











International Symposium - cum - Workshop

on

# INNOVATIONS IN TRANSLATIONAL THERAPY AND TARGETED DRUG DELIVERY (ITTD-2025)



# ABSTRACT BOOK

Birla Institute of Technology and Science, Hyderabad Campus, India













# International Symposium cum Workshop on Innovations in Translational Therapy and Targeted Drug Delivery (ITTD-2025)

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# International Symposium cum Workshop on

# Innovations in Translational Therapy and Targeted Drug Delivery

(ITTD-2025)



# Padma Bhushan Dr. Krishna Ella

Co-founder and Executive Chairman
Bharat Biotech



Padma Bhushan Dr. Krishna Ella is a distinguished Indian scientist, entrepreneur, and visionary leader known for his groundbreaking contributions to biotechnology, public health, and vaccine innovation in India and globally. Dr. Ella completed his bachelor's degree at Tamil Nadu Agricultural University and earned a master's degree from the University of Agricultural Sciences, Bangalore. Bolstered by a Rotary fellowship, he went abroad to pursue an M.S. at the University of Hawaii before earning his Ph.D. in plant pathology from the University of Wisconsin-Madison. Dr. Ella began his career at Bayer's agricultural division but quickly moved into academia, serving as a research faculty member at the Medical University of South Carolina, Charleston. In 1996, he returned to India and established Bharat Biotech International Limited in Hyderabad, alongside his wife, Suchitra Ella. In just a few years, Bharat Biotech became a beacon of innovation, launching its Hepatitis B vaccine in 1999 and exporting millions of doses to over 65 countries. Under Ella's leadership, Bharat Biotech developed several world-first vaccines, including ROTAVAC for rotavirus, Typbar TCV for typhoid, and most notably, Covaxin—India's first indigenous COVID-19 vaccine. Dr. Ella's commitment to "science as a passion" has positioned Bharat Biotech asa front-runner in vaccine research, from the world's cheapest hepatitis vaccines to cell-cultured swine flu and Zika virus vaccines. His approach blends innovation with accessibility, ensuring lifesaving vaccines reach underserved populations globally. He has also played a key role in developing biotechnology infrastructure in India, notably proposing the foundation of Genome Valley in Hyderabad, a hub for life sciences research and industry. Dr. Krishna Ella's work has earned him numerous accolades. In 2022, he was conferred the Padma Bhushan, India's third highest civilian award, in recognition of his significant contributions to trade and industry. His other honors include the Distinguished Alumni Award and Honorary Doctor of Science degree from the University of Wisconsin-Madison, BioAsia Genome Valley Excellence Award, JRD Tata Best Entrepreneur of the Year, Marico Innovation Award, ET Now Special Recognition for Healthcare Industry Award, and the Asia-Pacific Leadership Award from the University of Southern California. Beyond his corporate achievements, Dr. Ella is deeply involved in shaping science policy and education in India. He serves on various national committees, including the Scientific Advisory Committee to the Union Cabinet, CSIR Governing Council, CCMB Governing Council, and boards affiliated with global health institutes. Through Bharat Biotech, Biovet, and Innova Food Park, he has expanded his scope to animal health and food technology aiming for broad impact across multiple sectors. Dr. Krishna Ella's legacy lies in his relentless pursuit of innovative vaccine solutions and his unwavering commitment to public health. His journey—from a rural upbringing to becoming a biotech tycoon and Padma Bhushan awardee—continues to inspire future scientists and entrepreneurs in India and around the world.

# **PLENARY SPEAKERS**



Prof. Jimmy Hsia
Professor
NTU, Singapore



Dr. Bijaygopal Chakrabarti Senior Vice President Operations Eugia US LLC - Hyderabad office

# **INVITED SPEAKERS**



**Prof. Sarit Agasti** *Associate Professor JNCASR, Bengaluru* 



Prof. Saurabh Srivastava Associate Professor NIPER-Hyderabad



Dr. Vamsi Madgula
Senior Director, Head of
DMPK and non-GLP
Toxicology services
Sai Life Sciences



Dr. Nagendra Babu B
Principal Scientist
CSIR-IICT, Hyderabad



Prof. Animesh Ghosh
Professor
BIT Mesra

# **INVITED SPEAKERS**



Dr. Sampa Sarkar
Research fellow
RMIT University, Australia



Prof. Aniruddha Roy
Associate Professor,
Department of Pharmacy,
BITS Pilani



Dr. Mallinath Harwalkar Vice President - R&D, Heteron Hyderabad



Dr. Mukesh Gandhari Director- Preclinical Testing Palamur Biosciences, Hyderabad



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Associate Professor
NIPER-GUWAHATI



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Dr. DY Patil Institute of
Pharmaceutical Sciences and
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# BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE PILANI



BITS, Pilani - Hyderabad Campus Jawahar Nagar, Shameerpet Mandal, Hyderabad, 500078, Telangana State. INDIA



### **About SPARC**

The Scheme for Promotion of Academic and Research Collaboration (SPARC) is an endeavor of the Ministry of Human Resource Development, Government of India, which aims to improve the research ecosystem of India's higher education institutions by facilitating joint research projects involving faculty and student mobility between highly ranked Indian institutions and internationally ranked foreign institutions. SPARC aims to strengthen the collaboration of Indian researchers with top international research groups so that Indian students can experience research versatilities. The introduction of Indian academicians to the most successful international collaborators overseas and the development of strong bilateral research relationships would lead to enhanced visibility and exemplary research outcomes

Vision of SPARC- The major outcome of the SPARC initiative will be strong research collaboration between Indian Research groups with top research group in the leading Universities of the world, in areas that are at the cutting edge of science or with direct social relevance to the mankind, specifically India. The strong joint research should lead to tangible result that should include Joint Research Projects, Exchange of faculty and students, Joint Degrees, by supporting the following critical components that can catalyze impact making research, namely: (a) Visits and long-term stay of top international faculty / researchers in Indian institutions to pursue teaching and research (b) Visits by Indian students for training and experimentation in premier laboratories worldwide, (c) Joint development of niche courses, world-class books and monographs, translatable patents, demonstrable technologies or action research outcomes and products (d) Consolidation of Bilateral cooperation through academic and research partnerships through Workshops in India, (e) Publication, Dissemination and Visibility through a high profile annual international Conference in India and (f) training of researchers and students. SPARC should catalyze sustained and long term joint cutting edge research between India and other partner countries in areas of critical importance.

### **About SPARC and TTCI 2024**

The Scheme for Promotion of Academic and Research Collaboration (SPARC) is a prestigious initiative by the Ministry of Human Resource Development, Government of India, aimed at enhancing India's higher education research ecosystem by promoting collaborative projects between leading Indian and globally ranked international institutions. It facilitates research partnerships, faculty and student exchanges, and fosters exposure to international research practices.

### Looking back at a memorable event!

The SPARC-sponsored *International Symposium cum Workshop on Translational Therapies for Cancer and Infections (TTCI-2024),* held on July 22-24, 2024, was a remarkable success. The event brought together global experts to discuss advancements in cancer and infection therapies.

We had the privilege of hosting Prof. Jimmy Hsia (Nanyang Technological University, Singapore) and Prof. Adam Mechler (La Trobe University, Australia), who presented pioneering work in biomaterials, nanotechnology, and drug delivery. Their talks inspired engaging discussions and paved the way for future collaborations.

The event also featured a two-day workshop offering hands-on training in techniques like nanoparticle characterization, cytotoxicity assays, confocal imaging, FACS analysis, and in vivo animal studies.

Gratitude to BITS Pilani, Hyderabad Campus, the SPARC initiative, and everyone who contributed to making TTCI-2024 a truly impactful and memorable event!

We are delighted to announce that the second edition of this conference, once again supported by SPARC, is on the horizon. We eagerly invite you all to join us in making it an even greater success through your participation, knowledge-sharing, and collaborative spirit. We look forward to welcoming you to another enriching academic gathering!



### **About BITS Pilani**

BITS Pilani is a Deemed-to-be University, recognized as an Institute of Eminence by the Ministry of Education, Government of India, in 2020. It is currently offering on-campus programmes to more than 18,500 students across its campuses in Pilani, Goa, Hyderabad, Mumbai, and Dubai. BITS has been ranked 188 in QS Asia University Rankings 2023, the only private institute from India in the Asia Top 200. Further, BITS Pilani has been ranked among the top 300 in QS World University Graduate Employability Rankings 2022 and within the top 8 in India. The university is committed to innovation, excellence, and merit-based admissions. It prioritizes research, with faculty securing over ₹398 crore in funding over the past five years. Entrepreneurial success is also a hallmark of BITS Pilani, with 14 BITSian unicorns, 1 decacorn, and over 7500 founders and co-founders of various enterprises.

### **About Department of Pharmacy**

The Department of Pharmacy at Hyderabad Campus, established in 2008, is actively involved in various cutting-edge research areas, with a committed team of 16 faculty members and more than 90 research scholars. Several patents, faculty-led startups, sponsored research grants, and publications in prestigious journals with high-impact factors demonstrate our faculty members' dedication and research potential. Additionally, the department has a state-of-the-art infrastructure for teaching (B. Pharm., M. Pharm., and PhD programmes) and carrying out advanced pharmaceutical research. BITS Pilani (combined Pilani and Hyderabad) has been ranked 3rd by the MoE National Institutional Ranking Framework (NIRF) in 2023 and has been in the top six positions since 2017 in the NIRF Pharmacy subject category. It stands in the 101-150 band by QS World Subject Rankings-2023 for Pharmacy and Pharmacology

### Director's message



Dear Colleagues and Attendees,

It is my distinct pleasure to welcome each of you to the Symposium on Innovations in Translational Therapy and Targeted Drug Delivery (ITTD-2025). Organized by Prof. Swati Biswas and Prof. Balaram Ghosh of the Department of Pharmacy and proudly supported under SPARC (Scheme for Promotion of Academic and Research Collaboration), Government of India, this symposium marks another milestone in our collective journey to advance scientific knowledge and treatment modalities.

The ITTD-2025 Symposium gathers an exceptional assembly of experts, researchers, and practitioners united by the goal of pioneering novel therapies and transformative drug delivery solutions. By facilitating robust interdisciplinary dialogue, we aim to spark collaborations that can translate scientific innovation into tangible improvements for patient care. The passion and diversity represented here remind us that breakthroughs often arise from new perspectives and the blending of ideas across disciplines.

I strongly encourage all participants to take full advantage of this unique opportunity: engage in stimulating discussions, exchange ideas freely, and forge partnerships that can propel your work to new heights. Whether in sessions, workshops, or informal conversations, your involvement is critical to making ITTD-2025 a vibrant and impactful event.

May this symposium inspire you with fresh insights, lasting connections, and innovative strategies that pave the way for meaningful progress — particularly in our shared fight against cancer and infectious diseases. Let us embrace the spirit of collaboration and discovery, ensuring our collective efforts yield benefits for science and society alike. Wishing everyone an enlightening and productive conference experience!

With Best Regards

Prof. Soumyo Mukherji, PhD, FNAE, FNASc, Director BITS Pilani Hyderabad Campus

### **HOD's message**



Dear Colleagues and Attendees,

It is my great pleasure to welcome all the distinguished speakers and participants to the International Symposium on Innovations in Translational Therapy and Targeted Drug Delivery (ITTD-2025), hosted at the BITS Pilani, Hyderabad Campus. I would like to take this opportunity to express my sincere appreciation to Prof. Swati Biswas and Prof. Balaram Ghosh for organizing this prestigious symposium, with valuable support from SPARC (Scheme for Promotion of Academic and Research Collaboration).

The Department of Pharmacy at BITS Pilani, Hyderabad Campus is recognized as one of India's premier institutions, known for its cutting-edge research and excellence in teaching. Our faculty comprises experts from both academia and industry, enriching the learning and research environment. The department offers three academic programs: B. Pharmacy, M. Pharmacy with specializations in Pharmaceutics and Pharmacology, and Ph.D. programs. We have active collaborations with leading pharmaceutical companies, including Novartis, Natco Pharma, Hetero Labs, Daewoong Pharmaceuticals, AstraZeneca, Sun Pharma Advanced Research Company, Dr. Reddy's Laboratories, Slayback Pharma, Transform SciTech, Orbicular Pharma, Leiutis Pharmaceuticals, ISSAR Pharmaceuticals, among others. Our research initiatives are supported by major national funding agencies such as ICMR, ANRF, DST, DBT, CSIR, DHR, and PDA, with 51 ongoing research projects.

Notably, five faculty members from our department have been featured on Stanford University's list of the World's Top 2% Scientists. Our department has published over 407 Scopus-indexed journal articles since 2020, filed 45 patents, and has been granted 9 patents to date. BITS Pilani has consistently ranked among the top institutions in India, securing 3rd position in the NIRF 2023 rankings and maintaining a top 5 position in the Pharmacy category since 2018. On the global front, BITS Pilani is ranked 84th in Pharmacy & Pharmacology and within the top 250 universities overall in the QS World University Rankings 2025.

This symposium offers an excellent platform for participants to engage in meaningful discussions, explore innovative solutions, and translate emerging technologies into impactful healthcare outcomes.

I wish all participants and organizers a rewarding and inspiring experience.

With Best Wishes



Arti Dhar, M.S Pharm, Ph.D. Professor & Head - Department of Pharmacy BITS Pilani Hyderabad Campus

# Organizer's message



### **Dear Attendees**

Welcome to the symposium, Innovations in Translational Therapy and Targeted Drug Delivery (ITTD-2025)!

We are delighted to have you join us for this special event. The symposium has been organized to fulfill the objectives of the Scheme for Promotion of Academic and Research Collaboration (SPARC) implemented by the Ministry of Education (MoE), which emphasizes about establishing strong collaboration between Indian research groups and well-recognized international research labs. We are especially honoured to host Dr. Krishna Ella, Padma Bhushan awardee (2022), as the distinguished guest of honour for the symposium. Dr. Ella, co-founder and Chairman of Bharat Biotech, is a visionary scientist and entrepreneur whose pioneering work has transformed India's biotechnology landscape. His unwavering commitment to science and society was exemplified during the COVID-19 pandemic through the development of Covaxin, India's indigenously developed vaccine that reached millions worldwide. Beyond his entrepreneurial success, Dr. Ella has dedicated himself to strengthening India's research ecosystem, mentoring young scientists, and promoting translational research that addresses pressing global health challenges. For his extraordinary contributions to science, innovation, and public health, Dr. Ella has been recognized with numerous national and international honors, including the Padma Bhushan, one of India's highest civilian awards. His journey reflects a rare blend of scientific rigor, innovation, and social responsibility. In this symposium, we are immensely happy to welcome Professor. Jimmy Hsia, Chair Professor in the School of Mechanical & Aerospace Engineering and School of Chemistry, Chemical Engineering and Biotechnology at Nanyang Technological University in Singapore. Along with the international collaborators of the SPARC projects, we are extremely happy to welcome our invited speakers all over the globe.

We immensely thank all the students, scholars, faculty, and researchers for joining us today. The symposium promises to provide an exciting opportunity for learning, networking, and collaboration. We are thrilled by the overwhelming response to the poster submissions and are pleased to accommodate sixty-two posters spanning various research areas. Navigating the poster session would be highly enriching and would surely benefit all attendees.

Last but not least, we are extremely thankful to SPARC, the Ministry of Education, and the Government of India for providing us with the funding to conduct the symposium. We sincerely thank all our partners for their generous contributions, which have made this event possible. Once again, I thank everyone for your great support and enthusiasm. I hope everyone finds the symposium to be a valuable and enriching experience.

Kind Regards

Swati Biswas, Ph.D.

Professor, department of Pharmacy

BITS-Pilani, Hyderabad

Ja So Biswas

(Organizer, ITTD-2025)

# **Plenary Speaker**

**Prof. Jimmy Hsia** *Professor Nanyang Technological University, Singapore* 



Prof. K. Jimmy Hsia is the President's Chair Professor in the School of Mechanical and Aerospace Engineering and the School of Chemistry, Chemical Engineering, and Biotechnology at Nanyang Technological University (NTU) in Singapore. He received a B.S. from Tsinghua University, China, an M.S. from Beijing University of Aeronautics, and a Ph.D. from MIT. His research interests include mechanics of soft materials, mechanics of plant organ morphogenesis and morphing metamaterials, mechanics of mammalian cells, micro- and nanotechnologies in mechanical devices and structures, smart adhesive systems, and soft robotics. He is a Fellow of the American Association for the Advancement of Science (AAAS), Fellow of the American Institute for Medical and Biological Engineers (AIMBE), Fellow of the American Society of Mechanical Engineers (ASME), and recipient of NSF Research Initiation Award, Max-Planck Society Scholarship, and Japan Society for Promotion of Science Fellowship. He was Founding Dean of Graduate College and Vice President (Alumni & Dresident (Alumni & Professor of President (Al Mechanical Engineering and Biomedical Engineering and Vice Provost for International Programs at Carnegie Mellon University, and before then was W. Grafton and Lillian B. Wilkins Professor of Mechanical Science and Engineering at the University of Illinois at Urbana-Champaign (UIUC). From 2005 to 2007, Hsia served as Founding Director of the Nano and Bio Mechanics Program in the Directorate for Engineering at NSF. He is the Founding Co-Editor-in-Chief of an Elsevier journal, Extreme Mechanics Letters.

### Biomarker-triggered hydrogel swelling for ultrasensitive biosensing

The detection of trace-level biomarkers in complex biofluids remains technically challenging for point-of-care testing due to their low concentration and complex matrix environments. Here we present a new mBASE technology (metamaterial Buckling-Assisted Surface-acousticwave Enabled sensor), a biosensing platform that integrates bio-crosslinked hydrogel acoustic metamaterials with a surface acoustic wave (SAW) device for amplified and real-time signal transduction. Specific receptor-ligand pairs are copolymerized into a periodic hydrogel matrix that undergoes target-induced competitive de-crosslinking and swelling. This process triggers mechanical buckling under engineered gapped constraints, tuned to match the swelling strain of diverse hydrogel compositions. The resulting structural transition enhances SAW signal readout via three synergistic mechanisms: mass-loading, viscoelastic modulation, and phononic bandgap shift. This mechanism allows ultrasensitive and label-free detection of proteins, nucleic acids, and metabolites within minutes. As a clinical demonstration, the mBASE assay can detect Herpes Simplex Virus (HSV) IgG and DNA at concentrations as low as  $10^{-2}$  pg/mL and  $10^{-15}$  M, respectively. By coupling biomolecular recognition with acoustic metamaterial buckling, mBASE offers a versatile platform for rapid, ultrasensitive diagnostics with potential for accurate disease screening and monitoring.

