magnus Group

11th Edition of Global Conference on

Pharmaceutics

and Novel Drug Delivery Systems

19-21
Sept, 2024
Rome, Italy

Venue: NH Villa Carpegna Via Pio IV, 6, 00165 Roma RM, Italy

BOOK OF ABSTRACTS

SEPT

19-21

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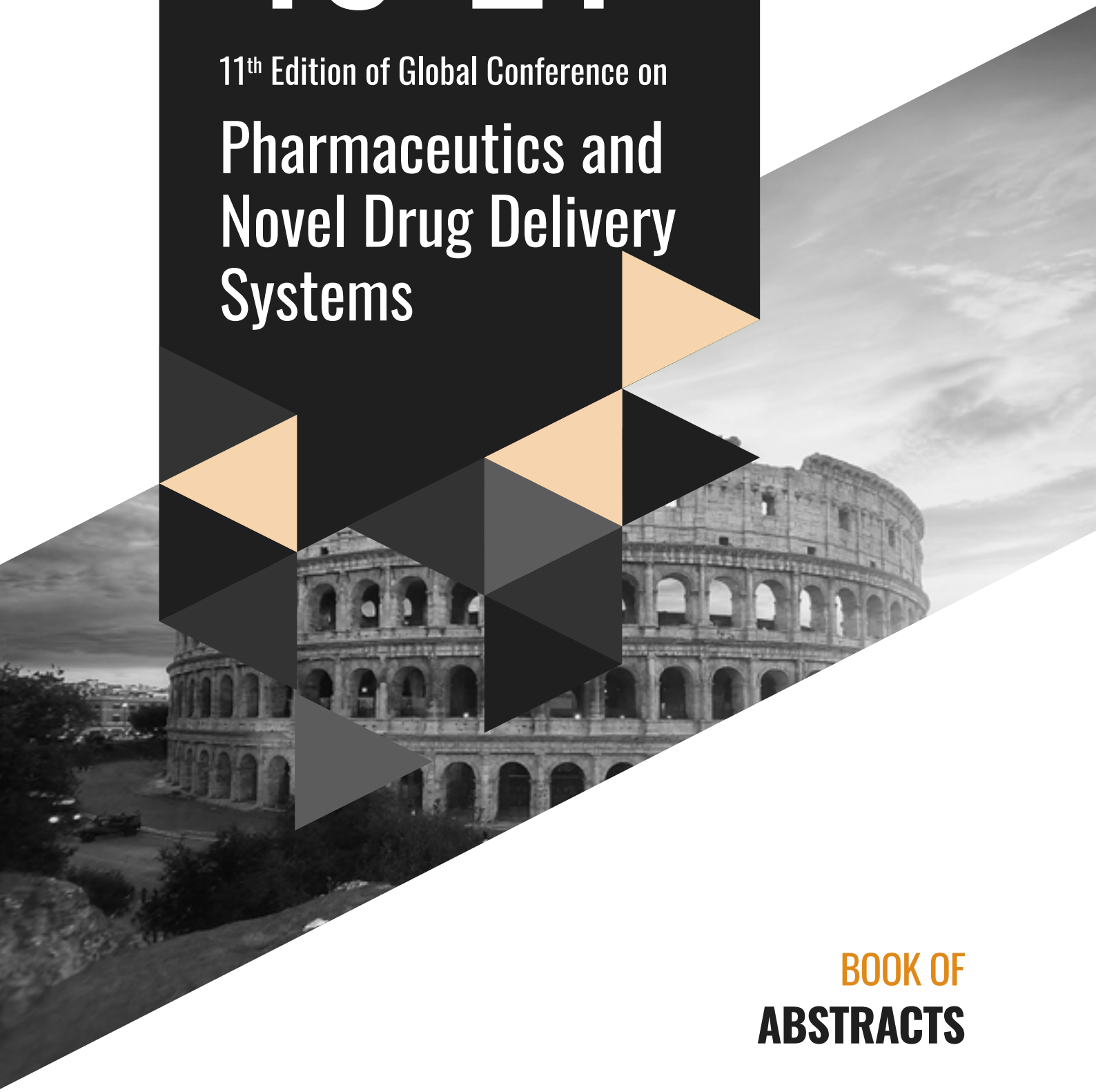
Pharmaceutics and Novel Drug Delivery Systems



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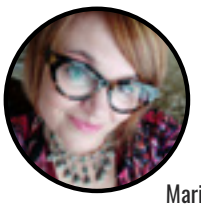

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Thank You All...

Speakers

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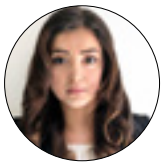

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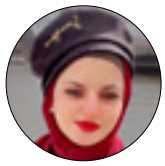

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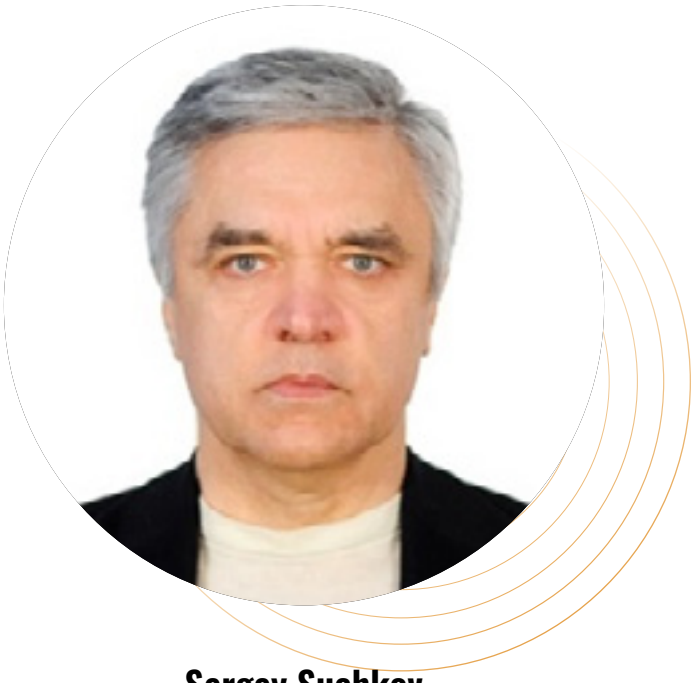
Thank You All...

Welcome Message



Sergey Suchkov

The Russian University of Medicine and Russian Academy of Natural Science-Moscow, Russian Federation

Dear Colleagues, Scientists, Biodesigners, Bioengineers, Clinicians and Friends,

It gives us a great pleasure to welcome you to the 11th Edition of Global Conference on Pharmaceutics and Novel Drug Delivery Systems, to be held in September 19-21, 2024, in Rome, emerged as a unique place, a promising idea, or as a phenomenal network of associated symbols and forms, and thus offering you a kaleidoscope of brilliances.

The Conference is designed to canvas a variety of contemporary considerations of interest to medical and biopharma world as well as other allied healthcare providers. The Conference will thus feature a highly interactive and multi-disciplinary Program including initiatives to address the entire Biomedical pathways to the latest fundamental, applied and translational applications in Drug Discovery, Drug Delivery and Biopharmacy.

This global wvent will be one of the great platform is to share our thoughts and exchange ideas on how to chart our journey forward to reach new heights, since the strategic goal of the conference is to promote translational and research and developmental activities in Drug Discovery and Novel Drug Delivery Systems. Another goal is to pro-mote scientific information interchange between researchers, drug designers, biodevelopers,, students, and practi-tioners working in the grand medicines-related world. And the third goal is the perfect blend of learning and net-working, whilst assembling a group of world leaders in the expanding pharmacy fields. So, this conference is a distinguished event offering a unique opportunity to explore and discuss the latest developments, breakthroughs, and challenges in the realm of drug delivery, and, globally, in the latest trends in design-inspired Biomanufacturing and Biopharma as a whole.

We hope you gain an insight into novel, cutting-edge translational technologies from brilliant experts, exuberant researchers, and talented student communities. And your presence is an implication towards your commitment to making positive moves in the integration of the Grand Academy, Design-driven Biopharmacy and Biomanufactur-ing in your country and throughout the world.

We hope to see you all in Rome on September 19-21, 2024, to enjoy the event along with the exceptional beauty of the ancient, modern simultaneously and unique Rome city globally. And thus extend a heartfelt Welcome on this occasion to see you at the Event!

Welcome Message

Luis Jesus Villarreal Gomez

FCITEC - Universidad Autónoma de Baja California, Mexico

Dear esteemed delegates and guests,

It is my great pleasure to welcome you to the 11th Edition of the Global Conference on Pharmaceutics and Novel Drug Delivery Systems. This gathering represents a pivotal opportunity for us to explore cutting-edge advancements in drug formulation and delivery technologies. As we convene, let us embrace the spirit of collaboration, share our latest research, and inspire innovative solutions that will transform patient care worldwide. Together, we can pave the way for a future where novel drug delivery systems enhance the efficacy and accessibility of therapeutic interventions.

ABOUT
MAGNUS GROUP

Magnus Group, a distinguished scientific event organizer, has been at the forefront of fostering knowledge exchange and collaboration since its inception in 2015. With a steadfast commitment to the ethos of Share, receive, grow, Magnus Group has successfully organized over 200 conferences spanning diverse fields, including Healthcare, Medical, Pharmaceutics, Chemistry, Nursing, Agriculture, and Plant Sciences.

The core philosophy of Magnus Group revolves around creating dynamic platforms that facilitate the exchange of cutting-edge research, insights, and innovations within the global scientific community. By bringing together experts, scholars, and professionals from various disciplines, Magnus Group cultivates an environment conducive to intellectual discourse, networking, and interdisciplinary collaboration.

Magnus Group's unwavering dedication to organizing impactful scientific events has positioned it as a key player in the global scientific community. By adhering to the motto of Share, receive, grow, Magnus Group continues to contribute significantly to the advancement of knowledge and the development of innovative solutions in various scientific domains.

ABOUT
PDDS 2024

Magnus Group is thrilled to invite you to the **11th Edition of the Global Conference on Pharmaceutics and Novel Drug Delivery Systems**, taking place virtually from **September 19-21, 2024**. This year's conference theme, "*Advancements in Pharmaceutics: Navigating the Future of Drug Delivery*," underscores our commitment to exploring the latest breakthroughs and innovations in the field.

This international summit is a continuation of our tradition of fostering collaboration and providing access to cutting-edge scientific insights, emerging trends, and revolutionary technologies in Pharmaceutics and Drug Delivery Systems. With significant strides in pharmaceutical innovation, PDDS 2024 offers a platform to delve into novel technologies, creative approaches, and strategies aimed at enhancing drug and biomedical research and development.

Throughout the event, participants can look forward to dynamic sessions, interactive discussions, oral and poster presentations, and inspiring keynote talks. This congress is crafted to promote collaboration and drive progress in the field, presenting a unique chance to connect with leading scientists globally and gain valuable insights on advancing pharmaceuticals from research to market.

Join us at PDDS 2024 and be part of this transformative experience!

ABOUT
CPD Accreditation

Continuing Professional Development (CPD) credits are valuable for PDDS 2024 attendees as they provide recognition and validation of their ongoing learning and professional development. The number of CPD credits that can be earned is typically based on the number of sessions attended. You have an opportunity to avail 1 CPD credit for each hour of Attendance. Some benefits of CPD credits include:

Career advancement: CPD credits demonstrate a commitment to ongoing learning and professional development, which can enhance one's reputation and increase chances of career advancement.

Maintenance of professional credentials: Many professions require a minimum number of CPD credits to maintain their certification or license.

Increased knowledge: Attending PDDS 2024 and earning CPD credits can help attendees stay current with the latest developments and advancements in their field.

Networking opportunities: Pharmaceutics Conference provide opportunities for attendees to network with peers and experts, expanding their professional network and building relationships with potential collaborators.

Note: Each conference attendee will receive 20+ CPD credits.

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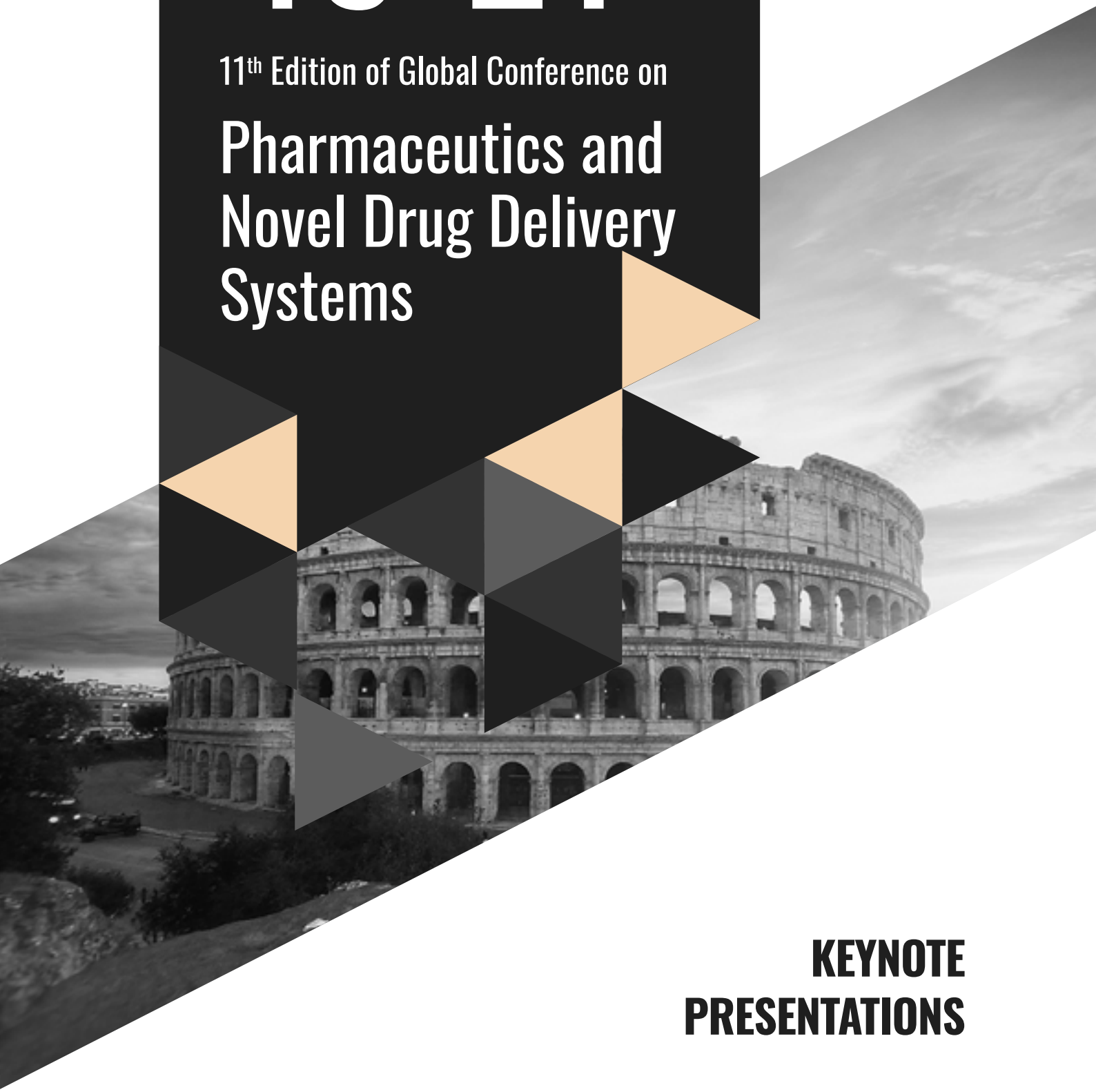


KEYNOTE PRESENTATIONS

Emerging formulation and delivery applications of vitamin E TPGS

Vitamin E TPGS (d-α-tocopheryl polyethylene glycol 1000 succinate) combines the functions of solubilizer, emulsifier, and absorption enhancer of lipophilic and poorly soluble drugs. In addition, it enhances drug bioavailability and efficacy through inhibition of the P-glycoprotein mediated drug efflux and other mechanisms which reduce first-pass metabolism and facilitate its transport, cell uptake and function. The safety and efficacy of TPGS expanded research and development in major areas. The presentation will review emerging applications of vitamin E TPGS which include:

- Multi-drug resistance and first-pass metabolism and their effect on drug efficacy, especially in cancer chemotherapy.
- Formation of prodrugs and drug conjugates and their role on drug efficacy and adverse effects.
- Synthesis of TPGS based polymers and their role in drug encapsulation, intracellular uptake, therapeutic effects, and safety.
- Excipient in nanomedicine and targeted drug delivery systems for increased therapeutic effect and reduced toxicity.
- Interactions with active pharmaceutical ingredients through antioxidant function and other mechanisms.
- Function as active pharmaceutical ingredient by selective induction of apoptosis of some cancer cells lines.
- Parenteral administration, a major component of the emerging applications of drug formulation including mRNA, peptide, and other novel drug categories.

