting, the faster analysis utilising "on-off" retention mechanisms, and the shift of novel mass spectrometry-based techniques to a wide range of development and QC activities will be discussed. Furthermore the desire to automate chromatographic and MS laboratory workflows and data processing, and opportunities for machine learning.

Finally the presentation will touch on other challenges and recent developments with the analysis of radioligand therapeutics and ultratrace analysis of another recent foe, nitrosamines, it's pre-cursors and nitrite.

ABOUT THE SPEAKERS

Dr. Manoj Kumar Singh
Senior Vice president –
Microlabs Analytical research Lab

Dr. Manoj K Singh hold over 30 years of professional experience of working with global pharma companies leading their Analytical labs to support different pharma work-flows. He holds a Ph.D. degree (Chemistry). He started his professional career in 1993 with Wockhardt and spent significant tenure at major pharma R&Ds like Lupin, Novartis, Orchid, Dabur, Fressenius-Kabi & Sentiss Pharma. Currently he is associated with MicroLabs Bangalore as Senior Vice President (ADL) leading team of Analytical Chemistry scientists to support formulation development, Validations and method transfer.

Abstract

A QBD approach of Analytical method development

In today's pharmaceutical manufacturing environment, companies face increasing pressure to respond to changing demands across the global medicines supply chain while still maintaining the quality of their drug products. The U.S. Pharmacopeia (USP) understands the importance of evolving and expanding our standards to adapt to new practices and approaches, thereby ensuring a beneficial impact on the quality of medicines.

The conventional approach to drug product manufacturing involves a complex series of steps, including testing of the batch to ensure that it complies with safety and quality regulations. Over the past decade, regulators and industry have been gradually embracing Quality by Design (QbD) principles as an alternative to conventional, quality-by-testing and compliance-driven approaches, previously the only strategies for ensuring quality. As a result, quality paradigm shifts are currently underway in which QbD is being hailed as a modern and innovative approach that offers key advantages over conventional approaches and helps promote continuous quality improvement.

ABOUT THE SPEAKERS

Dr. Sajesh P Thomas
Associate Professor, Department of Chemistry,
Indian Institute of Technology, Delhi

Sajesh P. Thomas completed his PhD in 2014 from the Indian Institute of Science, Bangalore, under the guidance of Prof. T. N. Guru Row, focusing on charge density and crystal engineering studies of pharmaceutical solids. Following his doctorate, he conducted postdoctoral research with Prof. Mark A. Spackman at the University of Western Australia, Perth, and later held a Marie-Curie fellowship with Prof. Bo B. Iversen at Aarhus University, Denmark. He is currently an Associate Professor in the Department of Chemistry at the Indian Institute of Technology Delhi, where he leads Materials and Quantum Crystallography Lab (MQCL). His research interests include quantum crystallography and crystal engineering of pharmaceutical solids and soft piezoelectric materials.

Abstract

Advanced Tools in Pharmaceutical Crystal Engineering: Beyond Conventional Crystallography

Recent advances in crystallography and crystal engineering are significantly expanding our understanding of pharmaceutical solids by enabling deeper insights into their structural, electronic, and functional properties. This lecture highlights three emerging directions where modern crystallographic approaches are transforming drug materials. First, the structural identity of multicomponent pharmaceutical crystals—salts, cocrystals, or intermediate continuum forms—is governed by intermolecular proton-transfer states that strongly influence drug stability and solubility. Using X-ray quantum crystallography (QCr), particularly Hirshfeld Atom Refinement (HAR), we demonstrate accurate proton localization and detailed mapping of electron density in proton-transfer regions, enabling reliable discrimination between different crystal forms and revealing subtle bonding features. Second, we present machine-learning strategies for rapid and reliable phase quantification in pharmaceutical solids. A regression-based artificial neural network trained on experimental powder X-ray diffraction data enables accurate prediction of phase fractions across varying conditions, offering a robust and high-throughput alternative to conventional Rietveld-based approaches. Finally, we explore pharmaceutical crystals as functional materials, demonstrating that certain drug polymorphs exhibit large polar domain structures that generate exceptionally high piezoelectric outputs. These findings highlight pharmaceutical solids as promising candidates for biocompatible energy-harvesting applications. Together, these developments illustrate how integrating advanced crystallography, spectroscopy, and machine learning may drive paradigm shift in pharmaceutical solid-state science, bridging fundamental structural understanding with emerging technologies.

ABOUT THE SPEAKERS

Dr. Sunil Kumar Panigrahi
Associate Vice President, Research Informatics,
Aurigene Pharmaceutical Services Limited, Bengaluru, India

Dr. Sunil Kumar Panigrahi leads the Research Informatics function at Aurigene Pharmaceutical Services, overseeing Computational Chemistry, Bioinformatics, and AI-driven drug discovery. With over two decades of experience in innovative drug discovery, he brings deep expertise in computational sciences—including cheminformatics, bioinformatics, AI/ML, and data science—and their application to solving complex challenges in therapeutic research. He has contributed to more than 50 integrated drug discovery programs across oncology, metabolic diseases, anti-infectives, inflammatory disorders, and pain. His experience spans a broad spectrum of therapeutic modalities, including small molecules, peptides, antibodies, oligonucleotides, targeted protein degradation, biologics, and advanced formulations. Dr. Panigrahi has played a key role in advancing multiple programs from early discovery through clinical development. He has co-invented 10 clinically progressing molecules, authored 17 peer-reviewed publications, presented 20 scientific posters, and holds over 30 patents. He holds a Ph.D. from the School of Chemistry, University of Hyderabad, and currently spearheads the development of Aurigene.AI, an integrated platform designed to accelerate data-driven drug discovery. His career is centered on leveraging computational and AI-enabled innovations to drive transformative solutions—particularly relevant for addressing global challenges in human health.

Abstract

Accelerating Drug Discovery with AI, ML and Physics-Based Simulations

Recent breakthroughs in Artificial Intelligence (AI) and machine learning (ML) are transforming various fields, including drug discovery. Traditionally, developing a drug takes about >10 years and costs billions of dollars.1 This high cost makes these medicines unaffordable for many patients. AI and ML are being used to streamline drug discovery, reducing both time and expense. AI-powered drug candidates show a significantly higher success rate in clinical trials compared to traditional methods.2 This success is due to combining fundamental scientific data, particularly physics simulations, with AI and ML. This approach optimizes the Design-Make-Test-Analyze (DMTA) cycle shorter, leading to faster and cheaper development.

We've demonstrated reduction in cost and development time through deployment of physics-based simulations along with AI/ML to identify of novel kinase inhibitors. This approach allows us to identify promising drug candidates (hits) in just 3 months, compared to the typical 6–9-month timeframe.

References:
1. Deloitte 2023 Report on Pharma R&D return on investment
2. Drug Discov Today. 2024 Jun;29(6):104009.

ABOUT THE SPEAKERS

Dr. Maloy Ghosh
CSO, Zumutor Biologics

Founder member of Zumutor Biologics. Designed and directed scientific, research, and technological operations to achieve overall R&D missions of Zumutor. My goal is to build a resilient scientific team at Zumutor, implementation of translational research and empower them to achieve height of their career.
A visionary, seasoned, and dynamic professional with extensive scientific, regulatory, and clinical expertise in developing biologic therapies within the field of immuno-oncology. I am dedicated to driving corporate growth and innovation by translating goals and objectives into actionable strategies that support Zumutor's mission of advancing a novel immuno-oncology biotherapeutic pipeline.

Reputation as a proactive leader driving innovation, fostering collaborations, and enhancing team performance. With a strategic vision for products and technology, I have effectively led the development of company's IP portfolio, managed tech transfers, and overseen CRO/CMO partnerships with meticulous attention to detail.

Built and expanded company valuation, securing $32M USD through multiple venture capital funding rounds. Led strategic decision-making to enhance valuation, enable product and platform out-licensing, and facilitate eventual M&A by strategic partners.

My work contributed to the successful progression of the Phase 1 clinical trial for a novel immuno-oncology biologic (mAb) product, the first of its kind from India. This program encompassed the entire lifecycle, from drug discovery and development to manufacturing, quality control, and patient dosing. The drug is designed to treat a range of advanced and metastatic cancers, offering a potential therapeutic option for patients with no existing alternatives.

Zumutor Biologics has developed INABLR®, a proprietary, integrated antibody discovery and engineering platform for generating fully human therapeutic monoclonal antibodies. The platform is built on a highly diverse human immunoglobulin gene library with extensive VH/VL and CDR coverage, enabling identification of high-affinity, target-specific binders. INABLR® incorporates phage and yeast surface display for parallel selection, affinity optimization, and functional screening in Fab and scFv formats, allowing early evaluation of binding kinetics, epitope specificity, and developability. The platform includes in silico and experimental novelty and freedom-to-operate assessment, followed by seamless reformatting into full-length IgG and transfer to mammalian expression systems for scalable production and downstream developability screening.

INABLR® has been clinically validated through Zumutor's lead program ZM008, a first-in-class monoclonal antibody targeting NK cell immune checkpoint pathways in oncology. ZM008 has received USFDA IND approval and is currently in Phase 1 clinical trials, with multiple cancer patients dosed

ABOUT THE SPEAKERS

Dr. Arati Ramesh
Principal Scientist at the
Tata Institute for Genetics and Society

Arati Ramesh is currently a Principal Scientist at the Tata Institute for Genetics and Society. She received her Ph.D from Texas A&M University, College Station and pursued her post-doctoral research at the University of Texas Southwestern Medical Center, Dallas after which she established her independent research group at the National Center for Biological Sciences, Bangalore before moving to TIGS. Currently her research group is developing antisense oligonucleotides as potential therapeutic molecules to target infectious diseases. More broadly, her lab is interested in the biology of RNA in bacteria, how RNA sensors help bacteria adapt to their environment, the role these RNAs play in making microbes resistant to antibiotics and how they can be targeted using antisense technology.

Abstract

Re-imagining antimicrobials: Antisense oligomer-based therapeutics against infectious disease.

The rising AMR problem has made several antibiotics obsolete and has resulted in increased use of some of the most potent antibiotics ever known. One of the approaches needed to address the AMR problem would be to develop novel therapeutics that microbes have not been exposed to thus far. We seek to develop novel therapeutic oligonucleotide molecules that would function as antisense molecules that bind specific bacteria mRNAs and prevent their translation in to proteins, thus decreasing the levels of essential proteins within the bacteria, affecting select aspects of bacterial physiology. Such Antisense Oligonucleotide (ASO) therapy is designed to either directly kill the microbe (acting as a new antimicrobial) or increase bacterial susceptibility towards existing conventional antibiotics (repurposing obsolete antibiotics). Screening an antisense oligo library designed against ~100 critical genes of Uropathogenic E.coli helped us identify 11 mRNAs that when targeted with our approach, result in bacterial killing. Among these, an ASO060 and ASO019 targeting the translation start site of a cell-envelope modifying enzyme and a central metabolic enzyme show potent, mismatch-intolerant antibacterial activity and show bactericidal activity with low cytotoxicity in a human bladder epithelial infection model. Uropathogenic E.coli cause often life-threatening urinary tract infections, hence the ability to target its growth poses a powerful way forward to alternative therapy. Using a similar ASO strategy, we have targeted Staphylococcus aureus, a common cause of respiratory infections, skin infections and abscesses and a critical priority pathogen in terms of growing AMR. We find that targeting antibiotic resistance genes with antisense oligo therapy reverts a drug-resistant bacterial strain to drug-sensitive, suggesting a way forward to bringing back obsolete antibiotics into action in future

ABOUT THE SPEAKERS

Dr. Narmada B C
Lead Scientist at Vantage Research

Dr. Narmada is a Lead Scientist at Vantage Research gaining expertise in translating complex biological data into predictive models for drug development. Over the last 15+ years, she has led large-scale multidisciplinary R&D at Singapore gaining expertise on the full spectrum of drug development from target identification, assay engineering to advanced disease modeling and lead optimization. Her work spans across diverse domains of therapeutics development, including fibrosis, cardiovascular health, oncology, and infectious diseases. Currently, Dr. Narmada works at the intersection of biology and computational science, where she focuses on integrating mechanistic modeling with data-driven insights to enhance the translatability and impact of therapeutics development.

Abstract

Metabolize this! A QSP story in the fight against Obesity and Diabetes

Glucagon-like-peptide-1 receptor agonists (GLP-1 RAs), including the mono-agonist Semaglutide and the dual GLP-1/GIP agonist Tirzepatide, are effective treatments for obesity and type 2 diabetes; however, gastrointestinal adverse events (GI AEs) such as nausea impede patient adherence and dose maintenance. To address this efficacy-safety trade off, we developed a multiscale Quantitative Systems Pharmacology (QSP) platform designed to simulate the complex interplay between drug pharmacokinetics, pharmacodynamics, and population-level safety profiles for GLP-1 and dual GLP-1/GIP agonists. The architecture integrates physiological models of energy balance and glycemia with a novel safety module that semi-mechanistically links drug exposure to gastric emptying delays and nausea incidence. By parameterizing drug-specific effects on satiety and insulin secretion, the model captures non-linear weight loss and HbA1c reduction across diabetic and non-diabetic cohorts. Validated against diverse clinical data (STEP and SURMOUNT trials) in diabetic and non-diabetic obese populations, this framework quantifies the divergence between mono- and dual-agonist therapies and informs drug development or dose escalation decisions.

ABOUT THE SPEAKERS

Dr. Ravi Shah

Professor and Head
Department of Pharmaceutical Analysis
NIPER Ahmedabad

Dr. Ravi Shah is a Professor and Head of the Department of Pharmaceutical Analysis at NIPER Ahmedabad. He earned his Ph.D. from NIPER Mohali under the mentorship of Prof. Saranjit Singh, a distinguished figure in pharmaceutical sciences. Dr. Shah began his career at Biocon BMS Research & Development Centre, where he served from 2010 to 2015 at various roles. In his last role as Senior Principal Investigator, he was responsible for taking care of formulation AR&D, API process AR&D and structural characterization group. He then joined Dr. Reddy's Laboratories as Associate Director and leading the Analytical R&D function for integrated product development. He was also a tech lead for complex generic projects for Dr. Reddy's Laboratories.

In 2019, He decided to join academia at NIPER-Ahmedabad, an institute of National Importance, Govt of India. In academia, Dr. Shah's research spans dynamic and multidisciplinary areas aimed at advancing analytical strategies for drug discovery and development. His work emphasizes the in-depth characterization of complex APIs, peptides, biosimilars, and oligonucleotides. He continues to lead advancements in biomarker analysis, and quantitative proteomics. Dr. Shah also brings extensive expertise in LC-MS and NMR-based characterization of impurities, drug-drug and drug-excipient interaction products, and degradation profiling. He is actively involved in designing discriminative and biorelevant dissolution media, establishing in vitro–in vivo correlations (IVIVC), and conducting pre-formulation studies.

Dr. Shah has led more than 20 industry-sponsored research projects in collaboration with leading pharmaceutical companies. He has addressed complex R&D challenges, mentored four start-ups, and filed three patents, reinforcing his focus on translational and applied research. One of his most impactful contributions is the successful technology transfer of the generic version of Vorinostat, an anticancer drug used to treat cutaneous T-cell lymphoma, to Trident Lifeline Ltd., marking a significant step toward making this rare cancer therapy more accessible and affordable to Indian patients.

Abstract

Unlocking Complexity of Oligo Therapeutics: LC-HRMS as the Indispensable Analytical Armory for Next Generation Therapeutics

With 21 approved products, oligonucleotides are a rapidly growing next generation therapeutics drug class. However, their production via solid-phase synthesis and degradation inherently generates structurally similar impurities that regulatory bodies (like the EMA) now scrutinize heavily. Ensuring drug safety and efficacy requires identifying both synthetic impurities and degradation products formed during

storage. Because these variants are difficult to isolate using standard chromatography, IP-RP LC-HRMS has become the industry standard. This technique provides the high resolution needed to distinguish minute mass differences. Utilization of H/D exchange MS technique can also provide a number of labile hydrogens. Furthermore, its tandem mass spectrometry (LC-HRMS/MS) capabilities enable detailed fragmentation analysis, proving invaluable for comprehensive oligonucleotide sequencing and the elucidation of impurity structures, thereby ensuring the quality, safety, and efficacy of these complex therapeutic agents

ABOUT THE SPEAKERS

Dr. M.V. Narendra Kumar Talluri
Director, ARD (Knowledge Management) &
Tech support-SEA at Daicel Chiral Technologies

Dr. M.V. Narendra Kumar Talluri, presently working as Director, ARD (Knowledge Management) & Tech support-SEA at Daicel Chiral Technologies India and serving as Hon. Secretary for Royal Society of Chemistry-LSD-India and Previous positions held by him include A/Professor and Head, dept of Pharmaceutical Analysis, In-Charge LC-MS-Central Analytical Instrumentation facility at NIPER, Hyderabad and Scientific Manager at Biocon, Bangalore. He received PhD degree from CSIR-Indian Institute of Chemical Technology, Hyderabad. He has published 90 scientific articles in his credit. He successfully supervised and guided 50 MS (Pharm) and 4 PhD research scholars @ NIPER for their research works. They are successfully working as team leads in reputed pharmaceutical MNCs.

He is the recipient of a CSIR-Research fellowship and, Institution of Chemists Associateship. He is a member of scientific societies, the Royal Society of Chemistry (London), and the Asian Council of Science Editors. Science Direct declared 4 times one of his articles published in the Journal of Pharmaceutical and Biomedical Analysis was among the “Top 25 hottest articles”. Another article on chiral separations (2023) was the “Top Downloaded Research Article”. The Indian Drug Manufacturer's Association conferred the prestigious “Young Pharmaceutical Analyst Award 2011” for his outstanding research contribution in Pharmaceutical Analysis and was elected and admitted as an Associate Fellow of Telangana and A.P. Academia of Sciences (2014).

Best Research Scientist Award (NIPER, 2016). Bharat Vikas Award, 2017, Institute of Self Reliance), Daicel Diamond Innovation Award 2023.Journal of Pharmaceutical & Biomedical Analysis was recognised by the JPBA Quality Award 2017 for outstanding contributions in reviewing and contributions made to the quality of the journal. Examiner for various National Exams-Drug Inspector posts, Government analysts, NIPER PhD, PhD examiner for various universities -BITS Pilani, J S S University-Mysore, Gujarat Technological University, Ahmadabad, Central University (Jamia Millia Islamia)- New Delhi, Sri Sathya Sai Institute of Higher Learning, etc. He is a Reviewer for many international journals including RSC Advances, Analytical Methods, New Journal of Chemistry, Journal of Pharmaceutical and Biomedical Analysis, Journal of Separation Science, Biomedical Chromatography, Scientific Reports (Nature), Chromatographia, Chemosphere etc. Trained GLP Inspector from National GLP Compliance Monitoring Authority, DST, Govt of India.

Abstract

Modern Approaches to Chiral and Complex Peptide Therapeutics Impurity Profiling:

Evolving Analytical Tools for Pharmaceutical Precision

The increasing structural complexity of modern pharmaceuticals, particularly chiral small molecules and peptide-based therapeutics, has intensified the demand for highly selective and information-rich impurity profiling strategies. Trace-level stereoisomers, sequence-related variants, epimers, deletion products, and process-derived impurities can significantly influence safety, efficacy, and regulatory compliance, necessitating analytical solutions that extend well beyond conventional methods.

This lecture will highlight modern approaches to impurity profiling that integrate orthogonal separation mechanisms with high-sensitivity detection technologies. Emphasis will be placed on recent developments in chiral stationary phases, mixed-mode and reversed-phase platforms, supercritical fluid chromatography, and multidimensional LC strategies that enhance resolution for structurally similar species. Case studies will demonstrate how rational method development can accelerate route scouting, improve impurity tracking, and strengthen method robustness throughout the product lifecycle.

Overall, the session aims to provide a practical perspective on how evolving analytical technologies are enabling precise, reliable, and regulatory-ready impurity assessment for next-generation chiral drugs and complex peptide medicines.

ABOUT THE SPEAKERS

Dr. Manikandan Ramalingam
Head R&D, Granules India Limited

Abstract

Challenges in Chemistry, Manufacturing, and Controls (CMC) for NextGeneration Therapeutics

Nextgeneration therapeutics—including adenoassociated virus (AAV) gene therapies, lipid nanoparticle (LNP)–enabled RNA medicines, engineered cell therapies (e.g., CART), and CRISPR-based gene-editing treatments—promise durable, disease-modifying outcomes by acting at genetic and cellular roots. Their translation to market, however, is increasingly gated by Chemistry, Manufacturing, and Controls (CMC) readiness. Analyses of US FDA Complete Response Letters (CRLs) show manufacturing/quality deficiencies as a leading cause of delays and rejections in cell and gene therapy submissions, with ~74% of CRLs between 2020–2024 citing CMC issues and a substantial fraction of early INDs being turned back for inadequate CMC packages. This review synthesizes contemporary CMC challenges across delivery systems—AAV vectors, LNPs, engineered cells, and CRISPR components—highlighting pain points in process consistency, potency and comparability, analytics, stability, facility readiness, and global supply chains. We discuss case examples (Zolgensma, mRNA vaccines, CART products, and exacel/CASGEVY), summarize evolving regulatory expectations, and propose mitigation strategies: early Quality by Design (QbD), advanced analytics/real-time monitoring, phaseappropriate validation and bridging, digital manufacturing, and partnership models with specialized CDMOs. The road to broad access depends on harmonized standards and scalable, validated processes that can withstand inspection across sites and scales

ABOUT THE SPEAKERS

Prof. Hiroyuki Kusuhara
President of JSSX, University of Tokyo

Hiroyuki Kusuhara received his BSc, MSc and PhD (Pharmaceutical Sciences) from the University of Tokyo (Japan). Hiroyuki started his carrier as an academic scientist in The University of Tokyo as Assistant Professor of Pharmaceutical Sciences (1998). He was promoted to Associate Professor (2004) and Professor (2012) of Graduate School of Pharmaceutical Sciences, The University of Tokyo. He is currently professor and chair of Laboratory of Molecular Pharmacokinetics at Graduate School of Pharmaceutical Sciences, The University of Tokyo, Tokyo, Japan. Hiroyuki's major research interests encompass interindividual variability in human drug disposition, specifically focusing on the identification of drug transporters involved in tissue distribution and clearance, pharmacokinetics, modeling and simulation, in vitro-in vivo extrapolation, and drug-drug interactions, including biomarker studies. Currently, he is also investigating the mechanisms underlying drug-induced gut toxicity using intestinal crypt-derived cells. He is the author of 276 research papers in these areas. Hiroyuki has experience as Council and Director in Japanese societies; JSSX Council (2004- present), Director (2014-2017, 2021-2022), Vice-president (2023-2025), President (2025-present); APSTJ Council (2010-present), Director (2017-2018), Vice-president (2021-2023), President (2024-present). Editorial Board membership: Drug Metabolism & Disposition; Biopharmaceutics and Drug Disposition. Society membership: ISSX, AAPS, ASPET and Japanese Societies; JSCPT, APSTJ, JPS, JSDDS. International Society: ISSX since 2013 Scientific Affairs Committee (2014-2016), and Nominations Committee (2014-2016, 2021-present).

Abstract

Application of Intestinal Stem Cell–Derived In Vitro Models for ADME and Toxicity Assessment in Drug Development

Accurate prediction of human efficacy and safety remains a major challenge in drug development, particularly when translating nonclinical findings to clinical outcomes. Animal-based in vivo studies are often confounded by species differences, underscoring the need for human-relevant New Approach Methodologies (NAMs) promoted by regulatory agencies. In this presentation, we introduce intestinal stem cell–derived in vitro models as NAMs for ADME and gastrointestinal (GI) toxicity assessment. Human intestinal stem cells differentiated into polarized epithelial monolayers recapitulate key features of the human intestine, including functional drug transporters (P-gp and BCRP) and CYP3A activity. We further demonstrate how culture conditions, such as air–liquid and liquid–liquid interfaces, influence cellular morphology and function. In addition to ADME assessments, we applied intestinal stem cells and their differentiated derivatives to GI toxicity assays for tyrosine kinase inhibitors, enabling evaluation of stem cell proliferation and serotonin release from enterochromaffin cell–enriched organoids. The resulting in vitro–derived safety margins showed positive correlations with clinical GI adverse event incidence, supporting informed candidate selection in drug development.

ABOUT THE SPEAKERS

Dr. Rama Sivasubramanian
Head of R&D, Teva Pharmaceuticals

Rama Sivasubramanian joined Teva Pharmaceuticals as Head of R&D – India in September 2025. In her role, she serves as a member of the Global R&D Leadership Team and leads India R&D organization, developing and overseeing its strategy and execution. Rama brings 19 years of industry experience prior to Teva. She has joined after a 17-year-long stint with Novartis where she led cross-functional teams both in research and clinical development, providing strategic and functional leadership to programs in cardiovascular diseases, rare kidney diseases and pediatric development. She started her career at Novartis as Pharmacokinetics scientist in Novartis Institutes for Biomedical Research (NIBR) where she remained for 6 years as a team lead and head for India group. She moved to clinical development in 2015 as a group head for the newly formed Clinical Scientific Expert team, where she was responsible for CVM and Global health (GH) development units.

Rama holds a PhD in Pharmacokinetics & Drug Metabolism from the University of Pittsburgh, in the U.S., and has published in high-impact international journals. She is active in scientific organizations and has given several invited talks at scientific conferences. She is a member of American College of Clinical Pharmacology (ACCP) and its Indian Chapter. She is also an organizing committee member of the Society for Study of Xenobiotics-India (SSX-I). She has been an invited speaker to several conferences in India and presented at the 2019 conference of the European Society for Developmental Perinatal and Paediatric Pharmacology in Basel, Switzerland. She recently presented the Pediatric formulation development for iptacopan at the 2023 World Congress of Nephrology (WCN) in Bangkok, Thailand.

Abstract

Emerging Trends in Drug–Drug Interaction Evaluation: From Mechanistic Models to AI-Driven Predictions

Drug–Drug Interaction (DDI) evaluation is undergoing a paradigm shift, driven by advances in computational modeling and regulatory harmonization. Traditional in- vitro and clinical approaches are increasingly complemented by physiologically-based pharmacokinetic (PBPK) modeling, which now plays a central role in regulatory submissions and risk assessment. The recent ICH M12 guidance underscores global efforts to standardize methodologies for enzyme- and transporter-mediated interactions. Concurrently, artificial intelligence (AI) and machine learning—including deep learning and large language models—are transforming predictive capabilities, leveraging molecular structures, pharmacological networks, and real-world data. Integration of multi-omics and pharmacogenomics is enabling individualized DDI risk profiling, particularly for vulnerable populations such as the elderly and polypharmacy patients. Emerging frameworks also emphasize patient-specific and disease–drug interaction assessments, recognizing the impact of comorbidities and physiological changes on drug response. Enhanced DDI databases and knowledge graphs further support mechanistic understanding and clinical decision-making. Collectively, these innovations are shaping a future where DDI evaluation is proactive, data-driven and personalized, ensuring safer and more effective therapeutic strategies.

ABOUT THE SPEAKERS

Prof. Sahadev Shankarappa
M. S. Ramaiah University of Applied Sciences, Bengaluru, India

Dr. Sahadev Shankarappa is a biomedical scientist and faculty member at M. S. Ramaiah University of Applied Sciences, Bengaluru, India. He holds a medical degree and completed his doctoral training in Neuroscience at Loyola University Chicago, followed by postdoctoral research in the Langer Laboratory at Massachusetts Institute of Technology. His research focuses on neural-tissue interactions, mechanisms by which neuronal inputs influence tissue function and regeneration, and the development of innovative drug-delivery and bioengineering strategies for the nervous system. He has been the recipient of several government- funded research grants and has led industry-collaborative projects. His work integrates interdisciplinary experimental approaches, including biomaterials, neurobiology, and small-organism models such as Caenorhabditis elegans, to address clinically relevant biomedical questions.

Abstract
Designing Nanoparticles to Navigate Axonal Routes for Targeted Neural Drug Delivery

Ahina Job1, Neeraj Katiyar 2, Gayathri Raju 3, Sahadev Shankarappa1*
1 Department of Biotechnology, Faculty of Life and Allied Health Sciences, Ramaiah University of Applied Sciences, Bangalore, Karnataka, India
2 Department of Materials Science and Engineering; Biomedical Engineering, Uppsala University, Uppsala, Sweden
3 Amrita School of Nanoscience and Molecular Medicine, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India

Delivering nanoparticles to the nervous system offers significant potential for treating neurological disorders but remains constrained by vascular barriers that limit neuronal access. This study uses axonal transport as an alternative pathway for direct intraneuronal delivery. Isolectin B4 (IB4)-functionalized gold nanoparticles were engineered to selectively target sensory neurons, and their uptake and axonal movement were characterized through complementary in vitro and in vivo models using confocal microscopy, SEM, microfluidic culture platforms, and ICP-AES analysis. In parallel, a membrane-stretching technique was employed to fabricate non-spherical polymeric nanoparticles, enabling evaluation of how particle geometry influences entry into high-curvature domains such as axons. Non-spherical nanoparticles displayed superior uptake relative to spherical counterparts, underscoring the combined roles of neurotropic ligand targeting and shape in modulating neuronal internalization. Together, these findings establish shape-engineered and ligand-functionalized nanoparticles as effective vehicles for axonal drug delivery in neurological therapies.

References: Katiyar et al, Sci. Rep., 2021

Acknowledgements
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ABOUT THE SPEAKERS

Dr. Kumar V. S. Nemmani
Associate Vice President (Head, Preclinical Pharmacology) at Sun Pharma Advanced Research Company Limited, Vadodara

An experienced Pharmacologist with 16 years of industry (drug discovery and development) and 12 years of academic research and managerial experience. Established and led research labs of immuno-oncology/oncology, neurodegenerative diseases, pain, inflammatory-, respiratory-, metabolic-disorders programs. Skilled at building and guiding diverse biology teams with the proven record of consistent performance, effective team management, cross-functional collaboration, motivation of scientists, and delivery of results intime. Some of the nominated compounds are in advanced stages of clinical development. Lead-/Co-author of 48 research articles and 20 presentations at national and international conferences. He is currently Associate Vice President (Head, Preclinical Pharmacology) at Sun Pharma Advanced Research Company Limited, Vadodara since June 2022. Before this, he has worked in Shri Vishnu College of Pharmacy, Lupin Limited, Nicholas Piramal India Ltd. (Piramal Life Sciences), Dr. Reddy's Research Foundation, Postdoctoral Fellow, McGill University, Montreal, Canada. He did his PhD from NIPER (Department of Pharmacology and Toxicology), Mohali, Punjab and M. Pharm (Pharmacology) from Andhra University, Visakhapatnam, and B. Pharm from Andhra University, Visakhapatnam.

Abstract

Integrating DMPK Principles to Engineer Next-Generation Antibody–Drug Conjugate Immunotherapies for Cancer

Novel Antibody-Drug Conjugates (ADCs) herald a new era of precision medicine for cancer. Comprising an antibody, linker, and payload, they deliver targeted therapy to tumors while minimizing systemic exposure but face challenges like resistance and off-target toxicities. Rigorous Drug Metabolism and Pharmacokinetics (DMPK) studies are critical to navigating these challenges, guiding molecule design, optimizing the therapeutic window, and selecting clinical dose regimens. This integrated DMPK approach is exemplified by ADCs with novel STING agonist payloads, which overcome the poor pharmacokinetics and systemic inflammation of free agonists while demonstrating over 100-fold greater preclinical potency. Preclinically, these targeted ADCs achieve complete and sustained tumor regressions and elicit immune memory, creating potential for a systemic, abscopal effect against metastatic disease. The successful clinical translation of such innovative ADCs is therefore contingent upon the rigorous integration of DMPK principles to develop safer and more effective precision immunotherapies for cancer.

ABOUT THE SPEAKERS

Mr. Prasad Chodavarupu
Founder & Managing Director at Aganitha.ai

Hands-on tech business exec with 25+ years of exp. in growing tech businesses from start-up stage to a billion-dollar scale, Expertise in building multi-disciplinary teams, Published author, with patents in Data and Process engineering

Co-Founder & Managing Director at Aganitha.ai

- Deep Science (Comp Bio & Quantum Chem) + Deep Tech (AI/ML, LLMs, Data, Cloud) for accelerating R&D at global BioPharma
- Re-imagining with Agentic & Generative AI, every process & app in disease studies, therapeutic design & dev, synthesis, clinical, medical & regulatory affairs.

Previously at:

- HCL Tech: SVP & Global delivery head for Transformation Services
- Univ. of Illinois at Urbana-Champaign (UIUC) & IIT Kharagpur

Social Media handle:

- https://www.linkedin.com/in/chprasad/
- @Omics_Chap on X, @omics-chap.bsky.social on Bluesky

Abstract

Lessons from a year of applying Agentic AI in Biopharma R&D

Deep Science & Deep Tech are in a virtuous cycle of innovation, accelerating the availability of next generation tools and methods for R&D. It is not humanly possible to stay on top of this rapid pace of change. Here's where Agentic AI can truly help in everyday practice - bringing the best of innovation contextually to researchers. Doing this right, however, requires deep expertise. Igniva™ AI agents from Aganitha.ai bring together experience from 8+ years of global R&D collaboration by 100+ researchers, combining the best of Generative AI models with the latest from Computational Biology & Chemistry. In this talk, Prasad will exemplify these advances with demonstrations of several real-world Agentic AI use cases in R&D.

ABOUT THE SPEAKERS

Dr. Vijay Kulkarni, M.Pharm
Co-Founder and Director,Swalava Enterprises Pvt. Ltd. Bengaluru

Dr. Vijay Kulkarni is the Co-Founder and Director of Swalava Enterprise Private Limited, Bengaluru, with over 17 years of distinguished experience in the pharmaceutical industry. He holds a B.Pharm from Manipal University, an M.Pharm from BITS Pilani, and a Ph.D. from MSU Baroda. His post-doctoral research at the University of Mississippi, USA, under the mentorship of Dr. Michael Repka, focused on Hot Melt Extrusion (HME) technology, where he also managed and guided a group of 10+ Ph.D. scholars.
An accomplished academician, Dr. Kulkarni has served three years in academia and is a recognized Ph.D. guide at Manipal University, mentoring 6 Master's and 2 Ph.D. students in pharmaceutical development. His expertise lies in formulation development of pharmaceuticals, nutraceuticals, and herbal products for both human and veterinary healthcare, with specialization in advanced technologies such as continuous twin-screw granulation and HME.

Dr. Kulkarni has contributed to leading pharmaceutical organizations including STEERLIFE, Piramal, IPCA Labs, and Cadila Pharma, and has been honored with the Rising Star Award in Formulation Development at the FDD 2019 Conclave, Hyderabad, organized by Indian Express and Pharma Express. His career reflects a unique blend of industrial leadership, academic mentorship, and innovation in product development.

Abstract

Hot melt extrusion- a new approach to enhance drug capability

Abstract: Up to 40% of drugs are poor solubility. The bioavailability of APIs depends on their solubility in water, and improving the solubility presents a significant challenge in drug development. Out of various efforts to improve solubility, Hot Melt Extrusion (HME) has been a highly successful application by dispersing APIs into hydrophilic polymer matrices at the molecular level to form solid solutions.

CASE STUDY: Due to the great difficulties associated with developing new anthelmintic molecules, optimization of the existing compounds has been a high priority for research in the field. A main strategy to optimize the use of existing anthelmintic drugs has been focused on the pharmacokinetic-based enhancement of parasite exposure. One of the pharmacological strategies is allowing the enhancement of drug systemic exposure bio-availability and parasite exposure by pharmaceutical approaches to improve drug formulations, improve the poor/erratic GI absorption and to enhance the systemic exposure of the widely used broad-spectrum Albendazole anthelmintics. The development of new formulations assuring increased parasite exposure to the active drug may help to avoid misuse and prolong the lifespan of the existing or novel anthelmintics. Enhancing the bioavailability of Albendazole by converting it into solid dispersion using hot-melt extrusion (HME) process will be discussed as one of strategies.

SPONSOR TALK

Mr. Gurwinder Saini
Application Manager: Corning IMEA

Gurwinder is seasoned LifeSciences specialist with 19 years of experience, he serves as Application Manager at Corning Life Sciences (India, neighboring countries, Middle East and Africa), where he leads the technical aspects for LifeSciences portfolio. His expertise spans vaccine and biologics research, process development, scale-up, commercial manufacturing, and facility design and validations. He holds an Engineering degree in Biotechnology and a Master of Business Administration, bringing together strong technical scientific training with strategic business and management expertise.

In his current role, he provides strategic technical support through product trainings, demonstrations, and process-optimization guidance, helping institutions and industry partners adopt innovative technologies. His deep scientific background and hands-on industrial experience make him a trusted expert in driving innovation across the ecosystem.

SPONSOR TALK

Dr. Vijay Saradhi Mettu
DMPK Biology Solutions, Aragen Life Sciences

Vijay earned Ph.D from Osmania University in Pharmacology and Postdoc's from Washington State University and John Hopkins University Medical School.

Dr. Vijay Mettu is actively involved in the field of DMPK for the last two decades, specialising in Anticancer and CNS drug discovery programs. From 2008 Vijay is working in leadership roles, ADME & PK lead in Forma Therapeutics Singapore, In vivo PK lead at GlaxoSmithKline Singapore and DMPK Head at A*SATR Singapore. At current role in Aragen Life Sciences, he is working as the ADME lead.

Over the years, Vijay has acquired a wealth of knowledge and expertise in progressing compounds, from early discovery to lead optimisation and clinical candidate nominations, experienced in small molecules, Protacs, Peptides and large molecules.

Abstract

Evaluation of potential endogenous biomarkers for Oat 1/3 in mice

Rodents are widely used in drug discovery for evaluating pharmacokinetic, efficacy, and toxicological studies. A large number of drug discovery companies use mice for their first-in-animal studies to assess pharmacokinetics and pharmacological effects. This trend is increasing due to the greater availability of genetically modified mice and the lower compound requirements resulting from their smaller body weights.

The aim of the current study is to identify targeted biomarkers (preclinical (rat, monkey) and clinical) and untargeted biomarkers in mice. OAT transporters are 80% homologous between humans and mice, and over 98% homologous between mice and rats, due this there could be overlapping biomarkers from preclinical species to humans. To evaluate the targeted and untargeted biomarkers furosemide (10 mg/kg, IV bolus) was dosed with and without probenecid (30 mg/kg, IV bolus), samples were analysed using Zeno TOF 7600 Sciex.

Furosemide AUCall was increased more than > 2 fold and clearance is decreased by > 2 folds. Furosemide AUCall was 2 fold higher in females than in males in both with and without probenecid. This is in line with previous published data. In targeted biomarkers, pyridoxic acid, Kynurenic acid, creatinine, m/z 319.1798, 183.0773, 126.0219, 269.1255, 160.1332, 162.055, 205.0937, 245.0921, 277.1434, 310.2168, 198.1239, 161.0949, 253.1432, were increased from 13 fold to 1.25 fold and m/z 530.2782, 190.0498 and 291.2237 repressed between 1.5 fold to 3 fold in blood, these biomarkers excretion in urine was decreased. We also found unique biomarker in mice with m/z of 197.1498 and 219.1723 with increase of > 2 fold and repressed by > 2 fold respectively.

The biomarkers which are specific in preclinical species and biomarkers which are common in both preclinical and clinical will give an early warning of possible drug drug interactions in the clinic and avoiding a sperate DDI study of OAT.

SPONSOR TALK

Mr. Shantanu Roychowdhury
Business Line and Group Leader-ADME-Toxicology, Eurofins

Shantanu Roychowdhury is the ADME-Toxicology Group and Business Line Leader at Eurofins Discovery. Shantanu's main area of expertise is Analytical Chemistry with applications to Absorption and Drug Metabolism with over 20 Years of Experience.

Shantanu obtained his Bachelor's Degree in Biochemistry from the University of Illinois at Urbana-Champaign and Master's Degree in Pharmacology and Toxicology from Michigan State University- East Lansing, Michigan. Past Experience included Protein Technology and Assay Development at Millipore-Sigma, Regulatory Protein Toxicology at Monsanto Company, GLP Bioanalysis at Seventh Wave Laboratories and ADME-Toxicology at Eurofins Discovery.

Abstract

New Approaches for Assessing Drug-Drug Interactions- CRISPR Modified MDCKII Cell Lines for Transporters and Proteomics Analysis for CYP Induction

ICH M12 Guidance for Drug Interaction Studies was released in August 2024 and highlighted several changes in requirements for assessing Drug-Drug Interactions for Investigational New Drugs (INDs). This talk will highlight key changes in the guidance document, and also Eurofins' Novel approach for DDI assessment in accordance with Guidance, highlighting Case Studies with CRISPR Modified MDCKII Cell Lines for PgP and BCRP transporter interactions, as well as mass spectrometry-based proteomics as an alternative analytical technique for assessment of induction of CYP2C isozymes.

ORAL PRESENTATION

Poster ID: PP-032 **Oral Presentation ID: OP-01**

PREPARATION AND CHARACTERIZATION OF BRAIN-TARGETED DELIVERY OF VENLAFAXINE USING SERUM ALBUMIN NANOPARTICLES

Salman K* and J. Josephine Leno Jenita

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Introduction: Most of the antidepressants available on the market for the management of depression are available through the oral route of administration and also have several drawbacks. The most innovative and adaptable class of delivery methods, nanoparticles can be used to deliver therapeutic medicines to a specific target site in a regulated manner and as both diagnostic and therapeutic agents. The purpose of the present study was to develop nano-based formulations of Venlafaxine for the management of depression.

Results: Different batches of venlafaxine-loaded serum albumin nanoparticles were prepared using the desolvation technique, with varying polymer concentrations. Among the six batches of nanoparticles, V4 was found to be ideal, considering its drug loading percentage of 32.57 ± 0.51% w/w, along with a yield of 94.89 ± 0.2% w/w, a particle size of 194 ± 1.2nm, a polydispersity index of 0.375 ± 0.08, and a zeta potential of -27.1 mV. *In vitro* drug release showed a biphasic pattern with initial burst release and later sustained release following the Fickian diffusion-based release mechanism based on release kinetics. The formulation V4 was incorporated into thermosensitive gelling systems, known as in situ gels, to enhance drug delivery to the specific target site. *Ex vivo* drug diffusion studies were conducted on freshly excised goat nasal mucosa with a Franz diffusion cell simulated nasal fluid for all three formulations up to 8h, and the *in-situ* gel showed 89% drug release. The targeting efficiency of VLF-BSA NPs incorporated *in situ* gel was compared with nanoparticles. Drug solution was administered through the nasal route to determine the antidepressant activity through the forced swim test.