# Prof. Sarit Agasti Associate Professor JNCASR, Bengaluru



Prof. Sarit S Agasti obtained a Ph.D. degree in Chemistry from the University of Massachusetts-Amherst. He worked under the guidance of Prof. Vincent M. Rotello. He joined Harvard University as a postdoctoral fellow, where he worked with Prof. Ralph Weissleder and Prof. Peng Yin. Dr. Sarit S Agasti is currently an associate professor at Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bangalore. His research group focuses on the application of synthetic non-covalent recognition motifs, including host-guest interaction and DNA-DNA interaction, for developing new tools for imaging, biosensing, and therapeutic delivery. He is the recipient of the prestigious DBT/Wellcome Trust India Alliance Intermediate Fellowship, the Innovative Young Biotechnologist Award (IYBA), Sheikh Saqr Career Award Fellowship, National Prizes for Research in Bio-Physical Chemistry, Merck Young Scientist Award, INSA Medal for Young Scientists, and the Asian and Oceanian Photochemistry Association (APA) Prize for Young Scientist. He also recently joined as an editorial advisory board member of the ACS journal Bioconjugate Chemistry.

### Smart Host-Guest Assemblies for Spatiotemporal Control of Microtubule-Targeting Drugs

Microtubules (MTs) are dynamic cytoskeletal filaments essential for cellular motility, intracellular trafficking, and proliferation, making them prime targets for anticancer therapeutics. Controlling MT stability with spatiotemporal precision can provide powerful avenues for both mechanistic studies and targeted drug delivery. Host-guest recognition, based on the reversible binding of complementary components, offers a powerful strategy to achieve such control in a biocompatible manner. Here, we present a supramolecular strategy for spatiotemporal regulation of MT dynamics in live cells using cucurbit[7]uril (CB[7])-mediated host-guest recognition. MTs were targeted using a docetaxel analogue derivatized with p-xylenediamine to introduce a CB[7]-binding site. This modification yielded a non-toxic complex with CB[7], as confirmed by live-cell imaging and cytotoxicity assays. Drug release was achieved through competitive displacement with the high-affinity orthogonal guest 1adamantylamine (ADA), restoring the activity of the docetaxel analogue. For precise spatiotemporal control, a photocaged ADA (cADA) enabled light-triggered release, while ADA-functionalized gold nanoparticles facilitated targeted delivery and on-demand drug liberation. This dynamic and reversible supramolecular platform allows external regulation of MT stability in complex cellular environments. The approach demonstrates a versatile framework for integrating synthetic host-guest chemistry into targeted drug delivery, enabling controlled therapeutic activation while minimizing off-target effects. Our results establish CB[7]-based recognition as a promising route for developing stimuli-responsive, biocompatible delivery systems, with potential for translation into precision cancer therapy and beyond.

# Prof. Subham Banerjee

Associate Professor NIPER-GUWAHATI



Dr. Subham Banerjee currently working as an Associate Professor in the Department of Pharmaceutics, National Institute of Pharmaceutical Education and Research (NIPER)-Guwahati, Assam. He is also a Visiting Staff Faculty of the University of Texas (UT) at Austin, USA. In addition, he also served as a coordinator cum co-principal investigator in the National Centre of Pharmacoengineering (State-of-the-art-facility) funded under the Drugs Pharmaceuticals Research Programme (DPRP), DST, Govt. of India. Dr. Banerjee did his doctoral degree from Birla Institute of Technology (BIT), Mesra in collaboration with Defence Research Laboratory (DRL), DRDO, Tezpur, Assam in the year 2015. After completion of his doctoral degree he was selected as an "Innovation Awardee in Devices" at Translational Health Science & Technology Institute (THSTI), NCR-Biotech Science Cluster, Faridabad. In the same year, he received the "Fast-Track Young Scientist Research Grant" by Science & Engineering Research Board (SERB), Govt. of India. He has more than 11 years of combined teaching and research experiences. He possesses 04 granted patents, 03 granted design patents, a 3D printed technology derived product transferred to Industry, 01 edited book on "Additive Manufacturing in Pharmaceuticals" by SPRINGER-NATURE, Singapore, 10 International book chapters in reputed publishing houses, published more than 105 research articles in peer-reviewed high impact National/International journals, with citations more than 3150+ & h-index of 32. Banerjee's research area focuses on Pharmacoengineering, including Pharmaceutical Additive Manufacturing (AM)/3D & 4D Printing, New Materials for Pharmaceutical AM, Drug Delivery, and Cutting-edge Translational Pharmaceutical Research.

### LAMP: Leveraging Additive Manufacturing in Next-Generation Pharmaceuticals

The next generation of personalized and customized medicines has gained much attention as an approach to drug therapy for individual needs. Although several factors affect the success of customized treatment, including the biological variances between people, differences in living conditions, working conditions, drug-drug, drug-food interactions, various types of diseases and so on so far. Consequently, it is essential to develop an innovative cutting-edge translational method for manufacturing innovative formulations capable of releasing drugs at the desired profile, according to specific patient needs that are customized and personalized but not generalized at all. Our research exclusively focuses on pharmaceutical additive manufacturing (PAM), or 3D/4D printing, deploying various impactful platform technologies such as fused deposition modeling (FDM), stereolithography (SLA), selective laser sintering (SLS), semi-solid extrusion (SSE), and direct powder extrusion (DPE). In pharmaceuticals, 3D/4D printing has been used to produce customized drug delivery systems and devices for personalized medicine. With the advent of these platform technologies across the board, efforts have been made to improve the quality of human health. AM or 3D/4D printing is a technology that can realize the long-due dreams of personalized drug delivery according to patient-specific requirements.

**Dr. Sampa Sarkar**Research fellow
RMIT University, Australia



**Dr. Sampa Sarkar** is a biotechnology researcher at RMIT University in Melbourne, where she develops cutting-edge drug and vaccine delivery systems using lipid nanoparticles. Her work focuses on tackling global health challenges like tuberculosis and antimicrobial resistance. Sampa is passionate about turning lab discoveries into real-world solutions and leading collaborative projects across Australia and internationally. She is a VESKI Fellow and has held research affiliations with MIT, Boston, contributing to global efforts in translational nanomedicine. Beyond the lab, Sampa is an enthusiastic science communicator, hosting public talks, podcasts, and academic events to make science more accessible and engaging.

# Lipid Nanoparticle Platforms for Precision Bioactive Delivery: Bridging Innovation and Translation

Lipid nanoparticles (LNPs) are tiny, fat-based carriers that are transforming how we deliver medicines and vaccines. These smart delivery systems can be engineered to transport drugs directly to specific tissues or cells, improving treatment effectiveness while minimising side effects. In recent years, LNPs have gained global attention for their role in mRNA vaccine delivery, but their potential goes far beyond COVID-19. At RMIT University, our research focuses on harnessing LNPs to address two critical global health challenges: tuberculosis (TB) and antimicrobial resistance (AMR). These conditions demand innovative delivery strategies that can overcome biological barriers and improve drug bioavailability. We are developing lipid-based formulations tailored to encapsulate diverse payloads, including immunomodulators, with tunable release kinetics and targeted biodistribution. presentation will outline our design principles, formulation strategies, and preclinical evaluation frameworks. Ultimately, our goal is to create drug delivery systems that not only push the boundaries of biomedical science but also make a meaningful impact on global health. By bridging research and real-world application, we hope to contribute to a future where advanced therapies are available to all who need them.

# Prof. Saurabh Srivastava

Associate Professor NIPER-Hyderabad



**Dr. Saurabh Srivastava** is an accomplished Associate Professor in the Department of Pharmaceutics at NIPER Hyderabad, leading the Pharmaceutical Innovation and Translational Research Lab (PITRL). He earned his Ph.D. in Pharmaceutics from Panjab University and brings over 17 years of combined academic and industrial expertise in developing novel drug delivery systems. His research spans cancer nanobiology, controlled drug delivery, dermal formulations, and translational pharmaceutics, with a prolific output of high-impact publications and interdisciplinary collaborations. Dr. Srivastava's work exemplifies the fusion of rigorous scholarship with impactful innovation, advancing drug delivery science on a global scale.

### Translational Nanomedicine: Lab-to-Life Challenges & Regulatory Bridging

Nanomedicine is the fastest-growing field in the pharmaceutical industry today. However, there still exist several hurdles preceding its clinical translation. The present talk will provide insights into the Translational challenges of Nanomedicine, along with the drug product approval pathways, and will attempt to address the lacunae amongst academic research, the pharmaceutical industry, and the perspectives of the regulatory authorities. The detailed SWOT analysis will exhibit an effort to overcome the hurdle to its clinical translation. The talk will further highlight the need and scope of the translational guidelines to be revisited in order to exhibit the successful clinical translation of Nanomedicine from academic research to commercial feasibility.

# **Prof. Aniruddha Roy** *Associate Professor, BITS Pilani, Pilani Campus*



Dr. Aniruddha Roy is an Associate Professor at the Department of Pharmacy, BITS Pilani, and an accomplished researcher in the areas of nanomedicine, targeted drug delivery, and regenerative biomaterials. His work bridges the fields of polymer chemistry, cancer biology, immunotherapy, and tissue engineering. He specializes in the development of stimuli-responsive nanoparticles for chemo-immunotherapy, photodynamic therapy, and in designing extracellular matrix (ECM) mimetic biomaterials for applications in organoid development and wound healing. Dr. Roy has authored over 44 peer-reviewed publications in high-impact journals, with more than 2,500 citations to date (h-index: 24; i10-index: 33). He is the inventor of four patented platform technologies, two of which are under active consideration for commercialization by FACIT (Canada) and Alicorn Med. Pvt. Ltd. (India). His translational research experience includes extensive in vitro, ex vivo, and in vivo studies of nanomedicine platforms, with an emphasis on tumor microenvironment modulation and regenerative tissue interfaces. He has secured over ₹268 lakh in extramural research funding as Principal Investigator and Co-Investigator from prestigious agencies including the Department of Biotechnology (DBT), Department of Science and Technology - SERB, Indian Council of Medical Research (ICMR), Shastri Indo-Canadian Institute, and INTAS Pharmaceuticals Ltd. These projects span advanced cancer nanotherapeutics, theranostic imaging systems, scaffold-based tissue regeneration, drug repurposing, and translational bioengineering devices.

# Tumor-Responsive Nanomedicine: A Synergistic Strategy Targeting Cancer and Its Microenvironment

Traditional cancer therapies have primarily focused on eradicating tumor cells, but this singletarget approach has often proven insufficient due to the complex nature of cancer. Tumors are not isolated entities; they thrive within a dynamic tumor microenvironment (TME) composed of cancer cells and various supporting components that promote growth, immune evasion, and drug resistance. As a result, advanced treatment strategies now aim to target both the cancer cells and the supportive TME components. Emerging evidence suggests that multidimensional therapies, which employ rational drug combinations to disrupt multiple aspects of the tumor ecosystem, hold great promise in enhancing treatment efficacy. However, achieving precise tumor-targeted delivery of such therapies remains a significant challenge. Nanomedicine offers a powerful solution by enabling the targeted delivery of synergistic drug combinations directly to the tumor site. In this work, we developed novel TME-responsive nanoparticles capable of delivering multidrug formulations with high specificity. These nanoparticles are designed to release their therapeutic cargo in response to the tumor's microenvironmental cues, allowing for simultaneous targeting of both the tumor cells and key components within the TME. By addressing both cellular and environmental drivers of tumor progression, these multidimensional nanoparticles have the potential to improve the rapeutic outcomes and reduce systemic side effects.

# Prof. Ravindra Wavhale

Dr. DY Patil Institute of Pharmaceutical Sciences and Research, Pune



**Dr. Ravindra D. Wavhale** is an Associate Professor at Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune. He holds a Ph.D. in Pharmaceutical Chemistry from Mumbai University and has more than a decade of experience across academia, research, and industry. His research interests include functionalized nanoparticles for advanced drug delivery, self-propelling nano/micromotors, drug design, synthesis of bioactive molecules, and conjugation chemistry. He has authored 30+ high-impact publications, published a patent on nanobots, and granted industrial design patents. A recipient of prestigious CSIR and DST-Nanomission fellowships, his notable contributions include the development of self-propelling nanomotors for drug delivery, selective capture of circulating tumor cells and fetal trophoblasts for early diagnosis, and dual-fuel Janus nanomotors.

### Self-Propelling Nano/Micro motors for drug delivery

Self-propelling Nano/Micro motors represent a promising technology in drug delivery. By intelligently utilizing internal or external stimuli or fuels, they generate motion that offers unparalleled advantages in delivering drugs precisely and deeply within targeted tissues. These Nano/Micro motors provide significant benefits for anticancer drug delivery. Over the past decade, they have made remarkable progress, particularly in drug delivery and biomedical diagnostics. Unlike conventional nanoparticles, self-propelled drug delivery systems effectively overcome challenges posed by bodily fluid dynamics, enabling enhanced mobility and deeper tissue penetration. These motors exhibit high drug-loading capacity combined with controlled, stimuli-responsive release profiles. Furthermore, integrating Nano/Micro motors with complementary treatments such as photothermal, photodynamic, ultrasound, and oxidative stress enhances therapeutic efficacy. During my presentation, I will share the development of self-propelling magnetic nanobots as a case study. The Fe-GSH-Protein-Dox, a novel magnetic nanobot conjugated with a biocompatible protein shell and loaded with doxorubicin, has demonstrated improved drug delivery in triple-negative breast cancer cells. The self-propulsion of these nanoparticles is driven by catalytic reactions between Fe<sub>3</sub>O<sub>4</sub> nanoparticles and hydrogen peroxide, generating oxygen bubbles that enable rapid movement in blood serum.

# Prof. Animesh Ghosh Professor BIT Mesra, Ranchi



With a tenure beginning in 2009 at the Department of Pharmaceutical Science & Technology, BIT Mesra, **Dr. Animesh Ghosh** has ascended to his current role as Professor in the Division of Pharmaceutics. Prof. Ghosh's research is focused on solid-state pharmaceutics, where he has distinguished himself as a leading authority in the development and optimization of pharmaceutical cocrystals, aimed at modulating drug properties. This focus culminated in the establishment of the & " Solid-State Pharmaceutics Research Laboratory; in 2020, reflecting his commitment to advancing this specialized area of study. With over 83 peer-reviewed publications that have garnered more than 3,600 citations and an impressive h-index of 34, Beyond his research publications, he has also secured multiple patents and successfully led numerous funded projects, demonstrating his ability to translate scientific innovation into practical applications. Dr. Ghosh's contributions have been recognized through several prestigious awards, including membership in the National Academy of Sciences, India (2022), and the IPA-ACG SciTech Innovation Award (2022–2023). His ongoing research and unwavering commitment to pharmaceutical science continue to push the boundaries of solid-state pharmaceutics, opening new avenues for drug development and delivery.

# A mechanistic elucidation behind the change in solubility and permeability of pharmaceutical cocrystals

Pharmaceutical cocrystallization has been explored as a promising strategy to improve drug physicochemical properties. However, rational design of cocrystals with optimal desired properties remains challenging. In this study, we investigated the mechanism underlying the negligible solubility and permeability improvement of Acetazolamide (ACZ) cocrystals with highly soluble and lipophilic coformers, 4-hydroxybenzoic acid, salicylamide, and 4,4'-bipyridine. Lattice energy calculations showed that strong lattice stability limited solubility improvements, while solution-state 1H NMR confirmed similar molecular states between cocrystals and physical mixtures, explaining the lack of solubility and dissolution improvement. Caco-2 permeability studies of cocrystals revealed no significant enhancement in ACZ permeability, consistent with the in silico molecular dynamics simulations showing unchanged stability of the ACZ-efflux transporter complex in the presence of coformers. These findings underscore the limits of conventional coformer selection and highlight the need for predictive tools. Based on the results, we propose an integrated model to predict cocrystal properties pre-synthesis and reduce trial-and-error.

### Dr. Omkara Muddineti

Senior Scientist Nexus Pharmaceuticals LLC, Illinois



**Dr. Omkara Muddineti**, Ph.D., is a pharmaceutical scientist with over 10 years of Formulation R&D experience [ANDA & 505(b)(2) based products] in injectable, ophthalmic, and solid dosage form development. He earned his Master's in Pharmaceutics and Ph.D. in lipid-based micellar-delivery from BITS Pilani. He is currently working as Senior Formulation Scientist at Nexus Pharmaceuticals, Illinois, USA. His industry background includes roles at Zenara Pharma, Dr. Reddy's Pharmaceuticals, and Vimta Laboratories etc. Dr. Muddineti has authored 15 publications, holds 2 Indian patents and 1 U.S. patent.

### Implementing QbD in Pharma: Bridging theory with Industrial Practice

Quality by Design (QbD) is a systematic, science and risk-based approach to pharmaceutical product and process development aimed at embedding quality from the outset rather than relying on end-product testing. Rooted in ICH Q8–Q11 guidelines, QbD begins with defining the Quality Target Product Profile (QTPP) and identifying critical Quality Attributes (CQAs), critical Material Attributes (CMAs), and critical Process Parameters (CPPs). It employs risk assessment tools, Design of Experiments (DoE), and multivariate analysis to establish robust design and control spaces, enabling efficient optimization, scale-up, and lifecycle management. The methodology reduces development time, manufacturing costs, product recalls, and post-approval changes while improving process understanding and regulatory compliance. Extensions such as Formulation by Design (FbD) and Analytical QbD (AQbD) apply the same principles to dosage form and analytical method development. Integrated with tools like Process Analytical Technology (PAT) and Real-Time Release Testing (RTRT), QbD enhances robustness, reproducibility, and continuous improvement, offering substantial benefits to patients, industry, and regulators throughout the product lifecycle.