Andreas M Papas PhD

Adjunct Professor of the College of Medicine, East Tennessee State University CEO, Antares Health Products Inc, USA

Biography

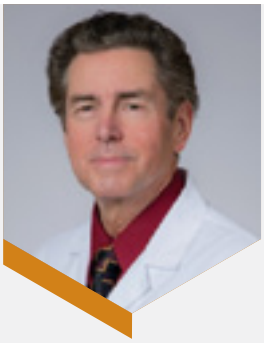
Dr. Papas is Adjunct Professor of the College of Medicine, East Tennessee State University and CEO and member of the Board of Directors of Antares Health Products, Inc. A Fulbright Scholar, Dr. Papas is a graduate of the University of Illinois and author of The Vitamin E Factor paperback and editor of the scientific book Antioxidant Status, Diet, Nutrition and Health. Dr. Papas also founded YASOO Health and led the company as President and Chair of the Board of Directors. He developed product concepts and managed successful commercialization including formulation, clinical evaluation supported by the National Institutes of Health and the Cystic Fibrosis Foundation, stability and safety testing, pilot, and commercial production.

Perillyl alcohol (NEO100), a monoterpene with versatile applications for cancer therapy

Perillyl alcohol is a naturally occurring monoterpene related to limonene. We have synthesized a clinical-grade version, called NEO100 (NeOnc Technologies, Inc., Los Angeles, California), which has revealed a variety of highly promising characteristics that we are exploring toward the development of improved cancer-therapeutic regimens. NEO100 can be delivered via intranasal applications, which exploits direct nose-to-brain transport, and an ongoing clinical Phase 2 trial with recurrent glioblastoma patients is generating promising results. In preclinical brain cancer models, we have further shown that intranasal NEO100 can act as a carrier to bring along other cancer drugs, such as bortezomib, for improved delivery to the malignant lesions in the brain. When given via intra-arterial injection, NEO100 was shown to safely and reversibly open the Blood-Brain Barrier (BBB) of mice, which enables other cancer drugs circulating in the bloodstream to effectively enter the brain and kill brain cancer cells; in the absence of NEO100, these drugs are unable to cross the BBB and do not exert brain-targeted activity. In further applications, we covalently conjugated NEO100 to several other, already established drugs. For example, conjugation of NEO100 to Temozolomide (TMZ), an alkylating agent, resulted in a novel fusion compound called NEO212 (NeOnc Technologies). Our studies in diverse preclinical tumor models established that NEO212 is well-tolerated and highly effective against different cancer types, and a Phase 1 clinical trial has begun. This talk will provide an overview of our research into the versatile applications of perillyl alcohol/NEO100 toward more effective cancer treatments.

Audience Take Away Notes

- Perillyl alcohol (POH) enables direct nose to brain transport of drugs.
- POH is able to open the blood-brain barrier (BBB).
- Conjugation of POH to established drugs enables BBB penetration.
- POH has entered clinical trials as NEO100.



Axel H. Schönthal[1]*, Clovis O. da Fonseca[2], Thomas C. Chen[3,4]

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[3]Department or Neurological Surgery, Keck School of Medicine, University of Southern California, Los Angeles, California, United States.

[4]NeOnc Technologies, Inc., Westlake Village, California, United States

Biography

Axel H. Schönthal, PhD, is Associate Professor in the Department of Molecular Microbiology and Immunology at the Keck School of Medicine of the University of Southern California (USC) in Los Angeles. He is also Associate Dean for Biomedical Masters Programs, and Faculty Fellow of the USC Center of Excellence in Teaching. He obtained his PhD from the University of Karlsruhe, Germany, and did his postdoc at the Cancer Center of the University of California in San Diego (UCSD). At USC, he pursues the development of novel anticancer agents and novel delivery methods to improve cancer therapeutic efficacy. As of 2024, he has authored over 200 scholarly articles and chapters with an H-Index of 53.

Why we need to advance from data focus to knowledge focus for managing healthcare transformation?

PHealth and social care systems around the globe currently undergo a transformation towards personalized, preventive, predictive, participative Precision Medicine (5PM), considering the individual health status, conditions, genetic and genomic dispositions, etc., in personal, social, occupational, environmental and behavioral context. This transformation is strongly supported by technologies such as micro- and nanotechnologies, advanced computing, artificial intelligence, edge computing, etc. For enabling communication and cooperation between actors from different domains in different context with different objectives, using different methodologies, languages and ontologies based on different education, experiences, etc., we have to understand the transformed health ecosystems and all its components in structure, function and relationships in the necessary detail ranging from elementary particles up to the universe. That way, we advance design and management of the complex and highly dynamic ecosystem from data to knowledge level. The challenge is the consistent, correct and formalized representation of the transformed health ecosystem from the perspectives of all domains involved, representing and managing them based on related ontologies. For mapping the domain perspectives, the ISO/IEC 21838 Top Level Ontologies standard is used. Thereafter, the outcome can be transformed into implementable solutions using the ISO/IEC 10746 Open Distributed Processing Reference Model. Model and framework for this system-oriented, architecture-centric, ontology-based, policy-driven approach have been developed by the author and meanwhile standardized as ISO 23903 Interoperability and Integration Reference Architecture. The formal representation of any ecosystem and its development process including examples of practical deployment of the approach are presented in detail. This includes correct systems and standards integration and interoperability solutions.

Audience Take Away Notes

- The audience will learn to formally and correctly represent and manage multidisciplinary business systems for any use case in any context
- This allows re-engineering any specification and artifacts to enable their integration and interoperability
- That way, the re-use of existing systems, but also the development of advanced solutions (e.g. 5PM) is enabled
- The presented solutions has been defined mandatory for all multi-disciplinary projects and specification at the Health Informatics TCs od ISO and CEN, but also other SDOs
- The approach assists in the design and management of existing and new solutions

AProf. Dr. Habil. Bernd Blobel, FACMI, FACHI, FHL7, FEFMI, FIAHSI

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[2]Faculty European Campus Rottal-Inn, Deggendorf Institute of Technology, 94469 Deggendorf, Bavaria, Germany
[3]First Medical Faculty, Charles University Prague, 11000 Staré Město, Czech Republic
[4]Department of Informatics, Bioengineering, Robotics and System Engineering, University of Genoa, 16145 Genoa, Italy

Biography

Dr. Bernd Blobel studied Mathematics, Technical Cybernetics and Electronics, Bio-Cybernetics, Physics, Medicine and Informatics at the University of Magdeburg and other universities in the former GDR. He received his PhD in Physics with a neurophysiological study. Furthermore, he performed the Habilitation (qualification as university professor) in Medicine and Informatics. He worked in Environmental Medicine, was Head of the Institute for Biometrics and Medical Informatics at the University of Magdeburg, before he moved as Head of the Health Telematics Project Group to the Institute for Integrated Circuits of the Fraunhofer Society in Erlangen. Thereafter, he acted until his retirement as Head of the German

National eHealth Competence Center at the University of Regensburg. He was German Representative to many SDOs such as HL7, ISO, CEN, OMG, SNOMED, etc., also chairing the national mirror groups. He is Fellow of several international academies, and published more than 600 papers and published/edited many books.

Integrating QbD for the solubility amelioration of Ivacaftor loaded solid lipid nanoparticles in-vitro & in-vivo

The present investigation is focused on the application of the Quality by Design (QbD) approach for the development and optimization of SLN formulation of Ivacaftor (IVF). IVF SLN was formulated with the help of homogenization and ultrasonication methods by incorporating Labrasol as liquid lipid, Cetyl palmitate as solid lipid and Polysorbate 20 as the surfactant. The independent variables such as the amount of Lipid (X_1) and amount of surfactant (X_2) were studied for their effect on dependent variables namely entrapment efficiency and particle size. The final formulation of IVF-SLN showed a narrow range in size distribution (PDI-0.276±0.014) with a particle size of 102.3±2.34 nm and entrapment efficiency of 78.32 ± 2.36. IVF incorporation into the imperfect crystal lattice was confirmed with the help of a DSC study. In-vitro and In-vivo diffusion showed enhanced profiles for the optimized formulation of IVF-SLN.

Audience Take Away Notes

- This methodology emphasizes understanding the process and product variables to ensure a high-quality final product.
- This knowledge can be used to create more effective and optimized drug formulations in their projects.
- This methodology can make the designer's job more efficient by reducing trial-and-error experimentation, leading to more consistent and predictable results.

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[1]Faculty of Pharmaceutical Sciences, The ICFAI University, Baddi, Himachal Pradesh, India

[2]Department of Pharmaceutics and Pharmaceutical Technology, Shree S.K. Patel College of Pharmaceutical Education and Research, Ganpat University, Mehsana, Gujarat, India

Biography

Dr. Bhupendra Prajapati is a Professor in Department of Pharmaceutics, Shree S.K.Patel College of Pharmaceutical Education and Research, Ganpat University, Gujarat, India. He has 20 years of academic and research experience and published more than 250 research and review works in international and national Journals. He authored 150 book chapters in the field of novel drug delivery. He edited 20 books with publishers like Elsevier, AAP CRC, Wiley, Springer and Jenny Stanford. He published three Indian patent and three applications under evaluation. He is a reviewer in many high impact journals and is on the editorial board member.

Pharmacokinetic properties of TNX-102 SL, a sublingual formulation of Cyclobenzaprine hydrochloride

TNX-102 SL is a sublingual formulation for Cyclobenzaprine (CBP) Hydrochloride (HCl) designed for bedtime dosing that is being developed for Fibromyalgia (FM) via improvement in sleep quality. TNX-102 SL is a eutectic formulation of CBP and D-mannitol (see companion abstracts, Fogarty et al., and Nebuloni et al.,), which contains potassium phosphate dibasic as a basifying agent, which formulation disintegrates in saliva and rapidly dissolves. The addition of the basifying agent results in a higher local pH, thereby rendering CBP in an un-ionized state at the mucosal membrane, thus rapidly driving CBP across the mucosa into the systemic circulation. TNX-102 SL tablets were produced and used in a Pharmacokinetic (PK) study in healthy human volunteers. TNX-102 SL was well tolerated, and side effects were similar to those of oral CBP although some subjects experienced local numbness in the mouth that was transient and self-limited. Our data show that TNX-102 SL 2.8 mg tablets deliver CBP rapidly across the sublingual mucosal membrane into plasma resulting in 12 times faster absorption relative to oral CBP Immediate Release (IR) 5 mg tablets and provides significantly increased plasma CBP levels during the first 2 hours post-dose (mean exposure was 338% higher at 1 hour and 83% at 2 hours post-dose). The relative bioavailability was 154% higher when compared to the oral CBP IR. Sublingual administration of CBP via TNX-102 SL bypasses hepatic "first-pass" metabolism resulting in substantially lower levels (via reduction of C_{max} and AUC) of the long-lived undesired active metabolite, Norcyclobenzaprine (nCBP). Our data show during typical sleep hours (0-8 hours post-dose), CBP steady state and AUC are higher than nCBP post TNX-102 SL administration, which optimizes the effects of CBP on the sleeping brain. Cyclobenzaprine has a unique receptor binding profile with high potency binding and antagonist activity at serotonin 5-HT_{2A}, a_1-adrenergic, H_1-histaminergic and M_1-muscarinic acetylcholine receptors. Antagonism at these receptors has been suggested to have roles in enhancing different aspects of sleep quality. The pharmacokinetic properties of TNX-102 SL in humans appear to be well-suited for its development as a potential chronic bedtime treatment for fibromyalgia.

Audience Take Away Notes

- Addition of a basifying agent promotes rapid transmucosal absorption, Sublingual administration by-passes first pass metabolism
- Expand their knowledge in the field of drug delivery
- This research could be used by other faculty to expand their research or teaching by offering alternative approaches for the delivery of pharmaceuticals
- This provides a practical solution to a problem that could simplify or make a designer's job more efficient

Bruce Daugherty[1]*, Siobhan Fogarty[2], Gregory Sullivan[1], Seth Lederman[1]

[1]Tonix Pharmaceuticals, Inc., 26 Main Street, Suite 101, Chatham, New Jersey 07928 USA

[2]Tonix Pharmaceuticals Inc. Suite 30, #3 Marine Road, Dun Laoghaire, Dublin A96 HW25, Ireland

Biography

Dr. Daugherty received his AB degree in Biology at Washington University in St. Louis and went on to receive his MS and PhD in Molecular Genetics, both from Rutgers University. Dr. Daugherty has held multiple positions at Hoffman La-Roche, Merck, and Tonix Pharmaceuticals, and has worked as a consultant for academia and industry. Dr. Daugherty also holds an MBA from Emory University. He has published more than 50 original research articles, has been an invited speaker at multiple international conferences, and is an inventor on several issued patents and patent applications.

Liver biopsy handling of Metabolic-Associated Fatty Liver Disease (MAFLD): The children's hospital of Eastern Ontario grossing protocol

Introduction: Metabolic-(non-alcoholic) Associated Fatty Liver Disease (MAFLD/NAFLD) has increasingly become a worldwide epidemic. It has been suggested that renaming NAFLD to MAFLD is critical in identifying patients with advanced fibrosis and poor cardiovascular outcomes. There are concerns that the progression to Non-Alcoholic Steatohepatitis (NASH) may become a constant drive in the future healthcare of children and adolescents. There is a necessity to tackle the emerging risk factors for NASH-associated Hepatocellular Carcinoma (HCC).

Methods: We carried out a systematic review study using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) parameters involving a literature search of academic databases (PubMed, Scopus, Medline, Google Scholar, and Cochrane Database, 2011– 2023) targeting specifically the handling of liver biopsies for MAFLD/NAFLD. Data were extracted and used to determine the current Children's Hospital of Eastern Ontario grossing protocol.

Results: The studies show the ability to detect MAFLD/NAFLD in liver biopsies with accuracy by implementing Oil red O staining and preserving the rest of the frozen tissue for studies involving Single Nucleotide Polymorphisms (SNPs). Here, we present the current protocol of liver biopsy separated between pre-analytical, analytical, and post-analytical handling. Genetic association investigations have identified single nucleotide polymorphisms implicated in the progression of MAFLD-HCC, many of which seem to belong to the lipid metabolism pathways. PNPLA3 rs738409 variant, TM6SF2 rs58542926 variant, MBOAT7 rs641738 variant, and GCKR variants seem to be significantly associated with NAFLD disease susceptibility.

Conclusions: A thorough examination of the liver biopsy in MAFLD/NAFLD is critical for the management of patients with this disease. Grossing of the liver biopsy is key to identifying histologic, immunophenotypical, and ultrastructure data and properly preserving tissue for molecular genomics data, specifically for SNPs identification.

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[3]Division of Gastroenterology, Hepatology and Nutrition, Children's Hospital of Eastern Ontario, University of Ottawa, Ottawa, ON, Canada

Biography

Consolato M. Sergi is the Chief of the Anatomic Pathology Division at the Children's Hospital of Eastern Ontario, Professor of Pediatrics and Pathology, University of Alberta and Ottawa, Canada. Dr. Sergi is Canadian, born in Rome (Italy), obtained his MD degree with honors, qualification in Pediatrics, and Pediatric Pathology Fellowship at the University of Genoa, Italy. Dr. Sergi obtained his qualification in Pathology at the Ruprecht Karl University of Heidelberg, Germany, the Clinical Reader title at the University of Bristol, UK, PhD/Habilitation at the University of Innsbruck, Austria, MPH in Austria, and FRCPC (Pathology) from the Royal College of Physicians and Surgeons of Canada. In his research, he established his Canadian laboratory in August 2008. He welcomed more than 100 graduate MSc/Ph.D. students, fellows, undergraduate and summer students with on-going teaching in Genetics and Pathology. Dr. Sergi is a Consultant of Carcinogenesis in Experimental Animals at the WHO/IARC, Lyon, France, and an "ad-hoc" Peer-Referee for the National Toxicology Program, NIH, USA. His areas of interest are Biology and Pathology of the Cardiovascular/Gastrointestinal System and Gut/Bile Microbiome as well as Bone Cell Biology. Dr. Sergi has >300 peer-reviewed PubMed publications (h-index: 23, RG-score: 44.26, > 2,500 citations). He identified the role of apoptosis in the ductal plate malformation of the liver (Am J Pathol, 2000), a new CTL4/Neu1 gene fusion transcript

in sialidosis (Hum Genet 2001, FEBS Lett 2002, J Med Genet 2003), two new genes, i.e., WDR62, which encodes a centrosome-associated protein (Nat Genet 2010) and OTX2, mutations of which contribute to dysgnathia (J Med Genet 2012), as well as characteristics of the bile microbiome (Infect Drug Resist 2019, HPB (Oxford) 2019, J Med Microbiol 2018, Eur J Clin Microbiol Infect Dis, 2018). He is editor in chief and in the editorial board of prestigious medical journals and international agencies.