Conclusion: The histopathology study revealed that V4 formulation when incorporated into *in situ* gel could retain 80% of the viable neuronal cells with only 20% of the cells being degenerated when compared to the control group which showed 40% of cell degeneration and concluded that nanoparticles when incorporated into a thermos-sensitive gelling system like *in situ* gel, they show enhanced efficacy and better targeting to the specific site

Key Words- Venlafaxine, Serum Albumin, Nanoparticles, Thermosensitivegels, Anti-depressant

ORAL PRESENTATION

Poster ID: PP-016 **Oral Presentation ID: OP-02**

ENHANCING TARGET-SITE EXPOSURE OF FORMONONETIN IN BONE MARROW VIA BIOENHANCER-ASSISTED PHOSPHOLIPID COMPLEXATION

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Formononetin (FNT), a phytoestrogen, has shown osteogenic effect in Ovariectomized (OVX) induced osteoporosis but is limited by poor bioavailability. Purpose This study aimed to compare the osteogenic potential of pure FNT and Formononetin-PiperinePhospholipid complex (FNT-PIP-PC) in OVX-induced osteoporosis and to quantify free FNT concentration in rat bone marrow.
Study design: An in vivo study was conducted using an OVX-induced osteoporosis rat model. Methods Adult Sprague-Dawley rats (SD) rats were ovariectomized and treated orally with FNT or FNTPIP-PC at 5mg/kg for 12 weeks. Evaluations included body composition analysis, µCT, L5 compression, bone markers, and pharmacokinetics in bone marrow using LC-ESI-MS/MS. Results FNT-PIP-PC treatment significantly restored trabecular bone volume and microarchitecture in femur and tibia, improved uterine mass, increased Osteocalcin (OCN), and reduced C-terminal telopeptide of type-1 collagen (CTX) levels. These findings aligned with enhanced mRNA expression of RUNX, RANKL, BMP2, and OPG. Additionally, FNT-PIP-PC improved pharmacokinetic parameters like Cmax, AUC0-t, and AUC0-∞ of free FNT from FNT-PIP-PC compared to pure FNT. Conclusion To conclude Oral dosing of FNT-PIP-PC in OVX-induced osteoporosis rats significantly improved the osteogenic potential of FNT and enhanced its free concentration in bone marrow for therapeutic use with less toxicities.
Keywords: Formononetin, Osteoporosis, Pharmacokinetics, Ovariectomy, Piperine.

ORAL PRESENTATION

Poster ID: PP-004 **Oral Presentation ID: OP -03**

INTEGRATIVE PHARMACOKINETIC AND TRANSCRIPTOMIC ASSESSMENT OF HERB-DRUG INTERACTIONS BETWEEN A DIETARY SUPPLEMENT AND A CONVENTIONAL ANTIDIABETIC DRUG

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Abstract

Herbal products are widely consumed for both medicinal and dietary purposes, often in conjunction with prescription and over-the-counter medications. Although often perceived as natural and safe, herbal supplements contain bioactive constituents capable of modulating drug-metabolizing enzymes and transporters, thereby altering pharmacokinetics and therapeutic outcomes. The present study investigated the potential herb-drug interaction between *Salacia reticulata* (SAL), a traditional antidiabetic dietary supplement, and empagliflozin (EMPA), a sodium-glucose cotransporter-2 inhibitor, in Sprague-Dawley rats. The inhibitory effects of SAL on major hepatic cytochrome P450 (CYP450) isoforms (CYP1A2, CYP2C9, CYP2D6, and CYP3A4) were evaluated using in vitro CYP inhibition assays. Pharmacokinetic parameters of EMPA were assessed using a validated LC-MS/MS method following oral administration of EMPA (1 mg/kg) alone or in combination with SAL (100 mg/kg). In addition, transcriptomic analysis was performed to examine differential gene expression of drug-metabolizing enzymes and transporters implicated in herb-drug interactions. Protein expression of hepatic CYP450 isoforms was evaluated by Western blotting. In vitro studies demonstrated that SAL exhibited inhibitory activity predominantly against CYP3A4. In vivo pharmacokinetic evaluation revealed that co-administration of SAL delayed the T_{max} (1.0 h) and a higher C_{max} of EMPA, indicating an alteration in the rate and extent of absorption. Conversely, overall systemic exposure of EMPA, as reflected by AUC_{0-t} and $AUC_{0-\infty}$, was reduced in the presence of SAL. A pronounced reduction in terminal half-life ($t_{1/2}$) and mean residence time further suggested enhanced elimination and reduced systemic exposure of EMPA when administered with SAL. Transcriptomic analysis indicated upregulation of organic anion transporters (OATs), which may facilitate increased uptake or clearance of EMPA, thereby contributing to reduced systemic exposure. These findings were supported by protein-level changes observed in hepatic CYP450 expression. Collectively, the results demonstrate a clinically relevant pharmacokinetic interaction between SAL and EMPA, characterized by higher peak concentrations but reduced overall exposure. This study highlights the importance of systematically evaluating herb-drug interactions to ensure the safe and effective use of herbal supplements alongside conventional antidiabetic therapies.

ORAL PRESENTATION

Poster ID: PP-060 **Oral Presentation ID: OP-04**

MECHANISTIC PBPK MODELING TO EXPLAIN ATAZANAVIR DOSE NONLINEARITY AND GUIDE BIOAVAILABILITY-ENHANCING FORMULATION STRATEGIES

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Atazanavir, a Biopharmaceutics Classification System (BCS) class IIb drug, exhibits nonlinear pharmacokinetics in single ascending dose (SAD) studies due to the combined effects of solubility-limited absorption and extensive first-pass extraction mediated by cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp). The objective of this study was to develop a mechanistic physiologically based pharmacokinetic (PBPK) model to explain the observed SAD nonlinearity of atazanavir and to guide formulation strategies, such as co-amorphous (CAM) systems and solid dispersions (SD), for evaluating potential bioavailability enhancement using enabling formulations.

A whole-body PBPK model was developed incorporating mechanistic representations of pH-dependent solubility, P-gp-mediated efflux, and CYP3A4-mediated metabolism in both the intestinal wall and the liver. Sensitivity analyses were performed to quantify the impact of solubility and dissolution parameters on plasma exposure, absorption rate, and fraction absorbed. The model was calibrated using SAD plasma concentration–time profiles across a dose range of 100–1200 mg, ensuring that nonlinear exposure was mechanistically attributed to absorption and intestinal processes rather than empirical adjustments to systemic clearance. Formulation-specific solubility and dissolution inputs for CAM and SD systems were subsequently integrated to simulate their potential impact on oral bioavailability.

A sensitivity analysis demonstrated that solubility and dissolution rate along with intestinal P-gp efflux and CYP3A4 metabolism are the key determinants of nonlinearity. The PBPK model successfully reproduced the nonlinear pharmacokinetics observed in SAD studies, capturing reduced exposure at lower doses and increased bioavailability at higher doses. Simulated plasma concentration–time profiles and exposure metrics showed good agreement with observed clinical data, with predictive performance within predefined acceptance criteria of 0.5- to 2.0-fold error for AUClast, Cmax, and Tmax. Incorporation of CAM- and SD-specific solubility and dissolution profiles resulted in no significant improvement in the rate or extent of systemic exposure suggesting metabolism targeted formulation approach.

This study demonstrates that a mechanistic understanding of SAD nonlinearity, supported by sensitivity analysis of biopharmaceutical and intestinal parameters, is essential for credible PBPK-based prediction of bioavailability enhancement for BCS IIb drugs that are substrates of CYP3A4 and P-gp. The developed PBPK framework provides a robust platform for formulation bridging and the rational evaluation of enabling drug delivery strategies

ORAL PRESENTATION

Poster ID: PP-052 **Oral Presentation ID: OP-05**

IN VITRO INVESTIGATION ON SMART DRUG DELIVERY USING POLYMERIC MICELLAR SYSTEMS FOR SKIN CANCER TREATMENT

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Skin cancer is the abnormal and uncontrolled growth of skin cells. This study aimed to develop and characterize polymeric micelles for the co-delivery of curcumin and quercetin as a potential anticancer system. The study focused on utilizing Poloxamer tri-block copolymers-specifically; Poloxamer 188 and 407 as carriers for the encapsulation of two distinct natural compounds and systematically evaluated how the drug-to-copolymer ratio affects encapsulation efficiency. Results revealing that Poloxamer 188 consistently achieved higher encapsulation efficiencies for both curcumin and quercetin than Poloxamer 407. In-vitro characterization, including entrapment efficiency, particle size, and zeta potential analyses, confirmed successful micelle formation. FTIR results indicated possible physical interactions between the drugs and polymers. SEM analysis revealed uniform, spherical micelles with sizes below 200 nm, supporting their suitability for tumortargeted delivery. Notably, in vitro characterization report indicates that the co-encapsulation of curcumin and quercetin within a single polymeric micelle formulation (dual-drug systems) may offer synergistic therapeutic benefits and improved delivery characteristics over formulations containing each compound alone.

Key words: Polymeric micelles, Curcumin, Quercetin, Poloxamer, Block copolymer, Solvent evaporation, Scanning electron microscopy.

ORAL PRESENTATION

Poster ID: PP-009 **Oral Presentation ID: OP -06**

EXPLORING THE AMELIORATING POTENTIAL OF THYMOQUINONE LOADED COPPER NANO PARTICLE AGAINST DMBA INDUCED BREAST CANCER IN RODENTS

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Background: Cancer is one of the most devastating diseases and ranks second in the total number of deaths globally. Breast cancer incidence has steadily increased due to several etiological factors. Current therapies can cause life-threatening side effects due to indiscriminate drug delivery and a lack of target specificity.

Aim: This study aims to test the therapeutic potential of thymoquinone-loaded copper nanoparticles in treating breast cancer. Thymoquinone, a bioactive compound derived from Nigella sativa, has shown promise in cancer therapy due to its anti-inflammatory, antioxidant, and anti-cancer properties.

Methods: The thymoquinone-loaded copper nanoparticle (TQ-CuNPs) was prepared and subjected for characterization using zeta potential, energy-dispersive X-ray spectroscopy (EDX), X-ray diffraction (XRD), and Scanning electron microscopy (SEM) analysis. The prepared formation was screened for their angiogenesis study using MCF-7 breast cancer cell line. Furthermore, the formulation was evaluated on DMBA induced breast cancer in female Wistar rats.

Results: the results obtained from the characterization datas conforms the presence of TQCuNPs. The TQ-CuNPs formulation on MCF-7 cells showed significant inhibition with an IC50 value of 7µM. The results in animal model on treatment with TQ-CuNPs showed increase in tumor size from 185.5 ± 2.00 to 204.00 ± 2.50 g at a concentration of 0.384mg/ml/kg when compared to the standard doxorubicin.

Conclusion: In conclusion, the comprehensive evaluation of TQ-CuNPs presented in this study demonstrate their potential as effective and targeted therapeutic agents for breast cancer therapy. Future research should focus on optimizing their delivery mechanisms and exploring their efficacy in clinical settings to translate these promising findings into clinical applications.

Keywords: Breast Cancer, Thymoquinone, Copper nano particle, drug delivery, cytotoxicity.

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PP-002	Assessment of PROTAC Permeability and Recovery in Caco-2 and MDCK-MDR1 Cell Systems
PP-003	In Vitro CYP2C Isozyme Induction Assessments Beyond mRNA Using Mass Spectrometry Based Proteomics
PP-004	SELECTED FOR ORAL PRESENTATION Integrative Pharmacokinetic and Transcriptomic Assessment of Herb-Drug Interactions between a Dietary Supplement and a Conventional Antidiabetic Drug
PP-005	Assessment of Cyanide-Trapped Reactive Metabolites of Hard Electrophilic compounds Using Liquid Chromatography-High-Resolution Mass Spectrometry
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PP-007	In Vitro Stability and Metabolite Profiling of 1-Cyclopentyl-4-nitrosopiperazine (NDSRI Control) in Human Hepatocytes Using HRMS
PP-008	Therapeutic Potential of Natural Bioactive Compounds in Breast Cancer Prevention and Treatment
PP-009	SELECTED FOR ORAL PRESENTATION EXPLORING THE AMELIORATING POTENTIAL OF THYMOQUINONE LOADED COPPER NANO PARTICLE AGAINST DMBA INDUCED BREAST CANCER IN RODENTS
PP-010	Investigation of the cytotoxic potential of standardized ziziphus mauritiana lam. Seed extract -an in vitro approach using cell lines
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PP-012	“AI-Guided Chrono-Nanoformulation: A New Paradigm in Circadian-Targeted Drug Delivery Systems”
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PP-016	SELECTED FOR ORAL PRESENTATION Enhancing Target-Site Exposure of Formononetin in Bone Marrow via Bioenhancer-Assisted Phospholipid Complexation
PP-017	Single-Handed Jugular Vein Blood Sampling in Conscious Animals for Toxicology Studies

PP-018	Optimizing First-in-Human Pharmacokinetic Predictions through Informed Use of Mechanistic and Allometric Scaling
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PP-023	In silico studies, phytochemical characterisation and in-vitro studies of anthelmintic and antioxidant activity of polianthes tuberosa linn., flowers extract
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PP001

DEVELOPMENT OF MDCK-II KNOCKOUT MODELS STABLY EXPRESSING HUMAN MDR1 OR BCRP: AN IMPROVED IN VITRO PLATFORM FOR DRUG EFFLUX AND DDI STUDIES

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Multidrug resistance protein (MDR1/P-gp) and breast cancer resistance protein (BCRP) are key efflux transporters that influence drug absorption, distribution, and brain penetration. Their inhibition can lead to clinically significant drug-drug interactions (DDIs), making early evaluation critical in drug development. Permeability assays using Madin-Darby canine kidney (MDCK) cells are widely employed to predict the intestinal absorption of small molecules. Typically, MDCK cells are engineered to overexpress human MDR1 and BCRP; however, endogenous canine Mdr1 (cMdr1) complicates interpretation due to overlapping substrate specificity with human MDR1.

To address this, MDCK II cells with cMdr1 knockout (MDCK KO) were generated using CRISPR/Cas9 and confirmed by sequencing and functional assays. Digoxin-based efflux studies showed a significant reduction in efflux ratio in MDCK KO cells versus wild type, confirming cMdr1 knockout. Human MDR1 or BCRP genes were introduced into MDCK KO cells via lentiviral transduction to create MDCK KO MDR1 and MDCK KO BCRP lines, validated by qRT-PCR and flow cytometry. Functional activity of MDCK KO MDR1 and MDCK KO BCRP cells were assessed using substrates digoxin and cladribine or prazosin, respectively, demonstrated efflux ratios >20 compared to MDCK KO, with activity stable across multiple passages. Inhibition assays with elacridar and Ko143 produced IC50 values consistent with literature.

Currently, MDCK KO MDR1 and MDCK KO BCRP models are being used to evaluate internal clinical compounds for inhibition potential. This platform supports reliable DDI risk prediction and serves as a useful tool for assessing human efflux transporter effects early in drug development.

PP002

ASSESSMENT OF PROTAC PERMEABILITY AND RECOVERY IN CACO-2 AND MDCK-MDR1 CELL SYSTEMS

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Proteolysis-targeting chimeras (PROTACs) represent a novel therapeutic modality; however, their large molecular weight and high polarity often hinder permeability and recovery in standard in vitro transport assays. This study explores whether pre-incubation with 5% fetal bovine serum (FBS) can mitigate nonspecific binding and thereby enhance the permeability and recovery of PROTAC compounds in Caco-2 and MDCK-MDR1 cell models.

Objective: To determine the effect of 5% FBS pre-incubation on the permeability, recovery, and efflux behaviour of PROTAC compounds under varying buffer conditions.

Methodology: Bidirectional transport assays were performed using Caco-2 and MDCK-MDR1 monolayers. Test compounds were pre-incubated with 5% FBS prior to experimentation, and assays were conducted with and without pre-incubation. Three buffer systems—HBSS, FaSSIF, and 0.5% BSA—were evaluated. Apparent permeability coefficients (Papp), recovery rates, and efflux ratios were quantified to assess the influence of FBS pre-incubation and buffer composition on compound transport.

Results: Pre-incubation with 5% FBS markedly enhanced both permeability and recovery across all buffer conditions. The 0.5% BSA buffer yielded the most consistent and favourable transport profiles. These findings indicate that serum pre-incubation reduces nonspecific binding and improves permeability, even for PROTACs with beyond Rule of 5 (bRo5) properties.

Conclusion: Pre-incubation with 5% FBS significantly improves the permeability and recovery of PROTAC compounds in cell-based assays. Optimizing assay conditions is essential for accurate permeability assessment and may accelerate the development of PROTAC-based therapeutics.

PP003

IN VITRO CYP2C ISOZYME INDUCTION ASSESSMENTS BEYOND MRNA USING MASS SPECTROMETRY BASED PROTEOMICS

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Abstract

Cytochrome P450 (CYP) enzymes play a central role in the metabolism of many therapeutic agents. The expression of CYP enzymes can be modulated by xenobiotics, including pharmaceuticals, which may lead to altered drug metabolism and clinically relevant drug-drug interactions (DDIs). Regulatory agencies, including those aligned with the ICH M12 guideline, recommend evaluating the induction potential of investigational drugs on key CYP enzymes using in vitro systems such as primary human hepatocytes (PHH). Specifically, the ICH M12 guideline highlights the importance of assessing induction of CYP1A2, CYP2B6, and CYP3A4 as part of the standard in vitro DDI evaluation. These enzymes are commonly regulated by nuclear receptors such as AhR, CAR, and PXR. Because CYP2C8, CYP2C9, and CYP2C19 are also regulated by PXR, same as CYP3A4, the guideline recommends evaluating induction of these CYP2C subfamily members when CYP3A4 induction is observed in initial screening. In previous work, we developed and validated mRNA-based induction assays for CYP1A2, CYP2B6, and CYP3A4 using real time quantitative PCR (RT-qPCR) in PHH. In this study, we extended this approach to determine whether the same assay platform could reliably evaluate the induction of CYP2C8, CYP2C9, and CYP2C19. Results were also further confirmed using Tandem Mass Tag (TMT®- Thermo, Framingham, MA) LC-MS/MS Proteomics Workflows.

PP004

SELECTED FOR ORAL PRESENTION

PP005

ASSESSMENT OF CYANIDE-TRAPPED REACTIVE METABOLITES OF HARD ELECTROPHILIC COMPOUNDS USING LIQUID CHROMATOGRAPHY-HIGH-RESOLUTION MASS SPECTROMETRY

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Abstract

The metabolic activation of small-molecule drugs into electrophilic reactive metabolites is widely recognized as an indicator of idiosyncratic adverse drug reactions (IADRs). Electrophiles exhibit high reactivity due to their electron deficient nature and have either a high positive charge density (hard electrophiles) or a lower positive charge density (soft electrophiles) at the electrophilic centre. The present study is to investigate the formation of iminium ion intermediate in human liver microsomes, using potassium cyanide as a trapping reagent to stabilize the iminium ion species.

Objective: The purpose of the study is to identify and structurally characterize cyanide-trapped reactive metabolites formed from hard electrophiles compounds in human liver microsomes.

Methodology: Mixed-gender human liver microsomes (HLM; Xenotech) were incubated with 10 µM test compounds in the presence of an NADPH regenerating system, $MgCl_2$, potassium phosphate buffer (pH 7.4), and KCN. Incubations were performed in 96-well plates at 37 °C, initiated by NADPH addition, and aliquots were collected at 0, 30, 60, and 120 minutes. Reactions were quenched with ice-cold acetonitrile, centrifuged, and supernatants analyzed by LC-HRMS to monitor parent drug depletion and cyanide adduct formation using first-order kinetics

Results and discussion: Cyanide adducts of iminium ion intermediates were successfully detected for clozapine, ketoconazole, and propranolol, confirming the formation of hard electrophilic species. In contrast, no cyanide adducts were observed for carbamazepine, a compound known to form soft electrophilic intermediates, demonstrating the selectivity of this approach for hard electrophiles. These findings highlight the utility of cyanide trapping combined with LC-HRMS as an effective screening tool for early identification of reactive intermediates that may contribute to drug-induced toxicity.

PP006

EFFECT OF COMMONLY USED PHOSPHATE BUFFER IONIC STRENGTH ON THE METABOLIC STABILITY OF DIFFERENT CLASS OF DRUGS IN HUMAN LIVER MICROSOMES

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Abstract

Determination of in vitro metabolic clearance is a critical step in drug discovery, as it directly influences oral bioavailability and systemic elimination. Data from these assays are essential for ranking and prioritizing compounds for further development. In this study, we evaluated the impact of phosphate buffer ionic strength on the metabolic stability of six drugs (carvedilol, verapamil, midazolam, quinidine, dextromethorphan, diclofenac). Notably, verapamil and midazolam exhibited significant changes in intrinsic clearance (Clint) and halflife (t½), highlighting the importance of buffer conditions in accurately predicting in vitro clearance and ensuring reliable pharmacokinetic modelling. Objective: The purpose of the investigation was to study the effect of Buffer Ionic strength on the invitro metabolism of different class of drugs in Human Liver Microsomes (HLM).

Methodology: Metabolic stability assay using human liver microsomes was performed on an automated Biomek i7 liquid handler with a temperature-controlled heating block. Test compounds (1 µM) were incubated with mixed-gender microsomes (0.5 mg/mL) and an NADPH-regenerating system in phosphate buffer (pH 7.4; 50, 100, and 200 mM) at 37 °C. Aliquots were collected upto 45 min, quenched with acetonitrile containing internal standard, and centrifuged. The resulting supernatants were analyzed by LC–MS/MS to measure parent depletion, and intrinsic clearance and in vitro half-life were determined using first-order kinetics.

Results: Phosphate buffer ionic strength significantly influenced CYP-mediated metabolism in a compound-specific manner. Verapamil and midazolam showed the greatest sensitivity, with intrinsic clearance (Clint) increasing up to 3-fold at higher buffer concentrations, likely due to CYP3A4/5 involvement. Quinidine exhibited moderate variability, while dextromethorphan and carvedilol were minimally affected. In contrast, diclofenac demonstrated a 65% decrease in Clint as buffer strength increased. Overall, ionic strength introduced up to ~3-fold differences in clearance, potentially driven by reduced substrate binding affinity or altered enzyme–substrate interactions.

Conclusion: Phosphate buffer ionic strength is a critical parameter in in vitro metabolic assays. Variations in buffer concentration can cause up to 3-fold differences in intrinsic clearance, potentially impacting compound prioritization and pharmacokinetic predictions. Standardizing buffer conditions is essential for accurate clearance assessment and robust IVIVE during early drug discovery.

PP007

IN VITRO STABILITY AND METABOLITE PROFILING OF 1-CYCLOPENTYL-4-NITROSOPIPERAZINE (NDSRI CONTROL) IN HUMAN HEPATOCYTES USING HRMS

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Background: Nitrosamine impurities have emerged as a major regulatory and scientific concern in pharmaceutical development due to their potential carcinogenicity. These compounds undergo metabolic activation, particularly through α-hydroxylation, generating DNA-reactive intermediates that pose significant safety risks. Accurate prediction and characterization of these pathways are therefore critical for impurity risk assessment and mitigation. This study establishes human liver hepatocytes as a physiologically relevant in vitro platform to investigate nitrosamine metabolism. Using the FDA-recommended control compound, 1-cyclopentyl-4-nitrosopiperazine, we benchmark metabolic outcomes and validate predictive models for nitrosamine activation. The hepatocyte assays enabled the detection of α-hydroxylated metabolites, highlighting the central role of this pathway in the biotransformation of nitrosamine.

Methods System: Cryopreserved human hepatocytes incubated with the compound. Analysis: High-resolution mass spectrometry (HRMS) is used for metabolite identification and profiling. Endpoints: Stability assessment, metabolic pathways, and identification of major and alpha-hydroxylated metabolites.

Results: The compound exhibited measurable in vitro stability over the incubation period. HRMS analysis revealed primary metabolic transformations, including oxidative and reductive pathways. Several minor metabolites were detected, consistent with the biotransformation patterns of nitrosamines.

Conclusion: The study demonstrates that HRMS-based profiling provides critical insights into the metabolic fate and predicts the alpha-hydroxylated metabolites of NDSRI controls. These findings support risk assessment strategies for test compound nitrosamine impurities in drug development.

PP008

THERAPEUTIC POTENTIAL OF NATURAL BIOACTIVE COMPOUNDS IN BREAST CANCER PREVENTION AND TREATMENT

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Breast cancer remains one of the most frequently diagnosed malignancies worldwide and continues to be a leading cause of cancer-related mortality among women. According to the World Health Organization (WHO), approximately 2.3 million new cases and over 670,000 deaths were reported globally in 2022, underscoring the significant public health burden of this disease. Conventional breast cancer management relies on surgery, chemotherapy, radiotherapy, and hormone-based therapies. While these approaches have improved survival outcomes, their long-term effectiveness is often limited by serious adverse effects, cumulative toxicity, and the development of multidrug resistance. In recent years, growing attention has been given to complementary and alternative therapeutic strategies, particularly those derived from natural sources. Substantial evidence indicates that natural products of plant origin possess significant anti-cancer potential and may serve as effective adjuncts to conventional treatments. Many naturally occurring compounds can inhibit tumour cell proliferation, induce programmed cell death, regulate oxidative stress, and modulate key molecular signalling pathways involved in breast cancer development and progression. Moreover, these agents may reduce tumour aggressiveness and limit metastatic spread.

Ongoing research increasingly focuses on identifying bioactive natural and dietary compounds as safer and more effective options for breast cancer therapy. Several such compounds have demonstrated promising preclinical outcomes through diverse mechanisms of action. This fact compilation highlights on the selected natural chemical compounds with their roles in breast cancer treatment. With further optimization and comprehensive clinical evaluation, these agents hold strong potential to enhance therapeutic efficacy and improve patient outcomes.

Keywords: Breast cancer, Natural products, Phytochemicals, Anticancer activity, Molecular mechanisms, Complementary therapy, Multidrug resistance, Chemoprevention

PP009

SELECTED FOR ORAL PRESENTATION

PP010

INVESTIGATION OF THE CYTOTOXIC POTENTIAL OF STANDARDIZED ZIZIPHUS MAURITIANA LAM. SEED EXTRACT -AN IN VITRO APPROACH USING CELL LINES

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Background: Cancer remains a significant health concern, necessitating the development of safer and more efficient treatment alternatives, particularly those derived from natural sources. Cancer persists due to genetic changes causing uncontrolled cell growth. Plants are valuable sources for novel anticancer drugs, as natural compounds are sought to overcome the toxicity, side effects, and resistance of current chemotherapies. Hence, this study was conducted to evaluate the cytotoxic potential of Ziziphus mauritiana against cancer cell lines

Method: Phytochemical analysis of ethanolic extract was performed and total phenolic and flavonoid content were also determined. The extract was analyzed by GC-MS and LC-MS analysis. In vitro antioxidant study was conducted using DPPH assay method and cytotoxic potential was tested on N2a neuroblastoma cells using the MTT assay.

Results: Phytochemical studies revealed the presence of phenolic compounds, flavonoids, alkaloids, tannins and glycosides, Ethanolic extract showed higher phenolics and flavonoid content and bioactive compounds like sterols and triterpenoids in GC-MS analysis and flavonoids, phenolics, and saponins in LC-MS analysis. Ethanolic extract exhibited a significant antioxidant activity (67%). The cytotoxic evaluation of the seed extract revealed a concentrationdependent decrease in cell viability. At 100 µg/mL, the % cell viability was 88.95%, compared to 99.45% at 20 µg/mL, indicating increasing cytotoxic potential with higher concentrations.

Conclusion: Ziziphus mauritiana seed extract showed dose-dependent cytotoxicity against N2a neuroblastoma cells (IC50 137.46 µg/mL) and low toxicity is promising for safe use in nutraceutical or neuroprotective formulations.

Keywords: Ziziphus mauritiana, Cytotoxic potential, Neuroblastoma (N2a), Ethanolic extract.

PP011

NETWORK PHARMACOLOGY-BASED EXPLORATION OF TERMINALIA ALATA HEYNE EX ROTH LEAF CONSTITUENTS TARGETING EPILEPSY

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Hypothesis: Terminalia alata has been used in traditional medicine for the management of neurological disorders; however, the molecular basis in epilepsy-related conditions remains poorly understood. In the present study, a network pharmacology approach was employed to elucidate the multitarget and multipathway mechanisms of key T. alata leaf constituents in relation to epilepsy-associated molecular networks.

Methods: Initially, the key leaf constituents namely arjunic acid, arjunolic acid, arjunetin, maslinic acid, terminolic acid, and tomentosic acid were retrieved from IMPPAT database along with their SMILES format. Concurrently, the disease targets were retrieved from NCBI database using the search terms convulsion, seizure, and epilepsy. Later the overlapping targets were determined to establish the protein-protein interaction network, followed by Gene Ontology (GO) and KEGG pathway enrichment analyses.

Results: Putative protein targets for the selected phytoconstituents were retrieved, yielding a total of 600 constituent-associated targets. Integration of constituent-associated targets resulted in the identification 226 unique targets. Disease-associated targets were collected using the key terms convulsion, seizure, and epilepsy, resulting in 10, 168, and 873 targets, respectively, among which 918 were found to be unique disease-related targets. The number of common targets identified between disease- and constituent-associated targets was found to be 40. Protein–protein interaction network construction of the overlapping targets using STRING revealed node degrees ranging from 1 to 194, indicating a highly interconnected regulatory network. Key hub genes included TP53, EGFR, ALB, BDNF, IL1B, APP, GRIN2B, GSK3B, PTEN, HIF1A, DLG4, FN1, CREB1, APOE, and GFAP, highlighting their critical involvement in neuroinflammation, synaptic signaling, neuronal survival, and seizure susceptibility. Targets exhibiting node degrees greater than 75 were further subjected to Gene Ontology and KEGG pathway enrichment analyses. This analysis revealed enrichment across 753 biological processes, 32 molecular functions, and 95 KEGG pathways. The key biological process identified includes inflammatory response to wounding (GO:0090594), synaptic vesicle clustering (GO:0097091), and hyaluronan biosynthetic process (GO:0030213), while the significant molecular functions identified include positive regulation of signaling receptor activity (GO:2000273), promoterspecific chromatin binding (GO:1990841), neurotransmitter receptor activity (GO:0030594). Concurrently, the enriched KEGG pathways identified includes GABAergic synapse (KEGG:04727), Longevity regulating pathway (KEGG:04211), Cellular senescence (KEGG:04218).

Conclusion: Collectively, these findings suggest that the constituents of T. alata leaves might exert potential antiepileptic effects through modulation of multiple molecular targets and signaling pathways, providing a mechanistic basis for its traditional claim. However, the outcomes of this study warrant further validation through in vitro and in vivo experimental studies.

Keywords: Terminalia alata, Epilepsy, Network Pharmacology.

PP012

AI-GUIDED CHRONO-NANOFORMULATION: A NEW PARADIGM IN CIRCADIAN-TARGETED DRUG DELIVERY SYSTEMS

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Abstract: The synchronization of drug delivery with the body's circadian rhythm has emerged as a transformative approach in pharmaceutical drug development. Conventional dosage forms largely ignore biological time-dependent variations, often leading to sub-optimal therapeutic outcomes and increased adverse effects. Recent advances in chronopharmaceutics, coupled with nanotechnology and artificial intelligence (AI), have opened a novel and highly promising direction for precision drug delivery.

This abstract highlights the emerging concept of AI-guided chrono-nanoformulation, an innovative strategy that integrates circadian biology with intelligent formulation design. Nano-enabled delivery systems such as nanoemulsions, lipid nanoparticles, and polymeric nanocarriers allow controlled, site-specific, and time-programmed drug release. When combined with AI-based predictive models, these systems can be optimized to release therapeutic agents at biologically optimal time windows, enhancing drug efficacy while minimizing toxicity. AI tools, including machine learning and deep learning algorithms, are increasingly being employed to analyze circadian biomarkers, pharmacokinetic profiles, and formulation variables simultaneously. This enables rational selection of excipients, particle size optimization, release kinetics prediction, and personalization of dosing schedules based on individual circadian patterns. Such intelligent systems hold exceptional potential in managing circadian-linked disorders such as sleep disturbances, cardiovascular diseases, metabolic disorders, asthma, and hormone-related conditions.

The integration of AI-driven chronotherapeutic principles with nanoformulation technologies represents a paradigm shift in modern drug development. This approach not only enhances therapeutic precision but also supports personalized medicine and non-invasive drug delivery routes. Despite existing challenges related to regulatory acceptance and clinical translation, AI-guided chrono-nanoformulation is poised to redefine the future of pharmaceutical formulation science.

Keywords: Chronopharmaceutics, Artificial Intelligence, Nanoformulation, Circadian Rhythm, Precision Drug Delivery, Personalized Medicine.

PP013

PUSHING THE BOUNDARIES: ULTRA-SENSITIVE FRAGMENTATION FOR CONFIDENT DRUG METABOLITE IDENTIFICATION

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Metabolite identification is critical in drug discovery and development, often performed using LC-MS due to its sensitivity and structural elucidation capabilities. However, traditional collision-induced dissociation (CID) can lead to the loss of labile functional groups, limiting structural insights. Electron activated dissociation (EAD) offers a complementary approach, preserving labile groups and generating information-rich spectra for more confident metabolite identification. In this study, midazolam, diltiazem, and propranolol (1 µM) were incubated with rat liver hepatocytes at 37°C for 60 minutes. After protein precipitation with acetonitrile and centrifugation, supernatants were analyzed using a C18 column and a novel QTOF mass spectrometer. The mobile phases were 0.1% formic acid in water (A) and acetonitrile (B). A 5 µL injection volume was used for analysis. EAD enabled the identification of deacetyl diltiazem at 2.87 min with key fragments (m/z 178.0311, 150.0331, 109.0102). For 4-hydroxy midazolam, four unique EAD fragments (m/z 180.0211, 204.0442, 242.0842, 277.0543) were observed, all with <5 ppm mass error. Propranolol N-glucuronide was proposed based on fragments m/z 188.1280 and 374.1966 (<1 ppm error). Additionally, 4-hydroxy propranolol glucuronide was identified with four unique fragments, all within <4 ppm error (m/z 292.0932; m/z 304.1543; m/z 336.0837; m/z 362.1592). These results demonstrate the value of EAD in LC-MS/MS workflows for earlydrug discovery, offering enhanced structural clarity and confidence in metabolite identification.

PP014

COMPREHENSIVE FUNCTIONAL AND TRANSCRIPTOMIC CHARACTERIZATION OF HEPARG® CYP2D6+, AND HEPASH® HEPATOCYTES IN COMPARISON TO HEPARG® FOR ADME AND TOXICOLOGY APPLICATIONS

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Reliable in vitro hepatic systems are essential for predicting human pharmacokinetics and hepatotoxicity, yet the scarcity and variability of Primary Human Hepatocytes (PHH) continue to limit assay reproducibility and scalability. To address this, we characterize the metabolic and functional performance of two advanced human liver models HepaRG® CYP2D6+ and HepaSH® hepatocytes in direct comparison with wild-type HepaRG® cells.

A multiplexed Xenomix® assay covering nine CYP isoforms revealed that HepaRG® and HepaRG® CYP2D6+ exhibit similar broad-spectrum CYP functionality, with the expected selective enhancement of CYP2D6 activity in the engineered model. In contrast, HepaSH® hepatocytes displayed markedly higher CYP activity in suspension, notably for CYP2B6, CYP2C8/9, CYP2D6, CYP3A4, and CYP3A5. In addition to that, HepaSH® displayed a dynamic CYP profile, with a measurable recovery of several isoforms including CYP3A4 by Day 11, whereas both HepaRG® models maintained stable metabolic performance throughout the differentiation period, highlighting their suitability for long-term applications.

Induction with rifampicin, phenobarbital, and omeprazole confirmed the inducibility of CYP3A4, CYP2B6, and CYP1A2 across all three systems, each exhibiting model-specific response amplitudes. Fluorescent imaging using FluoBile®1 further confirmed that HepaRG® and HepaSH® hepatocytes displayed functional bile canaliculi networks at day 6 after plating.

Transcriptomic profiling via BRB-seq showed strong conservation of hepatic gene expression between parental HepaRG® and HepaRG® CYP2D6+, including key markers such as CYP3A4, CYP2E1, TTR, and albumin. By contrast, HepaSH® hepatocytes displayed a distinct transcriptional signature enriched in intracellular signaling, apoptosis regulation, wound repair, and tissue development pathways, reflecting their primary-like phenotype and metabolic responsiveness.

Together, these data define the complementary strengths of the models HepaRG® CYP2D6+ provides a targeted solution for investigating CYP2D6-dependent pathways while preserving the robust, long-term hepatic functionality of standard HepaRG®, and HepaSH® hepatocytes offer high initial metabolic capacity suitable for short-to-mid-term xenobiotic studies. When selected according to metabolic requirements and experimental duration, these models constitute reproducible and physiologically relevant alternatives to PHH for advanced ADME-Tox applications.

PP015

AN IMPLEMENTATION OF TRANSLATIONAL STRATEGIES FOR CRISPR-CAS9 BASED GENE THERAPIES

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Clustered Regularly Interspaced Short Palindromic Repeats and associated Cas9 endonuclease (CRISPR-Cas9) – based genome-editing therapeutics represent a transformative modality with the potential to treat a wide range of genetic and acquired diseases. Unlike conventional small-molecule or biologic drugs, CRISPR therapeutics have transient and often poorly measurable exposure and act primarily within intracellular and nuclear compartments. These features result in delayed but durable pharmacodynamic effects driven by irreversible genetic modification. These features challenge the applicability of traditional pharmacokinetic (PK)–based first-in-human (FIH) dose selection strategies, which rely on measurable systemic exposure, exposure–response relationships, and reversibility of effect.

In this review, mechanistic basis of CRISPR–Cas9 function and the translational challenges that limit the use of classical PK-driven frameworks is discussed. Kinetic–pharmacodynamic (KPD) modeling is an alternative, to quantify relationship between administered dose and PD response. KPD models are well suited to capture key features of CRISPR therapeutics, including saturation of editing, delayed onset of effect, and increase/decrease in protein turnover.

A prototype KPD-based simulation framework is implemented to translate preclinical PD data to humans, quantify uncertainty arising from delivery efficiency and biological variability, and inform rational, PD-driven FIH dose selection. FIH doses are defined based on achieving target ranges of the PD response across a virtual population. By integrating mechanistic understanding with model-informed simulations, this framework demonstrates a practical pathway for biologically informed FIH dose selection in the absence of measurable PK. KPD approaches provide a robust quantitative framework to support translational decision-making for CRISPR–Cas9 therapies and facilitate their safe and effective clinical development.

PP016

SELECTED FOR ORAL PRESENTATION

PP017

SINGLE-HANDED JUGULAR VEIN BLOOD SAMPLING IN CONSCIOUS ANIMALS FOR TOXICOLOGY STUDIES

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Abstract

Blood collection from laboratory animals is essential for clinical pathology and toxicokinetic evaluation in toxicity studies. Several efficient methods are available and widely practiced in scientific research. It is critical that blood sampling be minimally stressful, as anaesthesia stress can influence study outcomes. Key factors include sampling intervals and the animal's state of consciousness during collection. Jugular vein sampling in conscious rats offers multiple advantages: single handling, rapid collection, suitability for repeated sampling (reducing the need for satellite groups), and alignment with the 3Rs principles (Replacement, Reduction, and Refinement). This study aimed to standardize single-handed jugular vein sampling in conscious male rats and compare clinical pathology data with samples obtained under isoflurane anaesthesia via retro-orbital bleeding, abdominal aorta, and cardiac puncture. Rats were grouped by sampling route. No biologically or statistically significant differences were observed in clinical pathology parameters between jugular vein blood samples from conscious rats and samples collected via other routes under anaesthesia. We conclude that single-handed jugular vein blood sampling in conscious male SpragueDawley rats yields acceptable sample quality for toxicokinetic and clinical pathology assessments. This technique offers welfare benefits, as rats can return to their cages immediately without restraint or anaesthesia effects, thereby reducing stress. Furthermore, serial blood sampling from conscious rats enables interpretation of clinical pathology data without anaesthesia-related confounding.

PP018

OPTIMIZING FIRST-IN-HUMAN PHARMACOKINETIC PREDICTIONS THROUGH INFORMED USE OF MECHANISTIC AND ALLOMETRIC SCALING

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Predicting the first-in-human (FIH) dose remains a key translational challenge due to interspecies variability in pharmacokinetics (PK). Conventional allometric scaling, which extrapolates PK parameters from animals to humans based on body weight, can reasonably estimate the volume of distribution (Vd), yet often performs poorly for clearance (CL) because it does not account for interspecies differences in enzyme expression, metabolic pathways, and plasma protein binding. In this work, we investigated whether integrating mechanistic correction factors for CL with traditional allometric scaling for Vd could improve the accuracy of human PK predictions. Intrinsic clearance (CLint) data from in vitro hepatocyte assays across preclinical species were compared, and species-specific scaling factors (SF) were calculated as the ratio of in vivo to in vitro clearance (SF = CLin vivo / CLin vitro). Because in vitro assays frequently underpredict true clearance due to reduced metabolic activity or loss of essential cofactors, these factors were applied to correct human in vitro clearance estimates. Importantly, such correction factors should only be applied when the enzymology of the preclinical species used to derive the scaling factor closely resembles that of humans, ensuring comparable metabolic pathways and catalytic efficiency. Given the strong enzymatic similarity between monkeys and humans, a monkey-derived scaling factor (SFmonkey) was used to adjust human hepatocyte data (CLint,human,predicted = CLint,human,in vitro × SFmonkey). In parallel, Vd was estimated using body-weight– based allometric equations (Vd = a × BWb) to reflect physiological scaling. This combined framework reduced prediction error for human PK parameters by applying mechanistic rigor to elimination processes while maintaining empirical scaling for distribution. Overall, this hybrid extrapolation strategy enhances confidence in FIH dose selection and strengthens the translational reliability of preclinical data for early clinical development.

PP019

REFINING IONIZATION CONSTANTS OF POORLY SOLUBLE MACROLIDES: SIRIUS T3 PKA DETERMINATION OF SIROLIMUS AND TACROLIMUS

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Accurate characterization of ionization behaviour is essential for predicting solubility, permeability, and pH-dependent lipophilicity of drug molecules, all of which strongly influence ADME outcomes. Sirolimus and Tacrolimus are structurally complex macrolide immunosuppressants with extremely low aqueous solubility, making determination of their ionization constants experimentally challenging. Reported pKa values for Sirolimus (~10.40) and Tacrolimus (acidic pKa ~9.96; basic pKa ~−2.9) are derived from predicted chemical property models rather than experimental studies, highlighting a gap in experimentally validated ionization data. Using the Sirius T3 potentiometric platform, which enables pKa estimation under biphasic conditions for poorly soluble molecules, we sought to experimentally determine and validate the aqueous pKa values for both drugs across physiologically relevant conditions. The study demonstrates that Sirius T3 potentiometric titration can reliably characterize ionization behaviour of highly lipophilic, low-solubility macrolides, thereby supporting more accurate physicochemical inputs for DMPK modelling and formulation development.

Methods: The pKa values of Sirolimus and Tacrolimus were determined using the Sirius T3 automated potentiometric titration system under biphasic (octanol–water) conditions to accommodate their poor aqueous solubility and high lipophilicity. Drug samples were dispersed in an appropriate ionic-strength-adjusted aqueous medium, and titrations were performed across acidic and alkaline pH using standardized acid/base titrants.