# **Dr. Vamsi Madgula**Senior Director, Head of DMPK and non-GLP Toxicology services Sai Life Sciences, Hyderabad



**Dr. Vamsi Madgula,** is a proficient scientist and leader in Drug Metabolism, Pharmacokinetics (DMPK), and Toxicology Services with nearly two decades of expertise in drug discovery and development. He currently serves as Senior Director and Head of DMPK and Toxicology Services at Sai Life Sciences, where he drives strategic programs supporting global pharmaceutical partners. Dr. Madgula began his career with roles at Magene Life Sciences and GVK Bio, followed by a distinguished five-year tenure as a Postdoctoral Research Associate at the University of Mississippi, where he specialized in ADMET and preclinical pharmacology. He later held key leadership roles at Eurofins Advinus and Syngene International, contributing to cutting-edge areas like PROTACs, antibody-drug conjugates, and in-vitro/in-vivo PK studies. His work has been instrumental in advancing innovative therapies through robust ADMET strategies, bioanalytical sciences, and regulatory compliance, making him a trusted partner in accelerating drug discovery worldwide.

# Human Hepatocyte Multispheroid Array Method for the Assessment of Metabolic Clearance of degraders

Conventional in vitro ADME models, which uses liver microsomes, S9 fractions, and cryopreserved hepatocyte systems have been foundational for assessing drug metabolism studies. However, limited culture duration and rapid loss of enzymatic activity constrain their utility for evaluating compounds with low clearance compounds or long half-lives. Three-dimensional (3D) hepatic spheroid models offer extended viability and sustained metabolic functionality, enabling intrinsic clearance evaluation over periods of 3–4 weeks. In this study, we present a 3D hepatic spheroid array system designed for the metabolic stability assessment of small molecules and heterobifunctional degraders. A panel of 12 small molecules with reported hepatic blood clearance below 6.3 mL/min/kg was incubated for up to 3–5 days. The system achieved an average absolute fold error (AAFE) of 1.74 in clearance prediction, with high inter-experimental reproducibility, highlighting the robustness and sustained Phase I and Phase II enzymatic activity of the model. Assay conditions were optimized to mitigate non-specific binding associated with degraders, achieving >70% compound recovery after 72 hours in most cases. Overall, our results underscore the suitability of the 3D hepatic spheroid array as a long-term, physiologically relevant platform for evaluating the metabolic stability and hepatic disposition of small molecules and new therapeutic modalities.

# **Dr. Mukesh Gandhari**Director- Preclinical Testing Palamur Biosciences, Hyderabad



**Dr. Mukesh Gandhari** is a Director at Palamur Biosciences Pvt Ltd. His primary research interest is to bridge the gap between groundbreaking research and clinical application by providing robust preclinical support to the biopharma industry. This involves designing and executing comprehensive safety and toxicity assessments for novel biologics and advanced therapies, ensuring that they meet regulatory standards and can safely progress to human trials. His key achievements are as follows:

- Successfully led and validated preclinical studies for a number of novel biologics, cell, and gene therapies.
- Implemented a state-of-the-art preclinical framework for safety and toxicity assessment, resulting in a 20% increase in study efficiency and data quality.
- Authored and contributed to regulatory submissions that enabled the successful progression of multiple therapeutic candidates to first-in-human clinical trials.

# A Comprehensive Preclinical Strategy for Safety and Toxicity Assessment of CAR-T Cell Therapies in a Rhesus Macaque Model

Chimeric Antigen Receptor (CAR) T-cell therapy has emerged as a revolutionary treatment for various hematological malignancies. However, its translation to the clinic is challenged by potential severe toxicities, including cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). This study outlines a robust preclinical framework for the safety and toxicity assessment of novel CAR-T cell products using the rhesus macaque (*Macaca mulatta*) as a relevant non-human primate (NHP) model. Due to the high genetic homology and similar immune system complexity to humans, rhesus macaques are an ideal model for predicting potential human toxicities.

Our proposed strategy involves a multifaceted approach to characterize the safety profile of the CAR-T product. The protocol includes:

**In vivo Pharmacokinetics:** Monitoring CAR-T cell expansion, persistence, and biodistribution in various tissues using quantitative polymerase chain reaction (qPCR) and flow cytometry.

**Toxicity Profiling:** Detailed daily clinical observation, body weight monitoring, and a comprehensive panel of blood tests, including complete blood count (CBC) with differential, liver function tests (LFTs), and renal function tests.

**Biomarker Analysis:** Quantifying key inflammatory cytokines (e.g., IL-6, TNF- $\alpha$ , IFN- $\gamma$ ) and chemokines in serum to detect and grade the severity of CRS. Cerebrospinal fluid (CSF) analysis will also be conducted to assess for neuroinflammatory markers indicative of ICANS.

**Pathological Evaluation:** Comprehensive histopathology of major organs, particularly the brain, liver, and lungs, to identify any off-target tissue damage or pathological changes.

# **Dr. Nagendra Babu B**Principal Scientist CSIR-IICT, Hyderabad



Dr Bathini Nagendra Babu has completed B.Sc and M.Sc from Osmania University, Hyderabad. He obtained PhD in synthetic organic chemistry from CSIR-IICT, Hyderabad in 2006. Thereafter, he went abroad for Postdoctoral Studies at Uniformed Services University of Health Sciences(USUHS), Bethasda, & Department of Agriculture-Agriculture Research Services (USDA-ARS), Beltsville-MD, USA. In 2009, he moved to India and joined as Assistant Professor in the Department of Medicinal Chemistry, NIPER-Hyderabad, and was then promoted as Associate Professor. In 2016, he shifted to CSIR-IICT as a senior Scientist, subsequently promoted as Senior Principal Scientist. Since 2009, he has led independent, multidisciplinary research, seamlessly integrating synthetic organic chemistry with medicinal chemistry. His research bridges synthetic organic chemistry and drug discovery, with a strong focus on the development of new chemical entities (NCEs) using advanced methodologies such as organometallic and metal-free catalytic reactions, as well as metal-organic conjugates. His work has contributed significantly to the discovery of compounds with potential therapeutic applications against cancer, microbial infections, and neurological disorders like depression. Dr. Babu has also made notable contributions to synthetic methodology development, with his findings published in high-impact journals from the ACS, RSC Elsevier, and Wiley-VCH. He is also deeply committed to education and capacity building, having supervised 3 Postdoctoral fellows, 13 Ph.D. scholars, and over 60 master's students, and 10 students are currently working under his mentorship. His prolific output includes more than 87 publications and 4 patents. Recognized for his excellence, he has received several prestigious awards.

### Catalyzing Drug Discovery: The Role of Synthetic Chemistry in Designing

Synthetic chemistry is central to the rational design and synthesis of novel molecular entities with high pharmacological relevance. Its capacity to generate structurally diverse and functionally tailored compounds has significantly advanced the development of next-generation therapeutics targeting complex diseases such as cancer and microbial infections. It is particularly compelling to recognize the strategic potential of synthetic methodologies in constructing heterocyclic frameworks and metal-based complexes with amplified biological efficacy. In this pursuit, diverse molecular scaffolds such as indolylarylaminopropenones, diindoloazepinones, β-carboline sulfonyl piperazines, and hybrid architectures integrating triazoles, pyridines, and oxadiazoles can be meticulously engineered and fine-tuned to interact with defined cellular targets. These compounds operate through distinct and diverse mechanisms, that underscores a profound correlation between structural design and pharmacological intent, highlighting the elegance of molecular precision in therapeutic innovation. Concurrently, the rational design of bioessential metal complexes has paved the way for multifunctional agents exhibiting dual- and trimodal therapeutic capabilities, encompassing photodynamic, photothermal, and chemotherapeutic modalities. These complexes can be precisely modulated through rational ligand design to achieve selective tumor imaging and robust anticancer/antimicrobial efficacy under visible, red, and near-infrared light exposure. Taken together, these advances underscore the transformative potential of synthetic chemistry as a unifying force in drug discovery, where molecular ingenuity is guided by biological understanding and clinical imperatives. The resulting compounds embody a triad of essential attributes: multifunctionality, target specificity, and minimized systemic toxicity; that are increasingly instrumental in steering then future of precision oncology and advanced antimicrobial therapies, where therapeutic efficacy must be intricately balanced with safety and selectivity.

# Prof. Gyan Prakash Modi

Assistant Professor IIT-BHU, Varanasi



**Gyan Prakash Modi** earned a Ph.D. from the Department of Pharmaceutical Sciences, Wayne State University, Detroit, Michigan, USA, in 2013, followed by postdoctoral training at Brandeis University, Waltham, Massachusetts, USA. Currently, he is working as an Associate Professor in the Department of Pharmaceutical Engineering & Technology, Indian Institute of Technology (BHU), Varanasi, India. His research area includes drug development for neurodegenerative diseases, inhibitor design, and the development of novel NIR probes targeting various chronic central nervous system diseases like Alzheimer's disease. His laboratory has been funded through several projects from SER, ICMR, focused on therapeutic, diagnostic, theranostic, and formulation development for AD, besides funding from the institute (IIT-BHU). He published nearly 40 papers in high-impact journals like J Med Chem and filed several patents, and five are granted so far. He has been selected as a young investigator to attend YIM 2019, organized by IndaiBioscience at IIT Guwahati, and is the recipient of the travel grant from SERB. He is the recipient of the Best Teacher Award in 2022 under the UG category at IIT BHU. He is also the recipient of the Young Scientist Award from the Indian Academy of Biomedical Sciences (IABS), 2024.

### Development of novel NIRF theranostic probes for Alzheimer's disease

Alzheimer's disease (AD) is a multifactorial progressive neurodegenerative disorder characterized by gradual memory impairment. A definitive AD diagnosis still relies on the postmortem analysis of the diseased brain. Amyloid  $\beta$  (A $\beta$ ) aggregates start appearing several years before the onset of the symptoms of the disease. Cholinesterases also play a key role in AD. Our laboratory has been carrying out systematic structural modification in natural products to develop novel near-infrared fluorescent (NIRF) probes for the early diagnosis of AD. The lead probe molecule I43 has shown promising and selective A $\beta$  aggregation detection ability in different AD models, including transgenic AD mouse models and AD patient autopsy samples. The unique ocular imaging pattern in the AD Drosophila model strongly suggests that probes hold promise as a dependable indicator for rapid, noninvasive assessment of new therapeutic modulators or inhibitors in AD.

# **Speaker**

# **Prof. Swati Biswas**Professor BITS Pilani, Hyderabad Campus



Prof. Swati Biswas, is a distinguished Professor in the Department of Pharmacy at BITS Pilani—Hyderabad. Holding a Ph.D. from Wayne State University, she is a leading expert in nanomedicine, with specialized research in polymeric micelles, liposomes, and chemo-photothermal and photodynamic therapies for cancer, ocular delivery systems and infectious diseases. A prolific scholar, Prof. Biswas has published over 140 articles and authored numerous books, accruing more than 9300 citations and an impressive h-index of 44. Her recent accolades of 2025 include being named among the top 0.5% scholars worldwide, being awarded the Chair Professor at BITS Pilani and being nominated for the Advanced Materials Innovation Award in the area of Functional Materials, the highest honor endorsed by the International Association of Advanced Materials in Stockholm, Sweden, 2025. Prof. Biswas has delivered numerous lectures at various international conferences, highlighting her global recognition in nanostructure-based drug delivery

### **Advanced Nanomedicines for Cancer and Infectious Diseases**

Advances in nanotechnology using biocompatible polymers and bioinspired materials are revolutionizing therapeutic systems by enabling precise and sustained drug delivery. Our group has recently investigated multimodal therapeutic approaches by combining photodynamic, photothermal, and chemotherapeutic methods. Specifically, we have functionalized carbon-based nanomaterials such as graphene oxide with the anticancer drug oxaliplatin, achieving enhanced efficacy, reduced systemic toxicity, and improved targeting of both primary and metastatic breast cancer in animal models.

We have also engineered conjugates of human serum albumin, a natural transport protein, with hydrophobic vitamins, resulting in nanoparticles with greater stability and superior drug delivery efficiency. In parallel, our studies on nanozymes—particularly bimetallic nanocrystals—have revealed their potential as antibiotic alternatives. These nanozymes, designed with tailored surface modifications, demonstrate catalytic activity, light-triggered antibacterial effects, and pro-angiogenic properties, making them promising candidates for treating moderate to severe wounds.

Further, we have advanced the design of environmentally responsive nanomotors for smart drug delivery. A key example is our  $\mathrm{CO}_2$ -generating nanomotor system, capable of self-propulsion in acidic gastric conditions to deliver clarithromycin directly to Helicobacter pylori, a pathogen linked to gastric infections and cancer. Given the WHO's recognition of H. pylori as a critical infection, this platform offers a highly effective treatment avenue. Collectively, these innovations mark important progress toward next-generation targeted therapies with strong clinical translation potential.

# **Plenary Speaker**



Mr. Bijaygopal Chakrabarti Senior Vice President Operations Eugia US LLC - Hyderabad office

Mr. Bijaygopal Chakrabarti is an accomplished leader with over three decades of experience in the pharmaceutical industry, specializing in operations, manufacturing, and quality systems. He currently serves as Senior Vice President – Operations at Eugia US LLC and also heads the Eugia US Manufacturing site in East Windsor, New Jersey. Prior to this, Mr. Chakrabarti was Senior Vice President at Eugia Pharma Specialities Ltd., Hyderabad, where he successfully led critical operational strategies. His illustrious career spans 20 years at Dr. Reddy's Laboratories, where he held multiple leadership roles including Vice President, Head of Quality, and Head of Technical Operations. Earlier, he contributed to the growth of Intas Pharmaceuticals as General Manager – Manufacturing and began his career with Ranbaxy as Production Manager. Mr. Chakrabarti's leadership reflects a strong commitment to operational excellence, quality compliance, and innovation, making him a driving force in global pharmaceutical manufacturing.

# **Invited Speaker**



**Dr. Mallinath Harwalkar**Vice President - R&D,
Hetero Hyderabad

**Dr. Mallinath S. Harwalkar**, is an accomplished pharmaceutical professional with over two decades of experience in formulation development and strategic operations. He currently serves as Senior Vice President – R&D at Hetero Labs, where he heads the Injectable Division, driving innovation, regulatory compliance, and technology transfer for global markets including the US, EU, Canada, Brazil, and ROW. Mr. Harwalkar holds a Ph.D. in Pharmaceutics from Pune University and an M.Pharm in Pharmaceutics from the University of Pune. His expertise spans injectables, ophthalmics, oncology formulations, and complex sterile dosage forms, with strong proficiency in Para IV strategies, ANDA filings, and Quality by Design (QbD) implementation. Prior to Hetero, he held leadership roles at Sentiss, Aurobindo, Glenmark, Emcure, and other major pharmaceutical organizations, contributing to multiple successful product launches. His visionary leadership continues to advance affordable, high-quality healthcare solutions worldwide.

# **Schedule**











International Symposium cum Workshop on Innovations in Translational Therapy and Targeted Drug Delivery (ITTD-2025)

### Symposium (Day 1)

Date: 1st September 2025 (Monday)

Arrival and Registration: 8:00 AM to 9:30 AM				
Inaugural ceremony, Welcome Address by the Director, Deans, and Introduction to ITTD	9:30 AM - 10:00 AM			
Welcoming, the Guest of Honour, Dr. Krishna Ella Co-founder and Executive Chairman of Bharat Biotech (Padma Bhushan Recipient, 2022)	10:00 AM – 10:30 AM			
Plenary Talk				
Prof. Jimmy Hsia, NTU, Singapore  Title of talk- "Biomarker-Triggered Hydrogel Swelling for Ultrasensitive Biosensing"	10:30 AM - 11:05 AM			
Coffee Break	11:05 AM - 11:20 AM			
Invited Talks, Series 1: Chair: Bapi Gorain				
Prof. Sarit Agasti, JNCASR Bangalore Title of talk- "Smart Host–Guest Assemblies for Spatiotemporal Control of Microtubule-Targeting Drugs"	11:20 AM - 11:55 AM			
Prof. Subham Banerjee, NIPER Guwahati  Title of talk- "LAMP: Leveraging Additive Manufacturing in Pharmaceuticals"	11:55 AM - 12:30 PM			
Dr. Sampa Sarkar, RMIT University, Australia  Title of talk- "Lipid Nanoparticle Platforms for Precision Bioactive Delivery: Bridging Innovation and Translation"	12:30 PM – 1:05 PM			
Group Photos, Lunch, Poster and Oral Presentations	1:05 PM - 2:30 PM			
Invited Talks, Series-2: Chair: Bappaditya Chatterjee				
Prof. Saurabh Srivastava, NIPER Hyderabad  Title of talk- "Translational Nanomedicine: Lab-to-Life Challenges & Regulatory Bridging"	2:30 PM – 3:05 PM			
Prof. Aniruddha Roy, BITS Pilani, Pilani Campus  Title of talk- "Tumor-Responsive Nanomedicine: A Synergistic Strategy Targeting Cancer and Its Microenvironment"	3:05 PM - 3:40 PM			
Prof. Ravindra Wavhale, Dr. DY Patil Institute of Pharmaceutical Sciences and Research, Pune Title of talk- "Self-Propelling Nano/Micro motors for Drug Delivery"	3:40 PM - 4:15 PM			
Prof. Animesh Ghosh, BIT Mesra, Ranchi Title of talk- "A Mechanistic Elucidation Behind the Change in Solubility and Permeability of Pharmaceutical Cocrystals"	4:15 PM – 4:50 PM			
Hi-Tea and Networking	4:50 PM - 5:15 PM			
Vendor Talk	5:15 PM - 6:15 PM			
Cultural Event	6:15 PM - 7:00 PM			
Dinner	7:00 PM onwards			

# Schedule











International Symposium cum Workshop on Innovations in Translational Therapy and Targeted Drug Delivery (ITTD-2025)

### Symposium (Day 2)

Date: 2nd September 2025 (Tuesday)