Photodegradation of two pharmaceutical namely Levofloxacin and Atorvastatin via Chitosan/Ag/TiO_2 3D printed scaffold

Pharmaceuticals are highly persistent towards hydrolysis, adsorption, biodegradation, and abiotic degradation. As a result, such pharmaceutical compounds are not effectively removed during sewage treatment. Furthermore, sewage effluents and hospital effluents are important point sources of pharmaceutical residues in surface water and groundwater. The potential impact of pharmaceutical residues on aquatic organisms and potentially humans through endocrine-disrupting effects or pathogenic bacteria developing antibiotic resistance. In this study the photooxidation of levofloxacin and atorvastatin was performed by chitosan/Ag/TiO_2 3D printed scaffolds, Ag nanoparticles elevated the photocatalytic yields. For maximum removals of levofloxacin and atorvastatin the optimum operational conditions (nanocomposit dose, pharmaceutical concentrations, photodegradation time, pH, temperature) were researched. The reuse properties and physıcochemical properties of the Chitosan/Ag/TiO_2 3D printed scaffolds was also investigated.

Delia Teresa Sponza

Dokuz Eyll University, Engineering Faculty, Environmental Engineering Department, Buca İzmir Turkey

Biography

Prof. Dr. Delia Teresa Sponza is currently working as a professor at Dokuz Eylül University, Department of Environmental Engineering. Scientific study topics are; environmental engineering microbiology, environmental engineering ecology, treatment of fluidized bed and activated sludge systems, nutrient removal, activated sludge microbiology, environmental health, ındustrial toxicity and toxicity studies, the effect of heavy metals on microorganisms, treatment of toxic compounds by anaerobic/aerobic sequential processes, anaerobic treatment of organic chemicals that cause industrial toxicity and wastewater containing them, anaerobic treatability of wastewater containing dyes, treatment of antibiotics with anaerobic and aerobic sequential systems, anaerobic and aerobic treatment of domestic organic wastes with different industrial treatment sludges, treatment of polyaromatic compounds with bio-surfactants in anaerobic and aerobic environments, treatment of petrochemical, textile and olive processing industry wastewater by sonication, treatment of olive processing industry wastewater with nanoparticles and the toxicity of nanoparticles. Dr. Teresa Sponza has many international publications with an H index of 42 and 6000 citations.

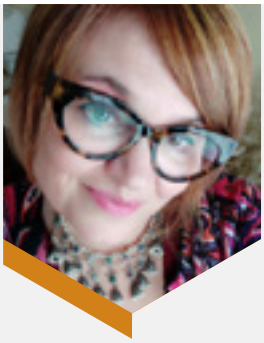
Crystallographic in pharmaceutical filed: New frontiers

Most commonly produced and marketed drugs are formulated with the pharmacologically active ingredient in solid form (crystalline or amorphous). The solid form is carefully chosen for its characteristics, to increase the stability of the drug, facilitate its formulation, optimize its dosage and simplify the use method. Now the importance of research (aimed at identifying, preparing and formulating new drugs) is recognized, both in the academic and productive fields, the pharmaceutical chemist is delegated with the task of finding new and rapid methods of investigation of solid forms. In this study, some aspects of the theory of crystal chemistry of drugs, techniques for identification and characterization are discussed and some examples of crystallization and characterization of drugs are reported. The frontier of knowledge in the development of new "crystallographic" theories constitutes the powerful numerical algorithms for data analysis. Today synchrotrons, computing power and new approaches to the structural problem in the pharmaceutical field are starting to have a new vision in the pharmaceutical crystal chemistry.

Keywords: Crystallographic, Chemical Characterization Pharmaceutical Solid Forms, Algoritms.

Audience Take Away Notes

- Knowledge of aspects of the theory of crystal chemistry of drugs
- Increase in knowledge of characterizations of pharmaceutical compounds Knowledge in the frontier of the development of new "crystallographic" theories



Gamberini M.C.

Department of Life Sciences, University of Modena and Reggio Emilia, via G. Campi 103, Modena, 41125, Italy

Biography

Maria Cristina Gamberini has a degree in Chemistry, her first period abroad at the Polytechnic of Lausanne has been dedicated to the study of nanomaterials using spectroscopic techniques. She is professor at the University of Modena and Reggio Emilia in the Medicinal Analysis Laboratory for the degree course in Chemistry and Pharmaceutical Technologies. She has published more than 60 articles H-Index 22 in SCI(E) journals.

Immunogenicity of therapeutic antibodies: Role of aggregation in T lymphocyte response

Immunogenicity has been described as a major concern to the clinical use of therapeutic antibodies, as treated patients frequently develop Anti-Drug Antibodies (ADA) with potential neutralizing capacities leading to loss of clinical response. Among other factors, it is now well accepted that protein aggregation is associated with an enhanced potential for immunogenicity. Moreover, the presence of ADA suggests a CD4 T-cell dependent adaptive immune response and therefore a pivotal role for antigen presenting cells, such as dendritic cells.

This talk will focus on the optimization of *in vitro* methods to evaluate the potential of aggregated therapeutic antibodies to induce early adaptive immune responses that could drive ADA development.

We first developed a model of nano-sized, well-characterized Infliximab (IFX) aggregates by exposing the native antibody to ultraviolet light. Then, using an original autologous co-culture model with monocyte-derived Dendritic Cells (moDC) and CD4 T cells, we identified a higher frequency of CD4 T cells specific of IFX aggregates compared to the native antibody. Even though IFX aggregates did not induce moDC maturation, they tend to be more internalized by healthy donors' moDC compared to native IFX, with endocytosis being the main pathway. The implicated receptors and mechanisms are currently under investigation. Our results indicate that nano-sized aggregates have a significant role in immune system activation, emphasizing the importance of assessing the implicated cellular mechanisms that drive the immune response to aggregated proteins. In conclusion, cell-based assays are valuable tools to anticipate and prevent immunogenicity of therapeutic antibodies.

Audience Take Away Notes

- Immunogenicity due to aggregation of therapeutic antibodies represent a significant challenge and our study highlights the importance of evaluating the immune effect of small aggregates as they could increase the probability of recruiting aggregate-recognizing CD4 T cells.
- Audience will learn information regarding the impact of therapeutic antibodies aggregates on innate and specific immune responses, and also some keys about the potential mechanisms that could give rise to immunogenicity.
- The presented data allow to gain insight the internalization and processing mechanisms of monoclonal antibodies by dendritic cells.
- In vitro cell-based models are non-clinical valuable tools for the assessment of therapeutic antibodies immunogenicity, and therefore can help for screening of therapeutic antibodies under development

Maria Lteif[1], Myriam Nabhan[1], Cécile Tardif[2], Claire Smadja[2], Marc Pallardy[1], Isabelle Turbica[1]*

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Biography

Dr. Isabelle Turbica is Assistant Professor in Biotechnology, at the School of Pharmacy of Paris-Saclay University since 2002, with skills that focus on therapeutic protein engineering and production. She is in charge of the Master degree "Pharmaceutical biotechnology and advanced therapies". Her research field of interest deals with the immunogenicity of biotherapeutics, as she develops cellular models to assess the potential of aggregated therapeutic proteins to induce immune responses. She's now interested in the description of cellular mechanisms involved in the activation of dendritic cells by the aggregates, along with the description of the switch towards adaptive immune responses, allowing the production of anti-drug antibodies.

Preparation and characterization of fibers crafted from PCL/PVP-ChAgG, coupled with investigating their suitability as wound dressings

Wound dressings play a pivotal role in wound care by cleansing, shielding, and covering wounds, thereby influencing healing duration, cost-effectiveness, and patient comfort. Electrospun fibers emerge as a promising avenue in this field due to their diverse attributes, including biocompatibility, biodegradability, mechanical robustness, and moisture management capabilities. The integration of antimicrobial properties is essential, motivating this investigation to develop wound dressings using electrospun nanofibers composed of a blend of Poly(Caprolactone)/Poly (Vinyl Pyrrolidone) (PCL/PVP) incorporated with a nanocomposite comprising Chitosan/Silver Nanocrystals/ Graphene Oxide (ChAgG). ChAgG, derived from corn-based Chitosan, garlic-sourced silver nanocrystals, and Graphene Oxide, was infused into the fibers via varying proportions of the ChAgG nanocomposite solution during electrospinning. Characterization employing techniques such as FTIR, XPS, and TEM confirmed the composition of the nanocomposites, while scanning electron microscopy assessed the morphology and diameter of the fibrous dressings. Thermal analyses and FTIR spectroscopy demonstrated successful incorporation of ChAgG into the polymeric matrix. Mechanical testing favored fibers containing 5% ChAgG for their suitability in wound dressing applications. Antibacterial assays revealed enhanced efficacy against Escherichia coli compared to Staphylococcus aureus. Future endeavors may entail biocompatibility assessments and animal studies to further validate the efficacy of the system, ultimately leading to the development of an optimized, antimicrobial wound dressing with competitive market potential.

Keywords: Wound Dressings, Electrospun Fibers, Chitosan, Silver Nanoparticles, Graphene.

Victoria Leonor Reyes Guzmán[1], Yoxkin Estévez-Martínez$_2$*, Rubi Vázquez Mora[2], Yesica Itzel Méndez Ramírez[2], Juan Antonio Paz González[1], Arturo Zizumbo López[3], Hugo Borbón[4], Eder Germán Lizarraga Medina[1], José Manue[1] Cornejo Bravo[6], Graciela Lizeth Pérez González, Arturo Sinue Ontiveros Zepeda, Armando Pérez Sánchez[1], Elizabeth Chavira-Martínez[5], Rafael Huirache-Acuña[8], Luis Jesús Villarreal Gómez[1,6]*

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Biography

Dr. Luis Villarreal, a research professor at the Faculty of Engineering and Technology Sciences, Autonomous University of Baja California, Mexico, is a Level 2 member of the National System of Researchers (SNII-CONACyT). With 47 indexed articles and 976 citations in Scopus, Luis has engaged in over 55 national and international congresses. Luis founded his leads the Journal of Technological Sciences (RECIT), contributing to editorial boards of Bentham, MDPI, and Hindawi. Serving as a thematic editor for INTECH, Luis reviews articles for Elsevier, Wiley, Springer, MDPI, and Hindawi. Dr. Villarreal evaluates research projects for funding in Mexico, Italy, and Peru and has supervised 12 bachelor's theses, 10 master's theses, and 5 doctoral theses. Luis research focuses on Biomaterials, including Tissue Engineering and Drug Delivery Systems, and Luis collaborates with companies like Corning (New York) and a private maxillofacial surgery clinic (Oakland, California).

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[8]Faculty of Chemical Engineering, Universidad Michoacana de San Nicolás de Hidalgo, Michoacán, Morelia, 58060, Mexico

Mannitol as eutectic forming agent for improved sublingual delivery of Cyclobenzaprine HCl

In solid drug product formulation, the knowledge of possible interactions between the drug substance and the excipients is a crucial point for the prediction of chemical and physical stability. Often, an excipient(s) can modify the biological activity and chemical stability of the API, even if the dissolution profile and/or chemical structure of the API are changed. In some cases, the excipient can improve the chemical and physical stability profile.

D-Mannitol is one of the excipients very often used in solid drug products and due to its physical properties, can improve or reduce the stability of the final formulation.

Following this statement, the compatibility of mannitol with Cyclobenzaprine HCl was investigated and interactions occurring were assessed.

Sublingual, transmucosal cyclobenzaprine is being developed for the treatment of fibromyalgia syndrome, Post-Traumatic Stress Disorder (PTSD), fibromyalgia-type Long COVID, acute stress disorder, agitation in Alzheimer's disease and alcohol use disorder. Furthermore, cyclobenzaprine has potential improving the quality of sleep, as a sleep deepener, or for treating sleep disturbances.

The compatibility between API (Cyclobenzaprine HCl) and D-Mannitol was investigated by DSC and based on findings, a eutectic formation was discovered during the mechanical mixing.

In order to confirm the eutectic formation and to characterize its physical properties, several binary mixtures at different ratios of API-excipient were prepared and analysed by DSC and by XRPD.

This type of interaction occurring between *Cyclobenzaprine HCl* and D-Mannitol (beta form) is an invariant physical interaction, because the mixture exists in thermal equilibrium when the two components are well mixed and stabilized.

The resulting solid macrostructure from a eutectic reaction depends on a few factors. The most important factor is the fact that the two solid solutions nucleate and bind together during a mechanical mixture.

This API is stable in tablet or capsule formulations for oral administration when combined with certain excipients. Increasing the absorption of a Sublingual formulation (SL) can have issues with the stability of the API and the physical compositions themselves, especially when a basifying agent (a chemical compound that increases the pH of solutions after dissolution of Cyclobenzaprine HCl is present).

M. Nebuloni[1]*, P. Colombo[1], S.Lederman[2]

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[2]Tonix Pharmaceuticals Holding Corp– South Dartmouth, MA (USA)

Biography

M. Nebuloni received his Doctorate Degree in Pharmaceutical Sciences from Milan University in 1974. From 1984 to 1995, he worked as a Senior Research Scientist at the Analytical Research Department of Lepetit Research Center, Milan DOW Chemical Pharmaceutical Group (European sites). His research focused on studying the chemical and physical properties of organic compounds during formulation development and safety aspects in industrial processes. From 1996 to 2012, he served as Senior Director for the Testing Lab (CRO) at REDOX snc in Monza, Italy (Consultant for international and national pharmaceutical companies for physical pharmacy of drug products development. Development of analytical methods in support to physical pharmacy troubleshooting in manufacturing plants). Currently, he is a Professor (annual assignment) at Milan and Parma Universities, Faculty of Pharmacy and Pharmaceutical Chemical Technology, Courses on Physical Pharmacy and Safety on Pharmaceutical Practice. He is also

Because eutectics have the potential to improve dissolution, they are employed to increase permeability in solid dispersions and absorption systems. The unexpected effect conferred by a mannitol eutectic on cyclobenzaprine SL properties include increased stability, despite intimate contact with a basifying agent and rapid dissolution. The compaction involved in tableting provides the intimate contact between API and D-mannitoland mutual solubility sufficient for eutectic formation. The cyclobenzaprine HCl – D-mannitol eutectic compositions is an unexpected example showing that eutectics can have improved stability and enable increase absorption than their non-eutectic counterparts.

the author of several publications in national and international journals on subjects related to Physical Pharmacy.

Hydrogen sulfide and substance P: Novel mediators and therapeutic targets for acute pancreatitis

Acute pancreatitis is a common clinical condition, for which there is no satisfactory treatment available at this time. Excessive Systemic Inflammatory Response Syndrome (SIRS) in acute pancreatitis leads to distant organ damage and Multiple Organ Dysfunction Syndromes (MODS), which is the primary cause of morbidity and mortality in this condition. Development of in vivo experimental models of acute pancreatitis and associated systemic organ damage has enabled us to study the role played by inflammatory mediators in the pathogenesis of acute pancreatitis and associated systemic organ damage. Using these models, recent studies have established the critical role played by inflammatory mediators in acute pancreatitis and the resultant MODS. Hydrogen Sulfide (H_2S) plays an important role in cardiovascular, central nervous and gastrointestinal systems and has been shown to act as a vasodilator. We have also shown that H_2S acts as a mediator of inflammation. Substance P is an 11 amino acid neuropeptide that is released from nerve endings in many tissues. Subsequent to its release, substance P binds to Neurokinin-1 (NK-1) receptors on the surface of effector cells. Using experimental models, recent studies in our laboratory have established the critical role played by H_2S and substance P in acute pancreatitis. Furthermore, early results point to the clinical relevance of this research. Studies with experimental animal models of disease will therefore help define the role of these mediators in the pathogenesis of acute pancreatitis, and can lead to the development of novel therapeutic approaches for this condition.

Audience Take Away Notes

- Acute pancreatitis is a common clinical condition, for which there is no satisfactory treatment available at this time.
- Research in our laboratory has shown a key role of hydrogen sulfide and substance P as novel mediators of inflammation for acute pancreatitis.
- Hydrogen sulfide and substance P can act as novel therapeutic targets for acute pancreatitis.

Madhav Bhatia

Department of Pathology and Biomedical Science, University of Otago, Christchurch, New Zealand

Biography

Professor Madhav Bhatia heads the Inflammation Research Group in the Department of Pathology and Biomedical Science at the University of Otago, Christchurch. Research in his laboratory has shown hydrogen sulfide and substance P as mediators of inflammation and potential therapeutic targets for inflammatory diseases such as acute pancreatitis, sepsis, burn injuries, and joint inflammation. He has received numerous grants, has authored more than 200 contributions to the peer-reviewed literature, given several invited presentations in different countries and is on Editorial Boards of 46 journals. His publications have been cited more than 16000 times, and he has an "h"-index of 63.