Results: Sirius T3 analysis successfully generated reproducible titration curves for both drugs despite their challenging solubility profiles. The experimentally derived pKa for Sirolimus was found to fall near the predicted value of ~10.40, consistent with deprotonation of a weakly acidic functional group. Tacrolimus exhibited an experimentally measurable acidic pKa near ~9.96, aligning with computational predictions, while the extremely low basic pKa (–2.9) remained outside practical experimental range and thus relied on modelled extrapolation rather than direct titration.

Conclusion: This study demonstrates the utility of the Sirius T3 potentiometric method for experimentally determining pKa values of complex, poorly soluble macrolide immunosuppressants. The experimentally measured pKa values for Sirolimus and Tacrolimus showed strong agreement with predicted literature values, validating their reported ionization behaviour and confirming that both drugs are weakly acidic with limited protonation under physiological pH. For DMPK modelling, this provides more reliable inputs for predicting pH-dependent solubility, permeability, and Log D behaviour. Sirius T3 offers a robust approach for ionization characterization of highly lipophilic, low-solubility drug candidates where classical aqueous titration methods fail.

PP020

EVALUATING THE ROLE OF INTESTINE IN FIRST-PASS METABOLISM OF ORALLY ADMINISTERED METOPROLOL IN RATS

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Metoprolol is a short-acting beta-blocker that enhances cardiac efficiency by reducing heart rate. Although metoprolol is almost completely absorbed orally, its high fist pass metabolism might be responsible for the low oral bioavailability. Current study was planned to evaluate the relative contribution of intestine and liver to the first-pass metabolism of orally administered metoprolol in rats. Dual cannulated (portal and jugular vein) male Sprague Dawley rats (8–10 weeks) received 5 mg/kg oral metoprolol. Blood samples were collected simultaneously from portal and jugular veins over 24 hours post-dose. Plasma drug concentrations were quantified using LC-MS/MS, and pharmacokinetics determined via Phoenix WinNolin v8.2. The median time to reach peak plasma concentration in portal circulation (0.083 h) was rapid than systemic circulation (0.50 h). The observed Cmax and AUClast values were 2948 ng/mL and 936 h*ng/mL for the portal circulation and 145 ng/mL and 128 h*ng/mL for the systemic circulation, respectively. The resulting low intestinal availability (Fa·Fg) indicates that although absorption is efficient, substantial metabolism occurs within the intestine before hepatic entry. Metoprolol also exhibited moderate intrinsic clearance in rat hepatocytes (CLint = 18.03 µL/min/10 cells), high permeability, and no involvement of efflux transporters. Collectively, these findings suggest that intestinal first-pass metabolism is a major contributor to metoprolol's reduced oral bioavailability.

PP021

MODEL INFORMED PRECISION DOSING IN PEDIATRICS USING PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING – A CONCEPTUAL FRAMEWORK FOR XENOBIOTIC OPTIMIZATION

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Antibiotic therapy is central to pediatric clinical care, yet achieving safe and effective drug exposure in children remains challenging due to profound pharmacokinetic variability driven by growth related physiological changes, organ maturation, and disease related alterations. Conventional pediatric dosing strategies are frequently derived from adult regimens using simple weight based adjustments, an approach that often fails to account for developmental differences in drug absorption, distribution, metabolism, and elimination. These limitations contribute to sub therapeutic exposure, increased toxicity risk, and the emergence of antimicrobial resistance. Physiologically based pharmacokinetic modeling offers a mechanistic means of describing age dependent drug disposition, while Model Informed Precision Dosing integrates such models with patient specific drug concentration data to support individualized dosing decisions.

This conceptual work hypothesizes that an integrated physiologically based pharmacokinetic driven Model Informed Precision Dosing framework can improve pediatric antibiotic therapy by reducing inter individual variability in drug exposure, increasing attainment of pharmacokinetic and pharmacodynamic targets, and minimizing toxicity associated with inappropriate dosing.

The proposed framework combines four interconnected components. First, pediatric physiologically based pharmacokinetic models are developed using age specific anatomical, physiological, and biochemical parameters to generate baseline exposure predictions across pediatric subgroups. Second, therapeutic drug monitoring provides real patient concentration data early during treatment. Third, Bayesian forecasting methods integrate prior model predictions with observed concentrations to estimate individualized pharmacokinetic parameters. Finally, a dose optimization algorithm evaluates alternative dosing regimens to recommend patient specific doses that maximize the probability of achieving established therapeutic targets. This approach effectively creates a virtual pediatric patient representation that evolves as new data become available, supporting adaptive and precise dose refinement.

The application of this framework is anticipated to enhance the achievement of important pharmacokinetic and pharmacodynamic goals, minimize variability in exposure, and decrease the likelihood of both under dosing and toxicity. In clinical practice, this could lead to better treatment outcomes, a reduction in adverse effects, and a lower chance of developing antimicrobial resistance. Additionally, the framework provides scalability by allowing integration with clinical decision support systems, which facilitates ongoing learning from gathered patient data.

A physiologically based Model Informed Precision Dosing framework represents a promising pathway toward precision antimicrobial therapy in pediatrics. By uniting mechanistic modeling with real time patient data, this approach has the potential to shift pediatric antibiotic dosing from empirical practice toward individualized, data driven decision making. Future validation through prospective clinical studies and integration into routine care will be essential to realize its full clinical impact.

PP022

PHYTOCHEMICAL ASSESSMENT OF ANTIOXIDANT AND ANTIFUNGAL POTENTIAL OF *CAESALPINIA BONDUCELLA* ROOTS

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ABSTRACT

Medicinal plants constitute an important source of therapeutic agents worldwide, offering cost-effective treatment options for a wide range of diseases. *Caesalpinia bonducella* has been traditionally used for the management of ailments such as leprosy, fever, edema, colic, malaria, and gastrointestinal disorders. The present study aimed to investigate the polar phytoconstituents and evaluate the antioxidant and antifungal activities of the ethanolic root extract of *Caesalpinia bonducella*, prepared using the Soxhlet extraction method. The roots were collected, authenticated, shade-dried, and extracted with ethanol. Antioxidant activity was assessed using the DPPH radical scavenging assay, wherein the extract was incubated with DPPH solution under dark conditions, and absorbance was measured at 520 nm using ascorbic acid as the reference standard. Antifungal activity was evaluated against *Aspergillus niger*, *Aspergillus flavus*, and *Candida albicans* using standard microbiological techniques. The ethanolic root extract exhibited significant antioxidant activity with a scavenging value of 87.83 µg/ml, comparable to that of ascorbic acid (93.55 µg/ml). Phytochemical analysis revealed the presence of bioactive secondary metabolites, including flavonoids, phenolic compounds, and alkaloids, which are likely responsible for the observed antioxidant activity through effective DPPH radical reduction. Furthermore, the extract demonstrated notable antifungal efficacy against the tested fungal strains. The findings of the present study suggest that *Caesalpinia bonducella* root extract possesses significant antioxidant and antifungal properties, supporting its potential as a natural therapeutic alternative.

Keywords: Caesalpinia bonducella, Antioxidant, Antifungal, DPPH, microbiological testing

PP023

INSILICO STUDIES, PHYTOCHEMICAL CHARACTERISATION AND IN-VITRO STUDIES OF ANTHELMINTIC AND ANTIOXIDANT ACTIVITY OF POLIANTHES TUBEROSA LINN., FLOWERS EXTRACT

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Helminthiasis remains a major neglected tropical disease worldwide, particularly affecting populations in developing countries and causing significant morbidity and economic burden. The emergence of drug resistance, limited efficacy of existing anthelmintic agents, and associated adverse effects have emphasized the need for safer and effective alternatives from natural sources. Medicinal plants rich in bioactive phytoconstituents continue to serve as promising candidates for the development of novel therapeutic agents. In this context, the present study was undertaken to evaluate the in-silico, phytochemical characterization, and in-vitro anthelmintic and antioxidant activities of the methanolic flower extract of Polianthes tuberosa Linn. The flowers of Polianthes tuberosa Linn. were collected, authenticated, shade-dried, and subjected to extraction by maceration using methanol as solvent. Preliminary phytochemical screening of the methanolic extract revealed the presence of flavonoids, terpenoids, phenolic compounds, steroids, glycosides, and other secondary metabolites. Chromatographic analysis was carried out using Thin Layer Chromatography (TLC), followed by Gas Chromatography– Mass Spectrometry (GC-MS) to identify major bioactive constituents present in the extract. Quantitative estimation of total flavonoid content (expressed as rutin equivalent) and total terpenoid content (expressed as ursolic acid equivalent) was performed using UV-Visible spectrophotometric methods. In-silico studies were conducted using SwissADME to evaluate drug-likeness properties based on Lipinski's rule of five. Molecular docking analysis of selected GC-MS identified phytoconstituents was performed using AutoDock and PyRx software against selected protein targets associated with helminthiasis to understand possible binding interactions and mechanisms of action. The in-vitro anthelmintic activity of the methanolic flower extract was evaluated using Pheretima posthuma (Indian earthworm) as the experimental model, and the results were compared with the standard drug albendazole. The extract exhibited significant, dose-dependent anthelmintic activity as evidenced by reduced paralysis and death times of worms. Antioxidant activity was assessed using the DPPH radical scavenging assay, and the extract showed notable free radical scavenging potential, indicating strong antioxidant activity. Overall, the findings of the present study suggest that the methanolic flower extract of Polianthes tuberosa Linn. possesses promising anthelmintic and antioxidant activities, supported by phytochemical constituents and in-silico molecular docking results. This study scientifically validates the traditional use of Polianthes tuberosa and highlights its potential as a natural source for the development of novel anthelmintic agents. Further in-vivo and clinical investigations are recommended to establish its safety and therapeutic efficacy.

Keywords: Polianthes tuberosa Linn., Phytochemical characterization, In silico studies, Anthelmintic activity, Antioxidant activity, Molecular docking, GC–MS analysis.

PP024

AI ENABLED DIGITAL TWIN FRAMEWORK FOR PRECISION ONCOLOGY INTEGRATING MOLECULAR BIOLOGY AND CHEMOTHERAPY DYNAMICS – A CONCEPTUAL FRAMEWORK

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Rationale: Cancer remains a major global health burden, marked by biological complexity, therapeutic resistance, and wide variability in patient response to treatment. Although chemotherapy continues to be a central component of cancer care, treatment decisions are largely based on population level evidence and standardized protocols. Such approaches fail to fully account for individual differences in tumor biology, host pharmacokinetics, treatment tolerance, and disease evolution. Rapid advances in molecular profiling and data generation have created new opportunities for personalization, yet the lack of integrative and predictive frameworks limits their clinical translation. There is a growing need for systems that can synthesize diverse data streams into actionable, patient specific insights.

Statement of Hypothesis: This conceptual work hypothesizes that an Artificial Intelligence enabled digital twin, designed as a dynamic computational representation of an individual patient's tumor and treatment response, can improve therapeutic precision by predicting chemotherapy efficacy, toxicity, and resistance patterns before clinical deterioration occurs.

Conceptual Methodology: The proposed framework describes a multi layered digital twin architecture that evolves alongside the patient. It integrates longitudinal clinical data, molecular and cellular biology, tumor microenvironment interactions, chemotherapy pharmacokinetics and pharmacodynamics, and artificial intelligence driven analytics. Genomic, transcriptomic, proteomic, imaging, and patient reported data are continuously incorporated to simulate tumor behavior and treatment effects. Machine learning and deep learning models identify complex biological patterns, while adaptive algorithms refine predictions as new data become available. The digital twin functions as a virtual testing environment in which alternative treatment strategies can be explored safely.

Expected Outcomes: Implementation of this framework is expected to enhance individualized treatment selection, enable early detection of therapeutic resistance, and support optimization of chemotherapy dosing and scheduling. By anticipating toxicity and inefficacy, the system may reduce unnecessary treatment exposure, lower healthcare costs, and improve patient quality of life. Additionally, digital twins may accelerate research through virtual clinical trials and hypothesis testing.

Conclusions: An AI enabled digital twin framework represents a transformative approach to precision oncology. By unifying molecular biology, chemotherapy dynamics, and predictive analytics within a continuously learning system, this model shifts cancer care from reactive decision making toward proactive and personalized management. While technical, ethical, and regulatory challenges remain, this conceptual framework provides a roadmap for future development and clinical integration.

Key Words: Digital Twin, Precision Oncology, Artificial Intelligence, Chemotherapy Modeling, Molecular Biology

PP025

SYNERGIZING PHARMACOGENOMICS, CLINICAL PHARMACY SERVICES AND HEALTH ECONOMICS FOR OPTIMIZED

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Rationale: Inflammatory Bowel Disease Care Rationale: Inflammatory Bowel Disease is a chronic and heterogeneous condition marked by wide variability in disease course treatment response and risk of adverse drug reactions. Despite therapeutic advances, a significant proportion of patients fail to achieve sustained remission and many experience treatment related toxicity. Current management strategies are largely reactive and population based, and do not adequately account for biological variability or long term value of care. Rising use of high cost biologic and targeted therapies has further intensified the economic burden on healthcare systems. These challenges underscore the need for an integrated personalized and value oriented approach to inflammatory bowel disease care.

Statement of Hypothesis: This conceptual work is based on the hypothesis that integrating Pharmacogenomics guided risk stratification with Clinical Pharmacist led therapeutic optimization and Health Economics and Outcomes Research based value assessment can improve clinical outcomes, enhance patient experience, and deliver more sustainable inflammatory bowel disease care.

Conceptual Methodology: A structured conceptual framework is proposed that brings together three interdependent domains within routine Inflammatory Bowel Disease care pathways. Pharmacogenomics is positioned as the predictive component enabling early identification of genetic variants that influence drug metabolism efficacy and toxicity. Clinical pharmacist function as the implementation arm translating genetic insights into actionable interventions through genotype guided dosing, Therapeutic Drug Monitoring, adherence support and patient education. Health Economics and Outcomes Research provides the evaluative layer assessing cost effectiveness, Quality Adjusted Life Years and budget impact of the integrated model compared with standard care. The framework is designed to be embedded within multidisciplinary teams and supported by electronic health records and clinical decision support systems.

Expected Outcomes: Clinically, the integrated approach is expected to improve remission rates, reduce Adverse Drug Reactions, and minimize treatment failures through better drug selection and dosing. From a patient perspective, improved disease control, fewer complications and pharmacist led education are anticipated to enhance quality of life and engagement in care. Economically the framework aims to reduce hospitalizations, emergency visits and unnecessary therapy escalation leading to meaningful cost savings while improving overall value of care.

Conclusions: This conceptual framework illustrates how the strategic alignment of pharmacogenomics, clinical pharmacy services and Health Economic principles can transform Inflammatory Bowel Disease management from a ‘one size fits all model’ to a personalized value based approach. By addressing biological variability, optimizing therapeutic execution and demonstrating economic value, the model supports safer more effective and sustainable care. Future prospective studies and policy support will be essential to translate this framework into routine practice.

Key Words: Inflammatory Bowel Disease, Pharmacogenomics, Clinical Pharmacy, Health Economics, Personalized Care

PP026

COMMUNITY PHARMACY PRACTICE MODEL FOR PHARMACOGENOMICS DRIVEN PATIENT CARE - A LITERATURE BASED CONCEPTUAL FRAMEWORK

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Variability in drug response remains a major challenge in routine clinical practice despite advances in pharmacotherapy. Adverse Drug Reactions, treatment failure and avoidable hospital admissions continue to place a significant burden on patients and healthcare systems. A large proportion of these medication related problems arise from genetic differences that influence drug metabolism transport and target response. Pharmacogenomics provides a robust scientific basis for predicting such variability, yet its clinical application remains limited and largely confined to specialist or hospital settings. This restricted model reduces accessibility, increases costs and widens inequities in care. Community pharmacies represent an underutilized but strategically positioned platform to extend pharmacogenomics into everyday patient care due to their accessibility, longitudinal medication oversight, and established role in pharmaceutical care. This conceptual framework is based on the hypothesis that a structured Community Pharmacist led Pharmacogenomics practice model can improve medication safety, therapeutic effectiveness and patient centered outcomes while supporting cost effective and equitable delivery of precision medicine.

A practice oriented, literature based conceptual framework is proposed that embeds Pharmacogenomics within routine Community Pharmacy services. The model outlines key components including service governance professional training, patient identification, pretest counseling, informed consent, sample collection, interpretation of genetic results and collaborative therapeutic recommendations. Evidence based international Pharmacogenomics guidelines are used to translate genetic information into clinically actionable advice on drug selection dosing and monitoring. Pharmacists work in collaboration with prescribers and integrate follow up and monitoring into ongoing pharmaceutical care. Secure data management and linkage with health records support continuity of care ethical practice and quality assurance. Clinically the model is expected to reduce preventable adverse drug reactions, improve therapeutic response and minimize trial and error prescribing. Patients are anticipated to benefit from greater understanding of their medicines increased confidence in therapy and stronger engagement in shared decision making. From a health system perspective, targeted Pharmacogenomics services delivered through community pharmacies may reduce hospital admissions, emergency visits and treatment failures thereby improving efficiency and value of care.

This conceptual framework demonstrates how Community Pharmacies can serve as a practical and ethical gateway for Pharmacogenomics driven patient care. By aligning genetic insights with pharmaceutical care principles, the model supports a shift from generalized prescribing toward personalized and safer medication use. Decentralizing Pharmacogenomics through Community Pharmacy Practice has the potential to transform precision medicine from a specialized service into a routine element of patient centered healthcare. The framework provides a foundation for pilot implementation outcomes research and policy development aimed at advancing next generation pharmacy practice.

Key Words: Pharmacogenomics, Community Pharmacy Practice, Precision Medicine, Medication Safety, Patient Centered Care

PP027

TARGETED XENOBIOTIC ACTIVATION FOR PRECISION THERAPEUTICS - A MOLECULARLY GUIDED CONCEPTUAL FRAMEWORK

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Rationale: Xenobiotics play a central role in the management of cancer and chronic inflammatory diseases, yet their clinical utility is often constrained by systemic toxicity, limited tissue selectivity, and unpredictable patient responses. Conventional therapeutic strategies rely on systemic drug exposure to achieve efficacy, frequently resulting in damage to healthy tissues and dose limiting adverse effects. Despite advances in targeted delivery and diagnostics, many drugs still fail to adequately distinguish between diseased and normal tissues. There is a clear need for therapeutic approaches that align drug activity more closely with disease specific molecular characteristics.

Hypothesis: This conceptual work hypothesizes that therapeutic precision can be enhanced by designing Xenobiotics that remain inactive during systemic circulation and are selectively activated within diseased tissues by disease specific molecular features such as enzyme over expression, altered metabolism, and redox imbalance, thereby focusing drug action at the site of pathology while minimizing toxicity to healthy tissues.

Conceptual Methodology: The proposed framework emphasizes molecular selectivity rather than passive targeting. It involves identification of disease specific biochemical features, rational chemical design of inactive Xenobiotics, site specific activation through molecular interaction, and localized therapeutic action. Enzyme specific activation strategies utilize elevated enzyme activity within pathological tissues to trigger drug release. Metabolism based activation exploits disease related metabolic reprogramming, particularly in tumors. Redox sensitive activation responds to oxidative or reductive environments characteristic of malignant or inflamed tissues. Together, these strategies enable spatial separation of drug distribution and drug action, supporting precise local therapy.

Expected Outcomes: Targeted Xenobiotic activation is expected to lower systemic toxicity by restricting the exposure of healthy tissues to the active form of the drug. Improved therapeutic index may allow higher effective local concentrations without exceeding safety thresholds. In oncology, selective tumor activation may spare normal proliferative tissues and enhance treatment tolerance. In inflammatory diseases, localized activation may reduce systemic immunosuppression and associated complications.

Conclusion: Targeted xenobiotic activation represents a biologically informed and clinically relevant approach to precision therapeutics. By integrating molecular understanding of disease with rational drug design, this framework addresses fundamental limitations of conventional pharmacotherapy. When combined with molecular diagnostics and patient stratification, it offers a promising pathway toward safer and more effective treatments across diverse disease settings.

Key Words: Precision Therapeutics, Targeted Xenobiotic Activation, Molecular Targeting

PP028

AI DRIVEN PREDICTION OF XENOBIOTIC RESPONSES FOR PRECISION THERAPEUTICS - A MULTI-OMICS CONCEPTUAL FRAMEWORK

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Xenobiotics - including therapeutic drugs, environmental chemicals and dietary compounds show wide inter-individual variability in efficacy safety and optimal dosing. Conventional pharmacotherapy largely depends on population-based strategies and limited biomarkers, which fail to explain complex biological responses in many patients. Although Pharmacogenomics has improved prediction for selected drug gene pairs, it does not fully capture the dynamic molecular processes that shape xenobiotic response. Persistent Adverse Drug Reactions, therapeutic failure and inappropriate dosing highlight the need for a more comprehensive and predictive approach. Recent advances in multi-omics technologies and Artificial Intelligence provide an opportunity to address this gap by integrating biological complexity into clinically meaningful decision support.

This conceptual framework is based on the hypothesis that integration of Genomic, Transcriptomic and Proteomic data through Artificial Intelligence driven modeling can reliably predict individual xenobiotic responses including efficacy, toxicity risk and optimal dosing thereby enabling proactive and precise therapeutic decision making.

The proposed framework adopts a systems level approach that combines patient specific multi-omics data with advanced Artificial Intelligence models. Genomic data capture inherited variation in drug metabolizing enzymes transporters and receptors whereas Transcriptomic data reflect dynamic gene expression changes influenced by disease state and environmental exposure. On the other hand, Proteomic data represent functional protein activity and provide a direct link to phenotype. These heterogeneous datasets undergo structured preprocessing integration and quality control before being analyzed using Machine Learning as well as Deep Learning models capable of identifying complex nonlinear relationships. Predictive outputs are designed to be interpretable and aligned with biological pathways to support clinical confidence. The final stage involves translation of predictions into actionable recommendations for drug selection toxicity risk estimation and individualized dosing supported by clinical decision systems.

The framework is anticipated to enhance the precision of drug response prediction, minimize reliance on trial and error prescribing, and enable earlier recognition of potential toxicity risks. Personalized dosing strategies may reduce under treatment and over exposure particularly for drugs with narrow therapeutic ranges. Collectively these outcomes support safer therapy improved effectiveness and better alignment of treatment with individual biology.

This conceptual framework illustrates how Artificial Intelligence combined with multiomics data can transform xenobiotic based therapy from a reactive model to a predictive and personalized paradigm. By integrating genetic predisposition molecular regulation and functional protein activity the approach addresses key limitations of conventional pharmacotherapy. While conceptual in nature the framework aligns with ongoing advances in molecular science and computational medicine and provides a foundation for future validation and clinical translation.

Key Words: Xenobiotics, Precision Therapeutics, Artificial Intelligence, Multi-Omics, Personalized Medicine

PP029

AI-DRIVEN CLINICAL DECISION SUPPORT INTEGRATING ANTI-CITRULLINATED PROTEIN ANTIBODIES FOR DETECTING SUBCLINICAL INFLAMMATION AND GUIDING THERAPY IN RHEUMATOID ARTHRITIS

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Rheumatoid arthritis (RA) is a chronic autoimmune disease that can lead to progressive joint damage, disability, and reduced quality of life. There have been many advances in Disease Modifying Anti-Rheumatic Drugs (DMARDs) that enables numerous patients to achieve clinical remission or low disease activity. The growing evidence suggests that immunological disease activity may persist even when clinical symptoms appear well controlled. This hidden, subclinical inflammation is an important driver of structural joint damage but is often missed by routine disease activity scores and standard laboratory markers. Although advanced imaging can uncover such inflammation but its routine use is limited by cost, accessibility, and operator dependence. Anti-Citrullinated Protein Antibodies (ACPAs) are highly specific to RA and are closely linked to disease pathogenesis, yet their role is beyond diagnosis particularly in ongoing disease monitoring and treatment guidance that is still underexplored. Integrating ACPA based biomarker information with artificial intelligence (AI) offers a promising opportunity to address this gap in care.

This conceptual framework hypothesize that an AI-driven Clinical Decision Support System (CDSS) incorporating quantitative and longitudinal ACPA profiles, alongside clinical, laboratory, and imaging data can improve the detection of subclinical inflammation and supports personalized therapeutic decision making in patients diagnosed with RA.

The proposed framework outlines a longitudinal and observational model for developing an AI based clinical decision support system. Anti Citrullinated Protein Antibodies are treated as dynamic indicators of immunological activity rather than static diagnostic markers. The system integrates serological data, disease activity measures, inflammatory markers, imaging findings when available, treatment history, and patient reported outcomes. Machine learning algorithms analyse complex interactions among these variables to identify patterns associated with hidden inflammation and disease progression. Model training and validation are conceptually designed using retrospective and prospective datasets, with performance assessed through clinically relevant metrics such as sensitivity and specificity. The resulting system provides risk stratification and actionable insights to support clinician judgement.

The proposed CDSS is expected to improve sensitivity for detecting subclinical inflammation particularly among patients considered to be in clinical remission. Earlier identification of immunological risk enables timely treatment adjustments, closer monitoring, or targeted use of imaging. This approach has the potential to reduce long term joint damage and preserve functional capacity by supporting individualized treatment strategies that can avoid unnecessary exposure to intensive therapies. More broadly, it illustrates the translational value of AI assisted biomarker integration in immune mediated diseases

This conceptual framework highlights the potential of combining disease specific autoantibody biomarkers with AI-driven clinical decision support to advance precision medicine in rheumatoid arthritis. By bridging immunological insight with computational analytics, this approach offers a scalable pathway to improving disease monitoring, optimizing therapy, and enhancing patient outcomes in routine clinical practice.

Keywords: Rheumatoid Arthritis, Anti-Citrullinated Protein Antibodies; Artificial Intelligence, Clinical Decision Support System

PP030

ISOLATION AND CHARACTERIZATION OF LEMON JUICE-DERIVED EVS FOR POTENTIAL THERAPEUTIC APPLICATION IN DIABETIC FOOT ULCER

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Aim: The study aimed to isolate and characterize extracellular vesicles (EVs) from lemon juice using optimized precipitation and analytical techniques, and to evaluate their physicochemical and biochemical properties for potential therapeutic application in promoting the healing of diabetic foot ulcer.

Methodology: Lemon juice-derived extracellular vesicles (LEVs) were isolated using polyethylene glycol (PEG) precipitation across a pH range of 1–9. EVs' yield was quantified at each pH, and size, zeta potential, and concentration were characterized using DLS and NTA. Vesicle morphology and structural integrity were confirmed using TEM analysis. The presence of phospholipid bilayer, protein and carbohydrate signatures was confirmed using AT-FTIR. Based on yield, pH 5–7 was selected for detailed analysis. Biochemical profiling within this range included nucleic acids (Nanodrop), proteins (Bradford assay), sugars (gravimetric method), lipids (HPTLC), vitamin C (DNPH assay), and antioxidant studies (DPPH assay), establishing the physicochemical and biochemical attributes of LEVs under optimal pH conditions.

Results and Discussion: EVs yield increased with an increase in the pH gradient. However, at an optimal pH (5–7), PEG interacted more effectively with EVs without causing aggregation or degradation, leading to a higher yield: 13 ± 1 mg/mL, 14 ± 2 mg/mL, and 13 ± 1 mg/mL. EVs showed a particle size of 191 ± 24, 116 ± 9, and 152 ± 26 nm at pH 5, 6, and 7, respectively. The zeta potential was observed to be > – 30mV, due to the presence of surface phospholipids and proteins, ensuring stability. The measured concentration of EVs by NTA was $1.62x10^9$, $1.80x10^9$, and $1.33x10^9$ particles/mL, at pH 5, 6, and 7, respectively. TEM images showed cup-shaped structures, providing the same size range, complementing DLS/NTA analyses. AT-FTIR provided a biochemical fingerprint of EVs by identifying functional groups (C–H stretching vibrations, C–O and C–C stretching, amide I/II bands, and broad O–H stretching). The total nucleic acid content at pH 5, 6, and 7 was 3.3 ± 0.5 ng/µL, 4 ± 0.3 ng/µL, and 3 ± 0.2 ng/µL, respectively. The total protein content at pH 5, 6, and 7 was 46 ± 4 µg/mL, 50 ± 7 µg/mL, and 37 ± 4 µg/mL, respectively. The total sugar content at pH 5, 6, and 7 was 17 ± 2 mg/mL, 20 ± 3 mg/mL, and 12 ± 2 mg/mL, respectively. HPTLC analysis revealed a slightly higher lipid content in EVs isolated at pH 5 compared to those obtained at pH 6 and 7. The total vitamin C content at pH 5, 6, and 7 was 180 ± 12 µg/mL, 312 ± 21 µg/mL, and 282 ± 13 µg/mL, respectively. The DPPH assay confirmed that EVs exhibit significant ROS scavenging activity across different pH conditions, with the highest activity (65–70%) observed at pH 6 compared to pH 5 and pH 7.

Conclusion: Taken together, LEVs can be efficiently isolated using PEG precipitation, producing bioactive vesicles for the healing of diabetic foot ulcer.

PP031

FORMULATION DEVELOPMENT AND EVALUATION OF SOLUBLE MICRONEEDLES BEARING TACROLIMUS CUBOSOMES

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The aim of the present investigation was to develop soluble microneedles bearing cubosomal Tacrolimus with an objective to enhance its oral bioavailability. Tacrolimus is an immunosuppressant having potential benefit in the treatment of Rheumatoid arthritis. The oral delivery of Tacrolimus is associated with limitations such as poor bioavailability due to extensive first pass metabolism and poor solubility. Moreover, its chronic administration leads to gastrointestinal disturbances. Transdermal delivery was thus selected as a preferred route for administration of Tacrolimus. However, the tough stratum corneum barrier poses resistance to penetration of most of the drug molecules. Thus, cubosomes were investigated as the vesicular carriers for enhancement of transdermal permeation as they are biocompatible, biodegradable, and comparatively economical and can entrap higher amounts of drugs compared to other vesicular carriers. In order to facilitate the penetration of the nanocarriers, soluble microneedles were fabricated. The optimization of the formulation and process parameters was done using quality by design approach and 3^2 factorial design. The optimized batch was evaluated for various *in-vitro*, *ex-vivo* and *in-vivo* parameters. The developed cubosomes had size around 150 nm with high entrapment efficiency of more than 90%. The small angle x-ray scattering analysis (SAXS) indicated the presence of water channels inside the cubosomes. *In-vitro* release study indicated significantly higher release from the cubosomes compared to plain drug. The developed microneedles had sufficient mechanical strength and sharpness to pierce the skin. Ex-vivo studies indicated more than 7 folds increase in the transdermal flux of soluble microneedles bearing cubosomal Tacrolimus compared to the plain drug. Histopathology studies showed clear formation of microchannels. *In-vivo* pharmacokinetic study showed more than 3 folds enhancement in bioavailability compared to the marketed oral tablet. *In-vivo*pharmacodynamic study was done using measurement of paw volume in arthritis induced joints, body weight, RA factor and bone X-ray and the results indicated comparable efficacy with the marketed tablet formulation. Stability studies indicated that the cubosomes of Tacrolimus were stable at room temperature while microneedle patch required special type of packaging to prevent moisture absorption as it leads to softening of microneedles. In conclusion, the developed microneedle patch bearing cubosomal Tacrolimus seems to be a safer and effective alternative to the oral dosage form.

PP032

SELECTED FOR ORAL PRESENTATION

PP033

COMPARATIVE EVALUATION OF SUSTAINED OCULAR NANOPARTICULATE SYSTEMS DELIVERING BIOACTIVE FOR DIABETIC RETINOPATHY

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Objective: Diabetic retinopathy is a progressive microvascular disease of diabetes that may result in severe vision impairment. Current ocular delivery of drugs is hindered by limited bioavailability and fast precorneal elimination, restricting prolonged therapeutic efficacy. This study aimed to design and comparatively evaluate two nanoparticulate systems containing a bioactive component (BIA) derived from Nigella sativa to facilitate prolonged and sustained ocular administration for the therapy of diabetic retinopathy.

Methods: The BIA was isolated from Nigella sativa seeds by Soxhlet and maceration methods, thereafter going through chromatographic purification to achieve a high-purity fraction. The characterisation of the isolated BIA includes thin-layer chromatography (TLC), UV–visible spectroscopy, highperformance liquid chromatography (HPLC), differential scanning calorimetry (DSC), Fourier transform infrared spectroscopy (FTIR), and powder X-ray diffraction (P-XRD). Two delivery platforms were developed: (1) a nanoemulsion hydrogel utilising selected surfactant and cosurfactant, optimised for solubility and emulsification efficiency, prepared through a lowenergy stirring technique and integrated into a hydrophilic polymer hydrogel to improve ocular retention; and (2) polymeric nanoparticles encapsulating BIA, fabricated using biodegradable polymer via the thin-film rotary evaporation method followed by probe sonication. The optimised nanoparticles have been incorporated into dissolving polymeric hydrophilic microneedles comprehensively characterised for physicochemical parameters, encapsulation efficiency, and in vitro drug release behaviour.

Results: The analytical characterisation confirmed the purity of the BIA and revealed no substantial interactions between the medication and excipients. The nanoemulsion hydrogel and microneedle nanoparticle systems were assessed for droplet/particle size, encapsulation efficiency, polydispersity index (PDI), adhesion characteristics, and in vitro drug release kinetics. Both formulations exhibited a homogeneous size distribution (<200 nm) and exceptional encapsulation efficiency. In-vitro release profiles demonstrated prolonged diffusion of BIA over an extended duration in comparison to conventional control formulations.

Conclusion: The optimised nanoparticulate ocular delivery systems demonstrated superior physicochemical stability, increased bioavailability, and extended release profiles, establishing them as promising candidates for effective sustained therapy in diabetic retinopathy. These results endorse additional preclinical research aimed at translational applicability.

PP034

DEVELOPMENT OF LORNOXICAM EMULGEL FOR RHEUMATOID ARTHRITIS

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The present study was intended for the development of an emulgel-based drug delivery system for rheumatoid arthritis. Rheumatoid arthritis is an enduring inflammatory disease that is categorized by bumping off the joint and rigidity, bone,and cartilage devastation all above the joints. The disease is allied with the molecules of major histocompatibility complex, dependent T- Cells. Emulgels are a combinationof emulsions of oil in water or water in oilemulsions gelled with a gelling agent. Lornoxicam-based emulgels were prepared by dispersing emulsion in gel in the ratio1:1. The developed emulgels were characterized for pH, viscosity, spreadability, drug content, zeta potential, *in-vitro* release studies and ex-vivopermeation studies. The results indicated the acceptability of the prepared emulgels by the evaluation tests. *In-vitro* release studies showed that the release of lornoxicam varied according to the percentage of gelling agent and permeation enhancer used in emulgel. Based on the *in-vitro* results, four formulations were selected for the ex-vivo studies and were evaluated for drug permeation across the skin. From the cell line studies it was concludedthat formulation FEG3 did not show any anti -inflammatory activity The results of this research work proved that the developed emulgels will provide a better delivery system for treating rheumatoid arthritis. The accelerated stability studies were carried for selected formulations and results showed an acceptable range of stability.

Keywords: Emulgels, Lornoxicam, Carbopol 934, Aloe, Eucalyptus oil.

PP035

FROM MINITABLETS TO MUPS: A PATIENT-CENTRIC ONCE-DAILY VONOPRAZAN PLATFORM WITH SUPERIOR INVIVO ANTI-ULCER PERFORMANCE

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Aim: To develop a once-daily sustained-release multiparticulate drug delivery system (MPDDS) of Vonoprazan Fumarate for consistent 24-hour acid suppression in the management of acid-related disorders.

Objectives: The study aimed to design and optimize sustained-release minitablets of Vonoprazan Fumarate using a Quality by Design approach and convert them into multiple unit pellet systems (MUPS) suitable for tablets and capsules, while evaluating their in vitro performance, in vivo efficacy, and shortterm stability.

Methodology: Sustained-release minitablets were formulated using hydrophilic (HPMC K100M) and hydrophobic (Ethyl Cellulose) polymers and optimized through a Central Composite Design. The optimized formulation (F10) was evaluated for physicomechanical properties, drug content uniformity, and in vitro release behavior. The minitablets were further assembled into MUPS tablets and capsules and assessed for disintegration and mechanical integrity. In vivo pharmacodynamic evaluation was conducted using a rat model of feed fast–induced gastric ulcers, with ulcer index determination and histopathological examination to assess mucosal healing. Shortterm stability studies were performed for 30 days.

Results and Discussion: The optimized formulation (F10) exhibited excellent mechanical properties with friability of 0.3%, hardness of 3.5 kN, uniform weight variation (±5%), and drug content of 98.2 ± 1.5%. Sustained drug release of 90.22% over 24 hours was achieved, following Korsmeyer–Peppas kinetics (R^2 = 0.8347), indicating an anomalous transport mechanism. MUPS tablets demonstrated acceptable weight variation (495.2–504.8 mg), hardness (5.5–6.2 kg/cm²), thickness (3.8–4.5 mm), and rapid disintegration (<5mins)

In vivo pharmacodynamic studies revealed markedly superior anti-ulcer efficacy of the MUPS formulation, with rapid mucosal healing evidenced by ulcer index reduction from 6 to 0 within 2 hours of treatment, whereas the marketed formulation required one week to achieve comparable healing. Histopathological analysis confirmed complete epithelial regeneration, restoration of gastric mucosal architecture, and absence of neutrophilic infiltration in animals treated with the optimized MUPS, indicating effective gastric protection and accelerated healing. Stability studies confirmed formulation robustness with 96.9% drug content and 88.13% cumulative drug release after 30 days.

Conclusion: The developed sustained-release MUPS of Vonoprazan Fumarate demonstrates robust in vitro performance and pronounced in vivo anti-ulcer efficacy, offering rapid mucosal healing and reliable 24-hour acid suppression. This patient-centric, once-daily MPDDS represents a significant advancement in the pharmacotherapy of acid-related disorders and highlights its potential translational relevance in xenobiotic drug delivery and gastrointestinal protection.

PP036

INVASOME-MEDIATED INTRAVAGINAL DRUG DELIVERY: A MUCOADHESIVE APPROACH FOR SUSTAINED CONTRACEPTION

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The current project centers on the creation of a mucoadhesive gel for intra-vaginal use, containing papaya seed extract loaded invasomes for prolonged effectiveness as a locally acting contraceptive delivery system. Carica papaya seed extract was opted for its spermicidal properties attributed to its variety of bio-active compounds.The decision to load it into invasomes was influenced by the consistent and reliable drug delivery performance of invasomes compared to other nanosystems. The invasomes loaded with the drug were then incorporated into a mucoadhesive gel, chosen for its suitability in vaginal drug delivery. An appropriate optimization plan was implemented to develop the most optimal formulation, with lipid concentration (X1), terpene concentration (X2) and chitosan concentration (X3) as independent variables, and particle size (Y1) and PDI (Y2) as dependent variables. The invasomes were created using the thin-film hydration technique, and after conducting 15 formulation experiments, the optimized formulation (F-2) was chosen based on various pharmaco-technical parameters. Invasomal colloidal dispersion was added to a Carbopol gel base to create a mucoadhesive gel. The INVs that were prepared underwent evaluation, with the optimal formulation resulting in a particle size of 176.7 nm and a PDI of 0.618.The viscosity was approximately 15.6 Pa·s, which was deemed suitable for mucoadhesion. Through TEM analysis, it was confirmed that the invasomes were present in a spherical form without any clumping. The gel, when inserted into the vaginal cavity, effectively immobilized the sperm.The treated group showed a lower rate of conception and fewer motile sperms compared to the control group, demonstrating spermicidal activity in rabbits.In conclusion, the C. papaya seed extract-loaded INV gel appears to be a safe and efficient formula that can prolong the presence of the extract within vaginal layers, aiding in birth control with minimal systemic side effects.

Keywords: C.papaya seed extract, Invasomes, Spermicide, Optimization, Mucoadhesion

PP037

ETHOSOMAL GEL-BASED DELIVERY OF COW URINE POWDER FOR ENHANCED TOPICAL MANAGEMENT OF PSORIASIS

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The primary objective of this study is to create an ethosomal gel loaded with cow urine powder for the treatment of psoriasis. Poor percutaneous penetration and targeting into the deeper layers of the skin frequently limit the administration of antipsoriatic medicines using traditional topical formulations. Ethosomes and other nanocarriers have shown promise in delivering antipsoriatic active substances to specific skin regions. By guaranteeing the drug's location within the skin and reducing adverse effects, these innovative formulations enhance healing. Using the cold method, fifteen formulations (ET1–ET15) of cow urine powder ethosomes were made with different amounts of phospholipid (3–5% w/w), cholesterol (0.1–1%), ethanol (20–30% v/v), and 1% cow urine powder. JMP statistical software with a Box-Behnken design was used for optimization. Formulations were assessed for PDI and vesicular size. Because of its ideal vesicle size and PDI, formulation ET2 (30% v/v ethanol and 5% w/w phospholipid) was chosen as the optimum formulation. On ET2, zeta potential and TEM studies were also carried out. The improved formula's particle size, PDI, and zeta potential were determined to be 186.8 nm, 0.201, and -46.3mV, respectively. Carbopol 934 (1% w/w) was used as a gelling foundation to further incorporate this into a gel. To improve the formulation's quality, nourishing ingredients including curcumin and aloevera were included.The formulations' anticipated antipsoriatic ability was tested in vivo using an imiquimod-induced psoriasis model in Balb-c mice. The findings suggested that CUP ethosomes could be a topical formulation that is both safe and effective. The improved formulation's accelerated stability tests revealed physicochemical integrity without appreciable degradation. Therefore, cow urine powder may be used as a possible psoriasis management tool.

Keywords: Cow urine powder, Cold method, Ethosomes, Ethosomal gel, Box Behnken design.

PP038

DEVELOPMENT AND EVALUATION OF TRANSUNGUAL ANTIFUNGAL NANOMIEMGEL FOR THE TREATMENT OF ONYCHOMYCOSIS

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Onychomycosis is a fungal infection of the nail unit characterized by discoloration and disfigurement of the nail often causing pain and discomfort. Voriconazole was formulated as a topical bioadhesive nanomiemgel for treatment of onychomycosis by combining nanomicelles and nanoemulsion in carbopol 940 gel base. A nanoemulsion was prepared by plotting a pseudo-ternary phase diagram. Oleic acid as oil, Tween-80 and isopropyl alcohol as S_{mix} were used for nanoemulsion preparation by aqueous titration method. Nanomicelles was prepared for 1:10 ratio using poloxamer 188 and soya lecithin by solvent evaporation and thin film hydration technique. Nanomiemgel was formulated by incorporating nanomicelles NM1 and nanoemulsion NEM2 from the trial formulations in carbopol 940 as a gelling agent. Penetration enhancers thioglycolic acid: transcutol and bioadhesive polymers HEC were incorporated into the nanomiemgel NMG1. Evaluation and characterization were done for the standardised nanoemulsion NEM2, nanomicelles NM1 and nanomiemgel NMG1 formulations. Entrapment efficiency of NM1 was found to be 82.45%. Residual Solvent analysis of NM1 confirmed that methanol and chloroform were within the ICH Q3 prescribed limit. Drug content of nanomiemgel was found to be 94.34%. Particle size, polydispersity index and zeta potential values of NEM2, NM1 and NMG1 was found to be 237.7, 117.6 and 387.4 nm; 0.005, 0.265 and 0.254; -9.10, -9.21 and -25.20 respectively. The prepared nanomiemgel was whitish in color with better spreadability and bioadhesiveness. Antifungal study of NMG1 exhibited convincing antifungal activity against *Candida albicans* with 32 mm of effective zone of inhibition compared to 35 mm of standard. *In vitro* and *ex vivo* permeability studies in dialysis membrane-70 and goat nail of NMG1 showed 92.16 % and 84.33% with flux of 1063.33 and 836 µg/cm³/h after 6 h respectively. Flux of NMG1 was more through dialysis membrane than the goat nail due to inherent limitations. Accelerated stability studies indicated better stability of the standard formulation without any striking changes in the physicochemical parameters. Thus, it can be concluded that nanomiemgel of voriconazole was proved to be a flexible and effective transungual system over individual formulations for the treatment of onychomycosis.