Breakfast	8:00 AM - 9:00AM
Invited Talks, Series-3: Chair: Tanmoy Ghosh	
Dr. Omkara Swami Muddineti, Nexus Pharmaceuticals, Illinois Title of talk- "Implementing QbD in Pharma: Bridging Theory with Industrial Practice"	9:00 AM - 9:35 AM
Dr. Vamsi Madgula, Sai LifeSciences, Hyderabad Title of talk- "Human Hepatocyte Multispheroid Array Method for the Assessment of Metabolic Clearance of Degraders"	9:35 AM - 10:10 AM
Dr. Mallinath Harwalkar, Hetero Labs, Hyderabad  Title of talk- "Bridging the Gap Between Academia and Industry: Industry Perspective and Opportunities"	10:10 AM – 10:45 AM
Coffee Break	10:45 AM - 11:05 AM
Mr. Bijaygopal Chakrabarti, Eugia US LLC, Hyderabad  Title of talk- "Navigating Opportunities and Challenges in Pharmaceutical Industry"	11:10 AM - 11:45 PM
Prof. Swati Biswas, BITS Pilani, Hyderabad Title of talk- "Advanced Nanomedicines for Cancer and Infectious Diseases"	11:45 AM – 12:20 PM
Dr. Mukesh Gandhari, Palamur Biosciences, Hyderabad Title of talk- "A Comprehensive Preclinical Strategy for Safety and Toxicity Assessment of CAR-T Cell Therapies in a Rhesus Macaque Model"	12:20 PM – 12:50 PM
Lunch Break and Poster and Oral Presentations	12:50 PM - 2:30 PM
<b>Dr. NagendraBabu Bathini, CSIR-IICT, Hyderabad</b> Title of talk- "Catalyzing Drug Discovery: The Role of Synthetic Chemistry in Designing Multifunctional/Multimodal Therapeutics"	2:30 PM – 3:05 PM
Prof. Gyan Modi, IIT-BHU, Varanasi  Title of talk- "Development of novel NIRF theranostic probes for Alzheimer's disease"	3:05 PM – 3:40 PM
Panel Discussion	3:45 PM – 4:30 PM
Valedictory and prize distribution ceremony	4:30 PM - 5:00 PM



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### ITTD-OP-01

# Exploiting Primary Cilia as a Novel Biologically Aligned Drug Delivery Vehicle

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Abstract: There is a recent shift of drug delivery research from traditional synthetic nanoparticles toward biologically aligned nano-systems that exploit natural cellular components for improved biocompatibility and reduced immunogenicity. While exosomes and membrane-coated systems offer advantages, challenges in isolation, stability, and scalability limit their clinical translation. Herein, in the present study we report for the first time an innovative use of primary cilia, cellular sensory organelles also known as "cellular antennae", as a novel, physiologically produced drug delivery vehicle. Primary cilia were isolated from renal epithelial cells and engineered with a specific-targeting chemotherapeutic payload to generate cilia-based drug delivery system. This platform demonstrated remarkable therapeutic efficacy in a mouse melanoma model, showing significant inhibition of tumor progression along with reduced drug-induced cardiotoxicity compared to free drug. Multimodal analyses, including confocal microscopy, IVIS-CT, and ultrasound imaging, confirmed targeted drug delivery, minimized off-target effects and improved local blood flow in tumor. Being naturally produced organelles, cilia could offer inherent biocompatibility, immune evasion, and ciliary membrane lipid-mediated protection of cargo from degradation, potentially outperforming many synthetic nanoparticles and even exosomes in delivery capacity. This proof-of-concept study establishes cilia as a potential unique and physiologically produced carrier system for drugs, genes, proteins, and other biomolecules, opening an entirely new avenue in the field of advanced drug delivery. Our findings also highlight the untapped potential of primary cilia in creating next-generation biologically aligned delivery platforms, laying the groundwork for transformative therapies against cancer and a broad spectrum of pathological conditions.

**Keywords:** Primary cilia, Novel delivery vehicle, Drug delivery, Exosome, Nanotechnology.

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Barui, A. K et al, Application of bioactive materials primary cilia as a novel delivery vehicle. Bioactive Materials, 2025, 51, 70-82. ISI 2024 IF # 20.3. [Featured on the Front Cover of Bioactive Materials]

### ITTD-OP-02

# Development of Multifunctional Electrospun Scaffolds for Potential Wound Healing

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Abstract: To alternate the overuse of traditional antimicrobials in skin wound healing, biopolymer-based composite scaffolds of Carboxymethyl Chitosan (CmCh.) and Gelatine (Gel.) were developed via electrospinning with polyvinyl alcohol added to lower surface tension. Vanillin, selected by docking score against Farnesyl Diphosphate Synthase, served as the vaporphase crosslinker. FTIR, DSC, X-ray Crystallography, SEM, HR-TEM, Optical Profilometry/Micro System Analyzer (OP/MSA), Goniometry, and Universal Testing Machine (UTM) were utilized for characterization of the scaffolds. Crosslinking of the polymers was confirmed by FTIR and showed to retain crystalline-amorphous balance up to 556.05 C. SEM images exhibited aligned pores with a nanofiber-like appearance, and X-ray and HR-TEM showed crystalline transitioning to an amorphous state. The roughness of the scaffolds was below 10 µm which confirms its fit for biomedical application. Hydrophilicity was proven by low contact angles. Swelling index, hydrolytic degradation, exchange of water vapor, and porosity were determined, and antimicrobial activity against E. faecalis, S. aureus, and Streptococcus mutans via well diffusion was evaluated. UTM results showed tensile strength >1 N. Swelling persisted for 15 days; degradation began at day 5. Water-vapor exchange was effective over 21 days, and high porosity favored fluid absorption. Antimicrobial assays showed optimal bacterial growth inhibition relative to ciprofloxacin (500 µg/mL). The rabbit dermal irritation test confirmed no significant inflammatory response. Overall, CmCh-Gel scaffolds displayed excellent physicochemical, mechanical, and biological performance, supporting potential biomedical applications.

**Keywords:** Primary cilia, Novel delivery vehicle, Drug delivery, Exosome, Nanotechnology.

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### ITTD-OP-03

### **Electrospun Nanomats for Regenerative Healing in Diabetic Wounds**

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Abstract: Diabetic wounds present a significant clinical challenge due to delayed healing, poor angiogenesis, and increased risk of infection, often leading to severe complications. This study focuses on the development and evaluation of electrospun nanofibrous scaffolds as advanced wound dressings for diabetic wound healing. Utilizing the electrospinning technique, polymeric nanomats were fabricated to mimic the native extracellular matrix (ECM). The nanomats were loaded with therapeutic agents such as metformin and insulin to enhance angiogenesis, reduce inflammation, and promote cellular repair mechanisms. Comprehensive physicochemical characterizations including porosity, swelling index, water vapor transmission rate (WVTR), and degradation profile were conducted, along with drug release kinetics and X-ray diffraction (XRD). Mechanical properties such as tensile strength and elongation at break were evaluated to ensure dressing integrity. In vivo studies on diabetic animal models demonstrated accelerated wound closure, re epithelialization, and collagen deposition in nanomat-treated groups. Histopathological evaluations confirmed enhanced tissue formation and neovascularization. Biocompatibility studies revealed no signs of cytotoxicity. The nanomats also exhibited sustained and controlled drug release over an extended period. In addition, short-term accelerated study confirmed the structural integrity, drug retention, and performance consistency of the scaffolds over time. These findings underscore the potential of electrospun drug-loaded nanomats as a stable, multifunctional, and biocompatible therapeutic platform for effective diabetic wound management.

Keywords: Electrospinning, Nanomats, Diabetic, Wound Healing, Scaffold.

## Model to molecule: Integrating structure and ligand-based design, synthesis and anticancer evaluation of indole-based HDAC8 inhibitors in solid tumors

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Abstract: Histone deacetylase 8 (HDAC8) is a critical epigenetic regulator that has emerged as a promising target in cancer therapy. Several HDAC8 inhibitors have demonstrated strong activity in hematological malignancies, however, their potential in solid tumors remains underexplored. In this study, we adopted a "Model to Molecule" approach to design, synthesize, and evaluate novel indole-based HDAC8 inhibitors with a particular emphasis on solid tumor applications. A combination of structure-based and ligand-based computational strategies, including classification-based QSAR and molecular docking, were utilized to identify key structural features governing HDAC8 inhibition. Guided by these insights, a focused series of indole derivatives were synthesized and subsequently evaluated for HDAC8 enzyme inhibition. Majority of compounds demonstrated higher potency than the reference molecule (5e), with the lead compound 6c exhibiting an  $IC_{50}$  of 480 nM and significant antiproliferative activity against A549 lung cancer cells (IC<sub>50</sub> = 7  $\mu$ M). Compound 6c induced apoptosis and caused G2/M cell cycle arrest in A549 cells. Additionally, the antitumor potential of compound 6c was supported by ROS generation and nuclear staining assays. Collectively, these results establish compound 6c as a potent HDAC8 inhibitor with promising therapeutic potential in lung cancer, supporting its further exploration and clinical development.

Keywords: QSAR modeling, molecular docking, HDAC8 inhibitor, solid tumors, indole derivatives.

### Bioengineered Tamarind Seed-Chitosan Biomaterial for Improved Wound Healing and Skin Regeneration

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Abstract: The present investigation aimed to develop a novel tamarind seed polysaccharide (TSP)-based biomaterial scaffold for enhanced wound healing and skin tissue regeneration. Tamarind seed polysaccharide was extracted using a hot-water method and chemically modified by thiolation to improve mucoadhesion and stability. The modified TSP was combined with chitosan, a natural biopolymer known for its antimicrobial activity, and crosslinked using cinnamaldehyde to form a stable, porous scaffold through freeze-drying. The developed scaffolds were subjected to comprehensive physicochemical characterization (FTIR, DSC, XRD) and evaluated for swelling index, porosity, water vapor transmission, and hydrolytic degradation. Biological assessments included antimicrobial activity against Staphylococcus aureus and E. coli, cytocompatibility via MTT assay on Human Dermal Fibroblasts, and cell adhesion studies, confirming non-toxicity and cell-friendly properties. In vivo excisional wound models on Wistar rats demonstrated significantly faster wound closure in scaffold-treated groups (~98% by day 14) compared to control and marketed formulations, supported by histopathological evidence of improved collagen deposition, fibroblast proliferation, and re-epithelialization. The synergistic effect of thiolated TSP (enhanced bioadhesion), chitosan (antimicrobial and structural support), and cinnamaldehyde (crosslinking and antibacterial properties) resulted in a biomaterial that mimics the extracellular matrix and promotes accelerated tissue regeneration. These findings suggest that TSP-based scaffolds hold strong potential as advanced wound dressings for chronic and infected wounds.

**Keywords:** Tamarind Seed Polymer (TSP), Thiolated Polysaccharide, Polymer, Biocompatibility, Wound Healing.

### Development and Evaluation of a Highly Plasticized Aqueous Based Film Forming Composition for Targeted Delivery of Crisaborole to Skin

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**Abstract:** Incessant exposure to pollutants has resulted in an alarming increase in cutaneous disorders and targeted delivery to the skin deserves urgent attention. The widely used semisolid topicals neither ensure sufficient residence time at the lesion nor prevent systemic absorption. The objective of this work was to develop a water-based film forming composition of crisaborole for treatment of atopic dermatitis. Aquacoat ECD®, an aqueous dispersion of the water insoluble polymer ethyl cellulose, originally used for coating applications, served as a base for the product. Polyvinyl alcohol was included as a water-soluble film-former and dibutyl sebacate (DBS - 70% w/w of polymer) served dual role of dissolving the active and plasticizing the film. Film forming compositions were prepared by dissolving crisaborole in DBS followed by admixture with the polymers dispersed/dissolved in water. Formulations were evaluated for spreadability, pH and drying time. Films prepared by casting were evaluated for presence of crystalline drug by microscopy, SEM and DSC studies. The mechanical properties of the film and in vitro and ex vivo permeation across dialysis membrane and porcine ear skin respectively were studied. The film forming composition was easily spreadable with a pH compatible with skin. Placebo films dried on the skin in 10 min giving a thin, transparent and flexible film with good tensile strength which stuck firmly to skin and resisted peeling. In vitro release studies revealed gradual release of crisaborole from the film and slow permeation across porcine ear skin. A novel film forming system which totally avoided the use of organic solvents and provided prolonged release of drug with developed. high substantivity was thus

**Keywords:** Atopic dermatitis, Aquacoat ECD, Targeted Delivery.

### Anti-solvent approach for fabrication of Bedaquiline nanosized particle: Physical Characterizations and Solubility enhancement

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Abstract: Pulmonary tuberculosis is an infectious caused by mycobacterium tuberculosis bacteria. Its robust waxy cell wall, shielding it from both hosting and outside influences, creates an aggressive bacterium that is resilient to disease. Bedaquiline drug inhibits the proton pump mycobacterium ATP synthase, an enzyme that Mycobacterium TB needs in order to produce energy. This study aimed towards the fabrication of nanosized particles by the anti-solvent method using spray drier for enhancing solubility of Bedaquiline. Pre-formulation studies were investigated where solubility studies were performed in various solvents as methanol, acetonitrile, acetone, ethanol and DMSO; the result reports partially soluble in acetonitrile, acetone, and ethanol while high solubility in methanol and DMSO was observed. Prepared formulation (Nanosized particles) were characterized for particle size measured using SEM at 425nm and zeta potential using Malvern zetasizer reports 8.505 mV. The spectral analysis was performed for nanosized formulation of Bedaquiline using FTIR reflecting the stretching vibration at 2158cm-1 C=C, bending vibration at 1384cm-1 CH3. The XRD spectral analysis reflects the crystalline nature of pure Bedaquiline, but peak intensities decrease reporting that powder generally becomes amorphous during spray-drying in nanosized formulation. In-vitro drug release was performed by dialysis membrane and found that when compared with pure drug the release of nanosized particle showed 88% in 6 hrs and the drug release kinetics found to be at Korsemeyer papas with R2 0.9448. Hence, the work demonstrates that the drug Bedaquiline in nanoformulation can be an approach which can be targeted for effective treatment in pulmonary tuberculosis.

**Keywords:** Phytochemical, Nanosilver, Antifungal activity, Cutaneous Candidiasis.

## Quality-by-Design abetted laboratory scale-up of progesterone emulgel as vaginal supplementation therapy for the management of experimental polycystic ovary syndrome

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**Abstract:** Background: Polycystic ovary syndrome (PCOS) develops from hormonal imbalances, hyperandrogenism, oligomenorrhea, and the presence of multiple cystic follicles in the ovaries. The combination of oral letrozole (LTZ) for ovulation induction, accompanied by intravaginal progesterone (PG) for luteal phase support, has gained clinical success due to the ability to target multiple pathways in the pathogenesis of PCOS.

Methodology: PG-nanoemulsion (PG-NE) was developed using Quality-by-Design (QbD) approach employing a risk assessment matrix. PG-NE was amalgamated with polycarbophil for the laboratory scale-up of PG emulgel. PG emulgel was subjected to rheological and permeation performance followed by examination of its therapeutic efficacy in PCOS induced rats.

Results: The PG-NE post-optimization yielded a globule diameter of  $89.74\pm1.6$  nm, with a polydispersity index of  $0.131\pm0.08$  and a zeta potential of  $-6.95\pm0.08$  mV. Intravaginal PG emulgel exhibited notable textural characteristics, and optimum viscosity along with a markedly higher ex vivo permeation rate ( $456.42\pm35.14~\mu g/cm2$ ) as compared to intravaginal commercial 8% w/w PG gel ( $35.14\pm4.90~\mu g/cm2$ ) with statistically significant difference (P<0.0001). The in vivo study demonstrated notable modulation of lipid and oxidative stress markers, followed by recruitment and development of normal follicles. Additionally, hormone levels in PCOS were normalized when treated with oral LTZ (5 mg/kg) and intravaginal PG emulgel ( $1.89\pm0.07\%$  w/w), compared to oral LTZ (5 mg/kg) and intravaginal commercial 8% w/w PG gel.

Conclusion: PG emulgel offered luteal support in experimental PCOS in the reduced dose regimen and warrants further testing and validation in clinical setting to explore translational opportunities.

**Keywords:** Polycystic ovary syndrome; Progesterone; Intravaginal emulgel; Letrozole; hormone regulation.

## ct-DNA compaction by nanoparticles formed by silica and gemini surfactants having hydroxyl group substituted spacers: In vitro, in vivo, and ex vivo gene uptake to cancer cells

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Abstract: Hybrid nanoparticles based on silica (SiO2) coated with hydroxyl-substituted gemini surfactants were developed and evaluated for efficient DNA compaction and delivery. Two surfactants with variable hydroxyl-substituted spacers, 12-4(OH)-12,2Br and 12-4(OH)-12,2Br, were compared with the conventional cationic surfactant dodecyltrimethylammonium bromide(DTAB). The results highlight that both the hydrophobicity of the spacer and hydrogen bonding interactions between the hydroxyl groups and DNA significantly influence the extent of compaction. Among the systems, 12-4(OH)2-12,2Br exhibited the strongest binding with calf thymus DNA (ct-DNA), resulting in greater efficiency than 12-4(OH)-12,2Br<sup>-</sup>. In the presence of SiO<sub>2</sub> nanoparticles, 50% ct-DNA compaction was achieved at 0.25 µM of 12-4(OH)<sub>2</sub>-12,2Br<sup>-</sup>, compared to 0.63 μM of 12-4(OH)-12,2Br<sup>-</sup>, while DTAB required a much higher concentration (7.0 μM) to reach the same level of compaction. Importantly, cytotoxicity assays revealed that the 12-4(OH)<sub>2</sub>-12,2Br<sup>-</sup>-SiO<sub>2</sub> system provided the highest cell viability (≥90%) in NIH3T3 fibroblasts, in contrast to ≤80% viability with DTAB, thereby addressing the common challenge of cationic surfactant-induced toxicity. Cellular uptake experiments in 4T1 mouse mammary adenocarcinoma cells confirmed efficient internalization of the gene-loaded nanocarriers after 3 h and 6 h incubation. In vivo studies further demonstrated enhanced DNA accumulation in tumor tissues in a time-dependent manner, while ex vivo analysis of mice organs confirmed preferential localization at breast tumor sites. These findings establish hydroxyl-substituted gemini surfactant-coated SiO<sub>2</sub> nanoparticles, particularly 12-4(OH)<sub>2</sub>-12,2Br<sup>-</sup>, as highly effective, biocompatible carriers for DNA compaction, with strong applications potential for gene delivery and oncological therapies. in

**Keywords:** Gene delivery, ct-DNA compaction, SiO2 nanoparticles, hydroxyl group substituted spacer, gemini surfactants.