Clinical pharmacology of Aprocitentan (an endothelin receptor antagonist) – The most recent quality progress in treatment of resistant hypertension

Hypertension is a common condition characterized by persistently high blood pressure (140/90 mmHg or higher). Lowering high blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. Regardless of outstanding results and improvements in the pharmacological management of hypertension, clinical programs in patients remaining hypertensive despite a minimum of three drugs at their optimal dose, and sometimes even up to six antihypertensives, clearly suggested a need for further investigations and transformational progress in this field. It has been determined that Endothelin-1 (ET-1), a potent vasoconstrictor, was implicated in the pathogenesis of hypertension. By targeting the ET transduction signaling pathway, to this point several vasoactive substances were identified to inhibit the binding of ET-1 to ET(A) and ET(B) receptors, to reduce the harmful effects of ET-1, including vasoconstriction, fibrosis, cell proliferation, endothelial dysfunction progression, as well as local inflammation. Aprocitentan is a recently registered endothelin receptor antagonist prescribed for the combination treatment of hypertension that is not adequately controlled with other drugs. Given the previous facts, the main objectives of this presentation will be to clarify the pharmacological properties of aprocitentan, including pharmacodynamics, pharmacokinetics, indications, and contraindications for use, adverse drug reactions, as well as the most important drug interactions. This will provide a better understanding of this new-in-pharmacotherapy drug for resistant hypertension, consequently helping clinicians in its suitable prescribing and adequate clinical use.

Prof. Miroslav Radenković, MD, MS, PhD

Department or Pharmacology, Clinical Pharmacology and Toxicology; Faculty of Medicine; University of Belgrade; Belgrade; Serbia

Biography

Miroslav Radenković, MD, MS, PhD, a full-time professor at the Department of Pharmacology, Clinical Pharmacology and Toxicology, graduated from the Faculty of Medicine – University of Belgrade (FMUB) in 1995, and from 1996 he is working at the FMUB. Miroslav received an MS from pharmacology, board certified in Clinical Pharmacology, PhD from Medical Sciences, and a sub-specialization degree in Clinical Pharmacology - Pharmacotherapy in 1999, 2000, 2004, and 2016 respectively, from the FMUB, as well as Bioethics MS in 2021 from the Clarkson University, NYC, USA. From 2002 Dr. Radenković officially participated in several scientific projects supported by the Ministry of Science – Serbia; the Austrian Science Fund; COST Action; as well as the NIH Fogarty International Center Project, USA. Dr. Radenković is a member of the Ethics Board of Serbia.

Unveiling the binding interactions of selected antimalarial drugs with major plasma transporter

Using a variety of spectroscopic methods and in silico analysis, the binding interactions between three antimalarial medications, Mefloquine (MEF), Lumefantrine (LUM), and Pyrimethamine (PYR) and the primary plasma transporter, Human Serum Albumin (HSA) were examined. Molecular docking analysis designated Sudlow's Site I, located in subdomain IIA of HSA, as the preferred binding site of these drugs, which was also supported by competitive drug displacement results. The quenching of protein (HSA) fluorescence induced by these drugs was characterized as static quenching, thus suggesting drug-HSA complex formation. This was also supported by UV-V is absorption spectral results. Moderate binding affinity between these drugs and HSA was revealed from the association constant, Ka values (1.32-7.27*104 M-1). Both molecular docking results and thermodynamic data predicted noncovalent forces, viz., hydrogen bonds, hydrophobic and van der Waals forces, to stabilize drug-HSA complexes. Smaller modifications to secondary and tertiary structures as well as microenvironmental alterations surrounding protein fluorophores were also brought about by drug binding.

Audience Take Away Notes

- The audience will learn about the characteristics of the antimalarial drug-HSA interaction
- It will reflect the efficacy of these drugs in the presence of other drugs, which bind to the same site on HSA
- Drug-drug interactions can be studied using the binding characteristics of antimalarial drugs

Saad Tayyab

Department of Pharmaceutical Chemistry, Faculty of Pharmaceutical Sciences, UCSI University, 56000 Kuala Lumpur, Malaysia

Biography

Dr. Saad Tayyab studied Biochemistry at Aligarh Muslim University, India, completing Masters and Ph.D. degrees in 1981 and 1987, respectively. He is currently working as a Professor of Pharmaceutical Chemistry at UCSI University, Kuala Lumpur, Malaysia. Before joining UCSI University, Dr. Saad served at Universiti Malaya (2004-2018), Haramaya University, Ethiopia (2001-2004), Aligarh Muslim University, India (1988-2001), and the University of Kashmir, India (1987-1988). He was admitted as a Fellow, Royal Society of Chemistry, UK, in 2017, Fellow, Royal Society of Biology, UK, in 2019, Member, American Chemical Society in 2020, and Member, Sigma Xi in 2024. He is serving as an Editorial Board member for several journals. He has published over 150 journal papers, 17 popular articles, 1 book, 2 book chapters, and 1 learning aid. Several research students (16 Ph.D., 6 M.Phil., 1 M.D., and 13 M.Sc.) completed their degrees under his supervision, and he guided 32 undergraduate projects. His research interests include drug-protein interaction, protein folding, protein/enzyme stability, and protein structure-function. He possesses an h-index of 27, and his name is included in the reviewers' lists of many international journals.

Personalized and Precision Medicine (PPM) as a unique healthcare model to be set up via biodesign, bio and chemical engineering, translational applications, and upgraded business modeling to secure the human healthcare and biosafety

Traditionally a disease has been defined by its clinical presentation and observable characteristics, not by the underlying molecular mechanisms, pathways and systems biology-related processes specific to a particular patient (ignoring persons-at-risk). A new systems approach to subclinical and/or diseased states and wellness resulted in a new trend in the healthcare services, namely, *personalized and precision medicine* (PPM).

To achieve the implementation of PPM concept, it is necessary to create a fundamentally new strategy based upon the biomarkers and targets to have a unique impact for the implementation of PPM model into the daily clinical practice and pharma. In this sense, despite breakthroughs in research that have led to an increased understanding of PPM-based human disease, the translation of discoveries into therapies for patients has not kept pace with medical need. It would be extremely useful to integrate data harvesting from different databanks for applications such as prediction and personalization of further treatment to thus provide more tailored measures for the patients and persons-at-risk resulting in improved outcomes and more cost effective use of the latest health care resources including diagnostic (companion ones), preventive and therapeutic (targeted molecular and cellular) etc.

Translational researchers, bio-designers and manufacturers are beginning to realize the promise of PPM, translating to direct benefit to patients or persons-at-risk. And thus both PPM and nanobiotechnologies are being integrated into diagnostic and therapeutic tools to manage an array of PPM-guided conditions to customize therapeutic management. Novel nanomedicines have been employed in PPM-driven treatment of several diseases, which can be adapted to each patient-specific case according to their genetic profiles. So, partnering and forming strategic alliances between researchers, bio-designers, clinicians, business, regulatory bodies and government can help ensure an optimal development program that leverages the Academia and industry experience and FDA's new and evolving toolkit to speed our way to getting new tools into the innovative markets.

Healthcare is undergoing a transformation, and it is imperative to leverage new technologies to support the advent of PPM. And it is urgently needed to to discover, to develop and to create new (targeted and/or smart/intelligent) drugs. And with the support of nanotechnology, new targeted therapeutic agents and biomaterials, or aid the development of assays for disease biomarkers and identification of potential biomarker-

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[5]ISPM, Tokyo, Japan

[6]AHA, Houston, TX, USA

[7]MGH, Boston, MA, USA

[8]Harvard Medical School, Boston, MA, USA

[9]MIT, Cambridge, MA, USA

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[11]T College of Biological Sciences, UC Davis, CA, USA

[12]Center for Autoimmune Disease Research, John Hopkins University, Baltimore, MD, USA

target-ligand (drug) tandems to be used for the targeting, PPM is making phenomenal steps in the future to come. This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM and design-driven translational medicine to elicit the content of the new trend. So, the Grand Change and Challenge to secure our Health and Wellness are rooted not in Medicine, and not even in Science! Just imagine WHERE?! In the upgraded Hi-Tech Culture!

Keywords: Personalized & Precision Medicine, Biomarkers, Targets, Nanoparticles, Nanocarriers, Nanotheranostics, Nanobiomedicine, Nanotechnologies.

Biography

Sergey Suchkov was born in the City of Astrakhan, Russia, in a family of dynasty medical doctors. In 1980, graduated from Astrakhan State Medical University and was awarded with MD. In 1985, Suchkov maintained his PhD as a PhD student of the I.M. Sechenov Moscow Medical Academy and Institute of Medical Enzymology. In 2001, Suchkov maintained his Doctor Degree at the National Institute of Immunology, Russia. From 1989 through 1995, Dr. Suchkov was being a Head of the Lab of Clinical Immunology, Helmholtz Eye Research Institute in Moscow. From 1995 through 2004-a Chair of the Dept for Clinical Immunology, Moscow Clinical Research Institute (MONIKI). In 1993-1996, Dr Suchkov was a Secretary-in-Chief of the Editorial Board, Biomedical Science, an international journal published jointly by the USSR Academy of Sciences and the Royal Society of Chemistry, UK. At present, Dr Sergey Suchkov is: Professor, the Russian University of Medicine, Moscow, Russia. Dr. Suchkov is a member of the: Russian Academy of Natural Sciences, Moscow, Russia. New York Academy of Sciences, USA. American Chemical Society (ACS), USA; American Heart Association (AHA), USA; European Association for Medical Education (AMEE), Dundee, UK; EPMA (European Association for Predictive, Preventive and Personalized Medicine), Brussels, EU; ARVO (American Association for Research in Vision and Ophthalmology); ISER (International Society for Eye Research); Personalized Medicine Coalition (PMC), Washington, DC, USA.

Drug design for the development of long-acting injectables

Long-Acting Injectable (LAI) medications represent the combination of a powerful drug substance and an injectable drug formulation that guarantees that the affected tissue is consistently exposed to the active molecule for an extended therapeutic treatment period without eliciting unwanted side effects. Many marketed LAI drugs owe their success to a formulation principle that is perfectly tailored to the drug substance, yet to date there is no comprehensive overview of how drug molecules can be designed in a smart way to facilitate and accelerate technical formulation development at a later stage. This presentation will summarize the key properties of low-molecular weight drugs that are predestined for different LAI formulations and suggest design principles as well as operational flow chart elements to streamline preclinical Research and Development (R&D) at the interface of chemical and pharmaceutical sciences.

Audience Take Away Notes

- Design principles of injectable drug products for patient compliance and safety
- Properties of injectable vs. oral drug substances
- Guidance for the discovery and optimization of Long-Acting Injectables (LAI)
- Practical aspects of LAI research (flow charts and assays)
- Importance of early collaboration between Research and Development

Thomas Ullrich

Global Drug Discovery, Novartis Biomedical Research, Basel, Switzerland

Biography

Thomas Ullrich studied Chemistry at Vienna University of Technology, graduated as PhD in 1999, and joined the National Institutes of Health in the United States as a Post-doctoral Fellow. In 2001 he started his industrial career with Novartis in Vienna and Basel and became a Group Leader and Director in Medicinal Chemistry. Thomas's team has advanced several drug candidates into clinical trials to treat musculoskeletal diseases, exploring long-acting injectable drug products and studying the physical and chemical properties of successful molecules. He has published more than 30 research papers in peer-reviewed journals

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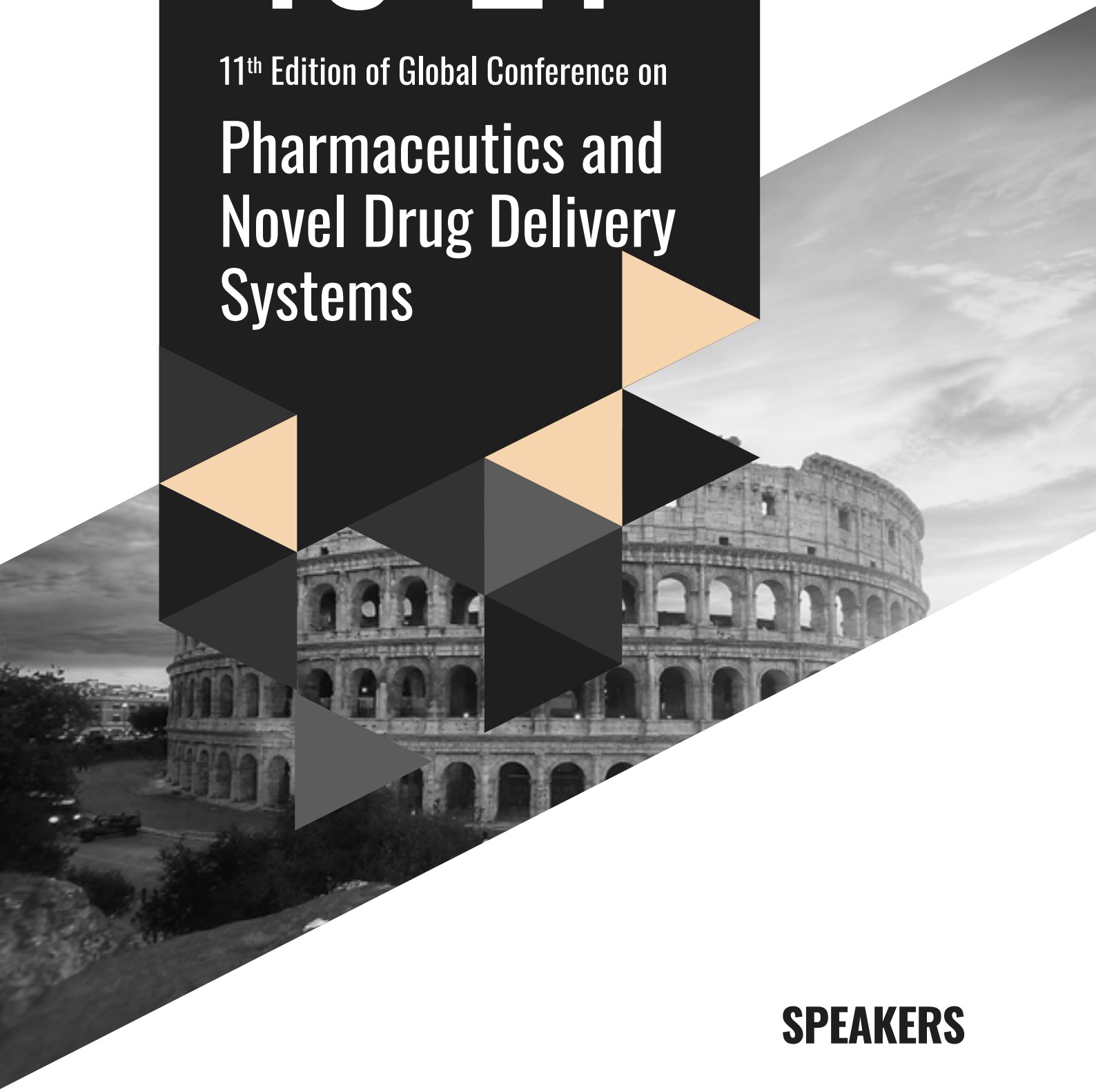

SPEAKERS

Abhay Tharmatt*, Sonia Guha, Anupama Mittal, Deepak Chitkara
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Targeted downregulation of VEGF-A to inhibit angiogenesis in psoriasis using CRISPR/Cas9 complexed lipopolymeric nanoplexes

Psoriasis, an incurable chronic inflammatory skin disease, is characterised by enhanced angiogenesis, abnormal keratinocyte differentiation, and immune cell invasion. Angiogenesis, a critical factor in endothelial cell proliferation, adhesion, and migration, is driven by the overexpression of the VEGF-A gene. Downregulating VEGF- A offers a potential therapeutic strategy for angiogenesis-related disorders. This study investigates the application of CRISPR/Cas9 gene editing to target and downregulate VEGF-A expression in psoriasis. However, their large size and negative charge hinder the delivery of CRISPR/Cas9 components in vitro and in vivo. To address these challenges, we developed lipopolymeric nanoplexes to deliver Cas9 RNPs specifically to target cells. The nanoplexes were characterised by a particle size of 142.2 nm, a PDI of 0.144, and a zeta potential of +4.27 mV. In vitro studies demonstrated over 70% transfection efficiency in HaCaT cells, with an Indel frequency of approximately 30% for the VEGF-A gene. The nanoplexes were further characterised using XPS, confirming their stability and low toxicity. Hemocompatibility assays indicated non-toxicity. Ex vivo skin permeation analysis showed a 66% permeation rate after 24 hours. The optimised nanoplex formulation was incorporated into a carbopol-based gel with non-Newtonian flow characteristics, exhibiting shear-thinning behaviour and variable thixotropy. This gel-delivered nanoplex achieved a 48% skin permeation rate after 24 hours in ex vivo mouse skin. In vivo skin toxicity testing confirmed a low toxicity profile. Efficacy assessment in a psoriasis-like inflammation model in Swiss albino mice demonstrated significantly improved PASI scores, reduced skin damage, and decreased proliferation compared to the naked RNP and Blank gel. The enhanced cellular uptake, high skin penetration with increased skin retention, and improved efficacy collectively highlight the potential for future clinical applications in treating psoriasis.