Keywords: Voriconazole, Nanoemulsion, Nanomiemgel, Transungual system, Onychomycosis.

PP039

FORMULATION OF COATED MULTI-NUTRIENT GRANULES FOR RUMEN BYPASS AND ENHANCED LIVESTOCK NUTRITION

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Ruminant nutrition faces persistent challenges in delivering essential nutrients efficiently, as conventional feed supplements are often degraded in the rumen before reaching the intestinal absorption sites, limiting their bioavailability and therapeutic efficacy. Traditional nutrient delivery systems fail to protect sensitive compounds from ruminal microbial degradation, necessitating higher dosages and increased costs for livestock producers. In contrast, rumen bypass technology protecting nutrients through specialized coating systems offers a more efficient pathway to enhance nutrient absorption by ensuring active ingredients reach the intestinal tract intact. Rumen bypass formulations provide a strategic approach to veterinary nutrition by utilizing protective coating technologies that shield nutrients from ruminal degradation, thereby maximizing bioavailability. In this study, wet granulation combined with dual coating strategies involving fat-based and acryl polymer-based systems was applied to develop multi-nutrient granules containing niacin, methionine, and QUAT for targeted intestinal delivery. This pharmaceutical approach integrates pre formulation compatibility studies using FTIR analysis and molecular docking simulations with bovine beta-lactoglobulin to predict nutrient-protein interactions and potential effects on milk production. Comprehensive characterization including pre-granulation flow properties, post-granulation performance evaluation, and in vitro release studies at physiological pH conditions (6.7 and 5.0) demonstrated controlled release profiles. Fat based coated granules showed 91.77% of drug release and acryl based coated granules showed 90.5% of drug release. QUAT content was estimated by titration method and was found to be 93.9% in fat based coated granules and 91.6% in acryl based coated granules. Assessment of formulation parameters reveals that dual coating strategies effectively achieve rumen bypass functionality while maintaining product stability under accelerated storage conditions (40 ± 2°C, 75 ± 5% RH). Targeted delivery through protective coating technologies continues to advance veterinary nutrition and guide future research toward effective solutions for ruminant health management.

Keywords: Rumen bypass technology, Targeted intestinal delivery, Dual coating strategies, Veterinary nutrition, Wet granulation.

PP040

DEVELOPMENT AND PHYSICOCHEMICAL CHARACTERIZATION OF FERMENTATION-DERIVED BIOCELLULOSE FILMS FOR WOUND DRESSING APPLICATIONS

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Hypothesis: Bacterial cellulose (biocellulose) has gained significant attention as a wound dressing material due to its high purity, biocompatibility, nanofibrous structure and exceptional moisture-retention properties. However, native biocellulose lacks inherent antimicrobial activity, which limits its effectiveness in managing infected and chronic wounds. Incorporation of trace elements known for their antimicrobial and angiogenic properties, represents a promising strategy to enhance the therapeutic performance of biocellulose-based dressings. The hypothesis of the present study states that trace element–impregnated biocellulose dressings will synergistically enhance wound healing by providing antimicrobial protection and promoting tissue regeneration while retaining the favorable physicochemical and mechanical properties of native biocellulose.

Methods: In the present phase of the study, biocellulose films were successfully produced by microbial fermentation, sterilized moist heat sterilization, and purified by alkali treatment. The obtained films were dried and evaluated for physicochemical and mechanical properties. Characterization studies included water holding capacity, swelling ratio, hydration behavior, tensile strength, and porosity measurement. Structural and morphological analyses were carried out using FTIR spectroscopy, SEM coupled with EDS, and X-ray diffraction (XRD) for dried biocellulose films. Based on these preliminary findings, the biocellulose films are planned for subsequent impregnation with trace elements, followed by evaluation of antimicrobial activity, in vitro cytocompatibility, and in vivo wound healing potential.

Supporting Data: The prepared biocellulose films demonstrated high water holding capacity, favorable swelling and hydration behavior, adequate tensile strength, and interconnected porous morphology. FTIR confirmed the characteristic cellulose functional groups, SEM revealed a dense nanofibrous network, EDS verified elemental composition, and XRD analysis confirmed the crystalline structure of biocellulose.

Results: The preliminary evaluations confirmed that the fermented biocellulose films possess physicochemical, structural, and mechanical properties suitable for wound dressing applications. The results establish a strong foundation for further functionalization of the biocellulose matrix with trace elements to enhance its biological performance.

Conclusion: The current findings indicate that biocellulose produced by fermentation exhibits properties desirable for wound dressing applications. The ongoing and future phases of this research will focus on trace element impregnation and comprehensive biological evaluation, including antimicrobial, cytocompatibility, and in vivo wound healing studies, to develop an advanced biocellulose-based dressing for accelerated wound regeneration.

Keywords Bacterial cellulose, biocellulose, fermentation, SEM, wound dressing.

PP041

DEVELOPMENT AND CHARACTERIZATION OF A CURCUMIN-BASED POLYHERBAL FORMULATION FOR ANTI-OBESITY ACTIVITY

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Obesity has emerged as a major global health concern and is closely associated with metabolic disorders such as diabetes, cardiovascular diseases and dyslipidemia. Although several synthetic anti-obesity drugs are available, their long-term use is often limited by undesirable side effects, highlighting the need for safer and more effective natural alternatives. In this context, the present study aimed to develop and evaluate a novel polyherbal formulation for obesity management using curcumin, piperine, and chlorogenic acid three well-known herbal bioactives with reported anti-obesity potential. The study involved solvent extraction of the selected herbal components followed by formulation development. Drug–excipient compatibility studies were performed to ensure formulation stability. Molecular docking studies were conducted to predict the binding affinity of the active compounds with obesityrelated targets and were compared with the standard drug orlistat. The formulation was further evaluated for physicochemical properties, powder characteristics, and in-vitro release behaviour. Accelerated stability studies were carried out to assess formulation robustness. Among the developed formulations, the optimized formulation (F6), containing varied concentrations of sweetening agents to improve palatability, exhibited superior performance. Docking studies revealed that the herbal actives showed strong binding affinity comparable to orlistat. In-vitro release studies demonstrated rapid and significant release of the active compounds in aqueous medium, with 95.45% release of chlorogenic acid, 90% release of piperine, and 93.52% release of curcumin within 60 seconds. Stability studies confirmed that the formulation remained physiochemically stable within acceptable limits under accelerated conditions. The results of this study indicate that the developed polyherbal formulation possesses promising potential as a safe, stable, and effective alternative for obesity management. The synergistic combination of curcumin, piperine, and chlorogenic acid may offer enhanced therapeutic benefits compared to individual components.

Keywords: Chlorogenic acid, Piperine, Curcumin, Anti-obesity, Polyherbal Formulation.

PP042

DEVELOPMENT OF FAST DISSOLVING TABLETS OF GLIMEPERIDE

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Glimepiride, a poorly water-soluble antidiabetic drug, exhibits limited dissolution which may affect its therapeutic performance. It was hypothesized that the development of fast dissolving tablets (FDTs) using the wet granulation method, along with suitable excipients and solubilizers, would enhance the drug's dissolution behavior, ensure rapid disintegration, and maintain acceptable stability without altering its chemical integrity.

Fast dissolving tablets of glimepiride were prepared using the wet granulation technique. Compatibility studies between the active pharmaceutical ingredient and excipients were carried out using ATR-IR and differential scanning calorimetry (DSC). The prepared granules were evaluated for pre-compression parameters such as bulk density, tapped density, Hausner's ratio, and compressibility index. Tablets were compressed using a B-tooling round punch and evaluated for post-compression parameters including hardness, friability, weight variation, thickness, and disintegration time. The optimized formulation was further subjected to in-vitro dissolution studies using the paddle method and analyzed by HPLC. Assay, uniformity of content, phase solubility, and stability studies were also performed.

Pre-compression evaluation showed satisfactory flow properties for all formulations, with formulation F5 exhibiting the most favourable bulk and tapped density values along with acceptable Hausner's ratio and compressibility index. Post-compression evaluation indicated that all formulations met pharmacopeial specifications. Formulation F5 showed rapid disintegration within 1 minute and 25 seconds. Dissolution studies demonstrated a cumulative drug release of 99.44% within 30 minutes. The assay of formulation F5 showed a drug content of 100.96%, while UOC values ranged between 97–100%, confirming uniform drug distribution. ATR-IR and DSC studies confirmed the absence of significant interactions between the drug and excipients. Stability studies conducted at 30°C/75% RH and 40°C/75% RH revealed no significant changes in physical appearance, drug content, or dissolution profile. The results of the pre-compression studies indicated that the wet granulation method effectively improved the flow and compressibility of the granules, facilitating uniform tablet compression. Post-compression evaluation confirmed that the prepared tablets possessed adequate mechanical strength while maintaining rapid disintegration properties. Among all formulations, F5 demonstrated optimal performance, as evidenced by its short disintegration time and superior dissolution profile. The enhanced dissolution of glimepiride from the optimized formulation can be attributed to improved wettability, rapid tablet disintegration, and the presence of suitable solubilizers and hydrophilic excipients. Although the wet granulation process does not modify the intrinsic solubility of glimepiride, it aids in improving apparent solubility and dissolution rate through better dispersion and increased surface area. The stability studies further confirmed that the optimized formulation remained stable under accelerated conditions, indicating its suitability for long-term storage.

The study successfully demonstrated the development of fast dissolving tablets of glimepiride with improved dissolution characteristics, rapid disintegration, uniform drug content, and satisfactory stability. The optimized formulation (F5) shows potential to enhance the therapeutic efficacy and patient compliance of glimepiride, making it a promising dosage form for the management of diabetes mellitus.

Keywords: Glimepride, Fast dissolving tablets, Phase solubility, Stability.

PP043

DEVELOPMENT OF NOVEL IN-SITU LIQUID BANDAGES

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Hypothesis: Conventional wound dressings and topical formulations often suffer from limitations such as poor flexibility, insufficient drug availability at the wound site, frequent dressing changes, and low patient compliance. In-situ liquid bandages, which transform into a thin and flexible film immediately after application on the skin, were hypothesized to overcome these drawbacks by providing uniform wound coverage, immediate drug release, protection from external contaminants, and enhanced therapeutic efficacy. The present research was undertaken with the aim of developing in-situ forming liquid bandages loaded with antiinflammatory drugs to achieve effective wound protection, rapid onset of drug action, and improved wound healing.

Methods:

Diclofenac sodium and Aceclofenac were selected due to their proven effectiveness in reducing inflammation and pain. In-situ liquid bandage formulations were prepared using different film-forming polymers, including Polyvinyl Alcohol, Eudragit RL 100, Ethyl cellulose, and Nitrocellulose, to study their influence on film properties and drug release behaviour. Benzalkonium chloride was incorporated as an antiseptic agent to prevent microbial infection at the wound site. A total of twelve formulations were developed using different polymer systems. The prepared formulations were evaluated for viscosity, film thickness, tensile strength, adhesion strength, surface tack, drug content uniformity, and in-vitro drug release studies. Based on preliminary evaluation, optimized formulations were further subjected to biological evaluation through in-vitro antifungal studies and in-vivo animal studies.

Results: All prepared formulations exhibited appropriate viscosity for easy topical application and formed clear, smooth, flexible, and non-sticky films with good adhesion to the skin surface. In-vitro drug release studies revealed that the liquid bandages provided rapid and immediate release of the incorporated drugs. Based on overall physiochemical and release characteristics, four optimized formulations (F2, F5, F8, and F11), each representing a different polymer system, were selected for further investigation. In-vitro antifungal activity was evaluated by incorporating Miconazole nitrate into the selected formulations, which demonstrated promising antifungal effectiveness. The optimized formulations exhibited excellent antifungal activity and showed significant anti-inflammatory and wound healing effects in in-vivo rat models when compared with control groups. Statistical analysis of the data using the Tukey–Kramer multiple comparison test confirmed that the observed results were highly significant. Accelerated stability studies performed on the selected formulations revealed no significant changes in physical appearance, viscosity, or drug content, indicating good stability. Overall, the study concludes that in-situ forming liquid bandages are a safe, stable, and effective topical drug delivery system for the management of wounds and inflammation.

Keywords: In-situ liquid bandages; Diclofenac sodium; Aceclofenac; Film-forming polymers; Immediate drug release; Antifungal activity; Wound healing.

PP044

DEVELOPMENT OF THERMORESPONSIVE IN-SITU GEL FOR CORNEAL REGENERATION

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Corneal wound healing presents a considerable challenge in ocular therapeutics because most topical drugs are rapidly cleared from the ocular surface, resulting in very low absorption and insufficient therapeutic levels at the target site. In-situ gelling formulations offer a promising solution, as they undergo a solution to gel transition triggered by physiological stimuli such as temperature, ionic strength, or pH. This transition enhances precorneal residence time and sustains drug release. The present study focuses on formulating an in-situ thermoresponsive gel containing Nano-calcium sulphate as a wound-healing agent. Polymers such as Pluronic F68, Pluronic F-127, and Carbopol-940 were incorporated to optimize gelation properties and improve therapeutic efficiency for corneal wound care.

Nano-calcium sulphate was Synthesized using a combine freeze drying and tray drying method. The nanoparticles were characterized using SEM to analyse surface morphology and particle size distribution. Multiple batches of in situ gels were prepared by varying concentration of the polymers to achieve desirable viscosity and gelation temperature. The formulation were assessed for visual appearance, clarity, pH, gelling capacity, drug content, and in vitro drug release behaviour. Based on these parameters, the optimized formulation (F6) was selected for further studies. In vivo evaluation included an ocular irritancy test to ensure safety, followed by corneal wound-healing studies using Wistar rats. The performance of F6 was compared with a standard marketed wound-healing formulation. Finally, accelerated stability studies were conducted to determine the formulation's long-term storage stability.

The prepared gels displayed satisfactory clarity, acceptable viscosity, and rapid sol-to-gel transition at ocular temperature. Among all batches, Formulation F6 exhibited the most favourable gelling behaviour due to its optimal ratio of Pluronics and Carbopol. SEM analysis confirmed that the synthesized nano-calcium sulphate particles were uniform and within the nanoscale range, supporting enhanced surface interaction and improved ocular penetration. In-vitro drug release studies showed that all formulations provided immediate onset of release followed by sustained diffusion. F6 demonstrated the most controlled release profile, indicating its suitability for maintaining therapeutic levels on the corneal surface. The ocular irritancy test showed no signs of redness, tearing, or swelling, establishing the formulation’s safety for ocular administration. In in-vivo wound-healing studies, F6 significantly accelerated epithelial regeneration and reduced inflammation when compared to the standard treatment. This enhanced healing effect is attributed to the regenerative properties of nano-calcium sulphate and the prolonged retention provided by the in-situ gel matrix. Stability studies confirmed that F6 maintained its physicochemical properties, drug content, and gelation behaviour under accelerated conditions, indicating good formulation stability.

The study demonstrates that nano-calcium sulphate-based in-situ gels represent a promising therapeutic approach for corneal wound healing. The optimized formulation F6 showed excellent gelation characteristics, controlled drug release, non-irritant behaviour, and significantly enhanced healing potential. The results support its potential application as an effective ocular delivery system for real-world corneal wound care.

PP045

A-GLUCOSIDASE AND A-AMYLASE INHIBITION BY BIOGENIC SILVER NANOPARTICLES SYNTHESIZED FROM MUSA PARADISIACA LINN AQUEOUS LEAVES EXTRACT

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Diabetes has caused a major burden to the health sector in the developing countries and has shown an increasing trend among the urban population. It is estimated that most patients are with type II diabetes which could be easily treated with dietary changes, exercise, and medication. Therefore, it is important to screen medicinal plants scientifically so they could be used safely and effectively in the traditional medical system and also be used for further investigations

The present study aimed to evaluate the in vitro α-amylase and α-glucosidase inhibitory activities of silver nanoparticles (AgNPs) synthesized using the aqueous leaf extract of *Musa paradisiaca* Linn. Dried leaf powder was extracted by cold maceration using distilled water containing 5% chloroform, followed by lyophilization. Silver nanoparticles were synthesized from the lyophilized aqueous extract and subjected to preliminary phytochemical screening. The antidiabetic potential of the synthesized AgNPs was assessed through in vitro enzyme inhibition assays against α-amylase and α-glucosidase using standard spectrophotometric methods. Percentage inhibition and IC50 values were calculated, with acarbose used as a reference standard. The AgNPs exhibited concentration-dependent inhibition of both enzymes, with significantly greater inhibitory activity against α-glucosidase compared to α-amylase ($p < 0.001$), suggesting a favorable profile for controlling postprandial hyperglycemia.The enhanced α-glucosidase inhibition may be attributed to the presence of bioactive phytoconstituents, particularly flavonoids, in the aqueous leaf extract that act synergistically with the nanoparticles. Traditional medicinal uses of *Musa paradisiaca* leaves further support their therapeutic relevance.

Musa paradisiaca (banana) leaves have traditional uses for skin ailments, respiratory issues, and wound care. They are applied as poultices for burns and blisters, used in syrups for coughs and bronchitis, and their ashes are taken internally for dysentery and diarrhea. Dried leaves coarse powder were extracted with distilled water using 5% of chloroform, extract was lyophilized and silver nano particles were synthesized from lyophilized powder of aqueous extract of leaves of Musa paradisiaca. Extracts was subjected to phytochemical screening, in vitro to evaluate antidiabetic activity of the silver nano particles. Overall, the findings indicate that silver nanoparticles synthesized from *Musa paradisiaca* leaf extract possess promising in vitro antidiabetic activity, particularly through inhibition of carbohydrate-digesting enzymes. However, further studies are required to isolate the active constituents and to evaluate in vivo efficacy, safety, and mechanistic pathways before therapeutic application can be considered.

Key words: Aqueous leaves extract, Musa paradisiaca linn, lyophilized powder, silver nano particles, alpha-amylase, alpha glucosidase, Antidiabetic activity. P-value

PP046

DEVELOPMENT OF DIRECTLY COMPRESSIBLE CO-PROCESSED EXCIPIENT USING SEDEM EXPERT SYSTEM

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Hypothesis: Role of SeDeM Analysis in selection of co-processed excipients for development of supplements for bone health.

Methods: Suitable excipients were identified using the SeDeM expert system based on flowability, compressibility, and moisture-related parameters, co-processed by wet granulation and solvent evaporation techniques, blended with nano calcium lactate and vitamin D_3, compressed into tablets by direct compression, and subsequently evaluated through pre-compression studies, post-compression quality tests, ATR-IR compatibility analysis, in vitro dissolution, assay determination, and accelerated stability testing under ICH conditions.

Supporting Data: Nano calcium lactate and vitamin D_3 exhibited poor flow and compressibility, as indicated by unfavourable angle of repose, Carr's index, and Hausner's ratio values. Co-processed excipient blends showed improved bulk and tapped densities with acceptable flow properties. All evaluated parameters complied with pharmacopeial requirements, supporting their suitability for direct compression.

Results: Tablets prepared using co-processed excipients showed acceptable hardness, friability below 1%, and rapid disintegration within 10 minutes. ATR-IR studies confirmed the absence of chemical interaction between actives and excipients. More than 95% drug release was achieved within 30 minutes, with assay values ranging from 97.0–99.5%. Stability studies demonstrated no significant physical or chemical changes under accelerated conditions.

Conclusion: The use of co-processed excipients significantly improved the flowability, compressibility, and uniformity of nano calcium lactate and vitamin D_3 tablets. The optimized formulation ensured rapid drug release, good stability, and compliance with pharmacopeial standards. This approach offers a scalable and patient-friendly platform for developing effective bone health supplements.

Key words: Co-processed excipients, Nano calcium lactate, Vitamin D_3, Direct compression, Bone health supplements

PP047

SYNTHESIS AND CHARACTERIZATION OF COPPER SULFIDE NANOPARTICLES FUNCTIONALIZED WITH HYALURONIC ACID FOR TARGETED PHOTOTHERMAL THERAPY IN BREAST CANCER

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Hypothesis: Photothermal therapy (PTT), is a therapeutic modality that uses photothermal conversion agents to convert light energy into heat, resulting in the localized killing of cancer cells. It is specific with respect to place and time, as well as its synergistic benefits and low invasiveness

Methods: Copper Sulfide (CuS) nanoparticles (NPs) were synthesized by simple co-precipitation method and functionalized with Hyaluronic acid (HA) for targeting cancer cells. The coprecipitation approach offers a facile and scalable route for producing CuS nanoparticles that is suitable for further physiochemical characterization and biomedical application. The nanoparticles were further characterized for its particle size and surface morphology. The thermal behaviour of the particles was analysed by TGA and DSC and the crystalline nature was determined by XRD. The suitability of CuS nanoparticles for photothermal therapy was confirmed by UV-Vis NIR and cytotoxicity was determined by MTT assay.

Results: The synthesized HA-CuSNPs exhibited the nanoscale particles size in the range of 10-250nm, while the -ve Zeta potential confirmed good colloidal imparted by hyaluronic acid functionalization. Thermogravimetric analysis (TGA) demonstrated enhanced thermal stability of the HA-CuS NPs with characteristic weight loss corresponding to surface-bound HA. X-ray diffraction (XRD) patterns confirmed the crystalline nature of CuS with well-defined 2θ value with diffraction peaks corresponding to the hexagonal covellite phase. Differential scanning calorimetry (DSC) revealed thermal transitions associated with HA coating and NPs stabilization. The CuS NPs showed broad absorptions in the UV–Vis and NIR regions due to excitonic absorption and localized surface plasmon resonance (LSPR). The optical band gap energy of CuS NPs varied in the range of 2.05–2.34 eV, UV-Vis-NIR spectroscopy showed strong and broad absorption in the near-infrared region, validating the suitability of HA-CuS NPs for Photothermal applications. Scanning electron microscopy (SEM) images revealed that the NPs were in the nano size with slight aggregation, while energy-dispersive X-ray spectroscopy (EDS) confirmed the elemental composition of copper and sulfur, confirming successful functionalization. The MTT assay showed an IC_{50} value of 14.04 µg/mL in the 3T3-L1 cell line.

Conclusion: In conclusion, HA-CuS nanoparticles were successfully synthesized using co-precipitation method and systematically characterized to confirm their physiochemical properties. The NPs exhibited a uniform nanoscale size, narrow PDI, and good colloidal stability due to HA surface modification. Structural and thermal analysis confirmed the crystalline structure of CuS, while optical studies demonstrated the strong NIR absorption, highlighting their potential for photothermal application in cancer treatment.

PP048

DEVELOPMENT OF BETAMETHASONE DIPROPIONATE LOADED AQUASOMAL GEL FOR THE TREATMENT OF PSORIASIS

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Hypothesis: The present study aimed to develop a Betamethasone dipropionate–loaded aquasomal gel for the effective topical management of psoriasis, a chronic inflammatory skin disorder. Owing to the limitations of conventional topical formulations such as poor skin penetration, rapid drug clearance, and systemic side effects, aquasomes— a nanoparticulate carrier system capable of preserving drug stability and providing controlled release were explored to enhance therapeutic efficacy and safety.

Methods: Aquasomes were prepared using a calcium phosphate ceramic core coated with lactose (1:2) and loaded with Betamethasone dipropionate (drug:aquasome ratio 1:9). The aquasomal gel was formulated using HPMC and xanthan gum as gelling agents. Optimization was carried out using Central Composite Design (CCD) under Response Surface Methodology (RSM). The optimized formulation was characterized for particle size, zeta potential, FT-IR, SEM, pH, viscosity, spreadability, and in vitro drug release. Ex vivo skin permeation was evaluated using a Keshary–Chien diffusion cell. Dermal safety was assessed in New Zealand white rabbits, and therapeutic efficacy was evaluated using an imiquimod-induced psoriasis model in Wistar rats.

Supporting Data: The optimized aquasomal gel, developed using Central Composite Design, exhibited acceptable pH, viscosity, spreadability, and controlled drug release. In vivo evaluation using an IMQ-induced psoriasis model, supported by PASI scoring, hematological analysis, histopathology, dermal irritation, and stability studies, confirmed the safety, stability, and enhanced therapeutic efficacy of the formulation.

Results and Conclusions: The optimized aquasomes showed a mean particle size of 263.2 nm with a zeta potential of −22.8 mV and sustained in vitro drug release of 87.11%. Ex vivo permeation studies demonstrated enhanced skin penetration compared to conventional gel formulations, while dermal irritation studies confirmed good skin tolerability. In vivo studies revealed a significant reduction in PASI scores and marked histopathological improvement. Statistical analysis using ANOVA confirmed the significance of formulation variables, and stability studies indicated satisfactory physical and chemical stability. Overall, the developed Betamethasone dipropionateloaded aquasomal gel represents a promising and effective approach for sustained topical treatment of psoriasis.

Keywords: Betamethasone dipropionate, HPMC, Xanthum gum, Aquasomes, Psoriasis

PP049

FORMULATION AND EVALUATION OF NANOCOCHLEATE DRUG DELIVERY SYSTEM FOR ANTICANCER DRUG

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As most of the anticancer drugs come under BCS class II and class IV, the aqueous solubility of the drugs is a matter of concern. The major problem associated with these drugs is the aqueous solubility and the bioavailability. Several approaches are designed to improve the oral bioavailability. Ibrutinib is a BCS class II drug having low aqueous solubility. Novel drug delivery system is a new approach to improve the solubility as well as the bioavailability of such drugs. Nanocochleate drug delivery system has some advantages over the nanoliposomal drug delivery system because of their improved encapsulation efficiency, improved stability and improved drug release. Ibrutinib loaded nanoliposomes were prepared using thin film hydration method and subjected for evaluation viz., particle size analysis, zeta potential measurement, encapsulation efficiency and in vitro drug release. Among the nanoliposomal formulations batch F2 was chosen to be formulated as nanocochleates. The nanocochleate batch (F4) was studied for particle size where the particle size resulted in 534.0 nm compared to the nanoliposome batch (F2) 284.5 nm. The zeta potential was found to be -45.1 mV and -14.5 mV for F2 and F4 respectively. The zeta potential measurement indicated good stability of the formulations. The encapsulation efficiency was found to be 44.57±1.332, 44.57±1.332, 51.14±2.3077 and 85.70±1.3403 respectively for F1 to F4 batches. The in vitro drug release study in pH 6.8 phosphate buffer demonstrated that formulation F4 achieved a cumulative drug release of 81.71% at 6 hours, whereas F2 exhibited 67.04% release, compared to 43.75% for the pure drug. IC_{50} value of the nanocochleate formulation was found to be 32.70 µg/ml.

Keywords: Nanocochleate, Nanoliposomes, Ibrutinib, Anticancer drug delivery Bioavailability enhancement, Invitro evaluation.

PP050

FORMULATION AND EVALUATION OF A MEDICATED LIP CARE PRODUCT FOR ANGULAR CHEILITIS TREATMENT

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Hypothesis: It was stated that a medicated lip care formulation incorporating basil essential oil as a natural antifungal agent could be effectively developed using suitable natural excipients and would exhibit significant antifungal activity, physicochemical stability, and safety for the management of angular cheilitis.

Methods: Basil essential oil was selected as the active ingredient and diluted with coconut oil and almond oil as carrier oils. Lip balm formulations were prepared using the melt and pour method with appropriate combinations of beeswax, butters, oils, and other excipients. Preformulation and compatibility studies were conducted, followed by dose fixation using microdilution techniques. A total of twenty formulations were developed and evaluated for physicochemical parameters including pH, melting point, softening point, spreadability, and organoleptic properties. In-vitro antifungal activity against Candida albicans was assessed using standard microbiological methods. Selected formulations were subjected to microbiological challenge testing and stability studies under different storage conditions.

Supporting Data: Among the twenty formulations, F17, F18, F19, and F20 demonstrated optimal physicochemical characteristics, superior spreadability, appropriate pH, and effective antifungal activity against Candida albicans in in-vitro studies. These formulations showed resistance to microbial growth during challenge testing.

Results: Formulations F17, F18, F19, and F20 successfully passed the challenge test and remained stable throughout the study period under different storage conditions. No significant changes were observed in physical appearance, performance, or stability parameters, indicating good formulation integrity and shelf stability.

Conclusion: The study successfully demonstrated that basil essential oil based medicated lip care formulations can be developed using natural excipients with satisfactory antifungal activity, stability, and safety. The selected formulations F17, F18, F19, and F20 showed consistent performance across all evaluation parameters, confirming their potential as safe, stable, and patient-friendly alternatives for the management of angular cheilitis.

Key words: Essential oil, lip balm, in-vitro evaluation, Antifungal activity

PP051

COMPARATIVE EVALUATION OF MANUFACTURING EFFICIENCY AND PERFORMANCE OF VITAMIN C TABLETS PREPARED BY WET GRANULATION, DRY GRANULATION AND DIRECT COMPRESSION TECHNIQUES

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Hypothesis: This study states that the manufacturing method significantly influences the process efficiency, tablet performance, stability and cost-effectiveness of high-dose ascorbic acid (vitamin C) tablets, with direct compression offering superior productivity without compromising quality.

Methods: Tablets containing ascorbic acid (IUPAC: (2R)-2-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxy-2H-furan-5-one) were formulated using wet granulation (F1–F4), direct compression (F5–F8) and dry granulation (F9–F12). Drugexcipient compatibility was assessed using ATR-IR spectroscopy. Pre-compression parameters (flow properties, compressibility) and post-compression characteristics (hardness, friability, disintegration time and weight variation) were evaluated as per Indian Pharmacopeial guidelines. Optimized formulations were subjected to HPLC assay, in-vitro dissolution studies, microbiological analysis (TAMC and TYMC), cost analysis and accelerated stability testing.

Supporting data: Pre-compression studies indicated superior flow properties for direct compression blends based on bulk and tapped density, Carr's index and Hausner's ratio. ATR-IR analysis confirmed drug-excipient compatibility. Microbiological evaluation showed acceptable limits (TAMC: 55 CFU/g; TYMC: <10 CFU/g). Accelerated stability studies revealed no significant physicochemical changes in the formulations.

Results: Optimized formulations F3 (wet granulation), F7 (direct compression) and F11 (dry granulation) exhibited rapid disintegration times of 2.30, 1.25 and 2.50 minutes, respectively. HPLC assay indicated drug contents of 108.9% for wet granulation, 110.7% for direct compression and 108.0% for dry granulation formulations. In vitro dissolution studies demonstrated cumulative drug release at 60 minutes of 123.67% (F3), 131.06% (F7) and 136.85% (F11), confirming efficient and rapid release profiles for all selected formulations.

Conclusion: The study demonstrates that while all three manufacturing techniques produce pharmaceutically acceptable vitamin C tablets, direct compression provides the best balance of process efficiency, rapid disintegration, higherv productivity and cost-effectiveness, making it the most suitable method for large-scale industrial manufacture of ascorbic acid tablets.

Keywords: Vitamin C, direct compression, wet granulation, dry granulation, tablets.

PP052

SELECTED FOR ORAL PRESENTATION

PP053

FORMULATION AND EVALUATION OF VORICONAZOLE-LOADED NIOSOMAL TOPICAL SPRAY FOR THE ANTIFUNGAL THERAPY

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Abstract

Voriconazole was formulated as a topical film-forming niosomal spray to enhance its effectiveness in the treatment of deep-seated fungal infections. Drug–excipient compatibility was assessed using FTIR and spectral analysis. Niosomes were prepared using rotary evaporation and ether injection methods. Various ratios of the surfactants Span-60 and Tween-80 were employed to evaluate their effect on vesicle formation and drug entrapment efficiency.The optimized niosomal dispersion was converted into a topical spray by adding Eudragit RLPO as a film-forming polymer. A central composite design was used to optimize the spray formulation, with Eudragit RLPO (X_1) and glycerine (X_2) as independent variables, and viscosity (Y_1), spray angle (Y_2) and spray pattern (Y_3) as dependent variables. Nine experimental runs were performed, and numerical optimization identified the optimized spray formulation (OSF) with desirable pharmaco-technical properties.FTIR studies confirmed that the drug remained chemically and physically stable without showing any significant interaction with the excipients used in the formulation. In-vitro diffusion studies indicated a controlled and sustained release pattern, with 75.6% of the drug diffused by the end of the ninth hour.Among all the prepared batches, formulation NRE-1 showed superior characteristics, exhibiting a high entrapment efficiency of 97.5% and a drug content of 98.2%. Dynamic light scattering analysis revealed that the optimized niosomes had an average particle size of 568.3 nm. Additionally, the formulation demonstrated good stability, as reflected by a zeta potential value of −23.2 mV. The optimized spray showed a viscosity of 9.81 cps, a spray angle of 36.24°, and a spray pattern diameter of 1.26 cm, with 96.33% drug content. Each actuation delivered ~0.48 ± 0.031 mL (≈2.31 ± 0.026 mg voriconazole). The final formulation was transparent, formed a uniform, easily washable skin film, and exhibited good dermal flexibility. In vitro release with 15% Transcutol showed 90.6% release from the niosomal dispersion and 75.6% from the spray after 8 h. Stability studies per ICH guidelines confirmed all parameters remained within acceptable limits.

Keywords: Niosomes, Film-forming spray, Central composite design, FTIR, Dynamic light scattering.

PP054

INHIBITING CRYSTALLIZATION OF AMORPHOUS SOLID DISPERSIONS CONTAINING FAST CRYSTALLIZING WEAKLY BASIC DRUG USING ACIDIC COUNTERIONS AND POLYMERS

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Abstract

In the present study, in situ salt amorphous solid dispersions (ASDs) of a fast-crystallizing drug Albendazole (ABZ) were developed to mitigate residual crystallinity during solvent evaporation and release. Three acidic counter ions- hydrochloric acid (HCl), p-toluene sulfonic acid (TSA) and docusic acid (DA) were employed to form in situ salt ASDs separately using hydroxypropyl methylcellulose acetate succinate (HPMCAS MF grade) or Polyvinylpyrrolidone-Vinyl Acetate (PVPVA) at different drug loads equivalent to the free base. Drug release and solution recrystallization were evaluated in phosphate pH 6.5 buffer. Polarized light microscope (PLM) and scanning electron microscope (SEM) imaging were used to detect residual crystallinity. Upon solvent evaporation, ABZ-MF ASDs displayed residual crystallinity above 5 % drug loading, whereas the salt ASDs remained X-ray amorphous up to 20 % drug loading. Similarly, free base and salt ASDs with PVPVA were X-ray amorphous up to 20 % drug loading, except ABZ_DA-PVPVA 20/80 ASD. Among MF based salt ASDs, all 10 % formulations achieved complete release without solution re-crystallization except ABZ_HCl-MF. In contrast, all PVPVA based ASDs re-crystallized during release with the only exception of ABZ_DA-PVPVA 10/90 ASD. Overall, the results demonstrated that in situ salt ASDs prevented crystallization during solvent evaporation and release, thereby enabling development of supersaturated formulations of a drug with high tendency for solution re-crystallization. A complex interplay of factors like higher apparent solubility of the salt and drug-counterion-polymer interactions reduce the effective supersaturation and slow nucleation sufficiently to suppress solution re-crystallization relative to the free base. Over PVPVA, HPMCAS efficiently stabilize ion pairs due to ionizable carboxylate groups, hydrophobic backbone and slower hydration creating a viscous polymeric matrix delaying precipitation and nucleation.

PP055

CHARACTERIZATION AND PERFORMANCE ASSESSMENT OF HYDROPHILIC POLYURETHANE FOAM FOR MEDICAL WOUND DRESSINGS

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Hypothesis: Conventional polyurethane (PU) foams used in medical wound dressings often show limited absorbency and inadequate moisture retention, which can compromise effective wound healing. It was hypothesized that the formulation and optimization of a hydrophilic polyurethane foam, through the incorporation of a hydrophilic polymer and controlled processing variables, would significantly enhance water absorption, moisture regulation, and mechanical performance, thereby providing an optimal environment for wound healing.
Methods: Hydrophilic PU foams were formulated using Specflex® NE 434 as the isocyanate component, Caradol SC56-18 S™ as the polyether polyol, and HPMC 4 K as a hydrophilic polymer. Three critical formulation variables—polyol concentration, HPMC 4 K concentration, and curing temperature—were identified and optimized using a Box–Behnken experimental design. Seventeen foam formulations were prepared and evaluated for water absorption capacity, density, and compression strength to determine an optimized formulation. The optimized foam was further characterized for mechanical strength, water vapor transmission rate (WVTR), absorption rate, and overall structural integrity. Internal morphology and porosity were examined using scanning electron microscopy (SEM) and micro-computed tomography (Micro-CT). The performance of the developed foam was compared with a commercially available polyurethane foam dressing. In vivo skin irritation studies were conducted on albino rabbits to assess the topical safety of the optimized formulation.
Supporting Data: Preliminary evaluation indicated that variations in formulation variables significantly influenced the absorbency, density, and mechanical strength of the PU foams. SEM analysis revealed a highly porous and interconnected internal structure, while Micro-CT analysis confirmed uniform pore distribution within the foam matrix, supporting effective fluid uptake and moisture management.
Results: The optimized hydrophilic PU foam demonstrated a high-water absorption capacity of 490.14%, a density of 190.50 g/cm³, and a compression strength of 1150.50 kPa. Micro-CT analysis indicated an overall porosity of approximately 18%. Compared to the commercial PU foam dressing, the optimized foam exhibited superior water absorption and an optimal WVTR, indicating improved exudate management. In vivo skin irritation studies revealed no signs of erythema or edema, confirming the foam's suitability for topical application.
Conclusion: The optimized hydrophilic polyurethane foam effectively addressed the limitations of conventional PU foams by offering enhanced absorbency, adequate mechanical strength, and efficient moisture regulation. These findings suggest that hydrophilic PU foam is a promising material for advanced wound dressing applications, capable of maintaining an ideal moist wound environment and supporting improved healing outcomes.
Key words: Hydrophilic polyurethane foam, wound dressing, optimization

PP056

DEVELOPMENT OF PISCEAN COLLAGEN BASED SCAFFOLDS FOR MANAGEMENT OF DIABETIC WOUND

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Hypothesis: It was hypothesized that a Piscean collagen-based scaffold incorporated with hyaluronic acid, nano calcium, and aloe extract would exhibit accelerated wound healing properties.

Methods: The wound healing Piscean collagen-based scaffolds were developed by using lyophilization method. Polymeric mixture containing Piscean collagen (PC), hyaluronic acid (HA) and hydroxypropyl methylcellulose K100 (HPMC) hydrated. To this mixture, nano calcium and aloe extract were incorporated. Nano calcium was prepared using probe sonication and was subjected to particle size analysis and EDX-SEM studies. Scaffolds were optimized using Design Expert software. Central composite design (CCD) generated 20 runs with three independent variables (concentration PC, HA, HPMC) and two dependent variables (swelling index and water vapor transmission rate). Based on the results, the optimized formulation was generated by the software, to which nano calcium and aloe extract were added and evaluated. This optimized formulation was then subjected to in-vitro and in vivo wound healing assay.

Supporting Data: Prepared nano calcium by probe sonication had revealed a particle size of 803.5 nm, with PDI of 0.183 and a zeta potential of -11.20. FTIR analysis confirmed the compatibility of scaffold components, while the SEM-EDX analysis revealed the scaffolds to have a porous morphology and the successful incorporation of nano calcium. The optimized scaffolds contained 2% of PC, 2% HPMC and 0.4% HA. To this optimized scaffold, 2% of Aloe extract and 100 ppm of nano calcium was incorporated. Swelling index and water vapor transmission rate was found to be 154.2% and 1631.85 g/m2 /day respectively.

Results: The MTT assay revealed good cell viability of L929 fibroblast cells which indicated its non-toxic nature. The scratch assay also showed good cell migration and proliferation in comparison to standard control groups which indicated its improved in-vitro wound healing performance. The in vivo wound healing studies showed that the percentage wound contraction of the treated scaffolds was 65.33 ± 1.38% on the 7th day and 100.00 ± 0.00% on the 14th day, while for the untreated control group it was 66.00 ± 2.67% wound contraction on the 7th day and 91.83 ± 1.30% on the 14th day.

Conclusion: The optimized Piscean collagen-based scaffolds that contained hyaluronic acid, nano calcium and aloe extract were revealed to have good wound healing properties due to their cell proliferation, tissue regeneration properties.

Keywords: Piscean collagen, diabetic wound, scaffold, Hyaluronic acid, nano calcium, wound healing.

PP057

MODELING THE DRUG RELEASE FROM PLGA-BASED MICROSPHERES: A CASE STUDY OF LEUPROLIDE ACETATE

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Objective: Long-acting injectable (LAI) formulations based on PLGA microspheres provide sustained drug release. Still, their complex *in vitro* and *in vivo* performance requires mechanistic modeling to understand drug release and predict pharmacokinetics (PK). Leuprolide acetate, a peptide used in prostate cancer and endocrine disorders, is a widely studied PLGA-based LAI system. The objective of this work was to develop a physiologically based pharmacokinetic (PBPK) model incorporating a mechanistic PLGA microsphere release module to characterize the *in vitro* and *in vivo* drug release behavior of leuprolide acetate from 1-month Lupron Depot® formulations.

Methods: The implemented mechanistic LAI microsphere model has elements representing the hydrated PLGA matrix, degradation-driven release, diffusion of drug molecules through evolving pores, and subsequent absorption into local adipose tissue. Key PLGA-related inputs, including lactide:glycolide ratio, polymer molecular weight, %CV of polymer size distribution, initial encapsulated drug mass, pore evolution parameters, and microsphere radius distribution, were obtained from literature or assumed where necessary (Zhou et al., 2018). Physicochemical and ADME parameters for leuprolide were integrated into a minimal PBPK framework. The model was evaluated using observed PK data for: (1) intravenous and subcutaneous solution dosing at 1 mg, and (2) Lupron 1-month depot microspheres (10 mg) in healthy volunteers. Release kinetics were compared with *in vitro* profiles generated in a pH 7.4 phosphate buffer.

Results: The PBPK model successfully reproduced the IV and SC plasma concentration–time profiles, confirming appropriate systemic disposition of leuprolide. The mechanistic PLGA module captured the characteristic multiphasic release pattern of Lupron Depot®, including burst release, polymer-controlled diffusion, and degradation-mediated release phases. Simulated *in vitro* release closely matched published kinetics reported by Zhou et al., while *in vivo* simulations demonstrated reasonable agreement with observed clinical PK for the 1-month depot.