### Nanotechnology-Driven Colorectal Cancer Treatment: Coencapsulation of Irinotecan and Cyclosporine A in SNEDDS for Superior Outcomes

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Abstract: Irinotecan (IRN), a Camptothecin derivative, has limited inadequate oral absorption due to efflux pump activity by intestinal P-glycoprotein receptors. To complete these challenges, we designed and fabricated irinotecan and cyclosporine. A co-loaded self nanoemulsifying drug delivery system (CO-IR-CP-SNs) can effectively prevent P-gp efflux and P450 enzyme metabolization, increasing oral bioavailability. To date, this combination is not been reported which gives uniqueness to our formulation. The CO-IR-CP-SNs were fabricated by using the Box Behnken design design tool with Capryol®90, Cremophor EL, and PEG-400 as the oil, surfactant, and co-surfactantThe optimized CO-IR-CP-SNs had an average globule size of 16.36 $\pm$ 1.09 nm and a polydispersity index of 0.250  $\pm$ 0.01. The combination index value supports the existence of synergy in human colorectal cancer cell lines (HCT-116). The combination index shows a value of 0.78 which is <1 indicating synergism. Coloaded SNEDDS (CO-IR-CP-SNs) showed greater cellular uptake, reactive oxygen species generation (ROS), and apoptosis. In-vivo pharmacokinetic studies demonstrated a 14-fold and 6.08-fold increase in Cmax and increased bioavailability compared to pure drug suspensions of IRN and CSP, respectively. Systemic toxicity signifies the non-toxic nature of CO-IR-CP-SNs in comparison to pure drug solutions of irinotecan, cyclosporine individual, and combination. Hence, CO-IR-CP-SNs show promising results and improved oral bioavailability, which is beneficial in anticancer therapy with minimal side effects associated with the drug.

Keywords: Colorectal, Self-emulsifying, oral bioavailability, Pharmacokinetic, Combination index.

### Novel nanostructured composites of antioxidant for management of agerelated macular degeneration

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Abstract: Age-related macular degeneration (AMD) is a leading cause of vision loss worldwide, largely driven by oxidative stress and pathological neovascularization mediated by vascular endothelial growth factor (VEGF) and platelet-derived growth factor (PDGF). Resveratrol, a natural polyphenolic compound, exhibits potent antioxidant and anti-angiogenic properties, making it a promising therapeutic candidate for AMD. This study aimed to develop and evaluate Resveratrol-loaded nanostructured lipid carriers (NLCs) novel ocular drug delivery Resveratrol-loaded NLCs were prepared using the hot-melt homogenization method and subsequently incorporated into a gel matrix through cold processing to maintain stability of thermosensitive components. A 2<sup>4</sup> factorial design was employed for NLC optimization, while a central composite design guided gel optimization. Drug-excipient compatibility was evaluated using DSC and FTIR. The optimized NLCs were characterized for particle size, entrapment efficiency, XRD, and SEM to assess physicochemical properties. The optimized formulation demonstrated a particle size range of 100–250 nm, high entrapment efficiency (80–90%), and sustained drug release (70–85%). The HET-CAM assay confirmed ocular safety, while MTT assay indicated >90% viability in retinal epithelial cells, suggesting non-toxicity at therapeutic concentrations. VEGF expression studies revealed 47.12% inhibition within 24 hours, supporting significant anti-angiogenic activity. The sustained release profile further validated the potential for prolonged therapeutic efficacy. In conclusion, Resveratrol-loaded NLCs were successfully developed with favorable physicochemical and biological characteristics. These findings suggest that Resveratrol-NLC gel represents a safe and effective strategy for AMD management, warranting further in vivo investigation.

Keywords: Resveratrol, Nanostructured Lipid Carriers, polyphenolic phytoalexin, Antioxidant

### Formulation and Evaluation of Fluconazole Based Nanogel

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Abstract: The objective of this study was to formulate and characterize a 0.4% fluconazoleloaded nanoemulsion gel to enhance its topical and vaginal delivery for antifungal therapy. Solubility studies were performed to select the optimal oil phase (oleic acid) and surfactant-cosurfactant mixture (smix) of Kolliphor EL and propylene glycol at a 1:1 ratio. Pseudo-ternary phase diagrams confirmed the stability of the nanoemulsion region. A 3<sup>2</sup> full factorial design was utilized to statistically optimize the formulation, followed by thermodynamic stability tests and physicochemical characterization. The optimized nanoemulsion was subsequently incorporated into a gel base using Carbopol 934. The optimized formulations demonstrated desirable properties, including high drug loading (up to 93.6%), low viscosity, and nanosized droplets (251.5–615 nm) with low polydispersity indices. Transmission Electron Microscopy (TEM) confirmed the presence of spherical, uniformly dispersed nanodroplets. The final 0.4% nanogel exhibited a suitable pH, good viscosity, and superior in vitro antifungal efficacy against Aspergillus niger (23 mm inhibition zones), outperforming a standard 0.5% fluconazole preparation (18 mm zones). Additionally, in vitro permeation studies showed sustained drug release over 8 hours. The developed nanoemulsion-based gel formulation of fluconazole is a stable and effective strategy for enhanced topical drug delivery. Its improved permeation and antifungal efficacy suggest a significant potential as a viable alternative to currently marketed preparations, allowing for a lower therapeutic dose and reduced side effects.

**Keywords:** Fluconazole, nanoemulsion, nanogel, Vaginal delivery, antifungal.

### Keratin-Infused Polymeric Buccal Film of Lignocaine hydrochloride for Targeted Stomatitis Therapy

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**Abstract:** Aim: The study intends to formulate a keratin-based buccal film with Lignocaine hydrochloride (LGH) to treat stomatitis.

Methodology: Keratin was extracted from the white feathers of a 42-day-old chicken. FT-IR and XRD characterized the isolated keratin protein. The solvent casting method was used to prepare a buccal polymeric film. The extracted keratin, in combination with chitosan and PVPK-30, was loaded with LGH as a model drug. Weight uniformity, thickness, folding endurance, swelling, and porosity were studied. Porcine cheek pouches were utilized for mucoadhesion testing. LGH was quantified at 263 nm using optimized HPLC in simulated salivary buffer (SSB) at 37°C during in vitro release studies. In ulcer-induced Wistar rats, the LGH-loaded polymeric film (1 cm2) was wetted with 30  $\mu$ l of SSB and applied to the ulcer.

Results and Discussion: All batches produced translucent, smooth, flexible films. The average thickness was 0.52--0.56 mm. Folding endurance exceeded 300 for films with higher keratin. The total drug content was  $95.25\pm5.231\%$ . The percentage swelling index was  $71.05\pm7.011\%$ . It was observed that there was a proportional increase in mucoadhesion time with an increase in keratin concentration in the films, i.e., from 1-2.5% w/w. In vitro release of LGH from the polymeric films showed zero-order kinetics, with cumulative percentage LGH release of  $91.57\pm5.675\%$ . Treatment with LGH-loaded keratin films resulted in significant (p<0.05) healing in ulcer-induced rats compared to other groups.

Conclusion: Taken together, the work suggested a keratin-based hydrogel buccal film containing Lignocaine hydrochloride could treat stomatitis.

Keywords: Keratin; Buccal film; Lignocaine hydrochloride; Stomatitis; In vitro; In vivo efficacy

### Controlled Drug Delivery of Metronidazole Hydrochloride Using Stimuli-Responsive PVA-Gelatin Blend Films Crosslinked via Freeze-Thaw Cycles

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**Abstract:** Aim: The work aims to utilize freeze-thaw cycles for controlled release of a stimuliresponsive, physically crosslinked Poly (vinyl alcohol) (PVA) and gelatin (GE)-film loaded with Metronidazole Hydrochloride (MTZ).

Methodology: Vacuum-dried MTZ-loaded PVA and GE blend, crosslinked via 30 freeze/thaw cycles, were evaluated for stimuli sensitivity, ionic concentration, oscillatory response, and dye absorption. Crosslinking was validated by FT-IR, DSC, and SEM. Diffusion behaviour and stimulus-responsiveness were assessed in phosphate-buffered saline (PBS, pH 1.2, 7.4, 8.5) at 25°C and 37°C. In vitro drug release was evaluated in 0.1 M HCl (2 h) and Sorensen's buffer (pH 7.4, 8.5), with HPLC measuring MTZ at 319 nm. Film sterility was monitored over 7–21 days. Biodegradability (B. subtilis, 25°C) and bactericidal activity (E. coli, 37°C) were measured by UV/Vis spectrophotometry.

Results and Discussion: The MTZ-loaded crosslinked film had a thickness of 141  $\pm$  16µm. The film exhibited enhanced integrity and responsiveness to pH, temperature, and ionic strength due to increased PVA and crystallinity. Tensile strength and Young's modulus were 10±1.684 MPa and 6±1.379 MPa, respectively. Contact angle ( $\theta$ ) decreased over time (<60). Percentage swelling was found to be 1500±121 at pH 1.2, 986±76 at pH 7.4, and 706±89 at pH 8.5. In vitro drug release was 98%  $\pm$  0.4 for neat MTZ; only 40%  $\pm$  4 was released at pH 7.4/8.5in 5 h (p<0.05), underscoring controlled release. The film was sterile, biodegradable, and non-bactericidal for 14 days.

Conclusion: Taken together, the findings showed MTZ-loaded crosslinked PVA-GE films could be developed for controlled delivery.

**Keywords:** Stimuli-responsive; Freeze-Thaw cycles; PVA-Gelatin; Metronidazole Hydrochloride; Controlled release

### Development of a Smart and Efficient Lyophilization Process for Stabilizing Anticancer Drug-Loaded Liposomes

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**Abstract:** Lyophilization is a critical process primarily used to stabilize the aqueous dispersion of liposomes, rendering an enhanced shelf-life and improving the clinical usage. However, drying at low temperatures and its overall processing make this process energy inefficient, expensive, and time-consuming. Additionally, a longer lyophilization cycle also impacts the physical attributes of liposomes. Thus, to overcome these drawbacks, we have developed an efficient lyophilization recipe to obtain physicochemically stable liposomes with desirable characteristics. The present research work is aimed at developing and optimizing a suitable lyophilization recipe to obtain stable anticancer drug-loaded liposomes. For this, the drug-loaded liposomes were optimized using QbD/DoE tools, followed by optimizing the lyophilization process for prototype formulation for various levels of cryoprotectant and freezing/drying conditions. The prototype formulation showed desirable results with respect to particle size less than 200 nm and entrapment of more than 90%. Application of a novel lyophilization strategy helped reduce the lyophilization time from ~55 hours to less than 20 hours without compromising the physical attributes of the liposomes. Thus, the implementation of faster drying helps in developing a highly efficient lyophilization process and enables stabilization of drug-loaded liposomes in a timeeffective and economic manner. The results facilitate the development of a stable, scalable, novel liposomal formulation for anticancer therapy with strong translational possibilities.

Keywords: Lyophilization, Liposomes, Freeze-drying, QbD, Process technology

### Development and optimization of a Lipid-Based Drug Delivery System for Enhanced Lung Cancer Treatment

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Abstract: Aims: This study aimed to formulate and characterize a TK-inhibitor-loaded lipid based and evaluate its potential for the treatment of system Objectives: 1. To develop a stable drug loaded lipid based formulation using Quality by Design (QbD) approach.2. To perform characterization and in vitro release testing of developed drug formulation. 3. To evaluate the efficacy of developed formulation using A549 lung cancer cell lines. Methodology: The TK-inhibitor-loaded lipid-based formulation was developed using quality-bydesign (QbD) approach. The physicochemical characterization of the developed formulation, including assay, encapsulation efficiency, particle size, zeta potential, morphology, etc., was performed using techniques like HPLC, dynamic light scattering (DLS), transmission electron microscopy (TEM), etc. Stability studies were performed under various conditions (40°C/75%RH, 25°C/60%RH, 2-8°C), and parameters such as encapsulation efficiency, particle size, polydispersity index (PDI), and zeta potential were monitored. In vitro, release kinetics, as well as cellular efficacy testing such as cell viability, ROS generation, apoptosis induction, and cellular uptake, were assessed using A549 Results and Discussion: The formulation was developed and optimized successfully using Box-Behnken design with nanodroplet size (158.8 nm), low polydispersity (PDI 0.230), high drug entrapment (90.07%), and negative zeta potential (-51.9 mV). The in vitro release up to 24h, along with formulation homogeneity, suggested prolonged and effective lung cancer therapy when administered intravenously. With reduced IC50 values in MTT assays and increased oxidative stress generation in ROS assays, which lead to increased apoptosis and efficient cellular internalization, in vitro cell line assays showed strong anticancer activity, underscoring the formulation's potential Conclusion: The developed lipid-based formulation showed desirable physicochemical along with better efficacy for lung cancer treatment. The promising results of this developed therapeutic system suggest further preclinical and clinical studies to validate this research work with possible translation clinic. from bench to

**Keywords:** Nanotechnology, Tyrosine kinase inhibitor, Lung cancer, QbD, Drug Delivery.

### Designing a Self-Microemulsifying Topical Gel System for Enhanced Tizanidine Hydrochloride Delivery

Sandeep Ishwar Kurani, Sujay Hulyalkar, Panchaxari M. Dandagi, Swati Desai.

KLE College of Pharmacy, Belagavi

Abstract: Tizanidine Hydrochloride, a BCS Class II compound, exhibits limited oral bioavailability (30-40%) and short half-life (~2.5 hours) due to extensive first-pass metabolism. This investigation aimed to enhance drug solubility and bioavailability by developing self-microemulsifying drug delivery systems (SMEDDS) incorporated into topical gel formulations. Microemulsions were prepared using clove oil (10%), Kolliphor EL (67.5%), and propylene glycol (22.5%), with the optimal formulation (F1) selected via construction of a pseudoternary phase diagram. The F1 system was characterized for particle size, viscosity, drug content, transmittance, and stability parameters. Subsequently, the optimized microemulsion was incorporated into gel matrices utilizing Carbopol 934 and HPMC K100M as gelling agents. Comprehensive evaluation included appearance, pH, viscosity, spreadability, drug content, in vitro release studies, and ex vivo diffusion analysis. Optimization employed a 3<sup>2</sup> factorial design methodology. Characterization of the selected microemulsion (F1) revealed nanoscale droplets measuring 11.37 nm with a polydispersity index of 0.1512. The optimized gel formulation (TF8) achieved 94.54% drug release, significantly superior to the conventional gel formulation (76.61%). The ex vivo diffusion of 90.66%. The SMEDDS approach successfully enhanced Tizanidine Hydrochloride solubility and release characteristics. Integration into gel base substantially improved diffusion properties and topical bioavailability, presenting a viable alternative to oral administration for poorly soluble pharmaceuticals.

**Keywords:** Tizanidine Hydrochloride, Micro emulsion, Micro emulsion based gel, In vitro diffusion study, Ex vivo diffusion study.

### Preparation and evaluation of herbal extract-based moisturizing lotion: an experimental study

Sandeep Ishwar Kurani, Sujay Hulyalkar, Panchaxari M. Dandagi, Swati Desai KLE College of Pharmacy, Belagavi

Abstract: Tizanidine Hydrochloride, a BCS Class II compound, exhibits limited oral bioavailability (30-40%) and short half-life (~2.5 hours) due to extensive first-pass metabolism. This investigation aimed to enhance drug solubility and bioavailability by developing selfmicroemulsifying drug delivery systems (SMEDDS) incorporated into topical gel formulations. Microemulsions were prepared using clove oil (10%), Kolliphor EL (67.5%), and propylene glycol (22.5%), with the optimal formulation (F1) selected via construction of a pseudoternary phase diagram. The F1 system was characterized for particle size, viscosity, drug content, transmittance, and stability parameters. Subsequently, the optimized microemulsion was incorporated into gel matrices utilizing Carbopol 934 and HPMC K100M as gelling agents. Comprehensive evaluation included appearance, pH, viscosity, spreadability, drug content, in vitro release studies, and ex vivo diffusion analysis. Optimization employed a 3<sup>2</sup> factorial design methodology. Characterization of the selected microemulsion (F1) revealed nanoscale droplets measuring 11.37 nm with a polydispersity index of 0.1512. The optimized gel formulation (TF8) achieved 94.54% drug release, significantly superior to the conventional gel formulation (76.61%). The ex vivo diffusion of 90.66%. The SMEDDS approach successfully enhanced Tizanidine Hydrochloride solubility and release characteristics. Integration into gel base substantially improved diffusion properties and topical bioavailability, presenting a viable alternative to oral administration for poorly soluble pharmaceuticals.

**Keywords:** Tizanidine Hydrochloride, Micro emulsion, Micro emulsion based gel, In vitro diffusion study, Ex vivo diffusion study.

### Deep Eutectic solvent- Enabled Alginate Encapsulation of Morin Hydrate: An Advanced Drug Delivery Approach to enhance Solubility and Stability

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Abstract: Morin hydrate (MH) is a naturally occurring promising flavonoid with multifarious biological activities. However, its application in clinical setup is restricted owing to its less water solubility and dissolution. Therefore, the study aimed to design a deep eutectic solvent (DES) system of MH for enhancement of its water solubility. DES encompassing hydrogen bond acceptor (HBA) hydrogen bond donor (HBD) was utilized in several ratios to prepare stable DES of MH. Further, the selected DES-MH was evaluated for pH, solubility, and 1H NMR study. The encapsulation of DES-MH was performed using the ionic gelation method using sodium alginate. The beads loaded with DES-MH were characterized for micromeritics properties such as Carr's Index, Hausner's ratio, and angle of repose. Moreover, the solid state characterization using FTIR, DSC, and PXRD reveals a transition in the crystalline nature of MH into an amorphous state. The in vitro dissolution study on beads indicates a slow release of MH in the acidic medium and a fast release of MH in the alkaline medium, suggesting the ability of beads to protect the release of MH in acidic medium and site-specific action. At the outset, the study proves the encapsulation of DES-MH into alginate beads elicits the gastric stability of MH and provides site-specific activity in the intestine. The work represents a template for promising molecules having solubility and stability issues, which could widen the scope for the advanced drug delivery of flavonoids in the pharmaceuticals.

Keywords: Morin Hydrate, Deep eutectic solvent, beads, flavonoids, site-specific delivery.