Audience Take Away Notes

- **Advanced Delivery Techniques:** How we've developed lipopolymeric nanoplexes to deliver CRISPR/Cas9 components precisely to target cells, overcoming traditional delivery challenges.
- The detailed characterization process, including particle size, PDI, and zeta potential, and how these parameters influence delivery efficiency.
- **Gene Editing for Psoriasis:** The crucial role of VEGF-A in psoriasis and the therapeutic potential of its downregulation using CRISPR/Cas9.
- The significant in vitro, ex vivo, and in vivo results demonstrate this approach's potential to alleviate psoriasis symptoms.
- **Formulating Topical Treatments:** The development of a carpool-based gel that effectively delivers our nanoplexes, featuring desirable properties like shear-thinning behavior.
- Insights into how these properties enhance the gel's performance and application in a clinical setting.
- **Safety and Efficacy:** Comprehensive methods for evaluating hemocompatibility, toxicity, and skin

permeation, ensuring the treatment's safety.
- Robust in vivo efficacy assessments, showing marked improvements in psoriasis models.
- **Future Clinical Potential:** The implications of this research for future clinical applications, including potential adaptations for other angiogenesis-related conditions.
- Steps towards translating this innovative approach into human treatments, paving the way for new therapies.
- **How the audience will be able to use what they learn:**
- **Research Applications:** Researchers can apply our delivery techniques and characterization methods to other gene-editing projects, potentially expanding the scope of their work.
- Insights from our study can inspire new research directions, particularly in targeting gene expression for various diseases.
- **Clinical Practice:** Clinicians will gain an understanding of emerging treatments for psoriasis, which could inform future therapeutic strategies and patient care.
- Safety and efficacy assessment techniques can be adapted for evaluating other topical treatments.
- **Pharmaceutical Development:** Pharmaceutical scientists can use our findings to design more efficient delivery systems for gene therapies and other treatments.
- Our methodologies for optimizing nanocarrier formulations can streamline the drug development process, making it more efficient and effective.

Benefits to the Audience:
- **Expanding Research and Teaching:** Faculty can incorporate these advanced techniques and findings into their teaching, enriching the education of students in the fields of gene therapy and nanotechnology.
- Researchers can build on our work to explore new treatment avenues, potentially leading to breakthroughs in other areas.
- **Practical Solutions:** The study provides practical solutions for delivering large and negatively charged gene-editing components, addressing a significant challenge in the field.
- Our optimized delivery system simplifies the development process for other gene therapies, making them more accessible.
- **Improved Accuracy and Information:** Enhanced delivery and targeting mechanisms improve the accuracy and efficacy of gene-editing therapies.
- Detailed characterization and assessment techniques offer valuable information for solving design problems in drug delivery systems.
- **Overall Benefits:**
    - The potential for improved therapeutic outcomes for patients with psoriasis and possibly other conditions.
    - A solid foundation for future innovations in nanomedicine and gene therapy, driving the field forward.

Biography

Abhay Tharmatt is currently a PhD scholar at BITS Pilani, India, specializing in the development of nanocarriers for therapeutic applications. He completed his B. Pharmacy from Lovely Professional University, Phagwara, and his M. Pharmacy in Pharmaceutics from Guru Nanak Dev University, Amritsar. Abhay's research focuses on the topical delivery of anti-VEGF nanomedicines for psoriasis using CRISPR/Cas9 gene editing. He has published several papers and is set to join the University of New South Wales for a research scholar program. His work aims to enhance treatment efficacy and safety in dermatological therapeutics.

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Potential Bruton Tyrosine Kinase (BTK) inhibitors determined by virtual screening, molecular docking, and molecular dynamics simulation studies

Bruton Tyrosine Kinase (BTK) is a downstream mediator of the B Cell Receptor (BCR) signalling pathway and affects B cell proliferation and differentiation. Evidence showing BTK expression in the majority of hematological cells has led to the hypothesis that BTK inhibitors such as ibrutinib may be an effective treatment for leukemias and lymphomas. However, increasing experimental and clinical data have revealed the importance of BTK not only in B-cell malignancies but also in solid tumours such as breast, ovarian, colorectal and prostate cancers. Additionally, increased BTK activity is associated with autoimmune diseases. This has led to the hypothesis that BTK inhibitors may be useful in the treatment of Rheumatoid Arthritis (RA), Systemic Lupus Erythematosus (SLE), Multiple Sclerosis (MS), Sjögren's Syndrome (SS), allergy and asthma. Recently, great efforts have been made to discover new BTK inhibitors. However, a limited number of BTK inhibitors have been designed and approved so far. Among these, ibrutinib, developed by Pharmacyclics and Janssen, was approved by the US FDA for the treatment of Mantle Cell Lymphoma (MCL) in November 2013 and Chronic Lymphocytic Leukemia (CLL) in February 2014, respectively. Ibrutinib is a selective and irreversible BTK inhibitor that forms a covalent bond with a non- conserved Cysteine residue (Cys481) proximal to the active site of BTK. As an ATP-competitive inhibitor, ibrutinib binds to the ATP-binding pocket of BTK and prevents autophosphorylation of Tyr223, abolishing full activation of BTK, which culminates the signal transduction cascade. It is noteworthy that ibrutinib is the first and only FDA-approved BTK inhibitor so far. Despite its unprecedented success, acquired resistance to ibrutinib has been observed in patients with CLL and MCL. Based on this situation, there is an urgent need to discover BTK inhibitors with new chemical scaffolds. Virtual screening, an effective tool, is important in drug development studies. Therefore, this study aimed to use computer-assisted approaches to identify potential inhibitors of BTK. A virtual screening, molecular docking, and Molecular Dynamics (MD) simulation and MM/GBSA calculations carried out to identify hit candidates for the treatment of BTK target-related diseases. MD Simulations showed the binding interactions between the identified molecules and BTK. This information will use to design and optimize new inhibitors with improved binding properties and stability. The findings obtained from this study will also emphasize the importance of computational methods in drug discovery.

Acknowledgement: This study was supported by the Çanakkale Onsekiz Mart University Research Coordination Unit (Project No: TSA-2024-4728).

Audience Take Away Notes

- Potential BTK inhibitors determined by in silico methods can lead to pre-clinical in vitro and/or in vivo studies that can benefit researchers working in this field.
- It is thought that the results we obtained will be guiding for further studies.
- This study will make a significant contribution to the literature with our drug discovery studies.

Biography

Dr. Onder received her PhD degree in Inorganic Chemistry at the Çanakkale Onsekiz Mart University, Türkiye, in 2021. He has approximately 10 years of experience in the private sector. Currently, he has been studying as a postdoctoral researcher for TÜBİTAK projects in the field of drug discovery and organic synthesis at the Natural Products and Drug Research Laboratory, Çanakkale Onsekiz Mart University. He has focused on drug design, synthesis, medicinal chemistry, and polymeric drug delivery systems. He has published more than 20 research articles in SCI(E) journals.

Ali Yetgin[1,2]

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[2]Cukurova University, Institute of Nature and Applied Sciences, Department of Biotechnology, Adana, Turkey

The impact of climate change on medicinal plant availability and efficacy

Medicinal plants have been fundamental in both traditional and modern medicine, offering a wide array of bioactive compounds crucial for therapeutic purposes. The escalating impact of climate change presents notable risks to the accessibility and effectiveness of these essential resources. The primary objective of this investigation is to explore the diverse effects of climate change on medicinal plants, concentrating on aspects such as their geographical distribution, growth environments, and medicinal properties. A thorough examination of current literature was carried out, encompassing scholarly articles, climate projections, and botanical research. The results demonstrate that climate change has a significant influence on the habitat ranges and population dynamics of medicinal plants. Elevated temperatures, modified precipitation patterns, and more frequent extreme weather events disrupt the growth cycles of plants, resulting in diminished biomass and compromised production of secondary metabolites. The study emphasizes the pressing necessity for adaptive conservation measures to protect the diversity of medicinal plants. The changing climate represents a significant menace to the availability and effectiveness of medicinal plants, with substantial repercussions for global health and the pharmaceutical sector. To ensure the continued use of these priceless natural resources in medicine, proactive measures are necessary for their conservation.

Keywords: Climate Change, Medicinal Plants, Phytochemicals, Therapeutic Efficacy.

Biography

Ali Yetgin completed his undergraduate degree in molecular biology and genetics and his graduate degree in biotechnology from Izmir Institute of Technology. He worked as a researcher at Dokuz Eylül University Microbiology Laboratory. So far, it has been included in 62 publications, including 24 articles and 38 conference presentations. He works as an R&D Specialist at Toros Agri company and fulfills the task of national/international project submission. He also continues doctoral studies at Cukurova University and carries out his thesis on the development of microbial fertilizers.

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An enteric encapsulation made from natural materials for oral delivery of drugs and probiotics to the intestine

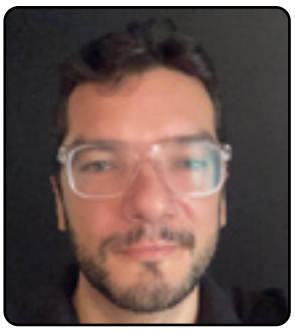
Apillet has patented a unique oral delivery concept (APIVault) which enable targeted release in the intestine of Sensitive (bio) pharmaceutical and Probiotics. Such compounds are prone to degradation in the stomach and must be protected by a gastro-resistant encapsulation to pass the stomach to maintain efficacy/efficiency. APIVault can, in different formats, be programmed for enteric release in the upper parts of the small intestine or for late release in the colon. There is a strong commercial and clinical need for a gastro-resistant enteric encapsulation made from safe bio-inactive materials (GRAS). The enteric encapsulations currently in use cannot be used for human consumption without a prescription. This makes them unwanted for delivery of Probiotics. The APIVault technology utilizes that Bacterial Cellulose (BC) cannot be digested in the Gastrointestinal (GI) tract but BC can protect drugs in the harsh conditions during stomach passing. Moreover, certain cellulase enzymes are inactive in the acidic stomach, but digest cellulose in the pH neutral intestine. By combining BC with a cellulase, a BC/cellulase combo material with enteric properties is obtained. The APIVault combo capsule is engineered to have highly manageable drug release properties.

Audience Take Away Notes

- Data on the technology and the enteric release properties of the APIVault encapsulations will be presented.
- Apillet has a significant innovation pipeline in the field of enteric encapsulations. This enables a sustained development of the company's business.

Biography

Dr. Christensen has a Ph.D in biotechnology from Copenhagen University (1997). Joined Novo Nordisk A/S in 2001 as a Scientist in process development and joined CMC biologics as a CMC specialist in 2013. In 2018 he joined Apillet ApS as head of development and became later the CEO of the company.



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From medicationalization to pharmacopollution: Raising awareness on the hidden costs of overprescribing

The overprescription of pharmaceuticals, a phenomenon known as medicationalization, has led to unintended environmental consequences, contributing to the rising issue of pharmacopollution. This article explores the intricate relationship between medicationalization and pharmacopollution, emphasizing the urgent need for awareness and action. It examines how the excessive use of medications not only affects human health but also contaminates ecosystems, leading to widespread environmental damage. By analyzing current practices and offering solutions for more sustainable pharmaceutical use, this paper highlights the critical importance of promoting responsible prescribing habits to mitigate the hidden costs of overprescribing. The article calls for increased public awareness and stronger policy measures to address these interconnected challenges, ensuring a healthier future for both people and the planet.

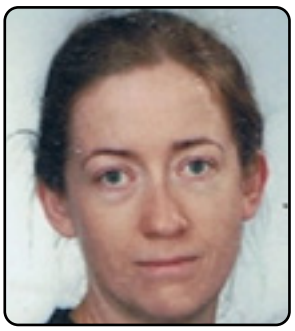
Audience Take Away Notes

- By understanding the connection between medicationalization and pharmacopollution, the audience will gain insights into the broader implications of overprescribing practices. This knowledge can empower healthcare professionals, policymakers, and environmental advocates to take actionable steps toward more responsible medication use and disposal. Attendees will learn strategies for promoting sustainable prescribing habits, such as advocating for policy changes, implementing educational programs for patients and healthcare providers, and supporting research into environmentally-friendly pharmaceutical alternatives. Ultimately, the audience will be equipped to contribute to reducing the environmental and societal impacts of overprescribing, fostering a healthier ecosystem and community.
- Healthcare providers can use this information to improve prescribing practices, reducing unnecessary medication use and minimizing the risk of contributing to pharmacopollution. Policymakers and administrators can leverage these insights to craft regulations and guidelines that promote sustainable pharmaceutical practices. Environmental professionals can use the knowledge to advocate for stronger environmental protections and collaborate with the healthcare sector to mitigate contamination risks. Overall, this understanding will help the audience enhance their professional impact by aligning their practices with the goals of public health, environmental sustainability, and ethical responsibility.
- This research could be used by other faculty to expand their research or teaching.
- This provides a practical solution to a problem that could simplify and enhance a designer's efficiency.
- It will provide new information to assist in a design problem
- List all other benefits:
    - Attendees involved in policymaking will gain evidence-based insights that can inform the creation of regulations aimed at reducing pharmacopollution. This could include policies that encourage responsible prescribing, promote safe disposal of medications,

and support the development of eco-friendly pharmaceuticals. By understanding the link between overprescribing and environmental contamination, healthcare professionals can contribute to reducing the overall burden on public health, leading to fewer cases of drug-related side effects and environmental exposure to harmful substances. The insights gained can foster collaboration between healthcare, environmental, and policy sectors, leading to more comprehensive and effective approaches to managing the impacts of pharmaceutical use.

Biography

Dr. Pereira has a Ph.D in Sanitation, Environment and Water Resources (Federal University of Minas Gerais–UFMG, Brazil), Master in Administration–reverse logistics (FUMEC University), and bachelor in Administration (UESB). Author of international articles, such as Environ Sci Pollut Res and others. Author of "Reverse Logistics and Sustainability" (Cengage) and "Solid Waste Management and Management" (Juris Lumen). Top 6 Fedex Reverse Logistics Professional 2014 Award and Top 3 9th Public Management Award. Dr. Pereira also has experience in Germany and Brazil. Dr. Pereira is Springer Nature, Pan American Journal of public Health Journal and Waste Management reviewer.



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Health risks associated with exposure to organic sunscreens during pregnancy

Pregnant women are exposed to a variety of environmental pollutants–pesticides, drugs, substances of abuse or cosmetic raw materials that enter the body of a mother-to-be by a variety of routes-oral (with contaminated food or water), through skin or mucous membranes or by inhalation. The placenta is an interface between the maternal and fetal compartments; molecules are transported across the placenta mainly via passive diffusion, but other mechanisms (involving facilitated diffusion, placental transporters, phagocitosis or pinocitosis) are also possible.

Organic sunscreens are expected to act on the surface of the skin or hair to protect them against harmful effects of UV radiation; some sunscreens are also used to prevent photo-induced degradation of products – fabrics, cosmetic preparations etc. Unfortunately, many compounds from this group meet the conditions of drug-likeness and are known to be absorbed through skin, from the gastro-intestinal or pulmonary tract. Some organic sunscreens are found in mother's milk, umbilical cord blood or placental tissues. Organic sunscreens are not neutral to human and animal health; they are known endocrine disruptors and, generally speaking, can influence the development of offspring (especially male fetuses) or are suspected neurotoxins.

Earlier reports exist that some organic sunscreens from the chemical family of benzophenones cross the human placenta. In this research it was shown using Discriminant Analysis (DA) and Artificial Neural Networks (ANN) classification models (based on a training set of 40 compounds and a test set of 14 compounds) that the majority of organic sunscreens authorized for use in the EC (and in many states worldwide), including those from chemical families other than benzophenone derivatives, are likely to cross the placenta easily. The passage of these compounds across the placenta is facilitated mainly by passive diffusion and their ability to enter the fetal blood circulation is strongly related to their drug-likeness according to Lipinski's Rule of Five. Apart from trans-placental passage, many sunscreens are likely to penetrate the fetal brain. They are also (as proved by molecular docking calculations) likely to bind to enzymes found in placenta, whose main task is to protect the fetus from harmful xenobiotics, e.g. glutathione s-transferase or N-acetyltransferase 2. The binding affinities of the sunscreens for studied proteins were analyzed to give an idea of the potential of these chemicals to block the enzyme targets. Binding sites of both proteins and protein-ligand interaction types were identified.