Conclusion: This work demonstrates that combining a mechanistic PLGA microsphere release model with PBPK modeling can successfully predict the PK of leuprolide acetate LAI formulations. The approach provides a quantitative framework for understanding release mechanisms and can support the design and optimization of future PLGA-based long-acting injectables.

PP058

COMPUTATIONAL STRATEGIES IN ONCOLOGY DRUG REPURPOSING: A SCOPING REVIEW OF MOLECULAR MODELLING APPROACHES

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Abstract

Cancer is a complex group of diseases characterized by the uncontrolled growth and spread of abnormal cells, making the discovery of universally effective treatments a significant challenge. Traditional drug discovery is expensive and time-intensive, often requiring years of research and substantial financial investment. In contrast, drug repurposing identifying new therapeutic uses for existing, approved drugs offers a more efficient pathway to accelerate anticancer drug development by leveraging known safety and pharmacokinetic profiles. Drug repurposing offers a rapid pathway to novel cancer therapies by leveraging existing FDA-approved compounds, bypassing lengthy de novo development. *Insilico* approaches, particularly molecular docking and virtual screening, have been widely applied to repurposing workflows to predict interactions between existing drugs and cancer-associated targets at the molecular level. This computational approach synthesizes current strategies that utilize molecular docking to screen large compound libraries against key oncogenic proteins, highlighting how binding affinity predictions and interaction analyses can prioritize promising candidates for downstream investigation. A scoping review of the literature reveals that molecular modelling which includes both molecular docking and molecular dynamics simulations is the most frequently implemented computational method in oncology repurposing research. Molecular docking continues to play a pivotal role in expanding the landscape of potential anticancer therapies, offering valuable insights and guiding future research efforts toward more effective and rapid therapeutic solutions.

Key words: Cancer, Drug repurposing, *In silico* drug discovery, Molecular docking, Molecular dynamics simulations.

PP059

PROTEIN PRE CANCER PREDICTION USING CNN

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The aim of this project is to design and evaluate a deep learning–based system to predict whether a given human protein is cancer-associated or non-cancer by analysing its 3D structural features converted into 2D image representations. Cancer is a major global health challenge, and structural abnormalities in proteins are often responsible for triggering uncontrolled cellular growth. Identifying these cancerassociated proteins at an early stage is essential for improving diagnosis, drug discovery, and precision medicine. With advancements in artificial intelligence, deep learning has become a powerful tool for detecting complex biological patterns that are difficult to capture using traditional laboratory-based analysis. Most existing computational prediction methods rely heavily on genomic expression data or histopathological images and often ignore structural-level protein variations that play a critical role in cancer development. Manual laboratory techniques used for protein analysis are slow, expensive, and require advanced biological expertise. Therefore, there is a strong need for automated and structure-aware computational tools that can efficiently detect cancer-associated proteins at the molecular level.

This work aims to overcome the limitations of current diagnostic approaches by leveraging protein structural information. The primary objective is to train a deep learning system capable of classifying proteins as cancer-associated or non-cancer. The motivation behind the study is to enable faster screening of oncogenic proteins, assist researchers in early biomarker discovery, and promote the integration of AI in cancer research. Protein structure files were collected from AlphaFold and labeled using OncoKB. These 3D structures were converted into biophysical 2D contact map images that capture geometric and physicochemical relationships between amino acids. Three highperforming convolutional neural network architectures—DenseNet201, EfficientNet-B4, and SE-ResNet50—were trained and evaluated on a large dataset of more than 23,000 labeled protein structures. Performance metrics such as accuracy, recall, F1-score, and ROC-AUC were used to measure classification effectiveness, particularly for minority cancer-associated samples.

PP060

SELECTED FOR ORAL PRESENTATION

PP061

COMPUTATIONAL AND BIOACTIVITY SCREENING OF REPURPOSED DRUGS TARGETING AGPCR TO TREAT BREAST CANCER METASTASIS

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Background: Metastasis remains the major challenge in breast cancer, as tumor cells spread to distant organs. G protein-coupled receptor 116 (GPR116), belongs to subclass F of the adhesion G protein coupled receptors (aGPCRs) has been implicated in driving metastasis through RhoA and Rac1 signaling via Gαq/p63RhoGEF. Suppressing GPR116 expression could inhibit metastatic progression, making it a potential therapeutic target. This study aims to screen drugs targeting GPR116, essentially repurposing approved drugs through In silico and In vitro cell line approaches. **Methodology:** The structure of GPR116 was predicted using I-TASSER and validated using Procheck. The model generated with high C score was subjected to protein preparation. The potential ligand-binding sites of GPR116 were identified using the SiteMap module of Schrödinger (Maestro). The 3D.sdf structures of USFDA-approved drugs sourced from Drug Bank and eighty-two ligands identified by literature search that could be repurposed to treat breast cancer were employed in docking studies against GPR116 by Schrodinger Maestro. Drugs displaying top docking scores and crucial amino acid interactions were shortlisted for Molecular Mechanics Generalized Born Surface Area (MM-GBSA) studies followed by molecular dynamics simulations (MDS). In the next step, the complexes with high stability in DESMOND simulation underwent cytotoxicity assay on MDAMB-231 cells. Finally, the ligands with low IC50 values were further evaluated for GPR116 expression studies.

Results: The sites 4 and 5 of GPR116 had a SiteScore exceeding 1.0 and a Dscore greater than 0.8. Based on these scores, ligands were docked separately against site-4 and site-5. Ligands with a docking score greater than -5.00 at both sites were then analyzed using MMGBSA. Twenty-one drugs with high negative binding free energy (MMGBSA dG Bind >-50) identified via MM-GBSA analysis and showed more interactions with amino acid residues of GPR116 were shortlisted for MDS for 100ns. Further to finalize the drug, RMSD and RMSF of the complexes were analyzed, revealing that 12 drugs exhibited notable stability profiles and dynamic interactions with GPR116 compared to other drugs. The drugs which showed low IC50 (1-200 µg/ml) on metastatic cell line were shortlisted for GPR116 expression studies.

Conclusion: The drug category shortlisted for protein expression studies based on low IC50 includes antipsychotic, anti-osteoporotic, anti-malarial, anti-fungal, tetracycline antibiotic and antihypertensive. Further, the drug which reduces the expression of GPR116 will be subjected to antimigration assays to validate their role as repurposed anti-metastatic therapeutic.

Keywords: GPR116, Metastasis, Drug repurposing, In silico, Cell line studies

PP062

DESIGN, SYNTHESIS, AND BIOLOGICAL EVALUATION OF NOVEL PYRIMIDINE LINKED AZETIDINONES

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Objective: The global health sector faces major challenges from antibiotic-resistant pathogens, emerging infections, and widespread antibiotic misuse. Concurrently, with high rates of late-stage diagnosis and death in India, cancer-especially breast cancer-remains a significant public health burden. These difficulties underscore the critical need for early identification and the creation of new, safer treatments. In this regard, derivatives of pyrimidines and azetidinones are attractive scaffolds in pharmaceutical research for the creation of specific, low-toxicity therapies against cancer and infectious disorders.

Methodology: A variety of pyrimidine-linked azetidinone derivatives were developed and assessed using molecular docking with AutoDock Vina and PyRx, in conjunction with ADMET predictions employing SwissADME, pkCSM, and ADMETlab 3.0. Compounds JJPM1–JJPM4, JJPM7–JJPM10, and JJPM13–JJPM15 were chosen for synthesis based on positive in silico results. The compounds were synthesized through a three step process that included condensation and cyclization using both conventional and microwave-assisted methods. They were then characterized by physical and spectral analyses, and their antibacterial and antifungal, properties were assessed using the well diffusion methods. The synthesized pyrimidine-azetidinone derivatives were identified and characterized by physical data and spectral data i.e., melting point, IR, 1H NMR and Mass spectral data.

Results and Discussion: In silico studies indicated that the molecule JJPM1 (Methyl derivative), JJPM15 (Methyl thio derivative) has promising results for all in-vitro studies performed. Compared to standard ciprofloxacin, JJPM1 (Methyl derivative) has demonstrated promising anti-bacterial activity against S.aureus while JJPM15 (Methyl thio derivative) has demonstrated promising activity against E.coli. Hence JJPM1 and JJPM15 can be used as promising leads for further studies

PP063

PERSONALIZED SEIZURE FORECASTING IN PEDIATRIC EPILEPSY USING ARTIFICIAL INTELLIGENCE: A CONCEPTUAL DIGITAL HEALTH FRAMEWORK

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Rationale: Pediatric epilepsy remains a major public health challenge, with a substantial proportion of children continuing to experience uncontrolled seizures despite advances in antiepileptic therapy. Current management approaches are largely reactive, relying on retrospective seizure diaries and intermittent clinical assessments, which fail to address the inherent unpredictability of seizures. Emerging evidence indicates that seizures are often preceded by measurable pre-ictal physiological, neurological, and behavioral changes. Advances in artificial intelligence (AI), wearable biosensors, and digital health platforms create an opportunity to transition pediatric epilepsy care from reactive management to proactive, personalized seizure forecasting.

Hypothesis: This conceptual framework is based on the hypothesis that AI-driven analysis of continuous, multimodal data can identify individualized pre-ictal signatures in children with epilepsy, enabling timely seizure risk forecasting and clinically meaningful anticipatory interventions.

Conceptual Methodology: The proposed framework outlines a non-interventional, digital health–based approach integrating multimodal data sources, including wearable device assisted electroencephalography, physiological signals such as heart rate variability, electro dermal activity, oxygen saturation, behavioral and motion data, and contextual clinical information. Advanced Machine Learning techniques such as Convolutional Neural Networks, Recurrent Neural Networks, long short-term memory models, transformers, and multimodal fusion architectures are conceptually applied to extract features, model temporal dynamics, and generate personalized seizure risk scores. A stepwise pipeline encompassing data acquisition, expert-validated labeling, model training, real-time inference, alert generation, and continuous learning is described, emphasizing adaptability to developmental variability in pediatric populations.

Expected Outcomes: Early seizure prediction, better safety and readiness for caregivers, better seizure recording, and improved therapeutic decision-making are all anticipated results. At a health system level, the framework supports reduced emergency visits, better resource utilization, and improved longitudinal monitoring. Integration with medication adherence data may further enable AI-assisted treatment optimization.

Conclusions: This conceptual digital health framework highlights the potential of personalized AI-based seizure forecasting to redefine pediatric epilepsy care. By combining multimodal monitoring with advanced analytics, the model supports a shift toward anticipatory, childcentered, and ethically responsible epilepsy management. Prospective validation, explainable AI, and caregiver-centered design will be essential for real-world translation.

Key words: Pediatric Epilepsy; Seizure forecasting; Artificial Intelligence; Digital Health; wearable biosensors.

PP064

COMPUTATIONAL MODELLING OF ADVERSE DRUG REACTIONS USING PHARMACOGENOMIC AND LARGE LANGUAGE MODELS

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Adverse drug reactions (ADRs) are a leading cause of patient harm and healthcare burden. Both drug properties and patient-specific genetic variation strongly influence ADR risk, motivating the integration of pharmacogenomics into predictive models. Recent advances in Large Language Models (LLMs) have introduced flexible and interpretable approaches to ADR prediction, particularly when combined with external biomedical knowledge through Retrieval-Augmented Generation (RAG). RAG-enhanced LLMs ground model outputs in curated pharmacovigilance and pharmacogenomic databases, reducing hallucination and improving reliability compared to standalone LLMs. In parallel, emerging genomic language models (Gene-LLMs) conceptualize DNA, RNA, and other biological sequences as structured languages. Transformer-based architectures can capture long-range genomic dependencies associated with drug metabolism, efficacy, and toxicity. Integrating genomic, clinical, and pharmacological information within LLM-based frameworks enables biologically informed ADR prediction and enhances model transparency. However, federated learning approaches such as FedLLM, while supporting privacy-preserving collaboration across institutions, face notable limitations. Restricted access to diverse, highquality, and well-annotated datasets constrains model robustness, fairness, and generalizability across populations. This review summarizes recent computational approaches for adverse drug reaction (ADR) prediction, focusing on Natural Language Processing (NLP), Large Language Models (LLMs), Retrieval-Augmented Generation (RAG), and Federated LLM (FedLLM) frameworks. It emphasizes the role of pharmacogenomic integration in improving interpretability, while discussing challenges related to fairness, bias, and clinical deployment.

A focused literature review was conducted on genomic language models, LLM-based ADR prediction methods, RAG architectures, and NLP-driven pharmacovigilance systems. Particular attention was given to approaches that integrate structured pharmacogenomic profiles with unstructured clinical narratives to link molecular-level data with clinical outcomes. The use of established ADR databases (e.g., SIDER) and pharmacogenomic resources (e.g., PharmGKB, CPIC) was analyzed, alongside strategies for fine-tuning, interpretability, bias mitigation, and federated model training. Across studies, RAG-augmented LLMs consistently outperform standalone LLMs in retrieving and reasoning about ADRs by anchoring predictions in structured pharmacovigilance and pharmacogenomic knowledge bases. Incorporating genomic data enables models to account for inter-individual variability in drug response and ADR susceptibility. In contrast, traditional machine learning models, while often achieving strong predictive performance, generally lack transparency and clinical interpretability. FedLLM approaches improve data privacy and regulatory compliance but demonstrate reduced robustness and fairness due to limited data diversity and cross-institutional heterogeneity.

Using pharmacogenomics to predict adverse reactions can improve the safety and effectiveness of medical care. To handle the increasing amount of complex, open-source pharmacogenomics data, AI algorithms that can perform large-scale computations and high-performance statistical analyses are crucial. Large language models (LLMs) offer a promising path with their user-friendly and interactive interfaces, which could streamline clinical workflows and support better decision-making.

PP065

IDENTIFYING NOVEL STOMATIN-LIKE COMPOUNDS: PROMISING ANALGESIC CANDIDATES

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Abstract

Stomatin, a 31kDa integral membrane protein, found to be expressed in the sensory neurons of mammals, influences the mechanosensation by the primary sensory neurons1 . Stomatin colocalizes with different acid sensing ion channels (ASICs)2 having highest interaction with ASIC33 . The distal C-terminus and the first transmembrane domain (TM1) of ASIC3 are responsible for interaction with stomatin3 . Stomatin can interfere with the activity of ASIC3 to sense the change in pH of the extracellular environment and inhibit ASIC3 to send a pain signal to the central nervous system2 . A large unprofessional population often practices selfmedication without considering the adverse effects of non-opioid drugs like aspirin and ibuprofen (non-steroidal anti-inflammatory drugs (NSAIDs)), and paracetamol (non NSAID), leading to chronic side effects. Prolonged and irresponsible use of aspirin and ibuprofen are often prone to cause gastrointestinal problems and stomach ulcer, while paracetamol may lead to hepatotoxicity5,6 . Therefore, this leads to a need for identifying novel non-hepatotoxic analgesics. This study aims to investigate the interaction between stomatin and ASIC3 for the identification of novel stomatin-like drugs that can act as potential pain killers. The interaction area of stomatin and ASIC3 was targeted for the pharmacophore modelling of stomatin-like compounds (SLCs) and using virtual screening, molecular docking, absorption distribution metabolism excretion and toxicity (ADMET) analyses, five compounds have been chosen and subjected to molecular dynamics (MD) simulation. The compounds with topological polar surface area (TPSA) less than 90 Å2 , moderate lipophilicity, moderate solubility, high gastrointestinal absorption, positive blood-brain barrier penetration, not a Pgp substrate, and, no violation of Lipinski's rule of 5, were selected. All the five chosen compounds have shown no hepatoxicity. The trajectory analysis of MD simulation reveals stable interactions between TM1 and the SLCs. MD simulation of TM1 with aspirin, ibuprofen, and paracetamol their stability was found to be lower compared to TM1 and the five selected compounds. Furthermore, change in binding free energy of the protein-ligand complexes was calculated which reveals that all the tm1-SLC complexes exhibit lower change in binding free energy compared to that of complexes with common painkillers indicating strong binding between tm1 and SLCs. In conclusion, this study proposes some novel stomatin-like compounds which are non-hepatotoxic and can act as potential analgesics.

Keywords: Stomatin, ASIC3, analgesic, toxicity analysis, MD simulation

PP066

FIT-FOR-PURPOSE SAFETY BIOMARKER PANELS USING KRISHGEN GENLISA™ ELISAS FOR EARLY DETECTION OF XENOBIOTIC-INDUCED LIVER INJURY AND COMPLEMENT ACTIVATION

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Drug-induced liver injury (DILI) and complement-mediated immunotoxicity represent major attrition risks in drug development, necessitating sensitive, translational biomarkers for early de-risking. Commercial cytotoxicity assays like LDH release lack mechanistic insight and early detection capability. Here, we validate Krishgen Biosystems' GENLISA™ ELISA kits for Complement 3 (C3), Complement Component 4A (C4A), and Malondialdehyde (MDA) as a multiplexed panel for superior xenobiotic toxicity profiling.

HepG2 hepatocytes and THP-1 monocytes were exposed to Acetaminophen (APAP, 0-20 mM; DILI model), Lipopolysaccharide (LPS, 0-10 µg/mL; inflammation), and Rituximab (0-100 µg/mL; CDC model) over 48h. Supernatants/lysates were analyzed using GENLISA™ kits (96-well format, colorimetric detection at 450 nm) alongside LDH assay. Validation confirmed <10% intra-assay CV, 90-110% spike recovery, and LLOQ of 0.5-1.2 ng/mL across human serum/plasma matrices.

Results demonstrate MDA elevation (4.2-fold at 12h, 5 mM APAP) precedes LDH release (24h), enabling 2x earlier DILI detection (AUC=0.94 vs 0.76). Complement activation showed C3 consumption (65% drop, 24h rituximab) and C4A depletion (52% at 6h), correlating with MAC formation (r=0.89). Integrated panel scoring predicted toxicity liability with 92% accuracy across models, outperforming single endpoints.

Krishgen GENLISA™ panels provide standardized, cost-effective tools for ADME/Tox workflows, supporting species bridging, IND-enabling studies, and regulatory bioanalysis. These ready-to-use kits accelerate decision-making in Indian CRO/pharma pipelines by combining high sensitivity with validated performance.

Keywords: DILI, complement activation, ELISA, biomarker panel, xenobiotics

PP067

FROM THEORY TO PRACTICE: DETECTING UREA BELOW TRIPLE QUADRUPOLE LIMITS

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Abstract: Triple quadrupole mass spectrometers are widely used in LC–MS/MS bioanalysis because of their high sensitivity and specificity, achieved through Multiple Reaction Monitoring (MRM). The operation of these analyzers is governed by the Mathieu equation, which defines ion stability within oscillating RF and DC electric fields. Quadrupoles consist of four parallel rods through which ions travel under a combined potential; only ions with stable trajectories—determined by their position within the stability diagram—reach the detector. Resolution is controlled by the scan line through RF–DC space: a straight line through the origin provides constant resolution but results in increasing peak width with mass, whereas a curved line maintains unit resolution across the range. LC–MS/MS instruments use straight lines based on experimental adjustments instead of the ideal curve, creating a small margin of error. This margin allows limited measurements beyond the usual calibration range.

To investigate the practical implications of this theory and verify the reliability of extrapolation for low-mass ion detection, we developed an LC–MS method for the small molecular weight compound urea (60.06 g/mol), which produces a precursor ion at m/z 61.00 and a fragment ion at m/z 44.00—values near or below the lower calibration limits of many triple quadrupole systems. We developed a fit-for-purpose LC–MS method for urea quantification in rat plasma and cross-validated a bioanalytical method using SCIEX API-4500 (m/z 59.05–1952.43) and API-7500 (m/z 42.03–922.01). Despite theoretical constraints such as narrow stability regions and increased susceptibility to noise and isobaric interference, optimized conditions enabled accurate quantification across 20–1000 µg/mL. Precision, accuracy, and parallelism experiments confirmed equivalence between instruments, demonstrating that extrapolation outside nominal calibration ranges is feasible when grounded in quadrupole stability theory.

Our findings highlight that the predictable behavior of quadrupole systems—derived from the Mathieu equation and stability diagrams—supports reliable detection of ions beyond standard limits. By bridging theoretical principles with experimental validation, this study advances understanding of mass analyzer performance and expands the applicability of triple quadrupole systems in bioanalysis.

Keywords: Practical quadrupole theory, Mathieu stability diagram, Extrapolation of Mass Analyzer, voltage scan lines & ion stability

PP068

RAPID AND SENSITIVE ANALYTICAL METHOD FOR AMYLIN ANALOGS IN BLOOD SUGAR REGULATION THERAPEUTICS

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Amylin analogs such as, pramlinitide, display rapid absorption and are administered in low dosage, require a highly sensitive analytical method to accurately quantify during the evaluation of efficacy and safety in humans. Pramlintide was spiked into 100 µL of human serum at concentrations ranging from 10 to 100000 pg/mL. Protein precipitation was performed using 0.3 mL chilled 1% formic acid in methanol, followed by vortexing (5 min) and centrifugation (1204 rcf, 5 min). The supernatant was processed via Strata XCW SPE, conditioned with methanol and 0.1% formic acid in water. After washing with water and 20% acetonitrile, elution was done using 100 µL of 1% TFA in 80:20 methanol:water. Samples were transferred to autosampler vials for LC-MS/MS analysis. Chromatographic separation was achieved on an ExionLC AE system using a Luna Omega Polar PS C18 column (100 × 2.1 mm, 1.6 µm) at 0.6 mL/min, with mobile phases of 0.1% formic acid in water (A) and acetonitrile (B), at 75°C. Injection volume was 10 µL. A lower limit of quantitation (LLOQ) of 10 pg/mL was achieved using 100 µL of human serum and a streamlined SPE method. The assay demonstrated a 6- minute run time with linearity across 10–100,000 pg/mL (4 orders of magnitude). Good quantitative performance was demonstrated with accurate and highly reproducible (%CV) results. An average recovery of 68.1% with a %CV <5.75 was demonstrated for pramlintide analysis in human serum.

PP069

FORM IDENTIFICATION AND QUANTIFICATION IN PHARMACEUTICAL DEVELOPMENT ENABLED BY SPECTROSCOPY

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The effective utilization of spectroscopic techniques—Raman, Near-Infrared (NIR), and Infrared (IR) has been demonstrated in this work for the polymorph identification and salt disproportionation in drug substances and drug products. Three case studies are presented to illustrate the practical utility of these techniques across different stages of drug development.
Case Study 1: Inline Raman spectroscopy was used to investigate API polymorphic form conversion in tablets during dissolution. The API present in the tablet in its as-such state was identified as form I, while the solid in contact during dissolution exhibited a different spectral pattern, referred to as form II. The conversion from form I to form II during dissolution was successfully monitored in real time using inline Raman spectroscopy.
Case Study 2: The API in an oral solid dosage (OSD) tablet formulation was present as a salt with a potential risk of disproportionation to the free base. NIR spectroscopy was used to assess this risk. Specificity for the free-base spectral region was established, achieving a minimum detection limit of 3 % free base in the formulation. A PLS (Partial Least Squares) model was subsequently developed for the quantification of the free base.
Case Study 3: It describes the application of FT-IR spectroscopy to investigate the risk of salt disproportionation in APIs. The studies evaluated under stressed conditions such as high relative humidity, elevated temperature, and the presence of water on salt stability, enabling identification of conditions that promote disproportionation.

PP070

INVESTIGATION, IDENTIFICATION AND MITIGATION STRATEGY FOR A LABILE AMINOL PROCESS IMPURITY

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Background & Objective: During thermolytic Boc-deprotection, an unknown impurity was intermittently observed, with batch-to-batch variability suggesting a non-specific origin. We sought to identify this impurity, understand its analytical behaviour, and establish conditions for reliable detection and mitigation.
Methods: Impurity behaviour was assessed under varied chromatographic systems; only methanol-containing mobile phases resolved it from the API, whereas other conditions led to co-elution with API. To avoid solution-phase degradation seen in protic media, isolation and characterization were performed under additive-free conditions. Structural elucidation leveraged high-resolution MS with targeted interpretation and 2D NMR. Quantitation used qNMR in DMSO to decouple chromatographic artifacts from true concentration.
Results: MS/NMR assigned the primary structure of the impurity as an aminol. Oxidation of this species generated a minor N-formyl impurity, while few other signals corresponding to a methyl-ether and an imine were traced to in-source methanol addition and dehydration artifacts, respectively. During drug-product development, changing the diluent from a fully organic solvent to one containing 20% water (to aid polymer dissolution) accelerated aminol degradation, broadening/flattening the peak and masking its presence. Restoring anhydrous diluent conditions re-established detection fidelity.
Conclusions & Impact: This work clarifies the chemical identity and atypical analytical behavior of a labile aminol impurity, links a formulation-driven diluent change to false-negative results, and demonstrates qNMR in DMSO as a robust, orthogonal quantitation strategy. The findings underscore the interplay among impurity stability, chromatographic conditions, and formulation variables, enabling durable control strategies for development and QC.
Keywords: aminol impurity; in-source adducts; methanol artifact; qNMR; diluent effect; Boc deprotection.

PP071

ANALYTICAL RESILIENCE IN STABILITY TESTING: CASE STUDIES ON METHOD PERFORMANCE AND TROUBLESHOOTING

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Stability testing is fundamental to ensuring the long-term quality and consistency of pharmaceutical products, demanding analytical methods that remain robust under extended routine use. This poster presents three QC-relevant case studies that demonstrate how proactive monitoring and evidence-based troubleshooting strengthen analytical resilience during stability testing.

In the first case, co-elution of two impurities observed at the 12-month interval triggered an Out-of-Trend (OOT) assessment. Early investigation identified a column-related performance issue prior to sample analysis. A comprehensive system suitability batch containing all critical impurities was subsequently employed to verify method performance and to rule out a false OOT. The second case highlights precision challenges encountered during dissolution testing under repeated, long-sequence loading typical of stability studies. Minor drift relative to the initial 1.5% RSD criterion prompted a robustness evaluation. The findings supported revising the acceptance criterion to 2.0%, aligning expectations with real-world method capability and ensuring consistent QC performance. The third case focuses on method transfer for stability initiation, where inconsistent resolution between two impurities was traced to impurity saturation caused by injection volume. Optimizing the injection volume successfully restored consistent resolution between the impurities without modifying core chromatographic conditions, thereby maintaining overall method integrity during method transfer activity. Collectively, these cases illustrate how targeted troubleshooting, adaptive criteria, and thoughtful system suitability design enhance analytical reliability during long-term stability testing. The learnings reinforce the importance of proactive QC oversight to sustain method performance, reduce false investigations and ensure high-quality stability data.

PPO72

INTEGRATED ANALYTICAL AND BIOANALYTICAL APPROACHES FOR ADDRESSING COMPLEXITY IN AAV-BASED THERAPEUTICS

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Adeno-associated virus (AAV) based gene therapies have emerged as a transformative modality for the treatment of genetic and acquired diseases. Despite their clinical success, AAV products present significant analytical challenges due to their inherent structural and compositional complexity. Critical quality attributes (CQAs), including capsid integrity, genome packaging efficiency, full-to-empty capsid ratio, genome integrity, process- and product-related impurities, and biological potency, must be thoroughly characterized to ensure product safety, efficacy, and consistency throughout drug discovery and development. Robust analytical and bioanalytical strategies are therefore essential to navigate these complexities and support the advancement of AAV therapeutics from early research to clinical and commercial stages.

Bioanalytical assays complement physicochemical analyses by providing functional and quantitative insights into AAV products. Quantitative PCR-based methods are widely applied for viral genome titer determination, while infectivity and potency assays assess functional transduction efficiency and biological activity. Genome titer, typically quantified using qPCR or digital PCR, remains the primary metric for clinical dosing, whereas capsid titer provides insight into total particle load. ELISA-based methods are commonly employed for capsid quantification but may overestimate titers due to the detection of free capsid proteins. Comparative analysis using ELISA, qPCR, and slot blotting demonstrated broadly comparable titers across different AAV serotypes, including AAV8, AAV6, and AAV2, underscoring the importance of orthogonal approaches for accurate vector titer determination and dosing.

Further, functional potency was evaluated through infectious titer determination using transduction-based assays. Flow cytometry-based analysis of eGFP expression in HEK293T cells demonstrated a dose-dependent increase in transduction efficiency across multiple AAV serotypes, underscoring the relevance of infectious titer as a critical indicator of vector potency. Capsid heterogeneity, including empty, partial, and full capsids, as well as aggregates, represents another major CQA influencing efficacy and immunogenicity. Traditional tools such as transmission electron microscopy (TEM) and analytical ultracentrifugation (AUC) enable detailed capsid analysis but are limited by low throughput and operational complexity. To address these limitations, we implemented imaged capillary isoelectric focusing (icIEF) and capillary electrophoresis-SDS using the Maurice platform, which offered reduced sample requirements by approximately one to two orders of magnitude, improved reproducibility with typical assay variability below 5% CV, and compatibility with GMP environments.

Additionally, DNA and protein impurities were characterized using complementary techniques, including qPCR, next-generation sequencing, SDS-PAGE, and ELISA. Integrating short- and long-read sequencing approaches provided a more comprehensive assessment of encapsidated and residual DNA species. In conclusion, comprehensive AAV characterization requires integrated, orthogonal analytical strategies to manage vector complexity and meet evolving regulatory expectations. Advances in analytical technologies, improved standardization, and process optimization are collectively enabling safer, more effective, and scalable AAV-based gene therapies.

PP073

CMC-ORIENTED BENCH-TO-PILOT SCALE AAV VECTOR PRODUCTION

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Purpose: Developing reliable and efficient AAV vector manufacturing processes is a top priority in the field of gene therapy to ensure broader accessibility. AAV vector production in fixed-bed bioreactor has shown high potential due to benefits like a single-use, fully integrated system with low surface area to generate high titre AAV vector. The main challenges in this process are low yield and prolonged production time, which lead to higher costs for the final product. We report an AAV vector production process with a significantly shorter timeline (10 days) in fixed-bed bioreactor. Our data shows that this process can serve as a scalable and cost-effective strategy for vector production.
Methods: All bioreactor runs were performed in Cytiva® iCELLis Nano bioreactor (1.07 m^2). The HEK293T cells were seeded at 30,000 cells/cm^2 following aseptic conditions and expanded to reach 1.7-2 × 10^6 cells/carrier strip before transfection with packaging plasmids [pRep2-Cap9, pHelper, and pAAV-ITR.GOI] and PEIPro® (Polyplus) transfection reagent in 1:2 ratio. The cell numbers and culture conditions (pH, Dissolved Oxygen, and Media Glucose concentration) were closely monitored throughout the run. Post-transfection (72 h and 120 h), culture media were harvested, followed by cell lysis from carrier strips. Post-harvest, AAV vectors were captured using an Affinity chromatography-based system. Vector titration and quality checks were carried out following standard methodologies.
Results: Our results indicate that process variables like cell seeding, DNA amount/per cell, and harvesting methods contribute most significantly towards increasing vector yields. The high cell seeding density (30,000 cells/carrier strip) resulted in a reduced cell expansion phase (3-5 days) compared to earlier reports. We have used lower amounts of total DNA (1-1.42 µg/million cells) for transfection and achieved 1.35-2.5 × 10^5 vg/cell at this ratio, improving upon previously published reports. Intensification of vector harvesting steps during these runs resulted in an average 8-fold increase (crude yield 4.92 × 10^{14} vg) compared to the first run (crude yield 5.66 × 10^{13} vgs). This enhancement was also evident during the vector purification process, with a recovery rate of 80-98.65% for different transgenes packaged in pRep2-Cap9 WT capsid.
Conclusion: To address challenges in the AAV vector production process, we have systematically optimised critical production parameters. The duration of the cell expansion phase had a significant impact on vector production, along with biological parameters such as pH, plasmid concentration, and metabolite concentration. As noted during several bioreactor production cycles in our study, these parameter changes affect vector yield favourably and result in high vector yield in an improved timeline-based process. We anticipate that our optimised bioreactor-based vector production protocol can be adapted effectively for pilot-scale production processes (2.26 m2 and 4 m2 bioreactors).

Keywords: AAV vector, Fixed-Bed Bioreactor, Large-scale vector production, Gene Therapy Product (GTP), Genetic disorder.

PP074

SPLICING-ENHANCED HYBRID DUAL AAV VECTORS IMPROVE INTRACELLULAR DISPOSITION AND PHARMACOLOGICAL EFFICACY OF ABCA4 GENE THERAPY IN STARGARDT DISEASE

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Background & Purpose: Recombinant adeno-associated viral (AAV) vectors are widely used for retinal gene therapy; however, their limited packaging capacity restricts delivery of large therapeutic genes such as ABCA4, which is implicated in Stargardt disease. Hybrid dual (HD) AAV vectors overcome size constraints but exhibit suboptimal pharmacological performance due to inefficient premRNA splicing across overlapping inverted terminal repeat (ITR) regions, leading to reduced transgene bioavailability. To address this limitation, we developed a compact 90-bp synthetic splice enhancer intron (SEI) to improve transcript processing, intracellular transport, and functional gene expression.

Methods: SEI-containing HD AAV vectors were compared with conventional 297-bp overlapping AP (OAP) sequences using LacZ and ABCA4 transgenes. In vitro analyses assessed splicing efficiency (spliced/unspliced mRNA ratios) and reporter expression to evaluate intracellular transcript processing and transport kinetics. Pharmacological modulation of splicing was examined using pre-mRNA splicing inhibitors. In vivo pharmacokinetics and pharmacodynamic efficacy were evaluated following subretinal administration in C57BL/6 mice and in Abca4−/− Stargardt disease models. Expression of endogenous spliceosomeassociated transport factors, SRSF1 and SRSF2, was analyzed in mouse retinal tissue and 661W retinal progenitor cells.

Results: SEI-based HD AAV vectors demonstrated significantly enhanced splicing efficiency and transgene expression compared to OAP vectors, reflected by increased reporter activity and higher spliced/unspliced mRNA ratios. Under splicing inhibition, SEI vectors retained superior transcript processing, indicating improved intracellular stability and reduced metabolic loss of unspliced RNA. In vivo, SEI HD vectors showed enhanced retinal transgene expression and superior restoration of visual function, as measured by electroretinography, in Abca4−/− mice. Transgene expression levels correlated with endogenous SRSF1 and SRSF2 abundance, supporting a role for host splicing machinery in modulating intracellular transport and pharmacological efficacy.

Conclusion: Incorporation of a synthetic splice enhancer intron represents a formulation-level optimization that improves the pharmacokinetic and pharmacodynamic profile of HD AAV vectors by enhancing mRNA processing, intracellular transport, and functional protein expression. This strategy significantly improves ABCA4 gene delivery and holds translational potential for Stargardt disease and other inherited retinal disorders.

PP075

AN OVERVIEW OF PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT IN EUROPEAN UNION, UNITED STATES AND SOUTH AFRICA

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Pharmaceutical Product Lifecycle Management (PLM) encompasses all stages from product development through regulatory approval to post-market changes. It encompasses scientific and quality activities as well as regulatory strategies to maintain product quality, safety and efficacy at every stage. The ICH Q10 guideline describes a pharmaceutical quality system implemented throughout all stages of the product lifecycle. Similarly, the ICH Q12 guideline provides a framework to facilitate predictable management of post-approval CMC changes, aiming to promote innovation and continual improvement while strengthening quality assurance and supply security. We hypothesize that global harmonization initiatives (ICH Q8–Q12) have improved lifecycle management consistency across major markets, but significant regulatory differences in the EU, US and South Africa continue to pose challenges for aligned LCM strategies. A comparative information gathered from official regulatory documents, the FDA database and SAHPRA, EMA website and literatures. Major regulatory jurisdictions - the European Union, United States and South Africa each maintain distinct frameworks for controlling product changes, the European Medicines Agency (EMA) of the European Union uses a detailed variation classification system (Type IA, IAIN, IB, II) and applies ICH Q12, providing a structured, harmonized approach to managing post-approval changes.

The United States Food and Drug Administration (USFDA) also implements ICH Q12, but uses its own system: PAS, CBE-30, CBE-0 and Annual report for post-approval changes, giving more flexibility for low-risk modifications. South African Health Products Regulatory Authority (SAHPRA) of South Africa has adopted the EU variation system, but includes local adaptations, there will be specific exceptions including: Alterations, Exclusions, Additions. It is important to compare these jurisdictions because each has distinct regulatory requirements that affect pharmaceutical development and supply. This overview compares these regional regulations and key lifecycle-management guidelines, highlighting how the ICH quality directives (Q8–Q12) provide a common Quality-by-Design framework to harmonize development and change management practices globally. Identified ongoing challenges such as divergent legal requirements and submission procedures, that companies face when aligning lifecycle strategies across multiple authorities. In practice, each authority often has unique requirements, which can complicate global planning and that differences in dossier format, submission portals and review timelines can add months or even years to a global launch. As conclusion alignment around ICH principles has facilitated more consistent LCM practice globally.

Keywords: Pharmaceutical Product Lifecycle Management, ICH Q8 - Q12 guideline EMA, USFDA, SAHPRA.

PP076

CROSS-JURISDICTIONAL ANALYSIS OF EXPEDITED REGULATORY PATHWAYS FOR ONCOLOGY THERAPEUTICS: NAVIGATING COMPLEXITIES IN GLOBAL DRUG DEVELOPMENT

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The development of innovative oncology therapeutics is often constrained by lengthy regulatory review timelines, despite the urgent and life-threatening nature of cancer. To address high unmet medical needs and accelerate patient access, regulatory authorities across the globe have established expedited approval pathways. However, differences in regulatory frameworks, evidentiary expectations and reliance practices across jurisdictions create significant challenges for global drug development. This study aims to conduct a cross-jurisdictional analysis of expedited regulatory pathways for oncology therapeutics and to evaluate how these variations influence regulatory strategy and global product development. A comparative regulatory review methodology was adopted, focusing on major regulatory agencies, including the United States Food and Drug Administration (USFDA), the European Medicines Agency (EMA), the South African Health Products Regulatory Authority (SAHPRA) and the Central Drugs Standard Control Organisation (CDSCO). Key expedited pathways such as Fast Track, Breakthrough Therapy Designation and Accelerated Approval (US FDA); PRIME and Conditional Marketing Authorisation (EMA); Priority Review and reliance-based review mechanisms (SAHPRA); and Fast-Track approval (CDSCO) were systematically examined. Regulatory guidelines, legislative documents, scientific advice publications and publicly available assessment reports were reviewed to identify eligibility criteria, review timelines, data requirements and post-authorisation commitments.

The analysis demonstrates that all selected regulatory agencies share a common objective of enabling earlier access to promising oncology therapies, particularly for serious or life-threatening conditions. However, notable differences exist in the degree of flexibility afforded in clinical evidence requirements, acceptance of surrogate endpoints and reliance on decisions from Reference Regulatory Authorities (RRA). The USFDA and EMA operate well-defined, structured expedited pathways supported by formal scientific advice and rolling review processes, while SAHPRA primarily facilitates expedited access through Priority review and reliance-based regulatory decisions. These variations significantly affect global development sequencing, dossier preparation and submission strategies for oncology products. In conclusion, although expedited regulatory pathways for oncology therapeutics are aligned in intent, their implementation differs considerably across jurisdictions. A thorough understanding of cross-jurisdictional regulatory nuances is essential for regulatory affairs professionals to design efficient and compliant global development strategies. Greater regulatory harmonisation and structured reliance practices may further reduce duplication, improve efficiency and enhance timely patient access to innovative oncology therapies.

Keywords: Oncology therapeutics, expedited approval pathways, regulatory affairs, US FDA, EMA, SAHPRA, reliance, global drug development

PP077

USFDA REGULATORY CONSIDERATIONS IN GENE AND CELL THERAPY (GCT) DEVELOPMENT

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Gene and Cell Therapies (GCTs) represent a transformative class of advanced therapeutics with the potential to address unmet medical needs, particularly in rare and life-threatening diseases. However, their complex biological nature, manufacturing variability and long-term safety concerns pose significant regulatory challenges. This study hypothesizes that early and continuous integration of U.S. Food and Drug Administration (FDA) regulatory requirements, as defined under 21 CFR, across preclinical, clinical and post-approval stages is critical for the successful development and licensure of GCT products. A systematic regulatory analysis was conducted using publicly available FDA guidance documents, regulations and policy frameworks issued by the Center for Biologics Evaluation and Research (CBER). The analysis focused on regulatory requirements governing investigational and licensed biological products under 21 CFR Part 312 (Investigational New Drug Applications) and 21 CFR Parts 600-680 (Biological Products). Key guidance documents related to investigational new drug (IND) applications, chemistry, manufacturing and controls (CMC), nonclinical development, clinical trial design, long-term follow-up and post-marketing surveillance were reviewed and synthesized. Emphasis was placed on identifying common regulatory expectations, risk-based approaches and development bottlenecks unique to GCT products.

The USFDA places strong emphasis on robust preclinical characterization, including biodistribution, persistence and tumorigenicity studies, to support initial human exposure under 21 CFR §312.23(a)(8). In clinical development, adaptive and early-phase trial designs prioritizing patient safety are encouraged, particularly for rare diseases with limited patient populations. CMC considerations were identified as a critical determinant of regulatory success, with challenges related to product heterogeneity, potency assay development, comparability following manufacturing changes and scale-up. Additionally, long-term follow-up requirements, often extending up to 15 years for integrating vectors, reflect FDA's focus on delayed adverse event monitoring under 21 CFR §601.70, address risks such as insertional mutagenesis associated with integrating vectors. The availability of expedited regulatory pathways, including Regenerative Medicine Advanced Therapy (RMAT) designation and early FDA interactions (Initial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs (INTERACT) meetings), was found to significantly support efficient development while maintaining regulatory rigor.

In conclusion, GCT development under the USFDA framework requires a comprehensive, lifecycle-based regulatory strategy grounded in 21 CFR-defined statutory and regulatory requirements**.** Understanding FDA expectations early in development can mitigate delays, enhance patient safety and accelerate the translation of promising GCT products from bench to bedside. This regulatory perspective is essential for researchers, developers and regulatory professionals engaged in advancing next-generation therapeutics.

Keywords: Gene and Cell Therapy, US FDA Regulation, 21 CFR Part 312, CMC, Long-Term Follow-Up

PP078

REGULATORY CHALLENGES IN THE APPROVAL OF PERSONALIZED AND PRECISION MEDICINES

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Personalized and precision medicine aims to improve therapeutic outcomes by tailoring medical interventions based on individual genetic, biomarker, environmental, and lifestyle characteristics. While this approach is transforming modern drug development, it presents significant regulatory challenges, as existing regulatory frameworks were primarily designed for conventional, population based therapies. Regulatory authorities, including the USFDA, recognize that individualized therapies often involve small patient populations, complex manufacturing processes, and innovative technologies that challenge traditional evaluation models. One major regulatory challenge is the limited feasibility of large randomized clinical trials, leading to increased reliance on biomarkers, surrogate endpoints, and real world evidence to support safety and efficacy. The co-development of therapeutics with companion diagnostics further complicates regulatory pathways, as drugs and diagnostics are often reviewed under separate regulatory frameworks, requiring coordinated assessment. In addition, the growing use of next generation sequencing and genomic testing necessitates robust validation standards and continuous regulatory oversight.