## Formulation and Characterization of Annona muricata and Curcumin Herbal gel for Skin Melanoma:in-vitro screening for the skin cancer cell lines

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Abstract: Skin melanoma, the most aggressive form of skin cancer, poses serious risks due to its high metastatic potential and limited safe treatment options. This study reports the formulation and evaluation of a novel herbal gel combining Annona muricata (soursop) and Curcumin, both known for antioxidant, anti-inflammatory, and anticancer properties. Soursop leaves were extracted via ethanol maceration and solvent partitioning to isolate bioactive acetogenins and alkaloids, while curcumin was incorporated into xanthan gum-based The gel exhibited favorable physicochemical properties, including semi-solid paleyellow appearance, mild aroma, smooth texture, skin-compatible pH (6.0), suitable viscosity (1,517 cP), good spreadability (7.2 cm), and homogeneity without phase separation. Stability testing confirmed integrity under varied conditions, with microscopic analysis showing uniform particle distribution (<10 μm). In-vitro cytotoxicity against A375 melanoma cells using MTT assay demonstrated enhanced anticancer activity of the combined gel (IC<sub>50</sub>: 25 μg/ml at 48 h) compared with A. muricata extract (IC<sub>50</sub>: 110  $\mu$ g/ml) and curcumin (IC<sub>50</sub>: 75  $\mu$ g/ml). The results synergistic effect in inhibiting melanoma cell proliferation. confirmed This study suggests the herbal gel as a safe, bioavailable, and patient-friendly alternative for melanoma therapy. Further in-vivo and clinical investigations are recommended to validate its therapeutic potential and improve treatment outcomes compared conventional therapies. to

Keywords: Skin melanoma, Herbal gel, Annona muricata, Curcumin, Cytotoxicity

## Exploring intranasal administration of azilsartan medoxomil-loaded in situ nanoemulgel for improved management in AlCl3-induced Alzheimer's dementia model

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Abstract: This study aims to develop and optimize an azilsartan medoxomil (AZL-M)-loaded thermoresponsive in situ nanoemulgel for targeted nose-to-brain delivery, addressing the challenge of restricted entry of non-brain-permeable angiotensin receptor blockers and validated through in vivo models. A Box-Behnken design was employed to optimize formulation parameters, including droplet size, gelation temperature, and drug release. The optimized drug-loaded nanoemulgel was characterized for physicochemical properties and evaluated for ex vivo nasal mucosal toxicity, in vitro cytotoxicity, and ROS reduction. Finally, in vivo efficacy of intranasal application of the optimized formulation was assessed in an AlCl3-induced Alzheimer's model. In due course of the experiment, Formulation-F20 showed optimal gelation at 33.4°C, pH-6.21, droplet size of 160nm, 60.4% drug release in 8h, high permeation, and flux, with confirmed safety and cell viability. TEER studies confirmed the integrity of RPMI-2650 monolayers, and while apparent permeability values of AZL-M solution and nanoemulgel were comparable, the nanoemulgel exhibited significantly higher cumulative permeation across the nasal epithelial barrier. In vivo study in the Alzheimer's model showed that nanoemulgel significantly improved cognitive performance and neuronal survival. At the molecular level, AZL-M treatment led to a marked reduction in brain inflammatory cytokines TNF-α and IL-1β, along with downregulation of specific markers of Alzheimer's dementia, including phosphorylated tau, amyloid precursor protein, and NF-κB. Simultaneously, a significant upregulation of brain-derived neurotrophic factors indicated enhanced neurotrophic support and synaptic plasticity. Overall, the intranasally delivered AZL-M-loaded nanoemulgel showed potential for safe and effective therapy in Alzheimer's dementia by attenuating neuroinflammation and Alzheimer's pathology markers.

**Keywords:** azilsartan medoxomil; in situ nanoemulgel; Alzheimer's dementia; neuroprotection; safety assessment

### Organ-Specific Metastasis in Breast Cancer: Correlation of Molecular Subtypes, Biomarkers, Imaging, and Prognostic Outcomes

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**Abstract:** *Background:* Breast cancer encompasses a diverse array of molecular subtypes, each shaping distinct patterns of metastasis, therapeutic responsiveness, and patient outcomes. The persistent challenge of organ-specific metastasis highlights the urgent need for reliable prognostic markers to inform individualized treatment strategies. Aim: To investigate the association between molecular subtypes, immunohistochemical (IHC) markers, and imaging findings with organ-specific metastatic patterns and overall survival in patients with breast cancer.

Methodology: An ambispective observational study was conducted involving 104 patients with histopathologically confirmed metastatic breast cancer. Inclusion criteria: Patients with complete records on molecular subtyping, IHC profiling (ER, PR, HER2, Ki-67), imaging modalities (MRI, PET-CT, bone scan, X-ray), and documented survival follow-up. Exclusion criteria: Cases with incomplete clinical or diagnostic data, or lacking confirmed histopathological diagnosis.

Findings: The most common metastatic locations were the brain (23.6%) and bone (34.4%). TNBC was associated with brain/lung spread, HER2+ with liver, and the Luminal B subtype with bone metastases. TNBC and HER2+ patients had the worst results (<12 months), while Luminal B patients had the longest survival (>24 months in 19.2%). Imaging revealed that MRI was very sensitive for multiple metastases, PET-CT was highly sensitive for liver metastases, and X-ray was sensitive for bone lesions.

Conclusion: IHC markers and molecular subtypes can forecast survival and organ-specific metastases in breast cancer. Biomarker-driven risk stratification is enhanced by imaging modalities, which highlight their importance in prognosis, early detection, and precision oncology strategy customisation.

**Keywords:** Breast cancer, organ-specific metastasis, molecular subtypes, biomarkers, precision oncology.

### Next Generation Linkers in Antibody- Drug Conjugates (ADCs) for Controlled Drug Release

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Abstract: Antibody–drug conjugates (ADCs) represent a rapidly advancing class of biopharmaceuticals that combine the selectivity of monoclonal antibodies with the potency of cytotoxic payloads. Central to their clinical performance is the linker, which dictates drug stability during circulation and precise release at the tumor site. Conventional cleavable and non-cleavable linkers have enabled the approval of multiple ADCs, yet they are often limited by premature drug release, off-target toxicity, and narrow therapeutic indices. In response, next-generation linker technologies have emerged, offering more sophisticated control over payload release. Stimuli-responsive linkers—including pH-sensitive, redox-responsive, enzymatically cleavable, and light- or heat-triggered systems—are engineered to exploit tumor-specific microenvironments, thereby enhancing safety and efficacy. Additionally, innovations such as self-immolative and dual-responsive linkers are broadening the scope of payload compatibility and improving pharmacokinetics. This review highlights the evolution of linker strategies, their underlying mechanisms, and their translational impact in ongoing clinical trials. By critically analyzing these advances, it underscores the indispensable role of linker chemistry in driving the next generation of ADCs, ultimately shaping safer and more effective precision cancer therapies.

Keywords: Monoclonal antibodies, Microenviranments, Indispensable, Conventional cleavage

#### Harnessing Antimicrobial Peptides to Overcome Antibiotic Resistance

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**Abstract:** Antimicrobial resistance (AMR) represents a global health crisis, threatening the effectiveness of conventional antibiotics and leading to increased morbidity, mortality, and healthcare costs. Antimicrobial peptides (AMPs), a diverse group of small, naturally occurring or synthetic molecules, have emerged as promising alternatives to traditional antibiotics due to their broad-spectrum activity and unique mechanisms of action. Unlike conventional antibiotics, AMPs target microbial membranes, leading to rapid cell death with a lower propensity for resistance development. Furthermore, many AMPs exhibit immunomodulatory, anti-biofilm, and anti-inflammatory properties, enhancing their therapeutic potential. This poster explores the structural diversity, mechanisms of action, and recent advances in AMP research aimed at addressing AMR. It also discusses challenges such as toxicity, stability, and delivery, as well as emerging strategies including peptide engineering, nanocarrier systems, and synthetic analogs to enhance AMP efficacy. AMPs hold significant promise as next-generation therapeutics in the global fight against drug-resistant infections.

**Keywords:** Morbidity, immunomodulatory, anti-biofilm, broad spectrum, synergy.

### Nanostructured Biomaterials: Emerging Tools in Tissue Engineering and Regenerative Medicine

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Abstract: Nanostructured biomaterials are revolutionizing the field of tissue engineering and regenerative medicine by providing structural and functional properties that closely resemble the natural extracellular matrix (ECM). Their nanoscale features enhance cell adhesion, proliferation, and differentiation, while enabling controlled delivery of bioactive molecules. Both natural nanomaterials, such as collagen, chitosan, and silk fibroin, and synthetic counterparts, including PLGA, PEG, and PCL, are widely utilized either alone or as nanocomposites. Fabrication techniques like electrospinning, nanoparticle synthesis, 3D bioprinting, and selfassembly have enabled the development of scaffolds with superior biological and mechanical properties. Applications of nanostructured biomaterials span across bone, cartilage, skin, neural, and cardiac tissue regeneration, where they significantly improve healing and integration with host tissue. In regenerative medicine, they serve as nanocarriers for controlled drug and gene delivery, promote vascularization, and enhance stem cell-material interactions. Despite their promise, challenges remain, including concerns of long-term biocompatibility, potential toxicity, large-scale production, and regulatory approval. Future advancements are expected through the development of smart, stimuli-responsive biomaterials and the integration of nanotechnology with stem cell therapy, personalized medicine, and advanced fabrication strategies. These innovations hold great potential to translate nanostructured biomaterials from experimental models to clinical applications, offering new solutions for complex tissue repair and regeneration.

**Keywords:** Nanostructured biomaterials, Tissue engineering, Regenerative medicine, Extracellular matrix (ECM), Stem cell therapy.

#### Revolutionizing Immuno-therapy with computational bio markers

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**Abstract:** Immunotherapy aims at immune checkpoint inhibition which offers profound clinical benefits, but it has limitations due to adverse effects and disease relapse. Static biomarkers like PD-L1 expression, Tumor mutational burden( TMB) and Micro-satellite instability are used based on patient condition. These are insufficient due to tumor heterogenecity, variations in testing interpretation and inability to capture full complexity of tumor environment. Hence computational bio markers driven by AI and multi omics like ,Tumor immune landscape modelling, Personalised Neo-antigen prediction, Liquid biopsy integration,Gene expression profiles and Metabolomics are used to derive insights from multi dimensional biological data.The study represents the real time examples of computational biomarkers to support immunotherapy against cancer treatment.

**Keywords:** PD-L1 - programmed death ligand 1, Tumour mutational burden, tumour immune landscape modelling, Metabolomics

### Development and Optimization of Cocoa-Based Herbal Face Pack Using Design of Experiments

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**Abstract:** Background: Skincare products featuring natural ingredients are widely favored for their perceived efficacy and safety. This study aimed to develop and evaluate cocoa fruit-based formulations for skincare, enriched with synergistic herbal constituents such as rose petals, guava peel and papaya leaf.

Materials and Methods: The cocoa fruit underwent processing and fermentation to yield cocoa beans. In this study, 12 facial pack formulations were developed using JMP 17 software, with variations in the quantities of cocoa powder, papaya leaf powder, guava peel powder and rose petal powder. The custom design generated by JMP facilitated the creation of optimized formulations, considering responses such as bulk density and angle of repose. The final optimized formulation was assessed for organoleptic properties, moisture content, washability, bulk density, angle of repose, total ash value and phytochemical constituents.

Results: Optimal formulations were determined for the product based on desired attributes and skincare benefits. The DoE-generated twelve facial pack formulations exhibited acceptable model fit, with the optimized formulation demonstrating positive outcomes in organoleptic and phytochemical analyses.

Conclusion: This study successfully formulated skincare products using cocoa bean and herbal constituents, demonstrating their potential for natural skincare formulations with desirable properties and therapeutic benefits. DoE enabled a data-driven approach to optimize the herbal facial pack formulation efficiently, ensuring robust physical properties and potential skincare benefits. Future research endeavors could focus on further refining formulations and exploring additional applications in skincare product development.

**Keywords:** Herbal face pack, Jmp pro-18, Optimization, Theobroma cacao.

### Targeting mTOR in Lung Cancer: Design, Synthesis, and Biological Evaluation of Novel Tetrahydroquinoline Derivatives as Potential Anticancer Agents

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Abstract: Lung cancer remains one of the leading causes of cancer-related mortality worldwide, necessitating the development of novel and effective therapeutic strategies. The mammalian target of rapamycin (mTOR), a central regulator in the PI3K/AKT/mTOR signaling pathway, is frequently dysregulated in lung cancer, contributing to uncontrolled cell growth and survival. This study aimed to design, synthesize, and biologically evaluate tetrahydroquinoline (THQ) and related heterocyclic derivatives as potential mTOR inhibitors through a structure-based drug design approach. Using computer-aided drug design (CADD) tools, novel THQ-based scaffolds were conceptualized and optimized for enhanced binding affinity, selectivity, and favorable physicochemical properties. Docking studies confirmed stable interactions with the mTOR active site, while ADMET predictions indicated good pharmacokinetic profiles and reduced toxicity. Multi-step synthesis of selected analogs was accomplished using classical organic reactions, with structural confirmation provided by mass spectrometry, 1H NMR, and 13C NMR analyses. In-vitro assays demonstrated potent antiproliferative activity against A549 lung cancer cells, with lead compound 10e exhibiting an  $IC_{50}$  of 0.033  $\mu M$ , alongside minimal cytotoxicity in normal VERO cells. Flow cytometry-based apoptosis analysis and molecular dynamics simulations further validated the stability and efficacy of lead candidates. These promising findings underscore the potential of THQ derivatives as mTOR-targeted anticancer agents, paving the way for further optimization, expanded biological evaluation, and potential preclinical development toward lung cancer therapy.

Keywords: mTOR, Lung Cancer, Tetrahydroquinoline, Apoptosis

### Preliminary Screening of Repurposed Drugs Targeting GPR116 to treat Breast Cancer Metastasis

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Abstract: Background: Metastasis remains the major challenge in breast cancer, as tumor cells spread to distant organs. G protein-coupled receptor 116 (GPR116) 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 aimed to screen drugs targeting GPR116, essentially repurposing approved drugs through In silico and vitro cell line approaches. Methodology: The structure of GPR116 was predicted using I-TASSER and validated by Ramachandran plot. Based on extensive literature study, 82 repurposable ligands were selected and docked against GPR116 using AutoDock Vina. Top-scored complexes were visualized using BIOVIA Discovery Studio and the highy stable complexes in DESMOND simulation underwent MTT assay on MDA-MB-231 cells. Finally, the ligands with low IC50 further migration values were evaluated in Results: Docking scores of drugs ranged from -10.3 to -3.9 kcal mol<sup>-1</sup>. Eight drugs with top docking scores and stability profiles were shortlisted for cytotoxicity studies. Sertindole and Raloxifene showed the lowest IC50 values (1.32 µg/ml and 1.303 µg/ml, respectively), which were selected for migration assays. Scratch assay revealed reduced wound closure (37.61% by Sertindole and 42.86% for Raloxifene after 48 h), while transwell migration assay confirmed inhibition compared untreated significant of cell migration Conclusion: Sertindole (antipsychotic) and Raloxifene (anti-osteoporotic) demonstrated promising anti-migratory potential in scratch assay and transwell assay. Further studies, including gene and protein expression analyses, are required to validate their role as GPR116-targeted repurposed anti-metastatic therapeutics.

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

### Uncovering miR-3154 as a Novel Therapeutic Regulator of Oncogenic Drivers in Pancreatic Ductal Adenocarcinoma: An Integrated in silico approach

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Abstract: Pancreatic ductal adenocarcinoma (PDAC), the most lethal form of pancreatic cancer. It is clinically characterized by the low 5-year survival rate of 12% and a high mortality rate of 94%. Although rare in India, its incidence is likely to increase due to lifestyle factors such as obesity and smoking. Standard treatment options are ineffective due to chemoresistance, early metastasis and intricate genetic heterogeneity of PDAC. This highlights the need for multi-target therapies to improve treatment efficacy and patient outcomes. MicroRNAs (miRNAs) have tumor suppressor capability, which modulates multiple oncogenic drivers, making them a promising therapeutic approach for PDAC. A comprehensive bioinformatics analysis of GEO datasets (GSE62165 and GSE183795) was carried out to evaluate differential gene expression patterns between PDAC tissues and normal pancreatic tissues. Kaplan-Meier survival analysis was performed to analyze the significance of these oncogenes on patient survival outcomes. Further, the miRDB-miRNA target prediction database was used to identify regulatory miRNAs targeting these oncogenic drivers. Differential expression analysis showed elevated gene expression of YAP1, KRAS and RELA in PDAC tissues compared to normal. Survival curve showed that increased expression of these genes correlates with poor overall survival of PDAC patients. miRDB prediction identified a novel miR-3154, which simultaneously targets the key oncogenic genes, suggesting its role as a tumor-suppressor miRNA. These findings convincingly establish miR-3154 as a therapeutic candidate capable of targeting multiple oncogenic drivers in PDAC. Restoration of miR-3154 through advanced miRNA-targeted delivery methods may constitute a novel therapeutic approach for enhancing clinical outcomes in PDAC patients.

**Keywords:** Pancreatic Ductal Adenocarcinoma, miRNA, Tumor Suppressor, miRNA-based Therapy, Oncogenic signaling.

### Role of Quality by Design (QbD) Based Method Development in Drug Discovery

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Abstract: Quality by Design (QbD) has emerged as a systematic, science-based, and riskoriented approach in pharmaceutical research, offering a paradigm shift from traditional trialand-error methods to knowledge-driven development. In the context of drug discovery and analytical method development, QbD emphasizes the identification of critical quality attributes (CQAs), critical process parameters (CPPs), and their relationships to ensure robustness, reproducibility, and regulatory compliance. Early application of QbD in drug discovery facilitates rational molecular design, optimization of physicochemical properties, and prediction of pharmacokinetic-pharmacodynamic (PK-PD) profiles. In analytical method development, QbD ensures the establishment of a method operable design region (MODR), supported by risk assessment and design of experiments (DoE), leading to robust, reliable, and cost-effective analytical procedures. Integration of QbD tools with computational approaches, artificial intelligence, and high-throughput screening accelerates the identification of lead molecules and optimization of formulation strategies. Furthermore, regulatory agencies such as the FDA and ICH strongly advocate QbD principles to enhance product quality, reduce variability, and minimize post-approval changes. Thus, the implementation of QbD in drug discovery and method development not only streamlines the developmental pipeline but also contributes significantly to patient safety, therapeutic efficacy, and faster market access. Overall, QbD provides a holistic framework that bridges innovation with regulatory expectations in modern pharmaceutical sciences.