Audience Take Away Notes

- What are the possible impacts of organic sunscreens on a human fetus?
- Can organic sunscreens cross the human placenta and what happens to them after they enter the fetal circulation?
- Are organic sunscreens likely to interfere with enzymes in the human placenta, e.g. glutathione s-transferase or N-acetyltransferase 2?

Biography

Dr. Anna W. Sobańska studied Chemistry at the Technical University of Lodz, Poland and graduated as MSc in 1992. She then joined the research group of Prof. Jeremy Robertson at Dyson Perrins Laboratory, Oxford University, UK. She received her PhD degree in Organic Chemistry in 2007 at the same institution. She obtained the position of a Formulation Chemist in Cosmetic Factory Pollena-Ewa in Lodz, Poland. In 2005 she joined the Department of Analytical Chemistry, Medical University of Lodz, Poland. She has published several research articles in SCI(E) journals. She has recently become a Professor of the Medical University of Lodz.

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Novel 2, 5-disubstituted Oxadiazole scaffolds act as potential antitumour and antibacterial agents

Introdution: 1, 3, 4-oxadiazole is a five membered heterocyclic aromatic compound containing two nitrogen atom at position three and four and one oxygen atom present at position one. 1, 3, 4 oxadiazole is thermally stable than other oxadiazoles, these oxadiazole are very important compound in medicinal chemistry due to their biological activities.

Aim and Objectives: The main aim and objective of the present research work is the synthesis, characterization and evaluation of antitumour and antibacterial potentiality of 2, 5-disubstituted 1, 3, 4 - Oxadiazole derivatives against EAC cells and HT 29 cell lines and bacterial 3G7E DNA gyrase.

Methodology: The target compounds were synthesized by reflux condensation method and were characterized by modern analytical techniques such as FTIR, H1-NMR and mass spectrometry. The toxicity of synthesized compounds was evaluated by OECD guide lines. In-silico studies were done by AUTO-DOCK programe against targeted proteins bacterial DNA gyrase. In vivo antitumor activity of synthesized compounds (AB1-AB8) on EAC mouse tumour models. Study was carried out with EAC cell line induced malignant ascites in mouse models and in vitro anti-bacterial activity was carried out by agar diffusion method.

Results and Discussion: In vivo antitumour activity against EAC mouse tumour models and HT 29 implanted mouse models showed that compound AB3, AB6, AB7 and AB8 had the potential ability to inhibit the growth and proliferation of cancer or tumour cells in comparison to other derivatives. The molecular docking studies showed sufficient interaction with the targeted proteins bacterial DNA gyrase in respect to standard drugs ciprofloxacin to show respective biological activity. However different interaction was observed for different compounds. In vitro antibacterial assay, among these eight synthesized oxadiazole derivatives, compound AB1; AB2 and AB7 were found to be very good antibacterial potentiality with an MIC range of 13-12 µg/ml.

Conclusion: From the present experimental discussion I was concluded that in vivo antitumour activity against EAC mouse tumour models and HT 29 implanted mouse models showed that compound AB3, AB6, AB7 and AB8 had the potential ability to inhibit the growth and proliferation and AB1; AB2 and AB7 were found to be very good antibacterial as well as antifungal potentiality with an MIC range of 13-12 µg/ml; 7-10 µg/ml.

Keywords: Antitumour, Antibacterial, Molecular Docking, EAC etc.

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AI-guided spectroscopy and recombinant DNA technologies to discover the new lantibiotics and phytobiotics against multi-drug-resistant infections

MDR-bacteria causes sepsis and death in patients due to their power to inactivate antibiotics like ampicillin, cefotaxime, tetracycline, streptomycin, chloramphenicol, erythromycin and ciprofloxacin. The mdr genes (amp, blaCTX-M, blaNDM1, cat, aac2'/3'/6', strAB, aad, aph, sul1/2/3) and drug-efflux genes (tetA. tetB, tetC, acrAB, acrCD, mexAB, macAB) were located in plasmids and chromosomes. Rifampicin and streptomycin resistant TB are a major problem in India due to rpoB, rrs, rpsL genes mutations and activation of MmpL5, MmpL7, Stp, JefA, drug efflux genes as well as penicillin resistance genes penA and ampH1. Still, we depend on newer 5th generation synthetic antibiotics like meropenem, moxifloxacin, amikacin and tigecycline. Research directed to make peptide antibiotics which known as lantibiotics like nisins, bacteriocins and salivaricins. Research also directed to discover newer phyto-chemicals to inhibit MDR-pathogens. Phytochemicals like artiminicin and quinine helped to eradicate chloroquine-resistant Plasmodium falciparum infections or malaria. The CU1 polybromophenol-saponins from Cassia fistula bark ethanol extract was found potent antibiotic against Mycobacterium tuberculosis RNA polymerase. Similarly, NU2 polyflurophosphate-glycosides from Suregada multiflora roots ethanol extract was found very inhibitory to XDR-bacteria targeting Escherichia coli DNA topoisomerase I. Recently, in vitro synthesis of many lantibiotics or cyclic peptide antibiotics were commissioned using computer-guided AI technologies and recombinant DNA technology. Our goal is to stop the spread of XDR-bacterial death which has predicted to be more as we will approach 2050.

Audience Take Away Notes

- The audience will learn genes that inactivate antibiotics
- The audience will know the new technologies like NMR, MASS, FTIR to find the structure of new antibiotics.
- This research could help other faculty expand their research and teaching on new phyto-drug discovery from Asian medicinal plants
- The peptide antibiotic discovery will be discussed explaining new AI-technology and Recombinant DNA technology
- Multi-drug resistance is a central problem and the talk will help to gain newer concept of new drug discovery.

Biography

Dr. Asit Kumar Chakraborty was performed his PhD at CSIR-Indian Institute of Chemical Biology, Kolkata and awarded PhD degree in 1990 from Calcutta University. He did postdoctoral work at University of California at Berkeley and visiting scientist at Johns Hopkins University School of Medicine. He was Associate Professor of Biochemistry at OIST, Department of Biochemistry Biotechnology, Vidyasagar University and now retired. He published 75 papers and one book.

Ayse Nur Oktay

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Comparison of in-vitro drug dissolution profiles: Current state and examination of Etravirine tablets

In vitro drug dissolution is a laboratory test of drug tablets to assess product quality. The test measures drug release (i.e. drug dissolution) from tablets. There are numerous scenarios during drug development, as well in post-market life-cycle management, when there are manufacturing changes, such that pre-change and post-change tablets need to be compared, including comparison of in vitro drug dissolution profiles. Given the importance of drug dissolution in product quality, there are numerous regulatory guidance on comparing in vitro drug dissolution profiles, typically employing f_2 metric. However, there are considerable differences in the selection of timepoints in comparing dissolution profiles via f_2. The objective was to examine the impact of timepoints on computed f_2 values.

In vitro dissolution profiles of etravirine were obtained for brand Intelence (Jannsen) and the AB-rated generic etravirine (Amneal) using the method described in the FDA dissolution database. Briefly, Dissolution used USP Apparatus 2 (paddle method) (Hanson SR8 Plus Dissolution Test Station; Chatsworth, CA) at 37 ± 0.5◦C at 70rpm with three replicates. Medium was two phases. Phase 1 was 500 mL of degassed 0.01 M HCl for 10 min. Phase 2 involved adding 400 mL of 2.25% Sodium Lauryl Sulfate (SLS) in 0.01 M HCl, yielding 900 ml of 1.0% SLS in 0.01 M HCl. After the start of phase 2, 2 ml of dissolution sample was withdrawn at 5, 10, 15, 20, 30, 45, 60, 90, 120, 240 and 480 min, filtered through a 0.45 mm Millipore filter, and assayed by UPLC analysis at 310 nm. Cumulative percentage drug dissolved from the tablets were calculated. f_2 was calculated using several different selections of timepoints.

Graphically, generic reached 80% dissolved by 20min, while brand required 45min. Qualitatively, generic profile was more rapid than brand, although both reflected immediate-release tablets. The generic has been shown to be bioequivalent to brand, and not superior to brand.

f_2 results indicate f_2 value was very dependent on selection of in vitro dissolution timepoints. Using the BCS M9 guidance timepoints of “5, 10, and 20 min”, f_2 was only 25.3, and substantially lower than the required value of 50 (or more) to be considered similar. The only examined dataset yielding greater than 50 was “60, 90, 120, 240, and 480 min”, resulting in f_2=57.4.

In conclusion, f_2 value depended on the selection of timepoints, which is problematic since there is a lack of regulatory harmonization in the selection of timepoints. This lack of harmonization reflects the differing points of views from a conservative regulatory perspective and a scientific oral biopharmaceutics perspective.

Audience Take Away Notes

- Role of in vitro dissolution profiling in drug product quality
- F_2 as metric to compare dissolution profiles
- Dependence of f_2 values on the selection of dissolution sample timepoints

Biography

Ayse Nur Oktay is an assistant professor at University of Health Sciences, Gulhane Faculty of Pharmacy, Department of Pharmaceutical Technology in Turkey. She completed her Ph.D. degree at Gazi University Department of Pharmaceutical Technology under the mentorship of Professor Dr. Nevin ÇELEBİ and then she joined the research group of Prof. James Polli as a visiting Scientist in University of Maryland, Department of Pharmaceutical Sciences. Her research focused on nanosuspension, high pressure homogenization technique, nanogel, skin permeability studies, Quality by Design, drug delivery, dissolution and permeation systems, micelle diffusion and mathematical modeling. She is inventor of three project which are supported by Scientific Research Project Foundation of Gazi University and The Scientific and Technological Research Council of Turkey. She has oral/poster presentations on national/international conferences and has published research articles in SCI(E) journals.

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Hybrid compounds: A useful strategy to overcome limited pharmaceutical profile

Hybrid compounds are artificial scaffolds made of two or more pharmacophores that are jointed or overlapped in a single chemical entity. The strategy of combining two different and independently acting compounds into one covalently linked hybrid compound aims to increase the pharmacokinetic and pharmacodynamic profiles with respect to the sum of each individual moiety. Hybrid compounds find application in many areas of medical interest: oncology, microbiology, cardiology, neurology, anti-inflammatory, anti-infectious, platelet anti-aggregating, analgesic, cardio- and neuroprotective properties.

In this presentation the results obtained in a recent research work in the field of wound healing are reported. Starting from the well-known biological properties of the caffeic acid and the antimicrobial activity of heterocycles such as quinolines, twelve novel molecular hybrids were designed and synthesized by combination through an ester or an amide linker. The detailed synthetic process, the *in vitro* biological properties are described, as well as the improved pharmacokinetic profile and chemical and thermal stability. An interesting SAR is discussed to suggest a promising multi-targeted approach for enhanced wound healing.

Audience Take Away Notes

- The advantages and practical application of hybrid drugs in different medical fields
- Information on the validity of the use of molecular hybrids in the pharmaceutical research
- Description of the design and results obtained in a concrete case of scientific application of natural phenol hybrids
- Interesting ideas for the design of novel molecules of pharmaceutical interest, not limited to the regenerative medicine field only
- Description of the rationale of the project as a starting point and practical suggestions on the synthesis technique

Biography
Prof. Barbara De Filippis got her PhD in Pharmaceutical Sciences at the University of Chieti (Italy) and is currently an Associate Professor in Medicinal Chemistry. Her research work is focused on the design and synthesis of small molecules with anticancer and antimicrobial activities. Her studies are related on derivatives of natural phenols, as resveratrol and caffeic acid. She is author/co-author of many international papers and guest editor and reviewer for many journals.

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[3]Department of Pharmaceutical Chemistry, Graduate School of Pharmacy, Gujarat Technological University, Gandhinagar-382028, Gujarat, India

Microemulsion based in situ gel of Erythromycin for ocular ailments

Background: Conventional preparation of erythromycin ointment is available in the market as an ocular formulation. Ointment dosage form is linked to many side effects, including transient blurred vision, irritation and redness of the eye. Ointment dosage form also shows very low ocular bioavailability of drug due to various anatomical and precorneal constraints such as corneal epithelium, tear turnover, nasolacrimal drainage, reflex blinking and induced lacrimation. Ointment also exhibits poor patient compliance for administration in eye. Erythromycin belong to BCS class 3 showing poor permeability through the restrictive precorneal barriers. Hence, there is a need to develop it in formulation that eliminate the limitations of ointment.

Aim: The aim of the research was to develop and evaluate a topical ocular dosage form that is capable enough to deliver entrapped drug to infected tissue and offering prolonged retention and higher permeation for ocular ailments without eliciting any side effects. In this research we have tried to develop microemulsion based in situ gelling system which may give prolonged and sustained release with higher permeation at the site of application and reduction in dose frequencies thereby, improving patient compliance.

Methods: Erythromycin was incorporated into the microemulsion. Quantitative method was used to perform solubility study of Erythromycin in various oils, surfactants, and co-surfactants. The oil, surfactant and co-surfactant which exhibited highest solubilization of drug was selected for microemulsion preparation. The optimized microemulsion was dispersed in a polymer solution of 0.2% gellan gum. This polymeric solution upon administration in to the eye was able for transition into gel triggered by the electrolytes present in the simulated tear fluid.

Results and Discussion: Microemulsion based in situ gel formulation approach provided better corneal permeation and prolonged retention of the drug that may lead to improved local bioavailability of the drug. The globule size of microemulsion formulation was ~47nm with PDI of 0.237 indicating monodisperse nature of the formulation. The viscosities of the formulation before and after gelation were 82 cp and 540 cp, respectively indicating good gelling capability of the developed formulation after administration. *Ex vivo* permeation study from goat eye cornea revealed that permeation of Erythromycin from developed formulation was comparatively high than from its ointment.

Conclusion: It was concluded from the research that novel microemulsion based in situ gelling formulation of erythromycin exhibited higher permeation and longer residence time and it could be potential drug delivery system for treatment of bacterial eye infections.

Audience Take Away Notes

- The audience will be able to use this research for development of novel alternate formulation to improvise local bioavailability of the drug in ophthalmic region
- The research will be useful for the audience in their job by providing them a systematic path for development novel drug delivery starting from preformulation, screening of excipients and optimization

- The incumbent teachers could use this research for teaching as well as research
- This research will definitely provide a practical solution to a problem for formulation designer scientists
- The detailed approach of novel formulation development will assist in formulation design and development
- **Other benefits**
    - The audience will learn about the systematic development of novel formulations to address the problem of existing formulations

Biography

Dr. Dasharath M. Patel is Associate Professor at Graduate School of Pharmacy, Gujarat Technological University, India. He has 23 years of blended experience of teaching, research and administration. He earned M. Pharm in 1999 from Gujarat University, India and Ph. D in 2005 from North Gujarat University, India. He has delivered 52 expert sessions. He has 01 Patent, 76 research publications, 10 review and 05 books to his credit. He guided 36 M. Pharm, 8 Ph. D Students and received a fund of 32 lakhs for research and completed 3 industrial consultancy projects. He is a referee of 10 journals.

Deepika Sharma
Department of Biotechnology, CGC Mohali Punjab, India

Synthetic antimicrobial peptides as potent therapeutic agents

Among the fungal genera, members of the genus Candida are most common causal organisms of human infections. In recent years, increasing drug resistance in fungal pathogenic strains specifically, clinical strains require immediate attention to develop alternative antifungal agents. Candida albicans is one of the most important fungal pathogen among the various Candida spp. It usually resides as a commensal in the genitourinary and gastrointestinal tracts, and also occur as oral and conjunctival flora (Naglik et. al., 2011) causing both superficial and invasive infections under immunocompromised condition. Superficial infections are known as candidiasis that affects mucous membranes or skin and usually treated with topical antifungal drugs with low successes rate. However, invasive fungal infections are reported recently to be life-threatening due to inefficient prognostic methods and unsuitable antifungal therapies. Only three classes of conventional antifungal drugs viz., fluconazole, caspofungin and amphotericin B are used extensively for candidiasis treatment (Lum et al., 2016). However, there are Candida strains which have been reported to be increasing resistant to these antibiotics (Eksi et al., 2013). Moreover, occurrence of Candida in mixed biofilms with bacteria resulting in increased virulence and antibiotic resistance (Trejo-Hernandez et al., 2014; Fox et al., 2014; Baindara et al., 2009). This increased occurrence of drug resistant candidiasis desperately requires alternative antifungal agents to overcome the resistance problem. Though few peptides such as melittin and protegrin exhibit potent antifungal activity, they also possess toxic effects on mammalian cells (Lum et al., 2015). Hence, synthetic peptide designing is need of the hour. (Wang et al., 2022; Barman et al., 2023). Synthetic peptide display enhanced antimicrobial activity, reduced cytotoxicity and resistance to protease enzymes (Kang et al., 2022). Synthetic short peptides display better permeability to cross the yeast membrane. Considering this fact we designed short antifungal peptide were using sequences from APD database. Antifungal potential of designed peptides was predicted in terms of protein binding potential, amphipathicity, hydrophobicity, hydrophilicity and net charge. In vitro synthetic peptides showed potent anticandidal activity against various test strains.