Regulatory harmonization across global jurisdictions remains limited, creating barriers to simultaneous international development and timely patient access. Precision medicine also depends on the collection and analysis of large volumes of genomic and health data, raising concerns related to data integrity, privacy, informed consent, and long-term data governance. Ethical and policy considerations, including equitable access, affordability, and reimbursement uncertainty, further influence regulatory decision making and implementation. Addressing these challenges requires adaptive regulatory frameworks, strengthened regulatory science, early stakeholder engagement, and increased international collaboration. Such approaches are essential to support innovation while ensuring the safety, effectiveness, and equitable availability of personalized and precision medicine.

Keywords: Personalized medicine, precision medicine, USFDA, biomarkers,Next Generation Sequencing (NGSs)

PP079

USFDA REGULATORY FRAMEWORK GOVERNING ADVANCED DRUG DELIVERY SYSTEMS

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Advanced Drug Delivery Systems (ADDSs) represent a rapidly evolving class of pharmaceutical technologies designed to enhance therapeutic efficacy, safety, and patient compliance through controlled drug release, targeted delivery, and improved bioavailability. These systems include implantable devices, transdermal patches, controlled- and sustained-release formulations, nanomedicines, and combination products that integrate drugs with medical devices and/or biological components. Due to their complex and multifunctional nature, ADDSs pose unique regulatory challenges that extend beyond conventional drug or device evaluation frameworks. In the (USFDA) regulates ADDSs through classification as drugs, medical devices, or combination products, with the assigned category determining the applicable regulatory pathway, preclinical and clinical requirements withquality system obligations. This study focuses on the USFDA regulatory framework governing ADDSs, with particular emphasis on quality and manufacturing regulations. Medical device–related ADDSs are subject to 21 CFR Part 820, the Quality System Regulation (QSR), which establishes current good manufacturing practice (CGMP) requirements covering design controls, management responsibility, production and process controls, corrective and preventive actions (CAPA), documentation, and recordkeeping to ensure product safety and effectiveness. For ADDSs classified as combination products, 21 CFR Part 4 provides a unified regulatory framework that clarifies the applicable cGMP requirements across drug, device, and biological constituent parts. This regulation enables manufacturers to implement an integrated quality management system that ensures compliance throughout the product lifecycle, including postmarketing safety reporting. Overall, the USFDA regulatory framework for ADDSs emphasizes robust quality systems, riskbased evaluation, and lifecycle management to address the scientific and regulatory complexities of advanced delivery technologies. Understanding and effectively implementing these regulations is essential for successful product development, regulatory approval, and commercialization, while supporting innovation and safeguarding public health. KEYWORDS: Advanced Drug Delivery Systems (ADDSs), USFDA Regulatory Framework, Combination Products, Quality System Regulation (21 CFR Parts 4 and 820), Current Good Manufacturing Practices (cGMP).

PP080

A COMPARATIVE ANALYSIS OF GLOBAL REGULATORY PATHWAYS FOR ACCELERATED DRUG DEVELOPMENT

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Accelerated regulatory pathways have become a cornerstone of modern drug development as global health systems confront rising burdens of rare, complex, and life-threatening diseases. Traditional development timelines, often exceeding ten years, delay patient access to transformative therapies. In response, major regulatory authorities including the FDA, EMA, Pharmaceuticals and Medical Devices Agency (PMDA), and National Medical Products Administration (NMPA) have implemented expedited programs designed to shorten review timelines while maintaining rigorous standards of safety, quality, and efficacy.

This poster presents a comparative analysis of global accelerated drug development pathways, focusing on the FDA's Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review the EMA's PRIME, Accelerated Assessment, and Conditional Marketing Authorisation Japan's SAKIGAKE designation and Conditional Early Approval System and China's Breakthrough Therapy and Priority Review mechanisms. Within the U.S. regulatory framework, these pathways are primarily governed under 21 CFR Part 312 (Investigational New Drug applications), 21 CFR Part 314 Subpart H (Accelerated Approval for drugs), 21 CFR Part 601 Subpart E (Accelerated Approval for biologics), and 21 CFR Part 314.100–314.170 (NDA review procedures, including Priority Review). Key differentiators include eligibility criteria, timing of designation, intermediate clinical endpoints, and the scope of post-marketing obligations.

The FDA's National Priority Voucher (NPV) program (2025) introduces unprecedented 1–2-month review timelines for therapies aligned with national priorities, building upon the statutory authority of FD&C Act Section 506 and the procedural framework of 21 CFR Part 314 and Part 601. The EMA's evolving PRIME framework emphasizes early scientific advice to prevent, while Japan's SAKIGAKE program offers a unique style review manager to accelerate consultations. Concurrently, China's NMPA has substantially reduced historical drug lag through reforms supporting rapid clinical trial initiation (ICH E6(R3) and (ICH E17) multi-regional clinical trials.

Keywords: Accelerated Regulatory Pathways, Expedited Drug Approval, Priority Review & Breakthrough Therapy, Global Regulatory Harmonization, Post-Marketing Commitments.

PP081

EVALUATION OF REGULATORY APPROVAL STANDARDS FOR ORAL ANTIDIABETIC FIXED-DOSE COMBINATIONS IN USA AND EU

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Abstract

Fixed-dose combinations (FDCs) of oral anti-diabetic agents have emerged as an important therapeutic strategy to address the multifactorial nature of type 2 diabetes mellitus by improving glycemic control, patient adherence, and treatment outcomes. However, the regulatory approval of such combinations remains complex due to the need to demonstrate added clinical value, safety, and quality beyond the individual components. This study evaluates and compares the regulatory approval standards applied to oral anti-diabetic FDCs in the United States and the European Union, focusing on scientific, clinical, and qualityrelated expectations. A qualitative regulatory analysis was conducted using publicly available guidance documents, approval pathways, and assessment principles issued by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Key regulatory elements examined include requirements for clinical efficacy, dose justification, bioavailability and bioequivalence studies, safety evaluation, and post-marketing obligations. The study also reviews selected approved oral anti-diabetic FDCs to illustrate practical regulatory decisionmaking in both regions. The findings indicate that while both the USA and EU emphasize a benefit–risk-based approach, differences exist in evidentiary expectations, flexibility in clinical data requirements, and approaches to therapeutic justification of combinations. The FDA places strong emphasis on demonstrating contribution of each active ingredient, whereas the EMA adopts a more integrated assessment aligned with overall therapeutic advantage and public health impact. Despite these differences, regulatory convergence is evident through the application of ICH guidelines and harmonized quality standards. This evaluation highlights critical regulatory considerations that can inform strategic development and global submission planning for oral anti-diabetic FDCs. Understanding regional regulatory expectations may support more efficient product development, facilitate international approvals, and ultimately enhance patient access to optimized combination therapies.

PP082

ACCELERATED APPROVAL PATHWAYS FOR INNOVATIVE DRUGS – USFDA FRAMEWORK: CASE OF IMATINIB

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Accelerated approval is a regulatory pathway used for drugs intended to treat serious and life threatening conditions involving an unmet medical need. Under the United States Food and Drug Administration (US FDA) framework this pathway allows earlier approval of drugs that demonstrate a meaningful therapeutic advantage over existing treatments. Regulatory frameworks like 21CFR 314.510 approval based on surrogate endpoint and 21 CFR 314.560 for Termination of requirements. As per the USFDA framework consider disease severity, rarity and availability of alternative therapies when evaluating products for accelerated approval.

Approval may be granted based on surrogate or intermediate clinical endpoints that are reasonably likely to predict clinical benefit with the condition that sponsors conduct post approval studies to confirm the anticipated benefit. Imatinib mesylate represents a landmark example of innovation aligned with accelerated approval principles. Initially developed as a targeted therapy, imatinib selectively inhibits the BCR-ABL tyrosine kinase produced by the Philadelphia chromosome abnormality, which is central to the pathogenesis of chronic myeloid leukemia (CML).

Early clinical trials demonstrated dramatic hematologic and cytogenetic responses using surrogate endpoints, enabling rapid regulatory approval and early patient access. The success of imatinib later led to its repurposing for additional indications such as gastrointestinal stromal tumors (GIST) illustrating how existing drugs can be developed for new therapeutic uses based on emerging scientific evidence. Following patent expiry, imatinib also highlights the role of Paragraph IV filings under the Hatch-Waxman Act In 2016 Sun Pharmaceuticals received FDA approval for a generic version of imatinib after demonstrating bioequivalence and challenging patent exclusivity. This regulatory mechanism promotes competition, improves affordability and expands global access to essential medicines.

Overall, the imatinib case demonstrates how accelerated approval, drug repurposing strategies, Paragraph IV pathways facilitate global drug development, drug repurposing and access to innovative therapies.

Keywords: accelerated pathway, innovative drug, repurposing,para1Vfiling,imatinib,chronic myeloid leukemia (CML).

PP083

REGULATORY COMPLEXITY IN CLINICAL DEVELOPMENT OF ADVANCED THERAPIES-AN EUROPEAN PERSPECTIVE

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Abstract

Advanced therapy refers to new drug products that use gene therapy, cell therapy, and tissue engineering. They can be used to treat diseases or injuries, such as skin in burns victims, Alzheimer's, and cancer or muscular dystrophy, and have huge potential for the future of medicine. European Medicines Agency (EMA): Defines Advance Therapy Medicinal Products (ATMPs) as products based on genes, tissues, or cells (gene, cell, tissue-engineered products) and notes they can be combined with medical devices, requiring specific EU regulations (Regulation 1394/2007) for marketing authorization.

ATMPs including gene therapies, somatic cell therapies, and tissue-engineered products, are at the cutting edge of innovation and offer a major hope for various diseases for which there are limited or no therapeutic options. Therefore, they have attracted significant interest and discussion. To support their development and approval, the European Union introduced specific regulations for ATMPs, creating a common regulatory framework. A central part of this framework is the Committee for Advanced Therapies (CAT) at the EMA, which brings together scientific experts from all EU Member States and European Free Trade Association countries, as well as representatives from patient and medical organizations.

In ATMPs the heart of concern is to deal with diseases where traditional medicines have been proved ineffective. Regulatory complexity exists for advanced therapies (such as gene therapies, cell therapies, and tissue-engineered products) because they raise unique scientific, clinical, and ethical challenges that traditional medicines do not. Despite their transformative potential, the development and availability of ATMPs are constrained by challenges related to scientific complexity, manufacturing processes, regulatory approval pathways, and market access.

PP084

NAVIGATING THE REGULATORY LANDSCAPE AND UNDERSTANDING THE CHALLENGES FOR IMPLEMENTATION OF PRECISION MEDICINES IN THE U.S. MARKET

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Abstract

Precision medicine has emerged as a revolutionary approach in healthcare, aiming to optimize therapeutic outcomes by tailoring medical treatment to individual patient characteristics such as genetic profile, biomarkers, environment and lifestyle. In contrast to conventional "one-size-fits-all" therapies, precision medicines offer targeted interventions that enhance efficacy and reduce adverse drug reactions. The United States has been at the forefront of precision medicine innovation; however, the successful implementation of these therapies within the U.S. market presents significant regulatory and operational challenges. Navigating the U.S. regulatory landscape for precision medicines is complex due to evolving scientific technologies and the need for flexible regulatory frameworks. The U.S. Food and Drug Administration (USFDA) plays a central role in regulating precision therapies, including targeted drugs, biologics, gene therapies and their associated companion diagnostics. One of the major regulatory challenges is the co-development and approval of companion diagnostics alongside therapeutic products, requiring coordination between drug and medical device regulatory pathways. Additionally, validation of biomarkers and genomic assays remains critical to ensure clinical relevance, analytical validity and patient safety. Clinical development of precision medicines often involves small, genetically defined patient populations, making traditional randomized clinical trials difficult to conduct. As a result, innovative trial designs such as adaptive trials, basket trials, and umbrella trials are increasingly utilized, posing further regulatory challenges in terms of data interpretation and approval decisions. The incorporation of real-world evidence and next-generation sequencing data into regulatory submissions also raises concerns related to data quality, standardization and patient privacy. Beyond regulatory approval, implementation challenges such as high development costs, reimbursement uncertainties, healthcare infrastructure limitations, and disparities in patient access significantly impact the adoption of precision medicines in the U.S. market. Differences in regulatory expectations across global markets further complicate development strategies for multinational companies. This abstract provides an overview of the U.S. regulatory framework governing precision medicines and highlights key challenges associated with their development, approval and implementation. Understanding these regulatory and practical barriers is essential for fostering innovation, ensuring patient safety and facilitating the successful integration of precision medicine into the U.S. healthcare system.

Keywords: Precision Medicine, USFDA, Regulatory Landscape, Companion Diagnostics, Biomarkers, Personalized Therapy

PP085

PATENT LITIGATION IN MONOCLONAL ANTIBODY BIOSIMILARS: CORPORATE STRATEGIES FOR INTELLECTUAL PROPERTY PROTECTION AND MARKET EXCLUSIVITY ACROSS GLOBAL JURISDICTIONS

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The approval of monoclonal antibody (mAb) biosimilars represents a critical mechanism for enhancing patient access and addressing healthcare disparities in both developed and developing nations. However, the translation of regulatory approval into clinical availability is frequently impeded by aggressive patent litigation strategies employed by originator companies to prolong market exclusivity and suppress competition. This study investigates the patent litigation dynamics surrounding mAb biosimilars across four distinct jurisdictions - the United States, the European Union, Canada, and India - over the period spanning 2010 to 2025. Specifically, this analysis characterizes the defensive tactics utilized by originator pharmaceutical firms, such as patent thicketing and evergreening, which serve to prevent market entry of biosimilars, safeguard revenue streams, and maintain monopolistic dominance. The findings indicate a higher prevalence of patent claims within the United States, while highlighting significant heterogeneity in court rulings and litigation practices across the other studied regions. The research suggests that despite the advancement of legal frameworks intended to encourage biosimilar competition, originator companies continue to leverage complex intellectual property strategies to sustain barriers to entry. This paper concludes by evaluating the implications of recent regulatory developments and key judicial decisions on fair competition, global policy alignment, and patient access to affordable biologic therapies.The study shows that patent claims related to biosimilars are more common in the United States and it also identifies significant variations in court rulings and patent litigation practices across other jurisdictions. Though legal frameworks have improved to encourage competition for biosimilars, originator companies still employ complex intellectual property strategies to maintain barriers to competition. The study looks at the implications for fair competition, global policy alignment and patient access to reasonably priced biologic medications in light of recent regulatory changes and important court rulings.

Keywords: Biosimilars, Intellectual Property Rights, Monoclonal Antibodies, Patent Litigation, Patent Thickets

PP086

COMPLEXITIES IN DEVELOPING DRUG- ELUTING STENTS FOR DIABETIC PATIENTS: BRIDGING CLINICAL PERFORMANCE AND REGULATORY PREREQUISIITIES

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The development of drug-eluting stents (DES) for diabetic patients with coronary artery disease presents unique clinical and regulatory challenges due to diabetes-associated alterations in vascular biology, including diffuse atherosclerosis, impaired endothelial healing, and heightened risk of restenosis and late stent thrombosis. These complexities necessitate careful integration of clinical performance considerations with stringent regulatory prerequisites to ensure both safety and therapeutic effectiveness.

This poster examines the multifaceted challenges encountered during the development of DES intended for diabetic patients, focusing on the alignment between device design, clinical outcomes, and regulatory expectations. Key developmental complexities include optimization of stent platform design, selection of antiproliferative drugs, polymer biocompatibility, and controlled drug-release kinetics tailored to diabetic pathophysiology. From a regulatory perspective, emphasis is placed on preclinical evaluation, diabetes-relevant clinical trial design, subgroup analyses, long-term follow-up requirements, and post-market surveillance obligations mandated by global regulatory authorities.

The analysis highlights gaps between clinical innovation and regulatory evidence requirements, particularly in demonstrating sustained efficacy and safety in high-risk diabetic subpopulations. Bridging these gaps requires early regulatory engagement, scientifically justified clinical endpoints, and harmonized evidence-generation strategies that link clinical performance data with regulatory decision-making frameworks. The findings underscore the need for integrated development approaches to support efficient regulatory approval and improved clinical outcomes for drug-eluting stents in diabetic coronary artery disease.

Keywords:
Drug-eluting stents, Diabetic coronary artery disease, Regulatory prerequisites, Clinical performance, Device–drug combination products, Restenosis risk, Polymer biocompatibility, Clinical evaluation strategies, post-market surveillance, Regulatory approval pathways.

PP087

TECHNOLOGICAL INNOVATIONS DRIVING REGULATORY CONVERGENCE AND THEIR IMPACT ON INDIAN PHARMACEUTICAL EXPORTS

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Technological innovation has become a central force in modern drug discovery and development, influencing not only how medicines are designed and manufactured but also how they are evaluated and approved by regulatory authorities worldwide. Scientific tools such as Quality by Design (QbD), risk-based Good Manufacturing Practices (GMP), electronic Common Technical Document (eCTD) submissions, advanced analytical methods, and lifecycle management systems are embedded within the regulatory frameworks of leading agencies, including the US Food and Drug Administration (USFDA), European Medicines Agency (EMA), World Health Organization Prequalification Programme (WHO-PQ), and the South African Health Products Regulatory Authority (SAHPRA). These innovations aim to improve product quality, enhance patient safety, and accelerate access to medicines. However, incomplete adoption by India's Central Drugs Standard Control Organization (CDSCO) has resulted in regulatory divergence affecting global approval and export performance of Indian pharmaceutical products.

This study applies a comparative regulatory and technology-focused framework to evaluate how modern drug development innovations are integrated into global regulatory systems and compared with CDSCO requirements. Regulatory guidelines and technical standards from the USFDA, EMA, WHO-PQ, SAHPRA, and CDSCO are systematically reviewed. Key domains, including QbD, stability testing, impurity control, bioequivalence evaluation, GMP, electronic submissions, and lifecycle management, are mapped using structured comparison matrices to identify convergence and divergence. In later phases, regulatory inspection outcomes, approval timelines, and pharmaceutical export trends will be analyzed to assess the impact of these differences on Indian manufacturers. The study is supported by authoritative sources such as ICH Q8–Q12, WHO Technical Reports, PIC/S GMP, CDSCO NDCTR (2019), USFDA 21 CFR, EMA EudraLex, and SAHPRA publications, along with export and regulatory data from Pharmexcil and public databases.

Preliminary observations indicate strong regulatory convergence between the USFDA and EMA, primarily due to their full adoption of technology-based regulatory science, particularly in lifecycle management and electronic dossier review. SAHPRA shows essential alignment with these global frameworks, with some notable regional requirements to be considered both in lifecycle management and scientific flexibility in regulatory decision-making. CDSCO, however, has regional requirements to be considered & is considerably different both in terms of product lifecycle management as well as in submission dynamics. These divergences in SAHPRA are expected to be associated with increased regulatory queries, longer approval timelines, and higher compliance burdens for Indian pharmaceutical exporters. However, the approval timelines & regulatory queries in CDSCO seem to be better than those of the other international agencies that have been considered.

Overall, this research highlights the critical role of technological innovation in driving regulatory convergence. Strengthening India's adoption of globally accepted development and regulatory technologies has the potential to reduce regulatory barriers, improve approval efficiency, and enhance the global competitiveness of Indian pharmaceutical exports.

PP088

DATA INTEGRITY AND REGULATORY COMPLIANCE IN AI DRIVEN DRUG DISCOVERY: US FDA REGULATORY CONSIDERATIONS

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Drug discovery and development is a multiyear program (14 years), requiring more than US$1 billion to bring a single medicine to market. These challenges increase financial risk and drive higher drug costs. Artificial intelligence (AI) is transforming pharmaceutical research, by rapidly analyzing large datasets, identification of promising drug candidates, and improving compound–target predictions. AI is utilized across multiple stages of drug discovery, including target and hit identification, prediction of absorption, distribution, metabolism, excretion, and toxicity (ADMET), lead optimization, and drug repurposing. The increasing complexity of AI systems, particularly deep-learning models, introduces challenges related to validation, reproducibility, and interpretability. To mitigate these concerns, the U.S. Food and Drug Administration (FDA) has released a draft guidance titled "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products", which outlines a seven-step, risk-based credibility assessment framework for evaluating AI models that generate evidence supporting regulatory decisions on product safety, effectiveness, and quality.

The approach begins with definition of the task to be addressed by the AI model, followed by establishing the model's Context Of Use (COU). The risk level of the AI model is then assessed. Based on this assessment, a credibility evaluation plan is developed to demonstrate the reliability of the AI model outputs within the defined COU. The plan is subsequently executed through appropriate validation and testing activities, and the results along with any deviations from the planned approach, are systematically documented. Finally, the adequacy of the AI model for its intended COU is determined based on the generated evidence. AI generates predictions based on available data that require validation and interpretation by human experts; the combined use of AI's predictive capabilities and researchers' expertise can optimize drug discovery and accelerate the development of new medicines.

Keywords: Artificial intelligence (AI), drug discovery, drug repurposing, lead optimization, interpretability, reliability

PP089

MODEL-INFORMED DRUG DEVELOPMENT: A NEW ERA IN USFDA REGULATORY DECISION-MAKING

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Drug development takes almost $1 billion and many years of work to bring an innovative drug to market, which makes more creative and effective methods necessary to reduce cost as well as the duration of the study. Model-informed Drug Development (MIDD) is a crucial framework for promoting drug development and assisting with regulatory decision-making. MIDD is fundamentally built on three core elements: a deep understanding of the drug, disease and their interactions within the human body; integrating data from in vitro, preclinical and clinical studies; and application of this integrated knowledge to support drug development, regulatory decision-making and clinical use of drugs, biologics and generic products. The International Council for Harmonization (ICH) has expanded its guidelines to include MIDD, namely the M15 general guidance that USFDA and EMA have embraced, in order to standardize MIDD processes across various nations and regions. It uses the strategic application of computer modeling and simulation techniques which integrates nonclinical and clinical data with prior knowledge and information to produce evidence. Regulatory submissions under INDs, New Drug Applications (NDAs) or Biological License Applications (BLAs) frequently include findings based on MIDD techniques. It includes various modeling techniques like Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling, Disease Progression Models, Exposure-Response Relationships and Quantitative Systems Pharmacology (QSP). PK-PD modelings are becoming necessary for the clinical stages of oncology drug development under the model based methods. Tumor growth dynamic (TGD) modeling is one of the often used MIDD techniques in oncology. MIDD makes drugs to be approved more quickly for rare diseases and paediatric conditions, where it might be challenging to find enough patients for effective trials. The study of pharmacometrics combines biological, pathophysiological and pharmacological concepts with mathematical-statistical models to demonstrate xenobiotics interaction with patients in both positively and negatively. Its applications are potential contributions to the prediction of clinical outcomes, the design and efficiency of clinical trials, the reduction of discovery and trial costs. MIDD is a life-changing approach to overcome the challenges of modern drug development. By integrating advanced modeling techniques, MIDD not only enhances efficiency but also provides a deeper understanding of drug behaviour and patient response.

Keywords: Model-informed Drug Development (MIDD), Oncology, Tumor growth dynamic, Pathophysiological, Pharmacometrics.

PP090

COMPARATIVE ANALYSIS OF REGULATORY REQUIREMENTS ACROSS GLOBAL DRUG DEVELOPMENT SYSTEMS

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The increasing globalization of pharmaceutical research and development has amplified the need to understand and navigate diverse regulatory requirements across international drug development systems. Pharmaceutical companies now routinely design development programs intended for simultaneous or sequential approval in multiple jurisdictions, making regulatory alignment a critical determinant of development efficiency, cost control, and timely patient access. This comparative analysis examines regulatory requirements across major global drug development systems, with particular focus on the United States Food and Drug Administration (US FDA), the European Medicines Agency (EMA), and selected emerging regulatory authorities, to identify areas of convergence, divergence, and their practical implications.

The study evaluates regulatory expectations across key stages of the product lifecycle, including nonclinical studies, clinical trial authorization, quality and manufacturing standards, marketing authorization pathways, and post-approval obligations. Emphasis is placed on the role of international harmonization initiatives, especially the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), in promoting alignment of scientific and technical requirements. Widely adopted standards such as Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and the Common Technical Document (CTD) format are analyzed as foundational elements supporting regulatory convergence and facilitating global submissions. Despite significant progress in harmonization, the analysis highlights persistent regulatory differences that continue to challenge global development programs. Differences in accelerated approval mechanisms, conditional approvals, and special regulatory incentives-such as orphan drug and breakthrough therapy designations add further complexity, particularly for innovative products, biologics, and therapies addressing unmet medical needs. Emerging regulatory systems, while increasingly aligned with ICH principles, often retain additional national requirements that may result in duplicated studies or region-specific documentation.

The analysis further explores how regulatory heterogeneity influences strategic decision-making in drug development, including clinical trial site selection, sequencing of global submissions, and lifecycle management planning. It underscores the growing relevance of regulatory reliance, work-sharing arrangements, and collaborative review models as pragmatic approaches to reduce redundancy and optimize resource utilization while maintaining regulatory autonomy and public health safeguards. Examples of reliance-based assessments demonstrate their potential to accelerate approval timelines and improve access to medicines.

In conclusion, while global drug development systems are grounded in shared scientific principles, meaningful differences in regulatory implementation remain. Addressing these challenges requires robust regulatory intelligence, early and continuous engagement with regulatory authorities, and strengthened international cooperation. This comparative analysis provides valuable insights for regulators, industry stakeholders, and policymakers aiming to enhance efficiency, predictability, and patient access within the global drug development landscape.

PP091

BEYOND THE BLACK BOX: REGULATORY STRATEGIES AND CASE STUDIES FOR AI-DERIVED THERAPEUTICS

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Artificial intelligence (AI) derived therapeutics make use of generative AI. It reduces the time for identification and first human trials from years to months. The algorithms of AI used to develop new drugs work like a black box where the decision-making process is not fully visible. This is a challenge for regulatory systems which are designed for traditional hypothesis-based research therefore, regulatory agencies have to evaluate whether the AI system used is transparent, reliable, and produces consistent and reproducible results, not only about how well an AI-developed drug works in patients.

This poster examines how regulators worldwide are responding to the use of AI in drug development, using three key case studies. Firstly, Rentosertib (ISM001-055), which is currently in Phase IIb/III for idiopathic pulmonary fibrosis, represents the first therapeutic that is an AI generative target to reach late-stage clinical development, demonstrating regulatory acceptance when data provenance and biological validation are robust. Second, REC-994, an AI-identified candidate for neurovascular disease, highlights the risk of algorithmic overfitting, where strong early-phase signals failed to translate into sustained clinical efficacy, underscoring the regulatory importance of longitudinal validation beyond early datasets. Third, the FDA's 2025 AI-Assisted Scientific Review Pilot Program illustrates a transformative shift in regulatory practice, wherein agencies now deploy AI internally to review dossiers, indirectly favoring sponsors whose development workflows align with similar AI-enabled validation standards.

According to reviews of the EMA Reflection Paper on AI and the 2025 FDA Draft Guidance, regulators focus on whether AI models are transparent, explainable, and give consistent results. Although AI-driven drug programs show high success rates in Phase I trials (around 80–90%), identifying and validating the correct biological target remains the biggest challenge for regulatory acceptance.

In conclusion, generative AI tools used in drug discovery are treated like regulatory medical software and made part of submission. Interaction with regulators early and regularly is the most important factor in enhancing probability of approval of AI developed drugs in later stages of clinical trials.

Keywords: Regulatory transparency, AI explainability, Generative AI drug development, Validation and reproducibility, Early regulator engagement.

PP092

A CRITICAL REVIEW OF REGULATORY PATHWAYS FOR THE APPROVAL OF COMBINATION PRODUCTS CONTAINING MONOCLONAL ANTIBODIES BY USFDA

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Combination products containing monoclonal antibodies (mAbs) represent a rapidly expanding class of advanced therapeutics that integrate biologics with devices and/or drug components to enhance therapeutic precision, patient compliance, and clinical outcomes. Examples include prefilled syringes, autoinjectors, on-body delivery systems, and antibody–device co-packaged products. While these innovations offer clear clinical advantages, they also introduce regulatory complexity due to the need to assess the safety, effectiveness, and quality of multiple constituent parts within a single product. This paper presents a critical review of the regulatory pathways employed by the U.S. Food and Drug Administration (USFDA) for the approval of monoclonal antibody–based combination products, with particular emphasis on jurisdictional assignment, review processes, and associated regulatory challenges.

A structured qualitative review of USFDA regulatory frameworks was conducted using publicly available legislation, guidance documents, and policy statements. Key sources included regulations governing combination products, biologics license applications (BLAs), investigational new drug (IND) applications, investigational device exemptions (IDEs), and guidance related to the Primary Mode of Action (PMOA). The analysis focused on regulatory classification, center assignment through the Office of Combination Products, premarket submission pathways, coordination between reviewing centers, and post-market regulatory obligations. Critical evaluation was performed to identify gaps, overlaps, and limitations in the current regulatory approach as applied to monoclonal antibody–based combination products.

Results: The review indicates that USFDA employs a PMOA-based framework to assign regulatory jurisdiction, most commonly designating monoclonal antibody combination products to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This approach provides a clear procedural basis for review but may inadequately capture the functional interdependence between the antibody and device components. While the framework allows flexibility through cross-center consultation and coordinated review, challenges remain in aligning drug and device development timelines, managing divergent evidentiary expectations, and addressing human factors and device usability within biologics-led submissions. Additionally, regulatory uncertainty may arise during early development stages, potentially affecting development efficiency and innovation.

Conclusion: USFDA's regulatory pathways for monoclonal antibody–based combination products are scientifically robust and grounded in risk-based principles; however, they face limitations in fully addressing the integrated nature of these products. Greater regulatory clarity, earlier cross-center engagement, and enhanced guidance specific to mAb–device interdependence could strengthen the approval process. Addressing these challenges is essential to facilitate efficient development, timely market access, and sustained innovation in monoclonal antibody combination products.

PP093

A COMPARATIVE ASSESSMENT OF USFDA, EMA, AND MHRA REGULATORY FRAMEWORKS NAVIGATING THE COMPLEX EXPEDITED APPROVAL LANDSCAPE OF ADVANCED THERAPY MEDICINAL PRODUCTS

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Advanced Therapy Medicinal Products (ATMPs), including gene therapies, cell therapies, and tissue-engineered products, offer transformative potential for the treatment of serious and life-threatening diseases. Nevertheless, their scientific complexity, individualized manufacturing approaches, and small patient populations create significant regulatory challenges. To address unmet medical needs while maintaining robust standards of safety, quality, and efficacy, global regulatory authorities have introduced dedicated expedited development and approval pathways. This study presents a comparative evaluation of expedited regulatory frameworks for ATMPs implemented by the U.S. Food and Drug Administration, the European Medicines Agency, and the Medicines and Healthcare products Regulatory Agency, highlighting similarities, differences, and regulatory strategies aimed at accelerating patient access to innovative advanced therapies.

A qualitative comparative regulatory review was conducted using publicly available guidance documents, legislation, and regulatory frameworks issued by FDA, EMA, and MHRA. The analysis focused on expedited programs applicable to ATMPs, including eligibility scope, regulatory flexibility, scientific advice mechanisms, clinical evidence requirements, and post-authorization obligations. Key expedited pathways reviewed included FDA's Regenerative Medicine Advanced Therapy (RMAT) designation and Breakthrough Therapy designation, EMA's Priority Medicines (PRIME) scheme and Conditional Marketing Authorisation, and MHRA's Innovative Licensing and Access Pathway (ILAP) alongside Conditional Marketing Authorisation and Exceptional Circumstances routes. Comparative mapping was performed to identify similarities, differences, and regulatory convergence across jurisdictions.

The analysis demonstrates that all three regulators adopt a risk-based and patient-centric approach to expedite ATMP development, particularly for serious or rare conditions with unmet medical need. FDA's RMAT designation provides early and intensive regulatory interaction, facilitating accelerated clinical development and potential rolling review. EMA's PRIME scheme emphasizes early scientific support and enhanced engagement to optimize evidence generation, often coupled with conditional approval mechanisms. MHRA's ILAP offers a highly integrated pathway combining regulatory, health technology assessment, and NHS engagement, reflecting the UK's life-sciences-focused regulatory strategy post-Brexit. Despite shared objectives, notable differences exist in evidentiary flexibility, timelines, and post-approval commitments, with EMA and MHRA placing comparatively stronger emphasis on conditional approvals and long-term follow-up.

Expedited pathways for ATMPs across FDA, EMA, and MHRA demonstrate increasing regulatory alignment in principle, yet retain jurisdiction-specific procedural distinctions. Understanding these differences is critical for developers planning global ATMP development and regulatory strategies. Enhanced international collaboration and regulatory convergence could further streamline ATMP approvals while maintaining robust safety and efficacy standards.

PP094

LIFECYCLE MANAGEMENT OF BIOLOGIC-DEVICE COMBINATION PRODUCTS IN THE UNITED STATES REGULATORY LANDSCAPE

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Hypothesis: Effective lifecycle management of biologic-device combination products in the United States depends on early regulatory planning, accurate determination of the Primary Mode of Action (PMOA), and coordinated oversight across development, approval, and postmarket phases to ensure product safety, effectiveness and regulatory compliance.

Methods: This work is based on a regulatory analysis of the U.S. Food and Drug Administration (FDA) framework governing biologic-device combination products. Key regulatory pathways, guidance documents, and post-approval change management mechanisms were reviewed to evaluate how lifecycle requirements are applied across product development, pre-approval phase and post-approval phases. Emphasis was placed on PMOA determination, lead center assignment, premarket submission types and risk-based postapproval change management.

Supporting Data: Supporting data include FDA regulatory standards for combination products, such as current good manufacturing practices (cGMP), quality system regulations, and clinical evaluation requirements. Examples of applicable premarket pathways- Biologics License Application (BLA), Premarket Notification (510(k)), De Novo classification and Premarket Approval (PMA) were assessed. Post-approval change mechanisms, including Prior Approval Supplements, Changes Being Effected (CBE-30 and CBE-0) and annual reporting, were analysed to demonstrate risk-based change management.

Results: The analysis highlights that biologic-device combination products require an integrated regulatory approach due to their dual nature. PMOA determination plays a central role in defining FDA oversight and review pathways. Post-approval, manufacturers must implement structured change management and robust post-market surveillance systems to maintain compliance and ensure ongoing product performance.

Conclusions: Lifecycle management of biologic-device combination products within the U.S. regulatory landscape is inherently complex but manageable through proactive planning and regulatory engagement. Early PMOA determination, coordinated premarket review, and riskbased post-approval change control are critical to sustaining compliance while protecting patient safety, maintaining regulatory alignment and ensuring long-term product success.

Keywords: Biologic-device combination product, Lifecycle management, United States, Preapproval requirements,Post-approval requirements.

PP095

STANDARDIZATION OF HISTOLOGICAL PROCEDURES FOR DORSAL ROOT GANGLION EXAMINATION IN SPRAGUE DAWLEY RAT

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Dorsal root ganglia (DRG) are critical components of sensory pathways and are highly susceptible to neurotoxic injury from certain therapeutic modalities, including gene therapies and chemotherapeutics. Accurate histopathological evaluation of DRG is essential in nonclinical toxicity studies to identify potential neurotoxic effects. Microdissection methods often introduce mechanical artifacts that compromise tissue integrity. We standardised protocol for in situ recovery, fixation, and processing of DRG along with the spinal cord and vertebral column to minimize procedural artifacts. Using Sprague Dawley rat, the spinal cord was collected post-necropsy, fixed in 10% neutral buffered formalin, decalcified, and embedded longitudinally to preserve DRG architecture. Longitudinal horizontal serial sectioning followed by hematoxylin and eosin staining enabled reliable visualization of DRG and nerve roots without structural disruption. This approach enhances the accuracy of neuropathological assessments in toxicity studies and supports evaluating neurotoxicity in emerging therapeutic platforms.

Keywords: Dorsal root ganglion (DRG), Nonclinical toxicity studies, Neurotoxicity.

PP096

COMPARATIVE ANALYSIS OF THE POLICIES AND PROCEDURE FOR ADR REPORTING IN INDIA, BRAZIL, NETHERLAND AND UNITED KINGDOMS

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Background: Adverse Drug Reactions (ADRs) are a serious worldwide concern; they can affect the patient safety and increase healthcare costs. Pharmacovigilance systems help in identifying, monitoring, and preventing these ADRs, but these reported data differ from country to country depending on their healthcare and regulatory systems.
Aim: The aim of this work is to conduct a comprehensive comparative analysis of the policies and procedures for adverse drug reactions (ADR) reporting in India, Brazil, Netherland and United kingdoms.
Methods: A review of literature was carried out using databases such as PubMed, MEDLINE, and Google Scholar. Information was also collected from official websites of regulatory authorities. The ADR reporting programs included are Pharmacovigilance Programme of India (India), Yellow Card Scheme (UK), Lareb (Netherlands), and Notivisa (Brazil).
Results: The findings show that ADR reporting systems in all four countries have improved over time in post-marketing surveillance. However, differences are observed in reporting procedures and involvement of healthcare professionals and patients. Reporting of ADRs remains a major challenge, particularly in developing countries.
Conclusions: Although effective ADR reporting systems are in place, they are mainly dependent on hospitals and physicians. Increasing the involvement of pharmacists and patients, along with better awareness and simpler reporting methods, can further strengthen pharmacovigilance approach and improve patient safety.
Keywords: Adverse Drug Reactions, Pharmacovigilance, ADR Reporting, Patient Safety.

PP097

DESIGN AND CHARACTERIZATION OF NANOFIBERS FOR DUAL DELIVERY OF PHYTOCONSTITUENT AND ANTI-EGFR AGENTS IN ORAL CANCER THERAPY

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Oral cancer remains a major global health burden, with particularly high morbidity and mortality rates in developing countries. There is an urgent need for advanced drug delivery strategies that can enhance therapeutic efficacy while minimizing systemic toxicity. Nanofibers have emerged as a promising platform for localized and controlled drug delivery owing to their high surface area-to-volume ratio, tunable porosity, and ability to mimic the extracellular matrix. In the present study, electrospun nanofibers were developed as a co-delivery system incorporating a phytoconstituent in combination with an anti-EGFR agent to achieve synergistic anticancer effects. The developed nanofibers were systematically characterized using FTIR to confirm functional group interactions, DSC to evaluate thermal behaviour, NMR for structural confirmation, and XRD to assess changes in crystallinity following drug encapsulation. SEM analysis confirmed uniform nanofiber morphology with diameters ranging between 200–300 nm. In vitro drug release studies demonstrated a sustained and controlled release profile, achieving up to 85% cumulative drug release within 8 hours. Cytotoxicity was evaluated using the MTT assay, revealing an IC_{50} value of 45.23 µM. DAPI staining, revealed prominent nuclear condensation and fragmentation in treated cancer cells, indicative of apoptosis. Flow cytometry–based apoptosis analysis (Annexin V/PI staining) demonstrated a significant increase in early and late apoptotic cell populations following treatment with dual-drug nanofibers compared to free drug and control groups. In addition, scratch wound healing assays showed marked inhibition of cancer cell migration, confirming the enhanced anti-migratory potential of the nanofiber formulation. Overall, cell culture studies demonstrated a dose-dependent reduction in cell viability, with nanofiber formulations exhibiting significantly higher cytotoxicity and apoptotic induction compared to free drug counterparts ($p < 0.05$). In conclusion, these findings suggest that the phytoconstituent–anti-EGFR loaded nanofiber system induces apoptosis-mediated cell death, provides prolonged drug availability, and exerts synergistic anticancer and anti-migratory effects, highlighting its promise as an effective localized therapeutic strategy for oral cancer management.

Keywords: Nanofibers, Oral Cancer, Combination therapy, Chemotherapy

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PP098

FROM LOG P TO LOG D: ENHANCING ADME TRANSLATION THROUGH PH-RESOLVED LIPOPHILICITY PROFILING

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The lipophilicity of small molecules is a critical determinant of absorption, distribution, metabolism, and excretion (ADME) characteristics. While Log P describes the intrinsic partitioning of a neutral species between octanol and water, Log D accounts for both ionized and unionized forms and is therefore pH dependent. In this study, we systematically evaluated Log D across a broad pH range (2–12) and compared these values with the corresponding Log P to understand ionization driven shifts in apparent lipophilicity. Compounds with acidic functional groups exhibited increasing Log D values with decreasing pH, converging with Log P near fully unionized states. Conversely, basic compounds displayed lower Log D values under alkaline conditions due to enhanced ionization. Zwitterionic and ampholytic molecules showed characteristic biphasic Log D curves reflecting multiple ionizable centres. Across molecule classes, the magnitude of divergence between Log P and Log D was most pronounced near pKa transitions, highlighting the relevance of pH dependent speciation. These findings underscore the necessity of integrating Log D profiling—rather than relying solely on Log P—for accurate prediction of permeability, solubility, and in vitro–in vivo translation within DMPK workflows. Methods: Log D values for a diverse panel of marketed drugs—Warfarin, Propranolol, Chlorpromazine, Ketoconazole, Nicardipine, Tolbutamide, Labetalol, Quinidine, Tamoxifen, and Piroxicam— were determined across pH 2–12 using two complementary approaches. (1) Traditional shake-flask method: Each compound was equilibrated between 1-octanol and phosphate buffer adjusted to target pH values (ionic strength-controlled). After phase separation, compound concentrations were quantified by LCMS/MS, and Log D was calculated from the ratio of drug in the octanol and aqueous phases. (2) Sirius T3 potentiometric method: pH-dependent partitioning was determined by automated titration under biphasic conditions, enabling simultaneous measurement of acid/base ionization and distribution between octanol and water. Log D profiles were computed using instrument-specific algorithms that model ionization, solubility, and partitioning. Results: Both methodologies produced consistent qualitative Log D–pH curves that aligned with the known ionization profiles of the tested compounds, although quantitative differences were observed. Weak acids such as Warfarin, Tolbutamide, and Piroxicam showed increasing Log D at low pH, converging toward their intrinsic Log P values under unionized conditions. In contrast, weak bases including Propranolol, Quinidine, Labetalol, Nicardipine, Chlorpromazine, and Tamoxifen exhibited pronounced decreases in Log D under acidic pH due to high ionization, with Log D rising markedly in the neutral-to-alkaline range. Ketoconazole, an ampholytic and highly lipophilic molecule, showed a broad plateau with limited variation compared to other basic drugs.

Comparison of techniques showed that shake-flask Log D values were generally lower for highly lipophilic and poorly soluble molecules (e.g., Ketoconazole, Chlorpromazine, Tamoxifen), likely reflecting incomplete equilibrium and solubility limits in the aqueous phase. Sirius T3 measurements provided smoother, more continuous Log D–pH profiles, particularly

near pKa transitions where ionization changes rapidly. Across compounds, the deviation between methods was most noticeable for molecules with high Log P (>3.5), high basicity, or multiple ionizable centres. Conclusion: This study highlights the importance of integrating both experimental shake-flask measurements and potentiometric methods to fully characterize pH-dependent lipophilicity. While classical shake-flask measurements remain the reference standard, they exhibit limitations for highly lipophilic, low-solubility, or poly-ionizable drugs. Sirius T3 provides enhanced resolution around ionization transitions and more reliable profiles for challenging compounds. Overall, the consistent trends across the ten marketed drugs confirm that Log D varies significantly with pH, and relying solely on intrinsic Log P can lead to misleading predictions for ADME behaviour, permeability, and formulation strategies. The combined approach strengthens physicochemical characterization within early DMPK workflows.