**Keywords:** Quality by Design (QbD), Drug discovery, critical quality attributes (CQAs), Analytical robustness, Molecular optimization

### Next-Generation Modalities in Drug Discovery: PROTACs, Antibodies, and Beyond

A. Hasini\*, C H Pranaswi, V A N V Harita Marri Laxman Reddy Institute of Pharmacy

Abstract: The discipline of medicinal chemistry is increasingly moving beyond typical smallmolecule therapies. Many disease-associated proteins, such as transcription factors and protein-protein interaction complexes, are "undruggable" using traditional techniques based on Lipinski's Rule of Five. Emerging next-generation modalities offer novel answers by extending drug research beyond the "beyond Rule-of-Five" chemical domain. Proteolysistargeting chimaeras (PROTACs) and molecular glues use the ubiquitin-proteasome system to selectively degrade target proteins, providing long-term therapeutic benefits. Monoclonal antibodies (mAbs) and antibody-drug conjugates (ADCs) provide for very selective targeting, lowering systemic toxicity in cancer and autoimmune illnesses. Furthermore, peptide-based medications, oligonucleotide therapies (such as antisense oligonucleotides, siRNA, and mRNA vaccines), and macrocycles offer novel avenues for addressing complicated biological targets. These modalities show enhanced selectivity, unique modes of action, and the ability to reach previously inaccessible sites. However, problems such as low oral bioavailability, complicated synthesis, distribution hurdles, and high production costs persist. Overall, nextgeneration methods are redefining the future of drug development by allowing for novel therapeutic approaches and increasing the range of curable disorders.

**Keywords:** PROTACs, antibodies, molecular glues, peptides, macrocycles.

### Exploring innovative interventions for strategic improvement of steam distillation process for extraction of essential oil'

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**Abstract:** The apparent simplicity of steam distillation (SD), which is the most preferred in the essential oil (EO) industry, holds two major drawbacks such as low yield and long extraction duration. This work focuses on improvising the process of SD through a strategic sample pretreatment policy in order to rejuvenate the traditional process. The pretreatment process comprises of microwave exposure (425W) of fresh biomass for 10 min prior to SD. The pretreatment process was found to increase the yield of lemongrass oil by 2.7 times when compared to normal SD using only half of the processing time as applicable for SD. Citral content was 16% higher for the microwave pretreated sample as well. The reusability of biomass was also determined and findings clearly indicate depletion of phenolic and flavonoid principles by more than 65% in the biomass undergoing SD when compared to control sample (untreated biomass). Interestingly, pretreated biomass post extraction of EO showed 6.9% more phenolic content when compared to control sample indicating complete retention of phenolic and flavonoid principles during the process of distillation. This study highlights how a simple steam distillation process used for the extraction of EO can be improvised by a simple pretreatment process.

Keywords: lemongrass; essential oil; microwave; pre-treatment; Steam distillation

### Bioanalytical LC-MS/MS Method for Parent-Metabolite Quantification of Bexagliflozin and Its Glucuronide: Application to Rat Pharmacokinetics

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Abstract: Bexagliflozin, a selective sodium-glucose cotransporter 2 (SGLT2) inhibitor, is an effective oral antidiabetic drug that undergoes extensive glucuronidation to form the active metabolite, Bexagliflozin Glucuronide. Comprehensive pharmacokinetic (PK) profiling requires simultaneous quantification of both parent drug and metabolite; however, validated bioanalytical methods for this purpose in preclinical models are limited. This study reports the development and validation of a rapid, sensitive, and selective liquid chromatographytandem mass spectrometry (LC-MS/MS) method for the quantification of Bexagliflozin and its glucuronide in rat plasma, and its application to PK evaluation. Chromatographic separation was achieved on a ZORBAX SB-CN column using a mobile phase of methanol and 10 mM ammonium acetate (pH 4.0) (75:25, v/v) with a short run time of 3 minutes. Detection was performed in positive electrospray ionization (ESI) mode with multiple reaction monitoring (MRM), ensuring high specificity. The method was validated in accordance with US FDA and ICH guidelines, demonstrating excellent linearity ( $R^2 \ge 0.99$ ), high recovery (>92%), minimal matrix effects, and stability under varied conditions. Pharmacokinetic studies in Wistar rats following oral administration of Bexagliflozin (5 mg/kg) revealed rapid absorption (Tmax 1.5 h), with a Cmax of 60.3 ng/mL and an elimination half-life (t1/2) of 4.23 h. The glucuronide metabolite reached Tmax at 2.5 h, contributing ~52% of systemic exposure (AUC₀-∞ 378.67 ng·h/mL), indicating significant glucuronidation. The validated method enables reliable simultaneous quantification of Bexagliflozin and its glucuronide, providing critical PK insights for dose optimization and clinical translation in type 2 diabetes management.

**Keywords:** Bexagliflozin, bioanalytical, glucoridination, chromatography, pharmacokinetics.

### Nanoformulations for Targeting the Gut-Liver Axis: A Novel Therapeutic Approach

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**Abstract:** *Introduction and Background:* The gut-liver axis, a bidirectional communication system between the gastrointestinal tract and liver via the portal vein, plays a central role in the pathogenesis of several chronic diseases including non-alcoholic fatty liver disease (NAFLD), liver cirrhosis, and hepatocellular carcinoma. Approximately 25–30% of the global population suffers from NAFLD alone, with increasing incidence linked to gut dysbiosis and leaky gut syndrome. Current treatment strategies predominantly rely on systemic administration of antibiotics, anti-inflammatory drugs, and probiotics. However, these approaches often lack site specificity, require high dosages, and lead to poor bioavailability and off-target side effects.

Methodology: Recent advances in nanotechnology have enabled the development of nanoformulations such as polymeric nanoparticles, liposomes, and solid lipid nanoparticles, designed for targeted delivery to the gut-liver axis. These systems can encapsulate therapeutic agents, protect them from degradation in the gastrointestinal tract, and allow for controlled release at the target site.

Key Findings: Preclinical studies show that nanoformulations significantly enhance the bioavailability and stability of encapsulated drugs. Additionally, targeted nanoparticles have been shown to reduce systemic toxicity and improve therapeutic outcomes by concentrating drug action at the gut-liver interface. Some lipid-based nanoformulations demonstrated up to a 5-fold increase in hepatic drug concentration compared to traditional oral drugs.

Conclusion: Targeting the gut-liver axis via nanoformulations represents a promising strategy to overcome limitations of current therapies. This approach holds potential for transforming the clinical management of liver and gastrointestinal diseases, offering improved efficacy, reduced side effects, and precision delivery.

**Keywords:** Metallo-polyester nanocomposites; Quercetin delivery; pH-responsive release; Biocompatibility; Colon cancer cells.

### Targeted Delivery of 4-Phenylbutyric Acid through Thermoresponsive Gel for Improved Psoriasis Treatment

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**Abstract:** *Background:* Psoriasis is a chronic inflammatory skin disorder associated with keratinocyte hyperproliferation and ER stress. 4-Phenylbutyric acid (4-PBA), an epigenetic modulator and chemical chaperone, shows therapeutic promise but suffers from limited skin penetration and systemic side effects. This study aimed to develop and characterize a thermoresponsive 4- PBA gel for effective topical drug delivery.

Methodology: A poloxamer-based thermoresponsive gel coated with hyaluronic acid was formulated and evaluated for physicochemical and functional attributes. Particle size, polydispersity, and zeta potential were assessed using dynamic light scattering. XRD and FTIR confirmed structural integrity, while drug content and release kinetics were analysed by HPLC. Viscosity and gelation behaviour were studied across temperatures. Cellular uptake was examined in HaCaT cells, and therapeutic efficacy was validated in an imiquimod-induced psoriasis mouse model through histopathology and IL-17 immunohistochemistry.

Results: The optimized gel exhibited uniform particle size (~150 nm), stable zeta potential, and characteristic FTIR and XRD signatures confirming drug encapsulation. The system displayed thermoresponsive gelation at 32–34 °C with favourable rheological properties. HPLC analysis confirmed sustained 4-PBA release with controlled kinetics. HaCaT cell studies demonstrated efficient uptake, and in vivo studies revealed marked improvement in psoriatic lesions, epidermal thickness reduction, and IL-17 downregulation, particularly with the 0.01% 4-PBA gel.

Conclusion: The thermoresponsive 4-PBA gel provides a patient-compliant, site-specific delivery system that integrates physicochemical stability with robust therapeutic efficacy. This formulation represents a promising epigenetic-based drug delivery strategy for psoriasis management.

**Keywords:** Psoriasis, 4-Phenylbutyric acid, Thermoresponsive gel, Drug delivery, Epigenetic therapy.

# Glucosamine sulphate endorsed ibuprofen nanocrystals burdened polymeric gel demonstrated multidimensional anti-inflammatory and cartilage protective potential in experimental knee osteoarthritis: In vitro and in vivo studies

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Abstract: Osteoarthritis is a chronic degenerative musculoskeletal condition associated with progressive loss of hyaline cartilage, subchondral bone remodeling and inflammation. Despite of ongoing research, no FDA-approved drugs for osteoarthritis are available. Current investigation explores potential of ibuprofen and glucosamine sulphate nanocrystal loaded gel (IBU-GS-NCs gel) for its anti-inflammatory and disease modifying capabilities in osteoarthritic rat model. The optimized IBU-GS-NCs exhibited particle size 34.57±0.79 nm, zeta potential -2.81±0.6 mV, drug content 7.05±0.17% and stability upto 3 months. Submicronization of bulk IBU resulted into ~90-fold increase in aqueous solubility. Fabrication of IBU-GS-NCs gel demonstrated 0.507±0.029% drug loading with spreadibility and viscosity close to marketed diclofenac emulgel. At the end of 24 h, amount of IBU permeated through rat skin was found to be significantly high for IBU-GS-NCs gel (479.59±6.28 µg/cm2) as compared to conventional IBU gel (255.91±4.44 µg/cm2). Steady state flux and permeability coefficient for IBU-GS-NCs gel through rat skin was found to be 31.70±0.11 µg/cm2h and 63.41±0.23x10-3 cm/h, respectively. In contrast to positive control, radiograph for IBU-GS-NCs gel treated osteoarthritic rats indicated regeneration of articular cartilage with absence of osteophytes. Histological evaluation of IBU-GS-NCs gel illustrated marked recovery in articulate cartilage thickness as well as GAG level. In addition, western blot analysis for synovial tissue of positive control displayed 9.01, 2.66 and 2.51-fold increase in COX-2, TNF-a and IL-1β, respectively. In contrast, IBU-GS-NCs gel treated osteoarthritic rats demonstrated 1.43, 0.65, and 0.89-fold change in COX-2, TNF-α and IL-1β, respectively. These findings advocate for improved anti-inflammatory and cartilage regenerating potential of IBU-GS-NCs gel.

**Keywords:** Osteoarthritis, Ibuprofen, Glucosamine sulphate, Nanocrystals, Cartilage regeneration.

### Formulation and evaluation of thermosensitive in situ luteolin nanogel for the treatment of periodontitis

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Abstract: Periodontitis is a chronic inflammatory disease requiring localized and sustained drug delivery for effective management. Conventional therapies, including systemic antibiotics and scaling, often fail due to inadequate drug concentration, systemic side effects, and resistance. Luteolin, a natural flavonoid, shows anti-inflammatory, antimicrobial, and bone-regenerative properties. Delivering luteolin through a thermosensitive in-situ gel may overcome current limitations.Luteolin-loaded Solid Lipid Nanoparticles (LT-SLNs) were prepared using high shear homogenization and ultrasonication. A Central Composite Design optimized formulation variables, including Compritol 888, soy lecithin, and Tween 80. Optimized LT-SLNs were incorporated into a gel base of Poloxamer 407 and Carbopol 934. Characterization included particle size, PDI, zeta potential, entrapment efficiency, and structural analysis by FTIR, DSC, XRD, SEM, and TEM. Gel properties such as gelation temperature, pH, viscosity, syringeability, release, sterility, and stability were also evaluated.Optimized LT-SLNs had a mean size of 234.6 nm, PDI 0.039, and entrapment efficiency of 90%. Results confirmed successful encapsulation with improved solubility. The gel exhibited sol-gel transition at ~32°C, physiological pH (7.2  $\pm$  0.5), and viscosity of 80.5  $\pm$  5 cP. In vitro studies showed sustained release: 99.23% from LT-SLNs over 120 h and 99.65% from the gel over 144 h. The formulation remained sterile and stable for 28 days. This thermosensitive in-situ gel provides prolonged release, enhanced bioavailability, reduced systemic exposure, and regenerative potential, highlighting nanotechnology-based delivery as a promising strategy for periodontal therapy.

**Keywords:** Luteolin, Solid Lipid Nanoparticles, in-situ Gel, Periodontitis.

### Development and Optimization of Nebivolol-Loaded Self-Nanoemulsifying Drug Delivery System for Solubility and Dissolution Enhancement

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Abstract: Oral drug delivery remains the most convenient route of administration; however, poor water solubility limits the therapeutic performance of many agents. Nebivolol, a highly selective \( \beta 1 - blocker \) with nitric oxide-mediated vasodilatory properties, is effective in hypertension but exhibits low solubility and dissolution. This work aimed to enhance nebivolol solubility through the development of a self-nanoemulsifying drug delivery system (SNEDDS). Solubility screening was performed using various oils, surfactants, and co-surfactants to identify suitable components for ternary phase systems. Corn oil exhibited the highest solubilizing capacity (3.05 ± 0.69 mg/g) and was selected as the oil phase. Caproic acid and PEG 600 were chosen as surfactant and co-surfactant, respectively. Smix is the mixture of surfactant and co-surfactant prepared in defined ratios of (1:1, 2:1, 3:1) were explored, and formulations with oil:Smix ratios between 1:9 and 9:1 were evaluated. Preparations demonstrating >90% transmittance were considered suitable. Fourteen SNEDDS (F1-F14) were assessed for clarity, turbidity, stability against dilution, and in-vitro dissolution. The optimized formulation (F14), composed of 25% corn oil, 57% caproic acid, and 18% PEG 600, provided rapid self-emulsification, high drug content (99.23%), entrapment efficiency (98.51%), and almost complete drug release (99.96%) within 60 minutes. Characterization revealed a mean droplet size of 165.2 nm and zeta potential of -13.2 mv. Forced degradation studies confirmed pH-dependent degradation, while F14 remained stable under accelerated storage conditions (40 ± 2°C/75 ± 5% RH) for six months. These findings demonstrate that SNEDDS is an efficient strategy to improve the solubility, dissolution rate, and therapeutic efficiency of nebivolol in oral delivery.

**Keywords:** Nebivolol, Hypertension, SNEDDS, Solubility, Caproic acid.

### Zolmitriptan cubosomal in situ nasal gel for migraine treatment

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**Abstract:** Objectives: To develop Zolmitriptan-loaded cubosomal in situ nasal gel for enhanced migraine treatment with improved bioavailability and rapid onset.

Method: Cubosomes were formulated using glyceryl monooleate and Pluronic F127, optimized through Box-Behnken design. The cubosomal dispersion was incorporated into a thermoresponsive in situ gel using PF127. Characterization included particle size, zeta potential, entrapment efficiency, and Transmission Electron Microscopy. In vitro release, ex vivo permeation using sheep nasal mucosa, histopathological analysis, and pharmacokinetic studies in rats were conducted. Results: The optimized formulation showed: particle size (152  $\pm$  3.8 nm), zeta potential (-28.6  $\pm$  1.2 mV), and entrapment efficiency (85.7  $\pm$  2.3%). Transmission Electron Microscopy confirmed uniform cubosomes with cubic morphology. In vitro release showed sustained drug release over 10 hours, following Korsmeyer-Peppas model. The in situ gel demonstrated suitable gelation temperature (32 ± 0.5°C), mucoadhesive strength (3850 ± 120 dyne/cm<sup>2</sup>), and viscosity (15,200 ± 320 cP at 37°C). Ex vivo permeation showed higher drug permeation from cubosomal gel (78.6 ± 3.2%) compared to plain gel (45.3 ± 2.8%) after 8 hours. Histopathological analysis confirmed formulation safety. In vivo studies showed enhanced bioavailability (relative bioavailability of 186%), prolonged plasma drug concentrations (t1/2 of  $6.2 \pm 0.4$  hours), and rapid onset (Cmax of 42.5± 3.1 ng/mL within 30 minutes) compared to oral administration.

Conclusion: The Zolmitriptan-loaded cubosomal in situ nasal gel offers a promising approach for rapid migraine therapy with improved bioavailability. Clinical trials are evaluating the efficacy of this delivery system in migraine patients.

**Keywords:** Nebivolol, Hypertension, SNEDDS, Solubility, Caproic acid.

# Naringenin-Loaded Niosomal Vaginal In-Situ Gel: Preclinical Study in Polycystic Ovary Syndrome-Induced Female Wistar Rats.

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**Abstract:** Objective: This study aimed to develop and optimize a naringenin-loaded niosomal in situ vaginal gel for the effective management of Polycystic Ovary Syndrome (PCOS). This formulation aimed to enhance drug permeation, provide sustained release, and minimize the oral side effects of naringenin.

Method: The optimized niosomal formulation exhibited a vesicle size of 158.1 nm, entrapment efficiency of 71.68%, zeta potential of –28.6 mV, and drug content of 70.79±1.95%. Transmission Electron Microscopy confirmed that the nanosized vesicles were discrete and stable. In-vitro release studies demonstrated 74.1% drug release over 12 hours. Incorporation into an in-situ gel using Pluronic F-127 (18%) produced optimal thermoresponsive characteristics. The viscosity of the gel ranged from 192.71±1.23 cps at 25 °C to 1756.43±7.46 cps at 38 °C, reflecting temperature-dependent gelation. In-vitro diffusion studies showed an enhanced drug release of 84.67%.

Results: In vivo vaginal irritancy assessments revealed no signs of erythema or edema, confirming the non-irritant nature of the formulation. Histopathological evaluation further demonstrated the safety and pronounced therapeutic efficacy of the gel in managing mifepristone-induced PCOS compared with conventional treatments. Short-term stability testing verified the formulation's thermodynamic stability at room temperature.

Conclusion: The optimized Naringenin-loaded niosomal in-situ vaginal gel proved safe, stable, and effective, offering sustained drug release and significant improvement in PCOS management while overcoming limitations associated with oral delivery. This novel vaginal delivery approach holds promise for improving therapeutic outcomes in PCOS patients.