Audience Take Away Notes

- The lecture helps researchers to understand the concept of peptide designing.
- This research could help other faculty could to expand their research or teaching.
- This research provides a practical solution to a problem that could help in overcoming antimicrobial resistance problem.

Biography

Dr. Deepika Sharma has completed her PhD in year 2015 from Guru Nanak Dev University Amritsar, Punjab (India). She has done her postdoctoral studies from CSIR-Institute of Microbial Technology Chandigarh (India). She is currently working as Assistant Professor in Department of Biotechnology, Chandigarh Group of Colleges CGC Landran Mohali, Punjab (India) a premier organization. She has successfully completed to minor research projects funded by Department of Science and Technology (DST), New Delhi. She has published 14 research papers in reputed international journals and one book chapter as first author in Bergey's Manual of Systematics of Archaea and Bacteria.

Dr. Dharmendra Kumar*, Prof. (Dr.) Pramod Kumar Sharma
Department of Pharmacy, School of Health and Allied Sciences/Sanskaram University, Jhajjar, Haryana, India

Role of natural polymers in drug delivery system

In recent years, various types of natural polymers have gained prominence in drug delivery systems due to their biocompatibility, biodegradability, and ease of modification. Recent research has further enhanced the capabilities of these polymers, expanding their functions in drug delivery. This presentation will focus on the role of natural polymers in modifying drug release patterns, particularly the dual release pattern (immediate and sustained release) achieved through the natural composition of a single polymer. We have explored the recent discovery of banana starch, which demonstrates a promising combination of amylose and amylopectin, approximately in a 26-28:72-74 ratios. Amylose is a straight-chain polymer of D-glucose linked by 1-4 glycosidic bonds, while amylopectin is a branched-chain polymer of D-glucose linked by α-1,4 glycosidic bonds and α-1,6 glycosidic bonds. These structural differences impart unique drug release properties: amylose facilitates immediate release, while amylopectin provides sustained release. This dual release capability makes banana starch an intriguing candidate for drug delivery applications. Furthermore, banana starch is likely not the only natural polymer with such advantageous compositions. The presentation will highlight the need for continued research to identify other natural polymers that exhibit similar or superior functionalities for drug delivery. By delving into these topics, we aim to shed light on the potential of natural polymers to revolutionize drug delivery systems, enhancing therapeutic efficacy and patient compliance through innovative release mechanisms.

Audience Take Away Notes

- Designing Advanced Drug Delivery Systems: By understanding the properties of natural polymers like banana starch, the audience can design drug delivery systems that utilize dual release patterns. This can help in creating formulations that release drugs both immediately and over a sustained period, improving therapeutic outcomes.
- Developing New Formulations: The insights into the structural differences between amylose and amylopectin and their impact on drug release can guide the development of new drug formulations. This knowledge can be applied to tailor the release profiles of various drugs to meet specific medical needs.
- Innovating in Pharmaceutical Research: Researchers and scientists can use the information to explore and identify other natural polymers with similar beneficial properties. This can lead to the discovery of new materials that can be used in innovative drug delivery systems.
- Enhancing Product Performance: Pharmaceutical companies can apply the principles learned to enhance the performance of their existing products. By incorporating natural polymers that provide controlled release, they can improve patient compliance and satisfaction.
- Advancing Environmental Sustainability: By adopting biodegradable and biocompatible natural polymers, the audience can contribute to the development of eco-friendly pharmaceutical products. This aligns with global sustainability goals and can improve the environmental impact of drug delivery systems.

- Strengthening Competitive Edge: Knowledge of the latest advancements in natural polymer applications will provide a competitive advantage. Professionals can leverage this information to stay ahead in the industry by offering cutting-edge solutions that meet the evolving needs of patients and healthcare providers.
- Collaborating Across Disciplines: The multidisciplinary nature of drug delivery research can foster collaboration between chemists, biologists, materials scientists, and pharmaceutical professionals. The shared understanding of natural polymers can enhance cross-functional projects and innovations.
- Informing Clinical Practice: Clinicians can use the insights to better understand the pharmacokinetics of new drug formulations, leading to more informed prescribing practices and improved patient care
- It could help the audience in their job:

1. Enhance Knowledge of Drug Delivery Mechanisms: Understanding the dual release pattern (immediate and sustained release) of natural polymers like banana starch will enable professionals to design more effective drug delivery systems.
2. Inspire Innovative Solutions:
3. Improve Product Development:
4. Encourage Research and Development

- This research on natural polymers in drug delivery systems is highly valuable for other faculty and can be used to expand their research and teaching in several ways: Interdisciplinary Collaboration, New Research Projects, Grant Proposals, Publications and Conferences.
- This research on natural polymers in drug delivery systems provides several practical solutions that can simplify and make a designer's job more efficient:

    1. Enhanced drug formulation simplified development process versatile applications
    2.. Improved biocompatibility: Reduced adverse reactions
    regulatory advantages
    3. Sustainable design:
    Eco-Friendly solutions
    market differentiation
    4. Cost-effective production reduced costs scalability
    5. Functional flexibility customization
    multi-functionality
    6. Streamlined research and development focused research
    collaboration opportunities
    7. User-friendly products

- This research on natural polymers in drug delivery systems will improve the accuracy of designs and provide new information to assist in solving design problems in several key ways:
    - Improved Accuracy of Designs
    - Predictable Drug Release Profiles: Controlled Release: By understanding the specific properties of natural polymers such as amylose and

Biography

Dr. Dharmendra Kumar is an Associate Professor in the Department of Pharmacy at the School of Health and Allied Sciences, Sanskaram University, Jhajjar, Haryana, India. He completed his Ph.D. in Pharmaceutics under the guidance of Prof. (Dr.) Pramod Kumar Sharma, an eminent scientist in the field of pharmacy in India. Dr. Kumar has published over 12 Patents, 10 books and more than 20 research papers in prestigious journals indexed by SCI and Scopus. He is actively involved with various publishing houses worldwide as an editor, author, and reviewer.

Elisabetta Stretti[1]*, Efstathios Stratakos[2], Giancarlo Pennati[2], Spyridon Psarras[1], Vassilis Kostopoulos[1]

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Computational modelling for enhanced drug delivery in drug-coated balloon treatment

Drug-Coated Balloon (DCB) treatment has recently emerged as an effective non-stent-based strategy for the treatment of atherosclerotic arteries in Peripheral Artery Disease (PAD). DCBs are designed to dilate into the stenotic lesions while delivering antiproliferative drugs to local arterial tissue via prolonged coated-balloon angioplasty inflation. However, insufficient delivery and non-homogeneous drug-coating transfer onto the arterial walls remain outstanding issues, hindering the DCB use as standard-of-care therapy for PAD treatment. Recent clinical evidence indicates that pre-treating the lesion with conventional angioplasty balloons plays a crucial role in adequately preparing the vessel footprint for subsequent drug-coating delivery to the target lesion. As drug-coating transfer is mediated by the mechanical interaction between the device and the artery and driven by local Contact Pressure (CP) gradients, computational models can be exploited to study the biophysical aspects underlying the device-artery interaction, aiming for a better understanding of the proper operating conditions and overall DCB treatment optimization. Therefore, this study aimed to develop a numerical pipeline to simulate lesion preparation using Plain Old Balloon Angioplasty (POBA) in atherosclerotic arteries followed by DCB inflation in the pre-dilated vessels. The Finite Element (FE) models employed different angioplasty balloon devices commonly adopted for lesion preparation, drug-coated balloons, and diseased arteries with heterogeneous tissue composition and different anatomical features. Vessel lumen gain and wall stiffness degradation due to tissue injury at the high strain levels induced by balloon angioplasty have been introduced to mechanically describe the arterial wall, obtaining a reliable vessel footprint with whom the DCB will interact in the next step. Quantitative data from experimental ring tensile tests on carotid swine arteries and balloon inflations using polyurethane resin have been exploited to feed and validate the numerical models. The numerical analyses demonstrated their applicability and potential capabilities in accurately simulating the DCB treatment, providing insights into how the device-artery interaction determines the efficacy of local coating delivery. Specifically, the findings revealed that the experimentally validated FE folded balloon models, in combination with a reliable pre- dilated artery model, is essential to properly describe the irregular spatial distribution of the CP, which reflects the non-homogeneous local coating transfer and, consequently, the drug-delivery. The proposed approach is versatile and could ultimately be adapted to patient-specific geometries to obtain a deeper understanding of the mechanism governing DCB efficacy and provide insights in both balloon angioplasty manufacturing and clinical contexts for improved therapeutic outcomes.

Audience Take Away Notes

- The audience will learn how computational models can be exploited to predict and optimize the factors influencing drug delivery in drug-coated balloon treatment
- The developed models have the potential to indirectly support clinicians in the pre-operative planning phase and provide insights to medical device manufacturers into the influence of structural aspects of DCBs in their performances

- The audience will get a glimpse of how benchtop experiments and numerical simulations can feed and complement each other to develop reliable and robust computational models

Biography

Elisabetta Stretti completed her studies in Biomedical Engineering with a specialization in Biomechanics and Biomaterials at Politecnico di Milano (Milan, Italy), graduating with honors in 2021. She then joined the research group of Prof. Kostopoulos at the Laboratory of Applied Mechanics and Vibrations (Mechanical Engineering & Aeronautics, University of Patras, Greece), where she is currently pursuing her PhD under the Marie Sklodowska-Curie ITN project named DECODE, focused on drug-coated balloon simulations and optimization systems for the improved treatment of peripheral artery disease. Her research focuses on developing computational models in the cardiovascular biomechanics field to optimize therapeutic strategies for enhanced patient care.

Fatemeh Ahmadvand
Department of Pharmacology and experimental medicine, University of the Genova, Italy

Innovations in DNA and RNA vaccine technology their impact on treatment efficacy and delivery

Advances in genetic engineering vaccines have made DNA vaccines a highly promising option for hereditary and acquired illnesses. The main obstacle; nevertheless, is the absence of an ideal delivery system, which severely restricts DNA vaccines' capacity to generate an immune response. Furthermore, the recent emergence of SARS-CoV-2 vaccines has shifted attention towards RNA vaccines, especially mRNA vaccines.

Based on recent research, the goal of this study is to present a thorough overview and analysis of the current status and limitations of vaccines. It discusses and organize the new developments in the field of DNA and RNA vaccines, such as initiatives to enhance and develop delivery systems that are essential to the efficacy of treatments better delivery device design, find the best delivery locations, and personalize cancer immunotherapy through vaccines.

Audience Take Away Notes

- Attendees will gain a comprehensive understanding of how DNA and RNA vaccines work, including the key differences and similarities between them. This will enhance their knowledge of vaccine technologies and their role in combating both hereditary and acquired diseases.
- The presentation will explain the challenges associated with vaccine delivery, particularly for DNA vaccines, and explore emerging methods to improve delivery system design, targeting, and efficacy.
- Audience will learn how DNA and RNA vaccines are being used to personalize cancer immunotherapy, offering tailored treatments based on the genetic makeup of tumors. This could open new avenues for their research or clinical practice.
- The presentation will highlight advancements in vaccine design, including the use of novel delivery devices and identification of optimal delivery sites. This will be relevant for those involved in designing more effective vaccines, enhancing both research and practical applications.

Biography
The presenter completed her undergraduate degree in Cell and Molecular Biology at Azad University in Iran in 2018. After working in a biotechnology company and a research center for three years, she became more passionate about continuing her higher education in another country to gain additional experience. During these years, her first publication was released, and her other articles are currently under review. She is currently a second-year Master's student in Medical Pharmaceutical Biotechnology at the University of Genoa, Department of Pharmacology and Experimental Medicine.

Fatma Haddad*, R.C. Gopalan, Md Talat Nasim, K.H. Assi
School of Pharmacy and Medical Sciences, University of Bradford, Bradford BD7 1DP, UK

Preparation and characterization of inhaled Luteolin nano-liposomes for the potential management of pulmonary arterial hypertension

Luteolin is a natural flavonoid abundant in several fruits, vegetables, and medicinal herbs. Although luteolin has numerous pharmacological activities, its low water solubility and bioavailability restrict its therapeutic efficacy. This work aims to overcome these limitations by developing an inhalable luteolin-loaded nanoliposome and investigating its anti-pulmonary arterial hypertension effects. The thin-film rehydration method was applied to formulate the inhalable luteolin liposomes using two phospholipids with high-phase transition temperatures and cholesterol without surfactant. The aerodynamic behaviour of the developed luteolin nano-formulation was determined using the next-generation impactor, and its effects on the TGF-β pathway and anti-proliferative effects were determined using cell-based assays. The novel formulated inhalable luteolin liposomes had an average liposome size of 117±7.4 nm, a polydispersity index of 0.1, a zeta potential of −26.7±3 mV, and high encapsulation efficiency. The newly formulated luteolin nano-liposome exhibited excellent aerodynamic properties as follows: the mass median aerodynamic diameter was 3.91±0.04 μm, the fine particle fraction ≤5μm was 58.59±0.34%, and the percentage of particles ≤3μm was 38.84±0.28%. This indicates that the newly developed luteolin liposome possesses all the necessary characteristics for inhalation and is anticipated to be effectively delivered deeply into the lungs. The in vitro release study revealed a significantly enhanced luteolin release profile using nano-liposomes compared with free luteolin ($p \leq 0.001$). The TGF-β pathway is stimulated in individuals with pulmonary arterial hypertension lungs. The free luteolin and nano-liposomes encapsulated luteolin significantly inhibit the TGF-β/SMAD 3 dependent signalling in a dose-dependent manner using a TGFβ-responsive reporter assay ($p \leq 0.001$). Interestingly, the MTT assay results showed that the developed luteolin nano-liposomes have a markedly higher anti-proliferative effect than free luteolin on mutant mouse pulmonary arterial smooth muscle cells ($p \leq 0.001$). These findings indicate that the newly formulated luteolin nano-liposome could be used in experimental research and clinical settings for pulmonary arterial hypertension.

Audience Take Away Notes

- This presentation will provide a practical example of how nano-liposome formulation improves the *in vitro* effects of low-water-soluble natural compounds compared with delivering free compounds
- It will help the audiences to understand the factors that help maintain the stability of inhalable liposomes during nebulisation
- It will offer a successful example of formulating high-safety profile inhalable nano-liposomes for natural compounds without needing any surfactant or co-surfactant
- The newly developed luteolin nano-liposome inhibits TGF-β signalling and has anti-proliferative effects in cell-based studies and thus holds promise as a potential treatment for pulmonary arterial hypertension

Biography

Miss Fatma Haddad studied an MSc in pharmaceutical science from Al-Quds University, Palestine, ranking 1st place among the year's 685 graduate students in graduate studies in 2018. She has received the best MSc thesis award and the most active research group from Al-Quds University. She is in the last year of her PhD at the School of Pharmacy and Medical Science at the University of Bradford, Bradford, United Kingdom. Her research focuses on developing inhalable formulations such as nano-liposomes, nano-emulsions, and nanoparticles for potentially treating lung cancer and pulmonary hypertension. She has published several research articles in prestigious journals.