PP099

DUAL PERSPECTIVES ON DRUG TRANSPORT: GASTRIC VS. INTESTINAL CELL MODELS USING NCIN87 AND CACO-2

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Oral drug delivery involves sequential passage through both gastric and intestinal epithelia, each presenting unique physiological barriers. To capture these distinct perspectives, NCI-N87 cells, derived from human gastric adenocarcinoma, serve as a model for gastric epithelial characteristics, while Caco-2 cells, originating from colon adenocarcinoma, remain the gold standard for predicting intestinal absorption. NCI-N87 cells replicate the barrier properties of the stomach lining, including acidic pH tolerance and mucosal features, whereas Caco-2 cells provide critical insights into intestinal permeability. When employed together, these complementary models enable a comprehensive evaluation of oral drug behavior, encompassing gastric retention and intestinal transport. This study underscores the importance of integrating NCI-N87 and Caco-2 cell systems to achieve a holistic understanding of oral drug absorption and transport mechanisms. Caco-2 cells were cultured in Dulbecco's Modified Eagle Medium (DMEM) supplemented with 10% Fetal Bovine Serum (FBS), 1% Non-essential amino acid, 2 mM L-glutamine, and 100 U/mL penicillin–streptomycin. NCI-N87 cells were maintained in RPMI-1640 medium containing 10% FBS and 100 U/mL penicillin–streptomycin under standard conditions in a CO_2 incubator at 37 °C with 95% relative humidity.

Cells were sub-cultured upon reaching ~80% confluence and subsequently seeded into 96-well trans well plates. Cultures were maintained for 18–21 days to establish stable monolayers with optimal transepithelial electrical resistance (TEER) and validated using Lucifer Yellow (LY) permeability assays. Biopharmaceutics Classification System (BCS) compounds were included as controls to benchmark permeability outcomes. Apparent permeability coefficients (Papp) were determined in both apical-to-basolateral and basolateral-to-apical directions under physiologically relevant pH conditions. The resulting monolayers exhibited TEER values >100 $\Omega \cdot cm^2$ for NCI-N87 and >200 $\Omega \cdot cm^2$ for Caco-2 before and after sample collection, confirming robust barrier integrity. Monolayers were impermeable to the integrity marker LY (>0.2%), which confirms that monolayers withstood a relevant pH condition. Optimal seeding density was identified to be 0.45*106 cells/well and 0.12*106 cells/well for NCI-N87 and Caco-2 cell line, respectively, ensuring reproducibility of permeability measurements. In the NCI-N87 model, Papp values for compounds classified as low and moderate permeability in Caco-2 were 3. These findings support the use of BCS-classified compounds as positive controls when evaluating test compounds in NCI-N87 systems.

By integrating data from both models, this approach provides a physiologically relevant platform that links gastric barrier properties with intestinal permeability, improving the predictive accuracy of oral drug absorption. Such dual-model strategies enhance bioavailability predictions, inform formulation design, and advance the development of new therapeutic agents by addressing the complete spectrum of gastrointestinal transport mechanisms.

PP100

PRECLINICAL PHARMACOKINETIC EVALUATION OF A MODEL THERAPEUTIC PEPTIDE FOLLOWING MULTIPLE ROUTES OF ADMINISTRATION IN MICE

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Background: Therapeutic peptides represent an increasingly important class of drug candidates often designed to mimic natural ligands; however, their development is frequently challenged by several scientific, pharmacokinetic (proteolytic degradation, low oral bioavailability, short half-life and high clearance etc.), formulation (limited solubility at higher conc.), and translational (Species differences in protease activity and clearance) challenges. While larger preclinical species are commonly preferred for pharmacokinetic evaluation of peptide therapeutics, systematic characterization in mice remains limited. Despite species differences, mouse PK studies offer several scientific, logistical, and strategic advantages during peptide drug development.

Objective: With this background the study was designed to evaluate PK profile of a model therapeutic peptide via different routes of administration in mice.

Material and Method: In this study, the pharmacokinetics of a model therapeutic peptide, Goserelin, was evaluated in mice following four routes of administration: IV, SC, and IM at 1 mg/kg, and PO at 10 mg/kg. Plasma samples were collected at 0.083 (IV, SC, IM only), 0.25, 0.5, 1, 2, 4, 8, and 24 h and analyzed using a fit-for-purpose LC–MS/MS method. The metabolites identified in metabolite identification assay using mouse hepatocytes were also qualitatively analyzed during the bioanalysis. Pharmacokinetic parameters were estimated using noncompartmental analysis in Phoenix WinNonlin (version 8.4).

Results: Following IV administration, Goserelin exhibited clearance of 37.7 mL/min/kg, a volume of distribution of 0.78 L/kg (approximately equal to total body water in mice), and a short elimination half-life of 0.36 h. After SC and IM administration, Cmax values of 376 ng/mL and 810 ng/mL were observed at Tmax values of 0.25 h and 0.083 h, respectively, with corresponding bioavailability of 45.7% and 55.1%. The metabolite identification study revealed M4 (m/z 691.41) was the most abundant metabolite, it was also detected in mouse plasma following all routes of administration along with Goserelin. Across all the routes, M4 appeared rapidly and declined in parallel with Goserelin exposure.

Discussion & Conclusion: Overall, Goserelin demonstrated rapid clearance based on halflife and pronounced route-dependent pharmacokinetics. Based on the findings of the current PK study, we infer peptide PK studies in mice as rapid, sensitive, and cost-effective insights into in vivo stability, clearance, and exposure, enabling efficient lead optimization and dose selection.

PP101

BRAIN MICRODIALYSIS: UNLOCKING TRUE TARGET-SITE DRUG EXPOSURE IN CNS RESEARCH

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Understanding how drugs reach the brain and interact at their site of action is critical for developing effective treatments for neurological disorders. Brain microdialysis (BMD) offers a unique advantage by directly measuring drug levels in the brain's extracellular fluid. In this study, we compared the unbound concentrations measured using BMD and traditional approach like collection and estimation of concentrations in plasma, cerebrospinal fluid (CSF), and whole-brain. Three drugs (chlorpromazine, imipramine, and brivaracetam) with varied protein binding properties were selected for this study. Three drugs were administered as a cassette formulation by intravenous bolus into male Sprague Dawley rats. The plasma, CSF and whole brain, brain dialyasate (BMD) were collected at 0.5 h post-dose using traditional approach and BMD. The plasma and brain homogenate binding was determined using either RED or ultracentrifugation method, and the unbound fraction factor was applied to plasma, whole brain to calculate unbound fraction in each matrix. The compounds exhibited distinct binding profiles in brain (%UB: 0.13%, 0.87%, and 35.75%) whereas in plasma (%UB: 0.15%, 3.74%, and 78.05%, respectively for chlorpromazine, imipramine and brivaracetam). MD captured extracellular concentrations that aligned with these distinct profiles. The UB concentration by BMD was 4.85 ng/mL (chlorpromazine), 26.3 ng/mL (imipramine), and 228.46 ng/mL (brivaracetam). BMD successfully captured extracellular concentrations that reflected these differences in protein binding. When compared to calculated unbound brain concentrations, MD accounted for 36–88% (chlorpromazine 87.6%, imipramine 54.8%, brivaracetam 35.9%), confirming that MD primarily samples the extracellular fluid rather than the entire unbound tissue pool. The CSF did not consistently mirror brain extracellular exposure. For chlorpromazine and imipramine, CSF/MD ratios were below 1 (0.37 and 0.51), indicating underestimation, whereas for brivaracetam the ratio exceeded 5 (5.34), suggesting overestimation. The present study demonstrated that brain microdialysis provides a mechanistically informative readout of unbound ECF concentrations and discriminates compound-specific differences in brain binding and distribution. These findings highlight that CSF may not reliably predict brain ECF concentrations and its utility as a surrogate depends strongly on compound properties. Integrating MD with unbound fraction estimates improves translational PK/PD interpretation and target-site exposure assessment early in CNS drug discovery.

PP102

TARGET SPECIFIC DELIVERY OF CYTOTOXIC DRUGS: INTRAVESICAL ROUTE OF ADMINISTRATION

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Background: Intravesical administration of cytotoxic drugs offers a distinct pharmacokinetic and drug metabolism–pharmacokinetic (DMPK) advantage by enabling localized drug exposure within the urinary bladder while minimizing systemic distribution. From a PK standpoint, direct instillation results in exceptionally high luminal drug concentrations and prolonged contact with the urothelial surface, making local exposure and residence time the primary drivers of therapeutic efficacy rather than systemic plasma levels.

Objective: The study was designed to have a comparative PK profiling of Doxorubicin via IV bolus vs Intravesical administration in mice.

Methods: The study design comprised of total 6 groups (n=3/group, C57BL/6 mice (Female). The animals were assigned with Group 1: IV Bolus (Lipodox), Group 2: Intravesical (Lipodox) and Group:3-6: with Doxorubicin (Hydrogel formulation), with blood, Urinary Bladder and Urine collection for Drug Quantification as designated time points.

Results & Discussion: IV administration of Doxorubicin demonstrate as systemic circulation as primary compartment for exposure (100%) with High AUClast (183470.69 h*ng/mL)) which is well correlated with literature reported toxic effects. While Intravesical route of administration of Doxorubicin (hydrogel formulation), demonstrated minimal systemic exposure doxorubicin localised to urinary bladder lumen and adjacent tissue with negligible exposure (AUClast 110.10 h*ng/mL) which is <5% of dose administered. These observations are in line with literature reported limited transurothelial permeability and rapid urinary elimination (Urine conc. 104395.043 ng/ml) following voiding contribute to negligible systemic absorption, thereby reducing the risk of off-target toxicity and drug–drug interactions.

Conclusions: Intravesical delivery decouples local efficacy from hepatic metabolism and systemic clearance, allowing effective tissue/tumor exposure at substantially lower total doses. Advances in formulation strategies, including hyperthermia-enhanced delivery and sustained-release systems, may further improve bladder-specific PK profiles. Collectively, intravesical administration represents a PK-driven, site-selective approach that enhances therapeutic index and supports safer, more efficient bladder cancer treatment.

PP103

INTEGRATING PATIENT-CENTERED OUTCOMES, PHARMACOVIGILANCE, AND EMERGING COMPUTATIONAL APPROACHES IN THE SAFETY ASSESSMENT OF IMMUNOTHERAPY-INDUCED SKIN TOXICITIES

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Background: Cancer immunotherapy, particularly immune checkpoint inhibitors, has revolutionized the treatment of advanced malignancies. Despite their clinical benefits, these agents are frequently associated with immune-related adverse events, with dermatological toxicities being among the most common. Cutaneous manifestations such as rash, pruritus, vitiligo, and inflammatory dermatoses may significantly impair patient quality of life and contribute to treatment interruptions. Conventional safety evaluation approaches predominantly rely on clinician-reported outcomes, which may inadequately capture symptom severity and patient burden. Recent literature highlights the growing importance of patient-reported outcomes, caregiver perspectives, and real-world pharmacovigilance data to achieve a more comprehensive understanding of immunotherapy-induced skin toxicities. Furthermore, emerging computational and analytical tools are increasingly being explored to enhance adverse event detection and safety assessment.

Aim: To review and synthesize current evidence on immunotherapy-induced dermatological toxicities by integrating patient-, caregiver-, and clinician-reported outcomes with pharmacovigilance insights and emerging computational approaches for improved safety assessment.

Methods: A narrative literature review was conducted using published review articles, pharmacovigilance studies, and consensus reports focusing on dermatological adverse events associated with cancer immunotherapy. Evidence related to patient-reported outcomes, caregiver-reported outcomes, clinician assessments, quality-of-life instruments such as the Dermatology Life Quality Index (DLQI) and EORTC questionnaires, spontaneous reporting systems including the FDA Adverse Event Reporting System (FAERS), under-reporting of adverse drug reactions, and emerging computational approaches such as artificial intelligence-based models, signal detection algorithms, and pathway analyses was qualitatively reviewed and synthesized.

Results: The reviewed literature consistently identified dermatological toxicities as frequent immune-related adverse events associated with immunotherapy, ranging from mild cutaneous reactions to severe immune-mediated skin disorders. Patient-reported outcome measures revealed a higher perceived symptom burden and greater quality-of-life impairment compared to clinician-reported assessments, highlighting discrepancies in toxicity recognition. Pharmacovigilance analyses using spontaneous reporting systems demonstrated challenges related to under-reporting and delayed identification of dermatological adverse events. Emerging computational approaches, including artificial intelligencedriven safety models and analytical tools, were increasingly described as supportive methods for improving adverse event detection, risk stratification, and safety monitoring.

Conclusion: An integrated safety assessment framework combining patient-centered outcomes, pharmacovigilance data, and emerging computational approaches offers a more comprehensive understanding of immunotherapy-induced skin toxicities. Strengthening the incorporation of patientreported measures and advanced analytical tools may enhance early detection, reporting accuracy, and clinical management, thereby supporting safer and more patient-focused immunotherapy practice.

PP104

POPULATION PHARMACOKINETIC MODELS OF INTRAVENOUS FENTANYL IN THE PEDIATRIC POPULATION: A SYSTEMATIC REVIEW

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Introduction: Fentanyl, a strong synthetic opioid, is used widely in children for acute and chronic pain management. However, the drug's efficacy and safety are influenced by its pharmacokinetics.

Aim: The review aims at descriptively summarising the characteristics of various population Pharmacokinetic models published for Intravenous fentanyl in the pediatric population.

Methodology: A literature search was conducted in PubMed, Embase, Scopus, and Web of Science databases from January 1, 2000, to December 31, 2024, using the keywords population pharmacokinetics, children, and fentanyl. A systematic double screening approach was carried out in accordance with the PRISMA guidelines. Study characteristics and population pharmacokinetic model characteristics were summarised and reported.

Results: Five studies were included in the review. The drug's pharmacokinetics were well explained using a two-compartment model. Both proportional and mixed (proportional/additive) error models were used to describe the residual errors. Weight was the major covariate influencing intravenous fentanyl clearance, the volume of the central compartment, the volume of the peripheral compartment, and intercompartmental clearance. Age, CYP3A4/5 inducer coadministration, surgical severity score, and CYP3A5 genetic variants also influenced drug clearance. The model's predictability was validated through internal bootstrap testing, external validation and visual predictive check.

Conclusion: Most of the population Pharmacokinetic models reported weight as a covariate. These models could be potentially used for dose individualisation of the intravenous fentanyl in the pediatric population.

Keywords: Population Pharmacokinetics, Intravenous, Fentanyl, Children

PP105

DESIGN, OPTIMIZATION, AND MACHINE LEARNING–ASSISTED DEVELOPMENT OF A MOUTH-DISSOLVING FILM OF EDOXABAN TOSYLATE MONOHYDRATE FOR NON-VALVULAR ATRIAL FIBRILLATION

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Background: Non-Valvular Atrial Fibrillation (NVAF) is a frequently occurring form of irregular heart rhythm. There are presently 335 million people who have NVAF in the world, bringing the overall rate of prevalence to 2.9%. An oral anticoagulant is the first-line treatment for NVAF. In January 2015, Edoxaban Tosylate Monohydrate (ETM), was licensed by the Food and Drug Administration. ETM is a BCS Class IV drug with poor solubility and low permeability, which limits its bioavailability and therapeutic efficacy. As there is no commercially available oral liquid formulation of ETM, this study aimed to formulate and optimize a mouth-dissolving film (MDF) of ETM to enhance solubility, taste, and patient compliance in the treatment of nonvalvular atrial fibrillation.

Methods: To improve solubility, β-cyclodextrin inclusion complexes were prepared via the solvent evaporation method using a 1:1, 1:2, and 1:3 molar ratio of methanol and water as the solvent system. A 3^2 full factorial DoE was employed with HPMC E15 (22.59, 27.49, 32.39 mg) and PEG-600 (46.81, 54.98, 63.15 mg) as independent variables, while disintegration time (sec), % drug release at 8 minutes, and folding endurance were response variables. Eleven batches were prepared via solvent casting and evaluated for physicochemical and mechanical properties. Machine learning analysis was carried out using orange data mining software. Regression models included partial least squares (PLS), stochastic gradient descent (SGD), random forest, support vector machine, k-nearest neighbours, AdaBoost, and linear regression. Model performance was assessed using R^2, mean absolute error, and root mean square error.

Results and Discussion: Phase solubility analysis exhibited an AL-type curve, with maximum solubility enhancement of 32.23-fold at the 1:2 ratio and 29.16-fold at 1:1. The 1:1 β-cyclodextrin complex was selected due to its superior physical stability. A 3^2 factorial design was employed to optimize the ETM MDF, evaluating the effects of polymer concentration (2%-3% w/v) and plasticizer type (glycerol vs. PEG 400) on % drug release and disintegration time. ANOVA revealed significant main and interaction effects. The optimized batch (3% HPMC E5 and 15% w/w PEG 400) exhibited 98.5% drug release within 8 minutes (vs. 99.5% for the marketed tablet), a rapid disintegration time of 26 seconds, and excellent folding endurance (>300). Machine learning approaches provided predictive insights into formulation performance. Among the tested models, PLS yielded the best predictive accuracy ($R^2 = 0.964$ for % drug release; R2 = 0.953 for disintegration), followed by SGD ($R^2 = 0.957$ and 0.948, respectively). Taste-masking efficiency assessed using the brief access taste aversion (BATA) model in rats demonstrated significantly higher mean lick counts for the developed MDF compared to the pure drug, confirming improved palatability.

Conclusion: In conclusion, a patient-friendly, stable, and rapidly disintegrating MDF of ETM was successfully developed using β-cyclodextrin complexation, Design of Experiments, and machine learning. The formulation demonstrated enhanced solubility, strong mechanical properties, effective taste masking, and predictive design, offering a promising alternative to conventional oral tablets.

PP106

DESIGN, OPTIMIZATION AND EVALUATION OF A TADALAFIL-LOADED TRANSFEROSOMAL HYDROGEL FOR ENHANCED WOUND HEALING

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This paper presents the design, optimization, and evaluation of a tadalafil-loaded transferosomal hydrogel intended to enhance wound healing through improved topical drug delivery. Chronic and non-healing wounds continue to pose a significant challenge in clinical practice due to impaired angiogenesis, poor blood circulation, prolonged inflammation, and oxidative stress. In addition, effective topical treatment is often limited by the skin's barrier properties and inadequate drug penetration. This study presents the development of a tadalafil-loaded transferosomal hydrogel as a formulation-based strategy to address these challenges and improve wound healing outcomes. Tadalafil, a phosphodiesterase-5 (PDE-5) inhibitor, is known to enhance nitric oxide–mediated vasodilation and angiogenesis; however, its clinical utility in topical applications is restricted by poor aqueous solubility and low local bioavailability.

To overcome these limitations, ultra-deformable transferosomes were formulated using the thin-film hydration technique. A systematic Quality by Design (QbD) approach was adopted to manage formulation complexity and ensure reproducibility. Initially, a Plackett–Burman design was employed to screen critical formulation and process variables affecting vesicle characteristics. This was followed by a 3^2 full factorial Design of Experiments (DoE) to optimize key responses, including vesicle size, entrapment efficiency, and drug release behaviour. The optimized transferosomal formulation demonstrated high drug entrapment efficiency (88–96%), a nanoscale vesicle size of approximately 267 nm, and a strongly negative zeta potential (−42 to −56 mV), indicating good physical stability and suitability for topical delivery.

Successful drug encapsulation and compatibility between tadalafil and formulation excipients were confirmed using Fourier transform infrared spectroscopy (FTIR) and differential scanning calorimetry (DSC). The optimized transferosomes were subsequently incorporated into an aloe vera–based hydrogel to provide a moist wound environment, enhance patient acceptability, and support sustained drug release at the site of application. The final hydrogel formulation exhibited appropriate pH, good Spreadability, controlled in-vitro drug diffusion, and satisfactory short-term stability.

In conclusion, this work demonstrates how a rational, formulation-driven approach can effectively navigate the physicochemical and biological complexities associated with topical drug delivery. The developed tadalafil-loaded transferosomal hydrogel shows promise as a patient-friendly and effective topical system for enhanced wound healing, with potential relevance to translational drug development.

PP107

EXPLORATION OF NOVEL ANASTROZOLE-INDUCED ADVERSE EVENTS THROUGH FAERS DATA MINING AND BIOINFORMATICS ANALYSIS

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Background: Anastrozole is a non-steroidal aromatase inhibitor that suppresses estrogen biosynthesis by inhibiting the aromatase enzyme, thereby reducing estrogen-mediated signaling and tumor growth in hormone receptor–positive breast cancer, particularly among postmenopausal women. Objective: To identify potential novel adverse event signals associated with anastrozole using data-mining techniques applied to the US FDA Adverse Event Reporting System (FAERS) and to explore plausible molecular mechanisms through bioinformatics and molecular docking analyses.

Methodology: A case–non-case disproportionality analysis of anastrozole was performed using real-world data extracted from the FAERS database via the OpenVigil platform. Signal detection was conducted using Proportional Reporting Ratio (PRR) and chi-square (χ^2) statistics. Adverse events were considered signals when the number of reports (n) was >2, PRR >2, and χ^2 >4. Genes associated with the identified adverse events were analyzed through Gene Ontology (GO) enrichment, protein–protein interaction (PPI) network construction using STRING, and hub gene identification via cytoHubba. Molecular docking simulations were performed to evaluate the binding affinity of anastrozole with selected target proteins.

Results: A total of 21,422 adverse event reports associated with anastrozole were identified. Disproportionality analysis revealed diplegia, vaginal polyp, haemolytic uremic syndrome, amblyopia, and Barrett's oesophagus as potential safety signals. These adverse events demonstrated notable reporting frequencies (n = 7, 3, 5, 4, and 5), elevated PRR values (7.322, 74.948, 4.925, 13.711, and 3.485), and statistically significant χ^2 values (31.967, 142.891, 11.913, 34.905, and 6.53), respectively. Molecular docking analysis showed favorable binding affinities of anastrozole toward CYP19A1 (diplegia; −7.77), EGFR (vaginal polyp, haemolytic uremic syndrome, and Barrett's oesophagus; −7.405), and GABRB3 (amblyopia; −4.944), supporting potential mechanistic links between the drug and the observed adverse events.s

Conclusion: Diplegia, vaginal polyp, haemolytic uremic syndrome, amblyopia, and Barrett's oesophagus were identified as potential safety signals associated with anastrozole use through pharmacovigilance analysis. In-silico findings provide biological plausibility for these associations. Further pharmacoepidemiological and pharmacogenetic studies are warranted to validate these signals and enhance patient safety and therapeutic decision-making.

Keywords: Anastrozole; FAERS; Signal Detection; Molecular Docking; Bioinformatics

PP108

EXPLORATION OF NOVEL ETOPOSIDE-INDUCED ADVERSE EVENTS THROUGH FAERS DATA MINING AND BIOINFORMATICS ANALYSIS

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Background: Etoposide is an anticancer agent belonging to the class of topoisomerase II inhibitors. It exerts its effect by inhibiting DNA replication and cell division, leading to the death of rapidly proliferating cancer cells.

Objective: To unveil potential signals of Etoposide using data mining algorithms within the US FDA Adverse Event Reporting System (FAERS) database and to establish association with protein via molecular docking approach.

Methodology: A case–non-case disproportionality analysis of etoposide was performed using real-world data from the FAERS database. The OpenVigil platform was used to apply datamining algorithms, including Proportional Reporting Ratio (PRR), to identify adverse events (AEs). Signals were considered positive when the number of events (n) was >2, PRR >2, and χ^2 >4. Hub genes identified through Gene Ontology (GO) analysis were further refined using STRING and cytoHubba, and protein–protein interaction (PPI) networks associated with etoposide-induced signals were constructed using STRING. Binding affinity of etoposide with the identified target was assessed using molecular docking simulations

Results: A total of 68,443 reports were observed for etoposide. The FAERS and Open Vigil showed pulmonary embolism as a potential signal with n = 92, PRR = 2.543 and χ^2 = 84.817. Network research identified 11 intersecting genes, including hub gene such as ALB. Molecular docking analysis of etoposide with the proteins associated with pulmonary embolism showed that it exhibited binding affinity towards ALB with a docking score of -6.125.

Conclusion: The bioinformatics and molecular docking studies revealed strong binding affinities indicating a strong correlation between etoposide and pulmonary embolism. The authors suggest to conduct further experimental validation, pharmaco-genetic and pharmacoepidemiological research and greater clinical awareness among health care practitioners to improve patient safety.

Keywords: Etoposide, pulmonary embolism, FAERS database, network pharmacology, molecular dockin

PP109

ADVERSE EVENTS LINKED TO INTRAOCULAR LENSES [IOL]: IN-DEPTH ANALYSIS OF THE MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE DATABASE

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Introduction: Intraocular lenses (IOLs) are optical devices implanted in the eye, after cataract removal, to restore vision. While they significantly improve visual outcomes, their use is associated with potential risks and adverse events (AEs) that can impact patient safety and treatment success. The Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the U.S. Food and Drug Administration (FDA), is a critical resource for monitoring devicerelated issues.

Methods: This study investigated adverse events related to Intraocular Lense a Optical device reported to the MAUDE database from January 1, 2020, to May 31, 2025. Data for the device was extracted using specific product code and downloaded. A detailed analysis of the reports was performed to identify patterns and trends, providing valuable insights into the safety and performance of these devices.

Results: Over a 5-year period, the MAUDE database documented 18,606 unique adverse event (AE) reports involving optical devices. The most common device issues were break (15.8%) defective in device (3.71%), contamination (2.34%), crack (3.93%). Among reported event types, 33% (6,305) involved injuries, 66% (12,295) were malfunctions. The majority of reports originated from the United States, followed by Switzerland, Japan and Germany. Physicians were the primary reporters, with contributions from healthcare professionals and nurses.

Conclusion: The findings highlight the need for enhanced materiovigilance practices to reduce the risk of AEs associated with Intraocular Lense. By identifying high-risk and addressing common failure modes, stakeholders can work towards improved device safety and patient care outcomes. This study serves as a valuable reference for clinicians, manufacturers, and regulatory authorities aiming to enhance optical device safety.

Keywords: Optical devices, Intraocular Lense [IOL], Adverse events, MAUDE database, Materiovigilance.

PP110

METABOLIC STABILITY AND PHARMACOKINETIC EVALUATION OF A NOVEL SECRETORY PHOSPHOLIPASE A2 INHIBITOR USING A VALIDATED LC-MS/MS METHOD

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Cancer continues to be a leading cause of morbidity and mortality worldwide, necessitating the development of novel and effective therapeutic agents. Phospholipase A2 (PLA2) enzymes have emerged as promising molecular targets for anticancer therapy due to their critical role in inflammation, cell proliferation, and tumour progression particularly in breast, prostate, pancreatic, and colorectal cancers. In this study, we evaluated the metabolic stability and pharmacokinetic properties of a previously synthesized secretory PLA2 inhibitor, N-psubstituted-1-((5-p-substituted-1,3,4-oxadiazol-2-yl)methyl)-1H-1,2,3-triazole-4-carboxamide [Compound-9 (O)], to determine its drug-like potential. A sensitive, selective and robust bioanalytical method using Liquid Chromatography–Tandem Mass Spectrometry (LCMS/MS) was developed and validated in accordance with ICH M10 guidelines for the quantification of Compound-9 (O) in mouse plasma. The method demonstrated excellent accuracy, precision, and reproducibility across the calibration range. In vitro metabolic stability studies demonstrated that Compound-9 (O) remained stable in both mouse and human liver microsomes, suggesting a favourable metabolic profile. In addition, pharmacokinetic evaluation in mice confirmed a consistent plasma concentration–time profile and established the absolute bioavailability of the compound. These findings indicate that Compound-9 (O) possesses desirable pharmacokinetic characteristics and metabolic stability, supporting its further development as a potential anticancer agent targeting PLA2. The results contribute valuable preclinical data necessary for advancing Compound-9 (O) toward in vivo efficacy and safety studies. Keywords: Method Validation, LC-MS/MS, Pharmacokinetic study, PLA2, Anti-cancer, ADME, Microsomes Pharmacokinetic Parameters for IV & PO

PP111

DESIGN, SYNTHESIS, CHARACTERIZATION AND BIOLOGICAL EVALUATION OF NOVEL AMINO PYRIMIDINE DERIVATIVES

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Background: The global surge in multi-drug resistant (MDR) bacteria has made many antibiotics ineffective, creating a need for design of innovative, novel drugs with optimised antibacterial activity and better safety profiles. Pyrimidines, are biologically active molecules and their wide pharmacological features including antibacterial property has generated interest in their derivatives for discovery of novel antibacterial with great therapeutics efficacy. **Aim:** To design, synthesize and characterize novel amino pyrimidine derivatives and evaluate their antibacterial activity against E. coli and S. aureus.

Methodology: The computationally designed novel ligands were docked against DNA Gyrase and glutamine synthetase repressor using AutoDock Vina. PkCSM tool was used for determining ADMET properties. Based on docking scores, 10 most promising derivatives were synthesized through nitration of 4 chloroacetophenone, followed by Claisen-Schmidt reaction to form substituted chalcones and subsequent cyclisation to yield amino-pyrimidine derivatives. The compounds were characterised using IR, Mass and 1H NMR spectroscopy and The derivatives were evaluated for their antibacterial efficacy against S. aureus and E. coli using cup plate method, taking Trimethoprim as reference standard.

Result: Among the synthesized compounds, JJMK18 (3-fluoro), JJMK22 (4- methyl), JJMK23 (4-fluoro) derivatives exhibited very good activity towards S. aureus and E. coli and were close to the trimethoprim standard activity.

Conclusion: In-silico docking study identified ten analogous with good binding affinity for the essential proteins of the bacteria. The predicted ADMET properties indicate a favourable pharmacokinetic profile with no apparent toxicity. Furthermore, in vitro antibacterial evaluation of the synthesized analogues demonstrates activity comparable to the standard drug. Consequently, these compounds may serve as promising leads for structural optimization in the development of novel antibacterial agents.

PP112

OVERCOMING LC-MS/MS CHALLENGES IN POLAR, LOW-MOLECULAR-WEIGHT COMPOUNDS THROUGH AMINE-TARGETED DERIVAΘZAΘON

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Low molecular weight and highly polar compounds oft en pose significant challenges for LC MS/MS analysis due to poor reten on on conven onal reversed-phase columns and limited electrospray ioniza on efficiency. Such analytes may elute close to the void volume and generate weak or unstable mass spectrometric responses, making reliable quan fica on difficult, par cularly in in-vitro drug metabolism and pharmacokine c (DMPK) studies where sample concentra ons are typically low. Chemical deriva za on represents a prac cal analy cal strategy to address these limita ons by modifying key physicochemical proper es of analytes, including molecular weight, hydrophobicity, and ioniza on behaviour. Amine-targeted deriva za on is especially relevant in this context, as amine func onali es are prevalent across a wide range of small-molecule drugs and metabolites. Selec ve modifica on of amine groups can therefore provide a broadly applicable approach for improving LC-MS/MS performance for challenging polar compounds. In this work, 5-aminosalicylic acid (5-ASA) was selected as a representa ve low molecular weight, highly polar compound to evaluate the feasibility of amine-targeted deriva za on for LC-MS/MS analysis. In its underiva zed form, 5-ASA exhibited minimal reten on on a C18 column and very poor ioniza on response, rendering direct LC-MS/MS analysis imprac cal. Deriva za on of 5-ASA was carried out using three commonly employed amine-reac ve reagents- Propionic anhydride, Benzoyl chloride, and Dansyl chloride-under MS-compa ble condi ons. All three deriva za on approaches resulted in clear improvements in chromatographic reten on and enhanced mass spectrometric response compared to the non deriva zed analyte, demonstra ng the effec veness of amine-targeted deriva za on in enabling LC-MS/MS analysis. Overall, this study highlights chemical deriva za on as a robust and transferable strategy for addressing analy cal challenges associated with polar, low molecular weight compounds. Given the widespread occurrence of amine func onali es in drug molecules, the approach described here can be readily extended to support the LC-MS/MS analysis of other challenging analytes encountered across diverse in-vitro DMPK workflows. Keywords: LC-MS/MS, Chemical deriva za on, Amine-targeted deriva za on, Polar compounds, Low molecular weight analytes, Bioanalysis, In-vitro DMPK, 5-Aminosalicylic acid.

PP113

QUANTIFYING CHIRAL SWITCH DYNAMICS USING HIGH-SENSITIVITY LC-MS/MS AND MASS BALANCE ASSESSMENT

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Although enantiomers have similar Phys-Chem properties, yet they behave differently to biological systems, hence it is of immense importance to ensure that therapeutically active/safe form of an enantiomeric pair retains its chiral purity throughout the ADME process. Since enantiomeric interconversion can significantly influence therapeutic efficacy and safety of an enantiomer, reliability of Chiral bioanalytical methods plays a critical role in the pharmacokinetics and pharmacodynamics of a chiral drug. This study presents development of a robust and highly sensitive LC-MS/MS-based Chiral bioanalytical method and suggests an innovative approach to determine the suitability of chiral method for the quantitative assessment of chiral inversion compared against a regular method used to quantify total concentrations employing non-chiral stationary phase in a biological matrix. This comprehensive and unique mass balance approach was incorporated to evaluate the integrity of the analytical process. Both chiral and regular methods were developed to simultaneously quantify enantiomers and total concentration with exceptional accuracy, precision, and sensitivity. This approach enables precise monitoring of inversion kinetics under physiological conditions, providing insights into stereochemical stability and metabolic pathways. Application of this method to preclinical samples demonstrated its capability to detect low-level inversion events and maintain enantiomeric purity profiles over time. This work underscores the importance of advanced chiral bioanalysis in drug development and offers a reliable platform for assessing stereochemical behavior, ultimately supporting informed decision-making in pharmacological research. The method was developed on SCIEX Triple Quad 7500 system connected with Shimadzu Nexera LC using mobile phase, 5mM ammonium acetate in water as aqueous buffer and 0.1% formic acid in acetonitrile as organic phase with Phenomenex LUX Cellulose-4 150*2 mm, 3 µ as a chiral stationary phase. Gradient method was employed with flow gradient having total run time of 12.8 min. The developed method showed adequate chromatographic separation of both enantiomers with retention time of 2.68 min (for E1) and 8.30 min (for E2). The calibration curves demonstrated linearity over the range of 1-2000 ng/mL for E1 and 0.025-2.01 ng/mL for E2. The method was applied for analysis of Rat blood samples following 7 days repeat dose oral gavage administration of E1 (major enantiomer) at 1, 10 and 100 mg/kg/day (n=3 animals) where ~0.45% of E2 was inherently present as an impurity. Both the enantiomers were quantified in blood samples to monitor the conversion from E1 (major) to E2 (minor). The AUC0-24h ratio and Cmax ratio of E2 to E1 were calculated for each dose level, and consistently ranged between 0.01 and 0.02, indicating that only 1–2% of E2 was formed following administration of E1. To evaluate the mass balance of chiral methods, the same blood samples were analyzed using a conventional (achiral) method. The total concentrations obtained by the achiral method showed good agreement with the sum of E1 and E2 concentrations from the chiral method. The concordance between concentration values from chiral and achiral method confirms the accuracy and precision of the chiral method, particularly in quantifying low levels of the minor enantiomer E2, thereby supporting informed decision-making during early drug discovery.

PP114

BREAKING BARRIERS IN STEROID BIOANALYSIS: HIGH-SENSITIVITY LC-MS/MS METHOD FOR TESTOSTERONE IN MOUSE PLASMA

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Testosterone, a key endogenous steroid hormone, plays a critical role in regulating physiological processes such as reproductive function, muscle mass, and bone density. Dysregulation of testosterone levels is associated with various clinical conditions such as hypogonadism, infertility, osteoporosis, and metabolic disorders, making its accurate measurement critical for both diagnostic and therapeutic purposes. However, accurate quantification poses significant analytical challenges due to its inherently low circulating concentrations, extensive protein binding, and structural similarity to other steroid hormones, which can lead to interference. These factors necessitate the development of a highly sensitive, selective, and reproducible bioanalytical method capable of reliable data generation. Liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) has emerged as the gold standard for steroid hormone analysis due to its superior sensitivity, specificity, and robustness compared to immunoassays. Developing an LC-MS/MS method for testosterone requires careful optimization of sample preparation, chromatographic separation, and detection parameters to meet the requirements for accuracy, precision, and reproducibility. This study focuses on establishing an LC-MS/MS method for the quantification of testosterone in mouse plasma, addressing key challenges such as low-level detection (with limited sample volume from mouse), and method robustness to support pharmacokinetic investigations. The bioanalytical method for testosterone quantification was developed using a SCIEX Triple Quad™ 7500 mass spectrometer coupled with a Shimadzu Nexera UHPLC system. Given the endogenous nature of testosterone, calibration standards were prepared in a surrogate matrix consisting of 2% lipoproteindeficient serum (LPDS) in water. Sample preparation employed a protein precipitation approach using a uniquely optimized extraction solvent, which enabled efficient recovery from low-volume mouse plasma samples. This solvent significantly improved analyte recovery while minimizing background interference and enhancing signal intensity. These advantages eliminated the need for more complex extraction techniques such as solidphase or liquid–liquid extraction.

Chromatographic separation was achieved using an Agilent Eclipse XDB C18 column (150 × 4.6 mm, 5 µm) under isocratic conditions with mobile phases comprising 5 mM ammonium acetate in water (Pump A) and 0.1% v/v formic acid in acetonitrile (Pump B) at a ratio of 15:85 (v/v). Detection was performed in MRM mode using the transition m/z 289.2 → 97.1 for testosterone. Calibration curves exhibited excellent linearity across the range of 0.20–1000 ng/mL. Parallelism was assessed by preparing the quality control samples in mouse plasma and evaluated using basal level addition method. The quality control samples in surrogate matrix as well as mouse plasma showed % accuracy within acceptance limit of 80-120% of nominal value.

Overall, this method combines a simple, high-throughput extraction technique with low sample volume requirements and robust chromatographic and detection conditions. The approach delivers high sensitivity, reproducibility, and operational efficiency, making it well-suited for rapid quantification of testosterone in mouse plasma for pharmacokinetic studies.

PP115

REINVENTING LIPID ANALYSIS: SIMPLE EXTRACTION AND NON-TRADITIONAL LC-MS/MS CHROMATOGRAPHY FOR HIGH-THROUGHPUT QUANTIFICATION OF LNP EXCIPIENTS

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Lipid-based delivery systems remain the most widely used approach for transporting mRNA into mouse and human cells. These systems rely on fatty-acid–derived membranes, where liposomal layers encapsulate and protect the mRNA, subsequently fusing with cellular membranes to release the genetic cargo intracellularly. Among the components of lipid nanoparticles, DSPC (1,2-Distearoyl-sn-glycero-3-phosphocholine) and cholesterol are critical for structural and functional integrity. Monitoring the breakdown and biodistribution of these lipids is often a regulatory requirement, as it provides essential information on release kinetics, potential off-target accumulation, and perturbations in endogenous lipid levels that may contribute to systemic toxicity. Accurate assessment demands a robust and reproducible analytical method capable of quantifying both cholesterol and DSPC in complex biological matrices. Traditional analytical approaches frequently employ universal detectors such as CAD or ELSD. However, these detectors lack molecular specificity and are unable to distinguish between co-eluting compounds, leading to false positives or chromatographic interference. Additionally, conventional workflows often rely on labour-intensive extraction procedures and standard chromatographic systems that limit throughput and scalability. The present work describes an innovative LC–MS/MS methodology that redefines lipid quantification using a streamlined sample-preparation workflow paired with a non-traditional mobile-phase design. A novel single-step solvent extraction enables efficient recovery of both cholesterol and DSPC from complex biological matrices, eliminating the need for phase separation or solid-phase cleanup. The analytical methods for cholesterol and DSPC were developed on the SCIEX Triple Quad 7500 and 4500 LC–MS/MS systems, respectively, each coupled to a Shimadzu Nexera UHPLC platform. Because both analytes are endogenous it imposes another level of challenge. Tailor made Surrogate matrix having: 2% lipoprotein-deficient serum (LPDS) in water for cholesterol and 2% plasma in water for DSPC, were used to quantitate both the analytes. Sample extraction utilized a simple protein-precipitation with uniquely optimized extraction solvent to balance polarity for efficient recovery of lipids. This solvent system effectively solubilizes neutral sterols such as cholesterol and highly polar phospholipids like DSPC. It also ensures strong protein precipitation and provides excellent compatibility with mass spectrometer detection resulting in reduced matrix effects and improved signal stability. Chromatographic performance was further enhanced through a non-traditional mobile-phase design. A high-organic composition in Pump A facilitated early elution and improved desolvation of neutral lipids, significantly increasing ionization efficiency for cholesterol. Pump B, enriched with isopropanol and a low concentration of ammonium formate, provided strong elution strength for DSPC, minimizing peak tailing, and ensuring consistent retention and peak shape. Quantification was performed using MRM transitions m/z 369.3 → 147.1 for cholesterol and m/z 790.4 → 184.0 for DSPC. Calibration curves demonstrated excellent linearity over the ranges 100–50,000 ng/mL for cholesterol and 100.41–20,000 ng/mL for DSPC. Overall, the developed method—featuring a broad-solubility extraction solvent, simplified sample handling, and a fast-equilibrating, non-traditional mobile-phase system—supports rapid, high-throughput quantification of both cholesterol and DSPC in complex biological matrices. The approach provides robust chromatographic resolution for structurally diverse analytes and ensures high sensitivity, reproducibility, and operational efficiency.

PP116

DEVELOPMENT AND VALIDATION OF A HIGH-SENSITIVITY LC–MS/MS METHOD FOR QUANTIFICATION OF N-NITROSODIMETHYLAMINE IN HUMAN PLASMA AND LIVER MICROSOMES: APPLICATION TO IN VIVO AND IN VITRO RISK ASSESSMENT

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N-Nitrosodimethylamine (NDMA), a low-molecular-weight nitrosamine, is a ubiquitous contaminant formed during industrial processes, water disinfection, food preservation, and pharmaceutical manufacturing. Its occurrence detection in drinking water, foods, and drugs such as ranitidine and angiotensin receptor blockers (ARBs) has led to global recalls and heightened regulatory scrutiny. Classified as a probable human carcinogen (IARC Group 2A) and listed under ICH M7, NDMA undergoesCYP2E1-mediated bioactivation, leading to DNA alkylation, oxidative stress, and hepatocarcinogenesis. Accurate quantification in biological matrices remains challenging due to NDMA's volatility, ultra-trace levels, and matrix interferences, while most existing LC–MS/MS methods primarily target on drug products or water. To address these gaps, we developed and validated a streamlined LC–MS/MS method for NDMA determination in human plasma and liver microsomes, enabling integrated in vivo and in vitro risk assessment. The method employed simple protein precipitation followed by LC–MS/MS analysis using a Shimadzu Nexera LC system coupled to a Sciex 6500 QqQ in APCI mode. Chromatographic separation was achieved on a Phenomenex Kinetex® Biphenyl column (50 × 4.6 mm, 2.6 μm) at 50°C, with ammonium formate/formic acid buffer and methanol as mobile phases. NDMA and tolbutamide (IS) were monitored via MRM transitions (NDMA: m/z 75.1 → 43.0; IS: m/z 271.2 → 91.1). The method demonstrated an LLOQ of 50 ng/mL, a validated range of 50–2500 ng/mL, and dilution integrity up to 18,000 ng/mL. Accuracy (88–103%) and precision (≤12.7%) met ICH M10/FDA criteria, with recovery near 99% and negligible matrix effects (MF ≈ 1.1). NDMA stability was confirmed under shortterm, long-term, freeze–thaw, and autosampler conditions. Microsomal validation studies demonstrated applicability for ADME and metabolism studies, revealing species-dependent clearance: moderate in human and mouse microsomes, low in rat microsomes. In conclusion, this regulatory-compliant LC–MS/MS workflow offers high sensitivity, minimal sample preparation, and broad applicability for nitrosamine risk assessment. By enabling simultaneous plasma and microsomal analysis, the method facilitates pharmacokinetic, toxicokinetic, and metabolic profiling, providing critical insights into NDMA disposition and species dependent variability to strengthen human risk prediction.