**Keywords:** Naringenin, Niosomes, PCOS, Vaginal drug delivery, In-situ gel.

# Capsaicin nanocrystals burdened topical polymeric gel: An encouraging tactic for alleviation of paclitaxel-induced peripheral neuropathy

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Abstract: Chemotherapy-induced peripheral neuropathy (CIPN) is triggered by clinically recommended chemotherapeutics. Topical capsaicin (CAP) is a US-FDA-approved therapeutic entity for the mitigation of CIPN. Besides good skin permeation efficiency, CAP concentration in a topical dermal dosage form must be controlled due to its dose- dependent therapeutic and adverse effects. Therefore, in the present investigation, capsaicin nanocrystals (CAP- NCs) were scaled up using the nanoprecipitation technique. CAP-NCs exhibited  $145.4 \pm 0.90$  nm particle size,  $0.254 \pm 0.005$  polydispersity index (PDI),  $17.2 \pm 0.80$ mV surface charge ( $\zeta$ ), and markedly higher cumulative percentage drug release (85.68 ± 0.89 %) compared to pure CAP (12.56 ± 0.57 %) in 12 h. CAP-NCs-Gel depicted remarkable textural properties, and desirable viscosity along with ~2.23- fold enhancement in permeability, ~1.61fold augmentation of CAP steady-state flux, and permeability coefficient. Additionally, the in vivo therapeutic efficacy assessment of CAP-NCs-Gel in the paclitaxel-induced peripheral neuropathy (PIPN) demonstrated remarkable improvements in mechanical hyperalgesia, heat hyperalgesia, cold allodynia, and locomotor behavior. Capsaicin nanocrystals burdened polymeric gel once-a-day and twice-a-day applications outstandingly diminished the levels of TNF- $\alpha$  and IL-6 in the sciatic nerve contrast to the positive control group and insignificant difference was noticed compared to the normal control group. Correspondingly, significant modulation of oxidative stress biomarkers, and noticeable regeneration of nerve fibers, a typical arrangement of the axon, with preserved intact myelin sheath integrity were professed in sciatic nerve. In conclusion, CAP-NCs- Gel is a novel approach for translating into a clinically viable dosage form for treating CIPN.

**Keywords:** Paclitaxel, Chemotherapy-induced peripheral neuropathy, Capsaicin, Nanocrystals, Polymeric gel

### Formulation and evaluation of Rosuvastatin Calcium Liposomal Mucoadhesive Buccal film

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**Abstract:** Objectives: This study aimed to develop and evaluate a liposomal mucoadhesive buccal film to enhance the bioavailability and sustained release of rosuvastatin calcium, a potent lipid-lowering drug with low oral bioavailability due to limited water solubility and extensive first-pass metabolism.

Method: Liposomes were prepared using thin film hydration and optimized through Box-Behnken Design (BBD), considering sonication time, cholesterol content, and lipid concentration as independent variables. The optimized liposomes were incorporated into mucoadhesive buccal films using HPMC K4M and HPMC E5 through solvent casting. The films were assessed for physical characteristics, drug content, mucoadhesive strength, swelling index, and in vitro and ex vivo drug release. Stability studies were conducted under accelerated conditions for three months.

Results: The optimized liposomal formulation exhibited an entrapment efficiency of 84.42%, zeta potential of -24.73 mV, and vesicle size of 164.3 nm. Formulation F1 (containing HPMC K4M) demonstrated superior properties, including 80.23% in vitro drug release and 80.96% ex vivo permeation over 24 hours, following Higuchi kinetics. Stability studies confirmed consistent drug release and film integrity after three months under accelerated conditions.

Conclusion: The liposomal buccal film significantly enhances the bioavailability and therapeutic potential of rosuvastatin calcium by bypassing hepatic metabolism and providing sustained drug release. This delivery system offers a promising and patient-friendly approach for the effective treatment of hyperlipidemia, addressing the limitations of conventional oral administration and potentially improving long-term medication adherence for cardiovascular disease prevention.

**Keywords:** Rosuvastatin Calcium, Mucoadhesive Buccal Film, Liposomal Encapsulation, Box-Behnken Design, Hyperlipidaemia Treatment.

### Formulation and evaluation of dry syrup containing glutathione loaded liposomes

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**Abstract:** Objective: To formulate and evaluate a liposome-based dry syrup of glutathione with the aim of protecting it from gastric degradation, thereby improving its oral bioavailability and enhancing its antioxidant potential.

Method: Liposomes were prepared using the thin film hydration method and optimized using a 3<sup>2</sup> factorial design by varying soya lecithin concentration and sonication time. Characterization included particle size, zeta potential, entrapment efficiency, FTIR, DSC, and TEM imaging. In vitro drug release was studied using dynamic dialysis in simulated gastric and intestinal fluids. The optimized liposomes were freeze-dried and formulated into a dry syrup. Antioxidant activity was evaluated by the DPPH assay and stability of the liposome-based dry syrup formulation was studied as per ICH guidelines.

Result: The optimized liposomes had a particle size of 139 nm, zeta potential of -17 mV and entrapment efficiency of 72.18%. FTIR and DSC confirmed compatibility of components, and TEM showed spherical liposomes. The dry syrup showed 89.43% of drug content. Drug release was minimal (19%) in pH 1.2 and substantially higher (75–80%) in pH 6.8, indicating effective protection in the stomach and targeted intestinal release. Antioxidant activity had an IC50 of 71.87  $\mu$ g/ml, comparable to ascorbic acid. Stability studies of liposomal dry syrup indicated that its physicochemical properties remained stable over time.

Conclusion: The liposomal dry syrup effectively protects glutathione from gastric degradation and enhances its oral delivery and antioxidant efficacy, representing a promising novel oral delivery system.

**Keywords:** Glutathione, Liposomes, Oral bioavailability, Antioxidant activity, Dry syrup formulation.

# Development and Validation of a Robust UPLC Method for the Quantification and Stability Assessment of Berberine Hydrochloride in Cubosomal Formulation

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Abstract: The study aimed to develop and validate a robust, sensitive and accurate UPLC method for quantifying berberine hydrochloride in pharmaceutical formulations, specifically focusing on its application in stability assessments of berberine-loaded cubosomes. The method aimed to provide enhanced resolution, sensitivity, and speed compared to traditional HPLC, ensuring reliable quality control and therapeutic efficacy evaluation for berberine HCl. Berberine hydrochloride, an isoquinoline alkaloid, is gaining significant attention due to its broad-spectrum pharmacological activities, encompassing anti-inflammatory, antimicrobial and antidiabetic effects. Consequently, its quantification in pharmaceutical formulations is crucial for quality control and therapeutic efficacy. An effective and validated UPLC method was established for berberine HCl and berberine-loaded cubosomes, demonstrating excellent linearity. This method is highly sensitive, with berberine HCl detectable at 0.022 µg/mL (LOD) and quantifiable at 0.068 µg/mL (LOQ), respectively. Precision was confirmed with relative standard deviations (RSD) below 2.00% for both inter-day and intra-day analyses. Accuracy, assessed via standard recovery, ranged from 100.96% to 101.87% for berberine HCl. A robust UPLC method was developed and validated, demonstrating its suitability for accurate berberine HCl quantification, especially in stability assessments of berberine-loaded cubosomes. This method offers a promising tool for future pharmaceutical analyses of berberine HCl.

Keywords: UPLC, Berberine hydrochloride, Cubosomes, Degradation, RSD.

# Development, optimization and evaluation of drug loaded lipid nano emulsion using Design of Experiment (DoE)

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Abstract: Conventional drug delivery system faces significant challenges in the areas of formulation development, bioavailability, and eventually therapeutic efficacy. Lipid nanoemulsion, a thermodynamically and kinetically stable carrier system shows superior ability to carry unstable molecules. They offer higher surface to mass ratio with respect to conventional emulsions, along with greater stability and enhanced bioavailability. The plethora of variables involved in the formulation development process, makes it a challenging process with each change leading to significantly deviant outcomes. The exploration of Quality by Design (QbD) is an effective strategy to streamline the parameters governing the critical quality attributes (CQA). The objectives of this research include the development and systematic optimization of lipid nano-emulsion using the principles of Design of experiments (DoE). The statistical modeling enabled formulation design provided an optimized formulation with uniform particle size distribution, optimal surface charge and sufficient drug loading. PEGylation of the emulsion would impart stealth properties to the system, aiding in longer circulation time. Physicochemical characterization of the formulation revealed successful drug loading and desirable size range attainment. Short term stability studies highlight the effect of PEGylation in maintaining the desired attributes of developed formulation. The developed showed promising results and can be evaluated further for long term stability, application of lyophilization technique and further evaluation to understand the efficacy of the developed nanoformulation.

**Keywords:** Nanocarrier, Drug Delivery, Lipid Emulsion, QbD, DoE.

# pH-gated Charge-Reversal Nanostructured Lipid Carriers for Targeted Chemotherapy

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Abstract: A novel charge-reversing nanostructured lipid carrier (CR-NLC) system was developed for cabazitaxel (CBZ) delivery to address limitations of Jevtana® (micellar formulation; polysorbate 80-associated hypersensitivity and non-targeted delivery). Stearylamine (SA) and dimethylmaleic anhydride (DMMA) were conjugated to form a pH-labile lipid conjugate enabling surface charge modulation from a moderately negative state at physiological pH (7.4) to a cationic state under acidic tumor conditions (pH ~6.5), a property expected to facilitate tumor-selective delivery. NLCs were prepared by solvent-free hot melt homogenization and probe sonication using GRAS-listed lipids, with glyceryl monostearate as solid and oleic acid as liquid lipid, forming a stable lipid matrix. Critical quality attributes (CQAs) including particle size (D50), PDI, zeta potential ( $\zeta$ ), and entrapment efficiency (EE%) were optimized using Design of Experiments (DoE). Optimized NLCs showed a D50 of 172.6 ± 8.8 nm, PDI 0.162  $\pm$  0.01, EE% 89.8  $\pm$  1.9%, and  $\zeta$  of –15.3  $\pm$  1.5 mV (pH 7.4) reversing to +21.7 ± 2.1 mV (pH 6.5), confirming pH-responsive charge reversal. In vitro release studies indicated sustained CBZ release (88.3% at 48 hrs) with faster release under acidic conditions (76.1% in 12hrs). SEM revealed spherical particles, while FTIR and 1H NMR confirmed SA-DMMA conjugation; XPS validated surface chemistry changes. The nanoparticles showed strong biocompatibility, with no significant hemolysis (<3% hemolysis), and demonstrated excellent serum stability. Storage stability testing over two months showed no significant variation in CQAs. This pH-responsive CR-NLC platform offers a biocompatible, tumor-targeted alternative to Jevtana®, reducing hypersensitivity risks while enhancing therapeutic potential of CBZ.

**Keywords:** Tumor-targeted nanomedicine, pH-responsive drug delivery, Nanostructured Lipid Carrier.

#### Hybrid Nanoparticles For Overcoming Multidrug Resistance In Tumors

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Abstract: Multidrug resistance (MDR) remains a major barrier to successful cancer chemotherapy, arising from mechanisms such as drug efflux, enhanced DNA repair, altered apoptosis signaling, and the tumor microenvironment. Conventional therapeutic agents often fail to achieve adequate intracellular concentrations in resistant tumor cells, leading to relapse and poor prognosis. Hybrid nanostructures, which combine two or more functional nanomaterials within a single platform, have emerged as a promising strategy to overcome MDR in tumors. These systems integrate the advantages of organic nanocarriers (liposomes, polymers, dendrimers) with inorganic or metallic counterparts (gold nanoparticles, mesoporous silica, magnetic nanoparticles), enabling multifunctional delivery. Such hybrid architectures can co-deliver chemotherapeutics and gene-silencing molecules, thereby suppressing efflux pump expression or inhibiting survival pathways. Furthermore, their stimuli-responsive properties allow controlled drug release in response to pH, redox potential, or external triggers such as light and magnetic fields, ensuring spatiotemporal precision. Surface modifications with targeting ligands enhance selective uptake by resistant cancer cells while minimizing off-target effects. Importantly, hybrid nanostructures facilitate multimodal theranostics by combining therapeutic payloads with imaging agents, aiding realtime monitoring of treatment response. Recent advances in multifunctional hybrid nanosystems have demonstrated improved therapeutic efficacy, reduced systemic toxicity, and potential for personalized cancer treatment. Overall, hybrid nanostructures hold immense potential as next-generation platforms to circumvent MDR and improve therapeutic efficacy in tumor management.

**Keywords:** Multidrug resistance, Hybrid nanostructures, multifunctional delivery, efflux pump expression, multimodal theranostics.

# Theranostic nanoparticles for simultaneous Diagnosis and theraphy G.Lakshmi Saranya\*,K. Kedareswari, G.Praneeth Goud, P.Sri Jyothi

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Abstract: Theranostic nanoparticles have emerged as a promising tool in nanomedicine, enabling simultaneous diagnosis and therapy for various diseases, including cancer. These nanoparticles are designed to integrate diagnostic and therapeutic capabilities, allowing for targeted delivery of therapeutics and real-time monitoring of treatment response. By leveraging the unique properties of nanoparticles, theranostic platforms can enhance the efficacy of treatments while minimizing side effects. This review highlights the design and applications of theranostic nanoparticles in cancer treatment and personalized medicine. We discuss the advantages of theranostic nanoparticles, including targeted therapy, enhanced imaging capabilities, and multimodal therapy. Additionally, we address the challenges associated with theranostic nanoparticle development, such as biocompatibility, targeting specificity, and scalability. Recent advances in theranostic nanoparticle research have shown promise in improving patient outcomes. For example, nanoparticles can be engineered to target specific cancer cells, delivering therapeutics while simultaneously providing diagnostic information through imaging modalities such as MRI or fluorescence. This integrated approach enables personalized treatment strategies, allowing for real-time monitoring of treatment response and adjustments to therapy as needed. Despite the potential of theranostic nanoparticles, several challenges must be addressed before clinical translation can be achieved. These include ensuring nanoparticle safety and biocompatibility, achieving precise targeting of diseased cells or tissues, and scaling up nanoparticle production while maintaining quality and consistency. In conclusion, theranostic nanoparticles hold great promise for revolutionizing disease management and improving patient outcomes. Further research is needed to overcome the challenges associated with theranostic nanoparticle development and to fully realize their potential in clinical applications.

**Keywords:** innovation, Nanoparticles, penetrative action.

### Formulation and Evaluation of polyherbal topical hydrogel for acute wound healing in type 2 diabetes mellitus

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Abstract: Background: Diabetic foot ulcers (DFUs) affect nearly 25% of diabetic individuals and are primarily caused by persistent hyperglycemia and neuropathy. These conditions hinder wound healing, leading to increased risks of infection, amputation, and mortality. To address the multifactorial pathophysiology of DFUs—specifically delayed healing, inflammation, and infection—a novel polyherbal gel formulation was developed as a costscalable effective and treatment Methodology: The formulation was evaluated using multiple in vitro assays. Scratch assays assessed keratinocyte migration and wound closure, while MTT assays determined cell viability and cytotoxicity at various dilutions (1:1 to 1:16). Gene expression analysis measured the upregulation of key wound-healing biomarkers—VEGF, TIMP1, and IL-6. Texture profile analysis evaluated the gel's physical properties. Antimicrobial activity was tested using zone inhibition Results: At a 1:16 dilution, the formulation achieved 78.1% wound closure in scratch assays, indicating enhanced keratinocyte migration. MTT assays confirmed high cell viability and safety. Gene expression studies showed a 1.6-fold increase in VEGF (angiogenesis), a 2.5-fold rise in TIMP1 (matrix remodeling), and elevated IL-6 (inflammatory response). Texture analysis revealed ideal topical properties: gumminess (121.00 g), springiness (4.92 mm), hardness (175.00 g), and cohesiveness (0.69) at pH 6.8. Antimicrobial studies showed significant inhibition zones. Conclusion: The polyherbal gel exhibits excellent antimicrobial, angiogenic, and regenerative potential. Its safety, affordability, and ease of application make it a promising treatment for

DFUs, offering improved patient outcomes and reduced healthcare burden.

**Keywords:** Diabetic Foot Ulcer, Polyherbal, wound healing, gene expression.

### Esterase-induced release of a theranostic prodrug in lysosomes for improved therapeutic efficacy and lower systemic toxicity

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Abstract: 5-Fluorouracil (5-FU) remains one of the most widely used chemotherapeutic agents but suffers from severe systemic toxicity due to its non-selective inhibition of thymidylate synthase. To overcome this limitation, we designed a physiologically benign theranostic prodrug, PD, by conjugating 5-FU with a fluorophore and a lysosome-targeting morpholine moiety via an ester linkage. The design enables selective activation by esterase (Est), which is overexpressed in many cancers, including glioblastoma (U87) and ovarian (SKOV-3) cells.Upon Est-mediated cleavage, PD releases 5-fluorouracil-1-acetic acid (FUA), a precursor of 5-FU, leading to sustained and site-specific drug release within lysosomes. This mechanism translated into enhanced cytotoxicity:  $IC_{50}$  values of ~20  $\mu$ M (U87) and ~36  $\mu$ M (SKOV-3) were achieved after 48 h, significantly lower than the IC<sub>50</sub> ( $\sim$ 50  $\mu$ M) of free 5-FU. Notably, PD exhibited excellent biocompatibility in normal CHO cells (~95% viability at 50 μΜ), confirming its potential to reduce systemic toxicity. Beyond therapeutic action, PD provides a "turn-on" fluorescence signal upon esterase-triggered activation, offering simultaneous imaging capability. Flow cytometry confirmed both early and late apoptosis in U87 cells, while CAM assay revealed marked antiangiogenic activity. Furthermore, PD demonstrated superior performance in a 3D HeLa multicellular spheroid model, reinforcing its promise for clinically relevant tumor environments. Overall, PD represents a multifunctional platform combining selective 5-FU delivery, reduced off-target toxicity, and real-time fluorescence imaging, highlighting its strong potential for cancer theranostics.

**Keywords:** Theranostic prodrug, 5-Fluorouracil (5-FU), Esterase-responsive drug delivery, Tissue selectivity, Fluorescence imaging.









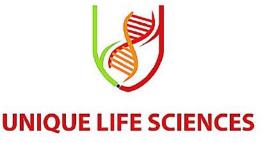










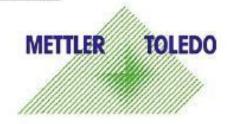




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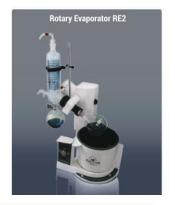






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