PP117

VALIDATION AND QUANTIFICATION OF LIPID NANOPARTICLE COMPONENTS USING TANDEM MASS SPECTROMETRY (ESI FOR SM-102, DSPC, DMG-PEG 2000; APCI FOR CHOLESTEROL)

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Abstract:

We developed and fully validated a rapid, sensitive, and selective triple-quadrupole LC–MS/MS method for the simultaneous quantification of the four canonical lipid nanoparticle (LNP) lipids-SM-102-(synthetic-amino-lipid-(heptadecan-9-yl-8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)-hexyl)-amino)-octanoate,DSPC(1-2-distearoyl-sn-glycero-3-phosphocholine),DMG-PEG-2000(1,2-dimyristoyl-rac-glycero-3-methoxypolyethyleneglycol-2000) and cholesterol in mouse plasma, enabling reliable bioanalytical support for pharmacokinetic (PK), toxicokinetic, and biodistribution studies. A targeted literature review shows that most published LNP workflows employ HRAM/Q-TOF or Orbitrap platforms for qualitative identification, profiling, or stability assessments rather than validated plasma quantification, or utilize compact LC–MS systems for rapid characterization at the formulation/QC level, while non-MS detectors such as CAD/ELSD are used mainly for formulation analysis, not plasma bioanalysis. Notably, the only triple-quadrupole LC–MS/MS reports in biological matrices quantify ionizable lipids alone (e.g., SM-102) rather than the complete four-lipid panel in one assay. To our knowledge, no prior triple-quadrupole LC–MS/MS method has simultaneously quantified SM-102, DSPC, DMG-PEG-2000, and cholesterol in plasma in a single validated workflow. Our method uses single-step protein precipitation, and chromatographic separation on a Phenomenex Kinetex C18 column (3.00 × 100 mm, 5 μm) with a gradient of acetonitrile: water (60:40, v/v) and acetonitrile: isopropanol (30:70, v/v) at 0.600 mL/min. Ionization is mode-matched for sensitivity: ESI for SM-102, DSPC, DMG-PEG-2000 and APCI for cholesterol. Detection in positive MRM employed transitions m/z 710.6→472.10 (SM-102), 790.4→184.20 (DSPC), 839.2→495.3 (DMG-PEG-2000), 369.40→147.20 (cholesterol) and 515.2→276 (Telmisartan, IS), with total run times of 8.50 min (ESI) and 6.00 min (APCI) and retention times of 4.39, 7.39, 3.98, 4.75, and 1.00 min, respectively. Validation to ICH M10 and US-FDA bioanalytical guidance confirmed excellent linearity and selectivity across broad dynamic ranges—5.27–5461 ng/mL (SM-102), 10.06–10152 ng/mL (DSPC), 10.13– 11047 ng/mL (DMG-PEG-2000), 50.4–35652 ng/mL (cholesterol)—with $r > 0.995$ for all analytes, and robust stability under diverse storage/handling conditions. Compared with HRAM/Q-TOF or Orbitrap strategies oriented to qualitative/stability insights and CAD/ELSD/QC-style workflows, this triple-quad MRM assay furnishes a single, validated, plasma-matrix solution that unifies all four LNP lipids in one run, filling a critical gap between discovery-oriented characterization and regulated bioanalysis.

PP118

VALIDATION OF LOGK (IAM) TO ESTIMATE THE LIPOPHILICITY OF TEST COMPOUNDS

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Abstract

Immobilized Artificial Membrane (IAM) chromatography offers a biologically relevant approach to estimating lipophilicity through Log k(IAM), which is considered superior to traditional octanol-water partitioning (logP) for predicting membrane permeability and absorption. The underlying hypothesis was that validating Log k(IAM) using wellcharacterized reference standards ensures assay robustness, reproducibility, and suitability for drug discovery applications. This study employed High-Performance Liquid Chromatography (HPLC) with UV detection using an IAM.PC.DD2 column (100 × 4.6 mm). The mobile phases consisted of 50 mM ammonium acetate and acetonitrile, and a mixture of acidic, basic, and neutral compounds—Carbamazepine, Warfarin, and Propranolol—served as assay controls. Standards were prepared as 10 mM DMSO stocks and analyzed in duplicate. Gradient retention times were converted to Chromatographic Hydrophobicity Index (CHI(IAM)) values, which were then transformed into Log k(IAM) using the calibration equation Log k(IAM) = 0.046 × CHI(IAM) + 0.42. Calibration was performed using set of standards with CHI(IAM) values ranging from 2.9 to 49.4, corresponding to Log k(IAM) values from 0.50 to 2.69. System suitability was confirmed when CHI(IAM) values for controls remained within ±5 units of reported values (Carbamazepine: 27, Warfarin: 20, Propranolol: 45). Across five trials, mean CHI(IAM) values were Propranolol (41.74), Warfarin (17.18), and Carbamazepine (26.06), with %CV ≤ 2.89%. Log k(IAM) reproducibility was high (%CV ≤ 1.97%), confirming precision and robustness of the method. The validated IAM-based HPLC approach demonstrated a strong correlation between CHI(IAM) and Log k(IAM), reinforcing its reliability for lipophilicity assessment. Notably, positively charged molecules exhibited higher IAM binding, consistent with membrane interaction principles, highlighting the physiological relevance of this technique. The method enables high-throughput screening and supports quantitative structure-retention relationship (QSRR) modelling, providing valuable insights for rational drug design. Compared to logP, Log k(IAM) offers a more accurate and biologically meaningful measure of membrane affinity, making it an essential tool for predicting oral absorption, tissue distribution, and pharmacokinetic behaviour in early drug development. Overall, the validated IAM-based HPLC method ensures reproducibility, robustness, and applicability for routine use, thereby enhancing decision-making in lead optimization and accelerating the drug discovery process.

PP119

DEVELOPMENT OF GASTRO-RESIDENT RAFT SYSTEM CONTAINING POORLY SOLUBLE ACIDIC DRUG

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Hypothesis: Raft-forming gastro-retentive drug delivery systems can prolong gastric residence time and improve the bioavailability of poorly soluble acidic drugs such as Atorvastatin calcium (pKa 4.46) by enhancing absorption in the unionized state.

Methods: A gastro-retentive raft formulation of atorvastatin calcium was developed using a full factorial design. The influence of polymers HPMC K100M, Sodium alginate, and Xanthan gum were evaluated as independent variables. Viscosity and total flotation time were selected as dependent responses to optimize drug–polymer interactions. In-vitro drug release kinetics were assessed using a fabricated dissolution test apparatus.

Supporting Data: The optimized formulation exhibited a viscosity of 40 ± 10 cPs and maintained buoyancy with a total flotation time of 360 ± 50 minutes. Sustained drug dissolution was achieved over a period of 6 hours.

Results" Preclinical evaluation studies were performed using albino Wistar rats for 21 days, including a 14-day induction phase with a high-fat diet to induce hyperlipidaemia, followed by a 7-day treatment phase. The optimized raft formulation demonstrated superior antihyperlipidemic activity compared to a marketed formulation, supported by improved biochemical serum lipid profile parameters.

Conclusion: The developed gastro-retentive raft formulation of atorvastatin calcium provided prolonged flotation, sustained drug release and enhanced antihyperlipidemic efficacy in-vivo. Accelerated stability studies confirmed that the formulation remained physically and chemically stable when stored in an amber bottle at room temperature. Raft-forming gastro-retentive systems offered a promising approach for improving the therapeutic performance of poorly soluble acidic drugs.

Keywords: Raft-forming system, gastro-retentive drug delivery, atorvastatin calcium.

PP120

FORMULATION-DRIVEN PEG–HA MICROGEL–PATCH SYSTEM ENABLING HISTORY-DEPENDENT MECHANICAL ADAPTATION AND STATE-COUPLED SEQUENTIAL DRUG RELEASE: AN IN-SILICO CONCEPTUAL STUDY

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Hypothesis: Conventional anticancer formulations predominantly rely on molecular targeting or time-dependent drug release, despite extensive evidence that solid tumors and post-surgical tumor resection beds exhibit pronounced mechanical, electrochemical, and transport instability at the tissue level. We hypothesize that these dynamic instabilities can be selectively exploited through a formulation-driven strategy in which architected poly(ethylene glycol)–hyaluronic acid (PEG–HA) microgels undergo a history-dependent, mechanically adaptive phase transition exclusively within tumor-like environments, enabling conditional and sequential local drug delivery.

Methods: A hypothetical formulation architecture consisting of PEG–HA microgels embedded within a thin, biodegradable patch was investigated exclusively using in-silico models. Microgels were architected into spatially distinct functional domains, including a PEG-rich deformable sensing shell, a viscoelastic PEG–HA reversible memory network, sparse latent locking nodes, and HA-enriched dense retention pockets. The formulation was designed to integrate three formulation-level functions: (i) spatial confinement via patch-based localization suitable for placement in a breast tumor resection bed, (ii) temporal control through diffusion– erosion-mediated microgel release, and (iii) environment-responsive mechanical adaptation via historydependent microgel network behavior. Synthetic ionic and mechanical fluctuation profiles were generated to represent normal-like stable and tumor-like unstable microenvironments. Viscoelastic and percolation-based network models were employed to simulate stress accumulation, thresholded rigidity transitions, and collective microgel interlocking. State-coupled drug incorporation was conceptually evaluated for a fast-acting local anesthetic (lidocaine) and a sustained anti-angiogenic agent (endostatin), with release governed by microgel activation and subsequent network degradation, respectively.

Results: In-silico analyses demonstrated that stable, low-noise environments failed to induce microgel activation or drug release, whereas tumor-like fluctuating conditions produced cumulative stress exceeding activation thresholds. This resulted in an abrupt, connectivity-driven transition from dispersed, deformable microgels to a percolated, fractal-like mechanical network. Lidocaine, localized within PEG-rich reversible domains, was rapidly released during microgel activation and internal rearrangement, while endostatin remained sequestered within HA-dense retention pockets and was released gradually during degradation-mediated loss of network connectivity. Patch confinement enabled localized microgel accumulation sufficient for collective behavior while preventing uncontrolled dispersion. Progressive degradation of the patch matrix and microgel network provided an intrinsic formulation-level off-switch.

Conclusion: This formulation-centric in-silico study supports the internal plausibility of an architected PEG–HA microgel– patch system that converts tumor-specific dynamic instability into a mechanically gated, sequential drugdelivery event. The work establishes a falsifiable framework that advances formulation science beyond payloadcentric paradigms toward adaptive, state-dependent material architectures for localized cancer therapy.

PP121

PEPTIDE HORMONE ENRICHED CARBOXYMETHYL CHITOSAN SCAFFOLDS FOR SYNERGISTIC WOUND HEALING: AN INVESTIGATIONAL STUDY

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Hypothesis of the present study states that insulin-loaded carboxymethyl chitosan (CMCh) based scaffolds synergistically enhance wound healing by promoting cellular proliferation and tissue regeneration while providing an effective antibiotic-free alternative to address antimicrobial resistance. Methods CMCh–gelatin crosslinked scaffolds were fabricated using a freeze-drying technique. An initial set of twelve scaffolds was characterized for physicochemical properties using FTIR, DSC, swelling index, hydrolytic degradation, and water vapor transmission rate (WVTR) studies to identify optimal formulations. Based on these findings, six optimized formulations (F1–F6) were developed and loaded with insulin. These scaffolds were evaluated using SEM, tensile strength, contact angle measurements, antimicrobial activity and MTT cytocompatibility assays. The optimal scaffold was further assessed through scratch assay, hemolysis testing, dermal toxicity evaluation, and in vivo wound-healing studies. Supporting Data The optimized insulin-loaded scaffold exhibited high porosity, suitable mechanical strength, controlled swelling, optimal WVTR, and sustained degradation, along with significant antimicrobial activity and high cell viability (>90%) in MTT assays. Results In vitro and in vivo evaluations demonstrated enhanced cell migration, accelerated wound closure, improved reepithelialization, and minimal hemolysis and dermal toxicity in the insulin-loaded CMCh scaffold compared to controls. Conclusion The findings confirm that insulin-loaded CMCh-based scaffolds provide a biocompatible, multifunctional, and antibiotic-free wound-healing platform, offering a promising strategy for advanced wound management in the context of rising antimicrobial resistance.

Keywords: carboxymethyl chitosan, insulin, cinnamaldehyde, scaffolds, wound healing

PP122

NIOSOMAL ENCAPSULATION OF CITRUS PEEL BIOFLAVONOIDS FOR IMPROVED ANTIOXIDANT AND ANTICANCER ACTIVITY IN SKIN CANCER CHEMOPREVENTION

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Skin cancer induced by chronic exposure to ultraviolet (UV) radiation remains a major public health concern, necessitating safer and effective chemopreventive strategies. Natural phytochemicals with antioxidant and anticancer properties have emerged as promising alternatives to conventional therapies, which are often associated with toxicity and poor patient compliance. Citrus peel, an abundant agro-waste, is rich in bioactive flavonoids such as hesperidin, naringin, and neohesperidin, known for their chemopreventive potential. However, poor skin permeability and stability limit their topical application.

Hypothesis: Encapsulation of Citrus peel extract rich in bioactive flavonoids into a niosomal gel will enhance its topical delivery, antioxidant activity, and anticancer efficacy, thereby providing an effective chemopreventive strategy against ultraviolet (UV)–induced skin cancer compared to conventional extract or plain gel formulations.

Methods: The peel extract of *Citrus sinensis* was acquired through Soxhlet extraction and analysed via preliminary phytochemical screening, FT-IR, GC-MS, and LC-MS methods. Niosomes loaded with CPE were created using the thin film hydration technique and refined through a central composite design. The optimized niosomes were assessed for particle size, polydispersity index (PDI), zeta potential, entrapment efficiency, and morphology (TEM). The optimized formulation was integrated into a Carbopol gel and assessed for pH, rheology, spreadability, and *in vitro* diffusion. The DPPH radical scavenging assay was utilized to evaluate antioxidant activity. MTT assay was utilized to assess in vitro cytotoxicity on A431 human skin cancer cells, while HaCaT keratinocytes were employed for safety evaluation.

Supporting Data: The optimized niosomal formulation exhibited a nanosized vesicle diameter (~82 nm), acceptable PDI, and stable zeta potential, indicating good stability. *In vitro* diffusion studies demonstrated significantly enhanced drug release from the niosomal gel compared to plain gel. The DPPH assay showed strong antioxidant activity with a low IC_{50} value. Cytotoxicity studies showed a significant reduction in A431 cell viability, while minimal toxicity was observed in HaCaT cells.

Conclusion: The developed CPE-loaded niosomal gel demonstrates enhanced topical delivery, potent antioxidant activity, and significant anticancer potential, supporting its suitability as a promising chemopreventive formulation for skin cancer.

Keywords: Citrus peel extract, niosomal gel, chemoprevention, in silico studies, skin cancer

PP123

MODULATION OF PALBOCICLIB PHARMACOKINETICS THROUGH CYCLODEXTRIN INCLUSION COMPLEXES WITH BIOENHANCERS AND ACID AUXILIARY AGENTS

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Palbociclib, a potent CDK4/6 inhibitor, is clinically constrained by poor oral bioavailability, attributed to its pH-dependent solubility, extensive first-pass metabolism via CYP3A4, and intestinal efflux mediated by P-glycoprotein. To strategically overcome these biopharmaceutical barriers, this study harnessed a Quality-by-Design framework to formulate a novel inclusion complex by integrating solubility and bioavailability enhancers. The formulation was developed using hydroxypropyl-β-cyclodextrin, succinic acid, and naringin through a twin-screw processor, followed by evaluation of solubility in alkaline biorelevant media. Advanced solid-state characterization techniques (FTIR, DSC, PXRD, SEM, and NMR) confirmed the formation of amorphous inclusion complexes, and the quality-by-design approach identified the concentrations of succinic acid and hydroxypropyl-β-cyclodextrin as critical formulation attributes affecting the solubility of palbociclib. Optimized formulations achieved a remarkable 65-fold enhancement in solubility in intestinal pH and exhibited improved dissolution profiles in biorelevant media. Ex vivo studies revealed a 2.15-fold increase in transport of palbociclib, while in vivo pharmacokinetic experiments demonstrated a 2.7 to 3.06-fold elevation in Cmax and up to a 1.9-fold reduction in systemic clearance as compared to pure drug administered as a suspension. Collectively, these results highlight the potential of amorphous inclusion complexes as a transformative drug delivery approach by significantly improving the solubility and pharmacokinetic profile of palbociclib, which would potentially amplify its therapeutic efficacy in breast cancer management.

PP124

ADVERSE EVENTS LINKED TO DENTAL DEVICES: AN IN-DEPTH ANALYSIS OF THE MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE DATABASE

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Introduction: Medical devices are crucial in modern healthcare, but their use is sometimes associated with adverse events (AEs) that can impact patient safety. The Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the U.S. Food and Drug Administration (FDA), serves as a key tool for monitoring these events. This study focuses on adverse events related to the medical device code CAC, analysing reports submitted over a 10.5-year period.

Methods: Adverse event reports associated with the device code CAC were retrieved from the MAUDE database, covering the period from January 1, 2015, to June 30, 2025. A total of 903 reports were analysed to identify year-wise trends, event types, patient problems, and device issues. Reports were further categorized based on reporter occupation and country of origin.

Results: From the 903 reports, the highest number of adverse events were reported in 2024 (114; 12.62%), 2020 (100; 11.07%), and 2017 (82; 9.08%). By event type, malfunctions accounted for the majority (74.97%), followed by injuries (20.48%) and deaths (2.21%). The most reported patient outcomes were “no known impact or consequences” (151 cases), “no consequences or impact” (112 cases), and “no information available” (57 cases). Frequent device issues included fluid or blood leaks (97 cases), cracks (42), mechanical problems (39), and breakage (27). Reports mainly originated from the United States and Japan, with the primary reporters being physicians, nurses, healthcare professionals, and biomedical engineers.

Conclusion: This analysis highlights significant trends in adverse events associated with device code CAC, particularly focusing on malfunction-related issues and nonserious patient outcomes. The results emphasize the importance of continued Materiovigilance and proactive monitoring to enhance device safety and patient care.

Keywords: Medical devices, Adverse events, MAUDE database, CAC device, Materiovigilance.

PP125

ADVERSE EVENTS RELATED TO ENDOBRONCHIAL BLOCKER REPORTED IN THE MAUDE DATABASE

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Introduction: An Endobronchial Blocker (EBB) is a medical device used to achieve one-lung ventilation (OLV) during thoracic surgeries or procedures requiring lung isolation. However, their use is associated with specific safety concerns that necessitate ongoing surveillance. The Manufacturer and User Facility Device Experience (MAUDE) database serves as a valuable source of post-market data on devicerelated adverse events (AEs). Despite their growing clinical application, devices used in tracheal/bronchial differential ventilation have not been extensively studied for AE trends. Analyzing their safety profiles is crucial for enhancing patient outcomes and guiding clinical best practices.

Aim: This study aims to assess the frequency, nature, and trends of AEs associated with Endobronchial blocker reported in the MAUDE database. It also aims to identify the most common device issues and reporting demographics.

Methods: A retrospective analysis was conducted on AEs reports linked to the Endobronchial blocker from January 1, 2015, to December 21, 2025. Data were extracted from the MAUDE database using devicespecific filters. Reports were categorized by year, event type (death, injury, and malfunction), device problem, reporter occupation, and country of origin. Descriptive statistics were used to analyze reporting trends.

Results: A total of 842 AE reports were identified over 10 years. The highest number of reports occurred in 2021 (154; 18.28%), followed by 2022 (104; 12.35%) and 2020 (101; 11.99%). Malfunctions comprised the majority of events (750; 89.07%), while injuries and deaths accounted for 88 (10.45%) and 5 (0.59%) reports, respectively. The most frequent device problems included breakage (211; 25.05%), leak or splash (112; 13.30%), and inflation issues (83; 9.86%). Most reports originated from the USA (41%), Japan(35%), and China(24%). Physicians, nurses, and other healthcare professionals were the primary reporters.

Conclusions: Endobronchial Blocker are associated with a high proportion of malfunction reports, particularly related to mechanical issues. These findings highlight the need for targeted design improvements and stronger post-market monitoring. Future research should explore root causes and prevention strategies.

Keywords: MAUDE database, medical device surveillance, Endobronchial Blocker

PP126

MITOXANTRONE HYDROCHLORIDE-LOADED LIPID POLYMER HYBRID NANOPARTICLES; FORMULATION AND EVALUATION AGAINST TNBC

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Introduction: Globally, Breast cancer (BC) is the most common disease in women, which is considered a major threat to the healthcare system. In India, most of the women affected by cancer suffer from Triple-Negative Breast Cancer (TNBC). Mitoxantrone hydrochloride (MT) is a synthetic anticancer agent that disrupts cancer cell proliferation and metastasis within the body. Lipid Polymer Hybrid Nanoparticles (LPHNPs) provide distinct characteristics such as high encapsulation efficiency, controlled drug release, biocompatibility, and improved stability in hydrophilic and lipophilic drugs.

Objective: To develop and optimize Mitoxantrone Hydrochloride-loaded lipid–polymer hybrid nanoparticles (MT-LPHNPs) to improve delivery in TNBC. To assess whether the developed formulation can enhance anticancer efficacy while reducing the toxicity with respect to free mitoxantrone.

Methodology: Pre-formulation studies were carried out to evaluate the purity of drugs and to establish suitable analytical methods. MT-LPHNPs were developed and optimized using DoE approach and characterized by FT-IR, DSC, XRD, TEM, and assessed for Particle Size (PS), Polydispersity Index (PDI), Zeta Potential (ZP), Entrapment Efficacy (%EE), in vitro drug release, in vitro cell line, and in-vivo studies.

Results: MT-LPHNPs were successfully developed and optimized. The optimised formulation showed a particle size of 162.5±0.54 nm, PDI of 0.169±0.01, and zeta potential of 20.35±0.11 mV. In-vitro drug release was found to be 89.62±1.75% at 72 hrs with %EE of 82.39 ±2.12%. The anticancer activity was tested on the MDA-MB-231 and MCF-7 cell lines, where MT-LPHNPs showed an mRNA level that prevents cell migration and induces apoptosis. The in-vivo studies demonstrated that the developed formulation significantly reduced tumour volume and improved pharmacokinetic parameters compared with the pure drug.

Conclusion: This work reports the utility of MT-LPHNPs as an effective therapy against TNBC.

Keywords: Triple-negative breast cancer, Mitoxantrone hydrochloride, Lipid polymer hybrid nanoparticles, Controlled drug release, In vitro cytotoxicity, In-vivo antitumor activity.

PP127

ADVERSE EVENTS ASSOCIATED WITH HYDROCEPHALUS SHUNTS: MAUDE DATA REVIEW

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Introduction: Hydrocephalus shunts are essential implants for managing cerebrospinal fluid buildup. This study utilizes the FDA's Manufacturing and User Facility Device Experience (MAUDE) database to evaluate reported complications and assess device safety. Understanding the nature and frequency of these events is vital for improving outcomes, especially in pediatric populations.

Aim: The aim of the study was to assess the patterns, frequency, and characteristics of AEs linked to hydrocephalus shunts.

Methods: A retrospective analysis of MAUDE reports using JXG product code were retrieved from January 1, 2015, to July 10, 2025. Data were categorized by event type, device problems, patient outcomes, reporter type, age group and geographic region. Descriptive statistics were applied to assess trends across pediatric, adult, and geriatric populations, including time-based and reporter-based comparisons.

Results: A total of 13,847 AE reports were documented. Reporting peaked in 2018 (10.7%), 2021 (10.6), and 2022 (9.6%), reflecting fluctuations over time. The United States accounted for highest reports (39.4%), followed by Japan (9.6%) and China (4.3%). Reports were mainly submitted by manufacturers and physicians. Pediatric patients made up the highest share (41.9%), followed by adults (30.2%) and geriatrics (27.9%). Injury was the most common event type (66.6%), followed by malfunctions (28.1%) and deaths (0.88%). Device-related problems included mechanical jam/problem (9.4%), obstruction/occlusion (10.1%), and break (7.7%). Common patient-related problems included failure to implant (4.7%), headache (4.18%), and injury (2.96%).

Conclusion: This study provides actionable insights for clinicians, manufacturers, and regulatory bodies to enhance device safety, reduce complications, and improve patient outcomes. These findings emphasize the need for rigorous post-market monitoring, materiovigilance and pediatric safety protocols.

Keywords: hydrocephalus shunt, pediatric safety, MAUDE database.

PP128

QUERCETIN-LOADED COLLAGEN COMPOSITE SCAFFOLD FOR DIABETIC FOOT ULCER: FORMULATION AND IN VITRO EVALUATION

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Diabetes mellitus (DM) is a chronic disorder characterised by an elevated blood glucose level resulting from insulin deficiency. DM results in many complications, particularly diabetic foot ulcers (DFUs), which is an important cause of amputation of lower limbs in diabetic patients. When these ulcers are not treated properly, they might become chronic, resulting in amputations due to failure to heal the wound. The immunopathy, neuropathy, and vasculopathy have a complex nature that is involved in the wound healing problems in diabetes that cause chronic inflammation and lowered growth factor expression. Current DFU therapeutic approaches mainly focus on glucose and wound care, whereas more sophisticated interventions exist; nevertheless, the treatment is still complex due to the pathophysiology and expensive nature. It was hypothesized that this research would design and characterize quercetin(QUR)-incorporated collagen scaffolds for the treatment of DFU, given the promising therapeutic potential of quercetin in diabetic wound healing. The combination of quercetin and collagen is a promising approach to the management of diabetic foot ulcers as they are anti-inflammatory and tissue-regenerative agents. The Quercetin-loaded PLGA Nanoemulsion was prepared using the solvent evaporation method, and subsequently added to a solution of chitosan(CS)which was followed by impregnation of the prepared QUR-CS nanoparticles into Collagen Scaffold. Box-Behnken design (BBD) was used to optimize the independent variables with respect to the dependent variables. Analysis of both the pre-formulation and optimized formulations using differential scanning calorimetry(DSC) and Fourier transform infrared spectrophotometry(FTIR) showed excellent compatibility among the drug, excipients, and the final formulation. The biodegradable crosslinked scaffolds, which were prepared by use of EDC-NHS crosslinking chemistry in MES buffer, displayed reduced matrix degradation, optimum porosity, and prolonged drug release as compared to non-crosslinked scaffolds. The scaffolds were evaluated for morphology, scanning electron microscopy, water absorption capacity, in vitro degradation, protein absorption, blood compatibility, and antioxidant activity. The antimicrobial tests showed strong activity against the most common pathogens, including Gram-negative bacteria (Escherichia coli) and Gram-positive bacteria. Stability studies as per ICH guidelines indicated that the scaffolds remained stable over a period of 90 days. Hence, the results suggest that the synergistic combination of QUR, CS, and scaffolds may represent a promising approach for the treatment of diabetic foot ulcer.

Keywords: Diabetes Foot Ulcers, Quercetin-Loaded Collagen Scaffolds, Solvent Evaporation, Box-Behnken Design, Antimicrobial

PP-129

PRECISION DOSING OF TACROLIMUS IN INDIAN ADULT RENAL TRANSPLANT POPULATION: CURRENT STATUS AND UNMET NEEDS

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Background: Tacrolimus is the backbone of maintenance immunosuppression in renal transplantation but exhibits a narrow therapeutic index and marked inter-individual pharmacokinetic variability. Precision dosing strategies—such as population pharmacokinetic (PopPK) models, Bayesian therapeutic drug monitoring (TDM), pharmacogenetic-guided dosing, and clinical decision support systems (CDSS)—have been developed to optimize tacrolimus exposure. However, most existing models and dosing algorithms have been derived from predominantly Caucasian populations, raising concerns regarding their applicability to the Indian population, which differs genetically, clinically, and in healthcare delivery settings.

Methodology of review: A narrative literature review was conducted using PubMed, Embase, and Google Scholar to identify studies on tacrolimus PopPK modelling, genotype-guided dosing, model-informed precision dosing, and CDSS implementation, with a specific focus on Indian cohorts. Systematic reviews, PopPK model publications, pharmacogenetic studies, and Indian clinical studies were evaluated to assess the current status, limitations, and unmet needs of tacrolimus precision dosing in India.

Results: The available literature indicates increasing use of precision dosing strategies for tacrolimus, including population pharmacokinetic modelling, Bayesian therapeutic drug monitoring, and pharmacogenetic-guided dosing. Key sources of variability commonly reported include CYP3A5 genotype, haematocrit, age, body size, time post-transplant, and drug–drug interactions. However, most published models and clinical decision support systems are derived from predominantly Caucasian populations, with minimal representation of Indian patients. Evidence from Indian studies suggests considerable variability in tacrolimus dose requirements and a clinically relevant influence of CYP3A5 polymorphisms, but these studies are limited by small sample sizes, single-centre designs, and lack of external validation. Consequently, the applicability of existing models to the Indian population remains uncertain.

Conclusion: Precision dosing of tacrolimus in India remains underdeveloped despite clear clinical need. Addressing this gap requires development and validation of Indian-specific PopPK and physiologically based PK models, pragmatic integration of CYP3A5 genotyping, standardized and accessible TDM practices, and prospective multi-centre implementation studies. Such efforts are essential to enable safe, effective, and equitable model-informed immunosuppressive therapy for Indian renal transplant recipients.

PP-130

EXPLORING PROTAC PERMEABILITY: COMPARATIVE INSIGHTS ACROSS DIFFERENT CELL LINES

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The permeability of Proteolysis Targeting Chimeras (PROTACs) is a crucial determinant of their bioavailability and therapeutic efficacy. PROTACs are bifunctional molecules that induce targeted protein degradation by binding both a protein of interest and an E3 ligase. However, factors such as high molecular weight, polar surface area, and exposed hydrogen bond donors frequently hinder this process. Unlike traditional small molecules that follow Lipinski's Rule of 5 for predicting permeability and oral bioavailability, PROTACs often exceed these guidelines, making their transport across biological barriers challenging. Therefore, choosing the right cell models to evaluate their permeability is essential. In this study, we evaluated the permeability characteristics of three PROTACs—ARV-771 (ALS-010), ARV-110 (ALS-011), and KT-474 (ALS-012), along with three quality control (QC) compounds: Propranolol, Atenolol, and Digoxin [P-glycoprotein (P-gp) substrate]—using three different cell lines. Experimentally, cells were seeded into the 96-well Millipore Multiscreen trans wells plates with a density of 12000 cells/well for Caco-2 and 25000 cells/well for MDCK-II, MDR1 MDCK-II and LLC-PK1 and the plates were incubated in a humidified temperature at 37°C with 5 % CO_2. Cells were taken for the permeability assay LLC-PK1 (5 days), MDCK-II and, MDR1 MDCK-II (7 days) and Caco-2 (21 days) after the post seeding Membrane integrity was measured and drug was introduced into respective chamber of 96 wells plate, incubated for 120 minutes and sample were collected and processed with acetonitrile containing internal standard followed by the quantification of compounds by using LC-MS/MS analysis. The results compared the permeability of PROTACs across three cell lines—LLC-PK1, MDR1 MDCK-II, and Caco-2—with the hypothesis that LLC-PK1 offers advantages over the other two models. The findings highlight differences in permeability, efflux ratios, and recovery rates, providing insights into the suitability of each cell line for assessing PROTAC transport and absorption.

PP131

CHARACTERIZATION OF ENDOGENOUS BCRP BIOMARKERS IN RAT MODELS: AN EXPLORATORY INVESTIGATION

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Clinical Inhibition of Breast Cancer Resistance Protein (BCRP/ABCG2) efflux transporter can significantly influence the pharmacokinetic (PK) behaviour of xenobiotics in combination drug therapy and in disease conditions. The present study aims to identify and investigate the impact of BCRP substrate (Rosuvastatin) PK when co-administered with a BCRP inhibitor (Novobiocin) in Sprague-Dawley (SD) rats. To investigate, an in vivo PK study was designed into two groups. In the first group, Rosuvastatin was dosed alone at 1 mg/kg. In the second group, Rosuvastatin was dosed at the same dose after 5 min of intravenous novobiocin (5 mg/kg). The bio-analysis was divided into two phases. Phase one, targeted screening, in which the concentration of rosuvastatin was measured alone and with novobiocin using LC-MS/MS. Phase two, untargeted screening, in which biomarkers were investigated in both conditions. In preliminary PK profile findings, Novobiocin significantly inhibit ($p<0.05$) BCRP at 10 -30 min. Rosuvastatin concentration increased by 1.8-fold at 10 min and 3.5-fold at 30 min. On the other hand, overall PK parameters are not significantly different at a particular dose. Additionally, we found approximately 4,000 biomarkers with 1.5-3.0-fold increases in significance ($p<0.05$-0.001). The above findings suggest that novobiocin may be a promising inhibitor and can be further explored for BCRP biomarker research.

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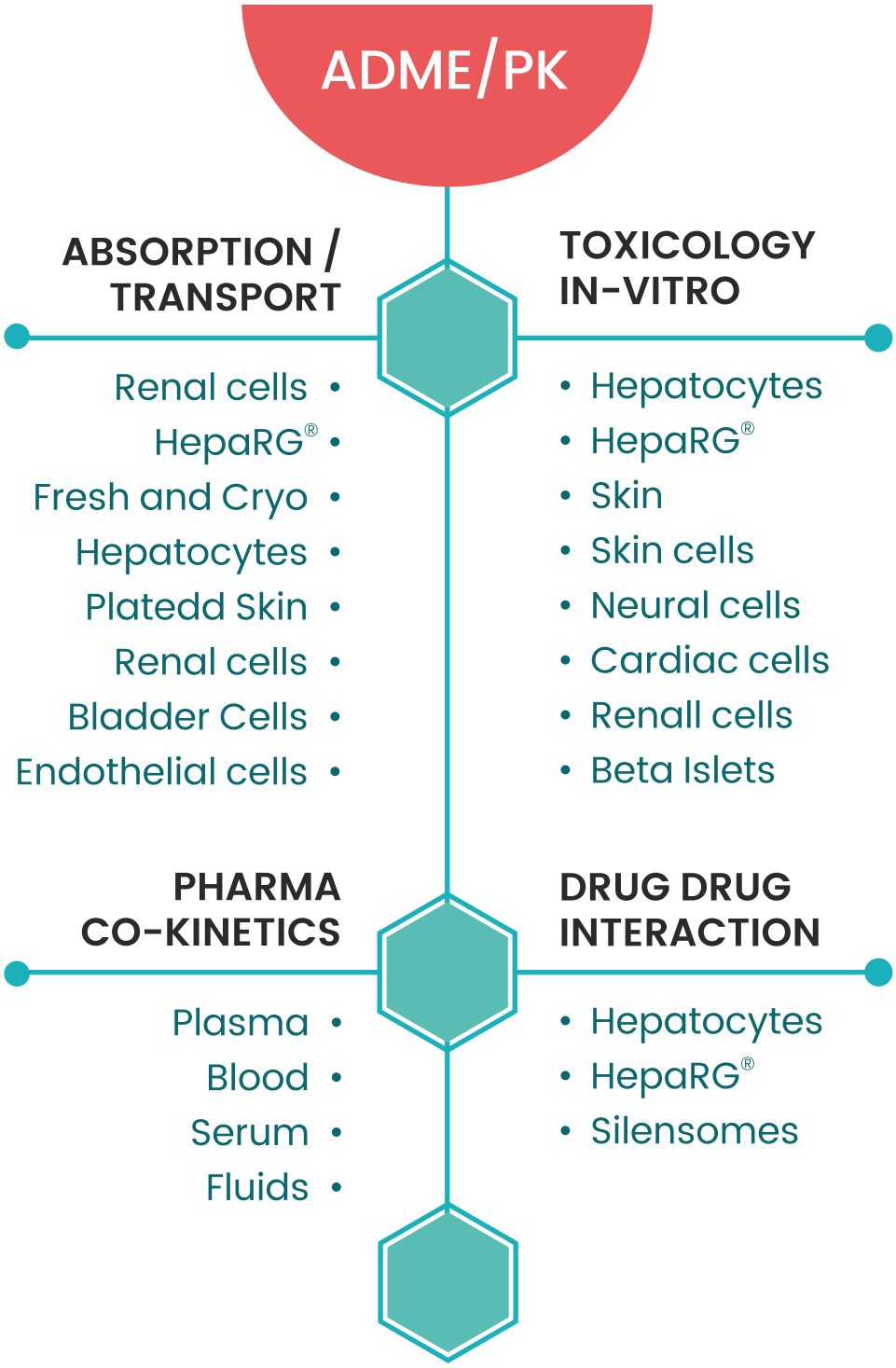

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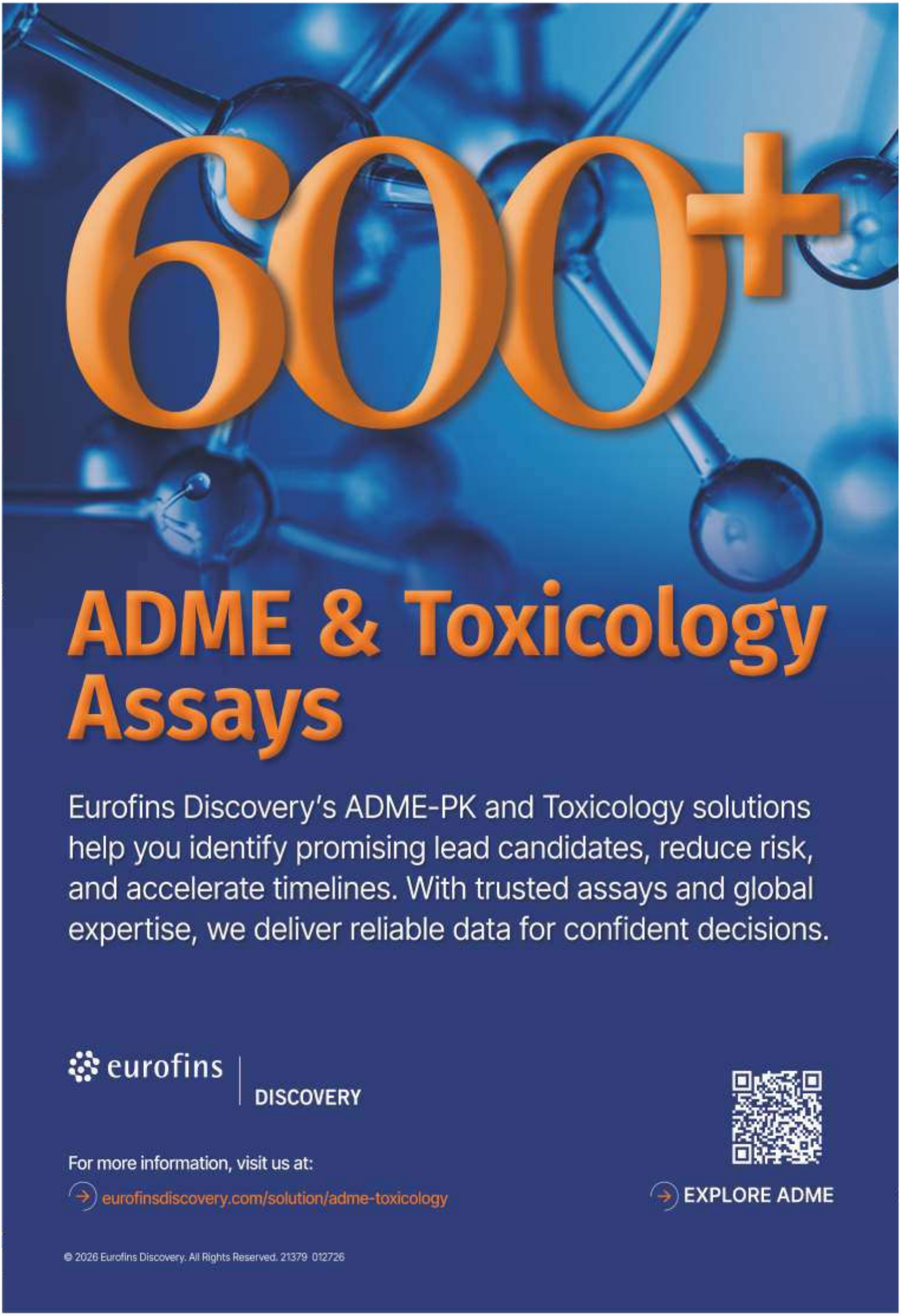
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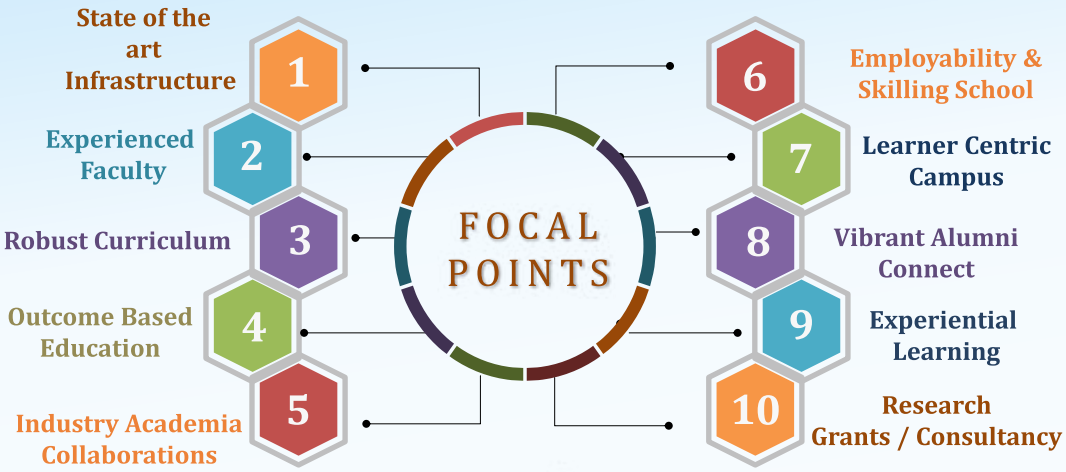

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