Ferah Comert Onder[1]*, Khaled A.N. Abusharkh[2-4], Venhar Çınar[5], Merve Sıkık[6], Alper Onder[3], Gulce Davutlar[6], Zuhal Hamurcu[5], Mustafa Guzel[7-9], Mehmet Ay[3], Bulent Ozpolat[10]

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In silico, synthesis, and in-vitro studies of novel FOXM1 inhibitors for targeted triple negative breast cancer therapy

Triple-Negative Breast Cancer (TNBC) is subtype of breast cancer is known for aggressive, leading to early relapses, metastasis and poor clinical prognosis. Significant heterogeneity and drug resistant phenotype and lack of effective targeted therapeutics contribute to poor patient survival. Forkhead box (FOX) protein M1 (FOXM1), a proto-oncogenic transcription factor, is overexpresses in TNBC cells and drives cell proliferation invasion and tumorigenesis. We have previously found that FOXM1 expression is a poor prognostic factor and associated with shorter patient survival in TNBC patients. Using genetic methods, we for the first time validated FOXM1 as a molecular target in TNBC. The inhibition of FOXM1 significantly suppresses the growth of TNBC tumour xenografts in mice by regulating the eEF2K signalling pathway. Currently, there is no FDA-approved FOXM1 inhibitor for clinical translation as existing inhibitors are not potent or selective for FOXM1 inhibition. Therefore, identification of novel, safe, selective and potent inhibitors are needed to effectively target FOXM1 TNBC tumours. In current study, we designed and synthesized novel potential FOXM1 inhibitors by using *in silico* studies such as molecular docking, Molecular Dynamics (MD) simulations, and ADMET predictions. The newly synthesized compounds were evaluated in vitro in TNBC cells lines by performing cell proliferation and colony formation assays, and western blot analysis for FOXM1 inhibition. Synthesized some thiazole-containing compounds were found to be highly active and inhibited cell proliferation and inhibited FOXM1 in TNBC cells. These promising results will be discussed.

Acknowledgement: This study was supported by the Scientific and Technological Research Council of Türkiye (TÜBİTAK) (Project no: 221S682).

Audience Take Away Notes

- This study may be possible to identify effective FOXM1 inhibitors for the treatment of Triple Negative Breast Cancer.
- In the field of health/pharmaceuticals, which is among the priority areas, our FOXM1 inhibitor/drug development studies for the treatment of breast cancer can contribute to cancer treatment, as well as to the quality of life by solving the disease and increasing the number of healthy individuals.
- Within this study, we want to carry out to solve these problems is related to this type of impact and development plan.

Biography

Dr. Comert Onder received her PhD degree in Organic Chemistry at the Çanakkale Onsekiz Mart University, Türkiye in 2019. She joined the research group of Prof. Dr. Ozpolat at MD Anderson Cancer Center, Houston, TX, USA in 2018. She has been studying as an Assistant Professor at the Faculty of Medicine Çanakkale Onsekiz Mart University since 2020. There are several published research articles, congress presentations, book chapters, and patent applications. Her research areas are drug design, discovery and development, medicinal chemistry, cancer biology, organic chemistry, and natural products.

Gurpreet Singh
Vice President, Managing Director Integrated Safety, IQVIA, United Kingdom

Global drug development- Current trends, challenges and opportunities

The entire process of developing a drug from preclinical research to marketing can take approximately 12 to 18 years and often costs well over $1 billion. Global Top Pharmaceutical Companies based on projected R&D spending in 2026 are Roche, Johnson & Johnson, Merck & Co, Pfizer and Novartis. The global CRO services market in terms of revenue was estimated to be worth $76.6 billion in 2023 and is poised to reach $127.3 billion by 2028.

Global Drug Development Trends

- Increased Focus on Quality, Compliance and Quality Management System
- Requirements of Audit and Inspection readiness
- Process Enhancements, Changes, Improvements
- Further adoption of Technology and Tools, Database migrations
- Focus on Data Analytics and Trends
- Organisational Culture Enhancement –Focus on People Development, Training and Retention
- Change Management – Mergers / Acquisitions and Integrations

Global Drug Development Challenges & Opportunities

- Requirement of skilled resources
- Retention of Talent
- People Development Needs
- Standard Operating Procedures
- Better quality and compliance
- Need for better productivity
- Adoption of Technology
- Reduce cost per transaction
- Improve Efficiency

Audience Take Away Notes

- Understanding of the Global Drug Development Industry. The current trends, challenges and opportunities
- Four important pillars of Drug Development – People, Process, Technology and Partnerships
- Digital Transformation in Drug Development
- Top 10 Trends in Drug Development like Personalized medicine, Orphan drugs for rare diseases & New clinical trial models (Decentralized Clinical Trials)

Biography

Gurpreet Singh is currently the Vice President, Managing Director Integrated Safety at IQVIA. He is based in UK and has a total of 18 years' experience in Pharma Industry of which 16+ years have been in Global Drug Development. During these years he has had the opportunity to work with some top Global companies like Cognizant, Tata Consultancy, Novartis and Parexel. At Novartis he was the Global Head of PV Operations managing all Global PV activities. At Parexel he was the Senior Director PV Operations responsible for managing PV projects of top Global Pharma and Biotech companies. Gurpreet is a certified Six Sigma and Project Management Professional. He has keen interest in Digital Transformation and Organization Culture and has successfully led various projects during his tenure in the Pharma Industry. He is an avid runner and a speaker at various Pharma conferences.

Ibrahim A Al Othaim
Saudi Food & Drug Authority, Saudi Arabia

Development of a sensitive method for the determination of Enrofloxacin in falsified veterinary products

Background: Enrofloxacin (enro) is a broad-spectrum fluoroquinolone antibiotic active against both Gram-positive and Gram-negative bacteria. It is used extensively in both animals and humans due to its high bioavailability and the wide range of susceptible infections. However the use of falsified and substandard veterinary products as poor quality and counterfeit formulations increase the risk of treatment failure due to Antimicrobial Resistance (AMR). Therefore there is need to screen for quality of veterinary products, thus twenty one suspicious veterinary products withdrawn from the market in Saudi Arabia and the RLMC Received a request from operation sector at Saudi Food & Drug Authority to evaluate these products.

Methods: Medicines Reference Laboratories developed method for quantification, determination and analysis of Norfloxacin and Enrofloxacin via utilizing Liquid Chromatography-Mass Spectrometry (LC/MS) which is very sensitive analytical instrument compared to previous USP method utilized the HPLC instrument.

Results: The results displayed 8 samples are found to be falsified veterinary products contaminated with Enrofloxacin and mislabeled ingredients due to other ingredients were added to the content of preparation.

Concolusion: This developed method can be used to assess the quality of veterinary products in the field and identify substandard, poor quality and falsified veterinary products, potentially our findings may be helpful to identify particular causes for concern such as accidental contamination with Enrofloxacin and will be essential in combating transnational veterinary medicine crime, and reducing the circulation of falsified veterinary products.

Biography

Dr. Ibrahim A. Al Othaim studied pharmaceutical analysis at the Strathclyde University, in UK and graduated as MS in 2009. He then joined the research group of Prof. David Watson at the Institute of pharmacy and Biomedical science, Faculty of Sciences (SIPBS). He received her PhD degree in 2018 at the same institution. After that Joined Saudi Food & Drug Authority particularly at Lab and research Sector, Then he obtained the position of Senior Chief Lab Research Expert at SFDA. He has published more than 5 research articles in Several journals.

Dr. K. Bhavyasri
RBVRR Women's College of Pharmacy, affiliated to Osmania University, India

Novel chromogenic method as a sensitive technique in estimating analytes

To develop and validate a simple and sensitive UV spectrophotometric method for Quantification of Hesperidin in bulk and Ayurveda formulation including plant extracts using chromogenic compound Gibb's reagent (2, 6-Dichloro quinone 4-Chloroimide). Chromogenic method was developed in visible region by using GIBBS Reagent. Hesperidin reacts with Gibb's reagent and 0.01N sodium hydroxide solution (Adjusted to pH 9 with dilute HCL) to produce blue colour complex.

The reaction between a chromogenic reagent and a drug is often specific to certain functional groups or chemical structures, allowing for selective detection and measurement. Gibb's reagent chiefly utilized for the identification and determination of phenols, unsubstitued and p-alkoxy phenols. which is measured at 500–670nm. Hesperidin is a category of bioflavonoid (Flavonoid-7-o-glycosides), is isolated from citrus fruits. It is used for blood vessel conditions such as hemorrhoids, varicose veins.

For the spectrometric analysis of Hesperidin using an ELICO SL210 UV-Visible spectrophotometer with spectral treats software in accordance with International Council for Harmonization (ICH) guidelines Q_2 (R1), the 613nm wavelength absorbance was considered the primary maxima given improved reproducibility for further dilutions at that wavelength. The method was then validated using validation parameters such as linearity, range, precision, accuracy, ruggedness and robustness as stipulated in ICH guidelines. Linearity was well demonstrated for a concentration series of 2µg/ml to 40µg/ml, with a linear regression coefficient (R_2) of 0.9999 observed. The %RSD of the precision was observed to be in limits <2%. Accuracy was found to be 98-99% within limits. LOD and LOQ were found to be 0.21318µg/ml and 0.64601µg/ml respectively. The Liquid-Liquid extraction method was used to design, validate, and expand the improved procedure to biological material.

Keywords: Hesperidin, Gibb's reagent, UV-Visible spectrophotometer, Ayurvedic Formulations.

Audience Take Away Notes

- The ability to quantify hesperidin using Gibbs reagent equips the audience, whether they are manufacturers, researchers, healthcare practitioners, or consumerswith critical information to enhance formulation quality, the exact amount of hesperidin allows practitioners to optimize dosages in formulations. Drive research advancements, and make informed health-related decisions.
- This provides students with practical examples of analytical techniques and their applications in pharmaceutical and herbal product development.
- For manufacturers, accurate quantification of hesperidin ensures that their products meet regulatory standards and quality specifications.

- It helps in maintaining consistency across batches, which is crucial for product efficacy and consumer satisfaction. This knowledge enables them to adjust formulations as needed to achieve desired hesperidin levels, thereby optimizing the therapeutic benefits of their products.
- Researchers and Scientists benefit from quantification data to study the pharmacological effects, bioavailability, and potential synergistic effects of hesperidin in various formulations and plant extracts. This knowledge contributes to advancing scientific understanding and may lead to the development of new formulations or therapeutic applications.
- Research on Hesperidin quantification using Gibbs reagent has the potential to inspire Research collaboration, Faculty members specializing in related fields such as analytical chemistry, natural products chemistry, pharmacognosy, or phytochemistry could collaborate to further explore different aspects of hesperidin quantification.
- This could include refining analytical methods, exploring its presence in various plant species, or investigating its stability under different storage conditions. enrich teaching curricula, foster student engagement in research, and contribute to the advancement of knowledge in both basic and applied sciences. It serves as a foundation upon which other faculty members can build to expand their research agendas and educational offerings.
- Other Benefits
    - Advancement of Scientific Knowledge
    - Application in Herbal Medicine and Ayurvedic Formulations
    - Potential Health Benefits
    - Interdisciplinary Collaboration
    - Commercial applications in the pharmaceutical, nutraceutical, and herbal product industries. Companies can use this information to develop standardized herbal extracts or improve existing formulations based on scientific evidence.

Biography

Dr. K. Bhavyasri is an accomplished academician and researcher currently serving as an Associate Professor and Head of the Department of Pharmaceutical Analysis. With over 13.4 years of teaching experience in the field, she has made significant contributions to the academic and research landscape of pharmaceutical sciences. Dr. Bhavyasri's academic journey is marked by a strong inclination towards research, evident from her extensive publication record. She has authored over 180 publications, showcasing her dedication to advancing knowledge in pharmaceutical analysis and related disciplines. Her research interests likely encompass various aspects of pharmaceutical analysis, contributing valuable insights to the field. In addition to her research endeavors, Dr. Bhavyasri has also played a pivotal role in mentoring the next generation of pharmaceutical professionals. She has guided 46 M.Pharmacy students, nurturing their academic growth and preparing them for impactful careers in the pharmaceutical industry or academia. Dr. K. Bhavyasri's professional achievements underscore her commitment to excellence in education, research, and student mentorship within the field of pharmaceutical analysis. Her contributions are pivotal in shaping the future of pharmaceutical sciences and fostering innovation in drug analysis methodologies.

Maria Borrell
Institut de Recerca Sant Pau, Barcelona, Spain ; CIBER-CV, Instituto de Salud Carlos III, Spain

PCSK9 roles beyond cholesterol lowering

Atherosclerosis, the leading cause of cardiovascular diseases, is driven by high blood cholesterol levels and chronic inflammation. The disruption of the hepatic interaction between Proprotein Convertase Subtilisin/Kexin 9 (PCSK9) and Low-Density Lipoprotein Receptor (LDLR) downregulates blood cholesterol levels and reduces cardiovascular events. Recent data suggest that other members of the LDLR superfamily may be targets of PCSK9.

In this presentation I will show that LDLR-related protein 5 (LRP5) is a PCSK9 target, and both proteins participate in foam cell formation and hence, in the mechanism of lipid accumulation and atherosclerotic plaque formation.

I will first show that LRP5 is needed for macrophage lipid uptake since LRP5-silenced macrophages have less intracellular cholesterol accumulation. Immunoprecipitation experiments will show that LRP5 forms a complex with PCSK9 in lipid-loaded macrophages opening the possibility that PCSK9 induces lysosomal LRP5 degradation in a similar manner than it does with LDLR. We have also studied the role of PCSK9 and LRP5 in the inflammatory response by TLR4/NFkB signaling pathway and show that PCSK9 gene interference decreases inflammation supporting a role for PCSK9 as an inflammatory mediator in atherosclerosis.

We then validated our results in an in vivo mice model. We analyzed the differential expression of cholesterol related genes and proteins including LRP5, PCSK9, VLDLR, LRP6, LRP2 and LRP1 in Wildtype (Wt) and LRP5 knock-out (*Lrp5-/-*) mice fed a Normocholesterolemic (NC) or a Hypercholesterolemic (HC) diet. Lipid uptake was studied in liver resident cells (HepG2) and in liver fat storing cells (hepatic stellate cells) with and without LRP5 and PCSK9. Results show that cholesterol accumulates in livers of Wt and *Lrp5-/-* mice. This accumulation can be explained by the increased expression of LRP receptors in HC Wt mice or scavenger receptors in HC *Lrp5-/-* mice. More importantly, PCSK9 and LRP5 bind intracellularly in fat storing liver cells but not in structural liver cells and both proteins are needed for lipid uptake.

Audience Take Away Notes

- They will learn new roles of PCSK9
- PCSK9 inhibitors are being used worldwide and are expected to increase their sales in the next years. However the roles of PCSK9 beyond lipid lowering are vastly unknown. In this presentation the audience will learn new roles of PCSK9 to be taken into account when prescribing/taking PCSK9 inhibitors.

Biography

Dr. Borrell is a senior investigator in the Cardiovascular Program at the Hospital de la Santa Creu i Sant Pau, Barcelona. Prior appointments include a postdoctoral position in the Neurology Department of the Curie Institut, Paris, France studying Huntington's disease. She leads a project based in lipoprotein receptors role in cholesterol metabolism. In the recent years she has been developing a project that analyzes the function of PCSK9 beyond its canonical function in cholesterol lowering. These results have been published in different journals including EHJ, BRIC or CVR and lead to the concession of projects financed by both, the government and the industry.

Muhammed Tilahun Muhammed
Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Süleyman Demirel University, Isparta, Türkiye

Structure elucidation of drug targets through homology modeling in the AI era

Target/Structure-based drug design needs the presence of the target structure to move forward in the drug discovery process. However, the number of macromolecule structures available in the available data banks is limited relative to the high macromolecule sequence release. Homology modeling comes as a crucial rescue to solve this challenge. Homology modeling is being influenced by the introduction of artificial intelligence (AI) to the computer-aided drug design arena. In this regard, AlphaFold is an AI-based program that is used to generate the structure of macromolecules. It is possible to get the AlphaFold predicted structures of macromolecules from the UniProt database. Researchers might prefer to use the ready-made structures available in the UniProt. This study aimed to explore the reliability of the available AlphaFold structures relative to the structures determined through I-TASSER and SWISS-MODEL.

In this study, five drug targets with undetermined structures (human alpha-glucosidase, AXL, CEMIP, DYRK1B, and PARP9) were selected. The structures of the targets were generated through I-TASSER and SWISS-MODEL. The AlphaFold predicted structures of the targets were retrieved from the UniProt database. The best structure of the targets among the I-TASSER and SWISS-MODEL generated models was selected based on ERRAT, Verify3D, and Ramachandran plot criteria. The best structure was then compared to the AlphaFold predicted ones by using ERRAT, Verify3D, and Ramachandran plot values first. Thereafter, the comparison was pursued by using Molecular Dynamics (MD) simulation to evaluate the stability of the predicted structures.

This study revealed that the AlphaFold structures had comparable reliability to the other two methods in terms of ERRAT, Verify3D, and Ramachandran plot values. Furthermore, none of the programs were found to be superior in every aspect. However, the AlphaFold predicted structures had low stability in the MD simulation study. In short, the computational study emphasized the role of consensus modeling in generating reliable structures.

Keywords: Drug Design, Drug Target, Homology Modeling, MD Simulation, Structure Validation.

Audience Take Away Notes

- The audience will be able to design Three-Dimensional (3D) structures of drug targets more accurately.
- The knowledge from this presentation will simplify the structure-based drug design process for researchers.

- Several programs and servers are used in homology modeling. Researchers might be confused about the right way towards a reliable structure modeling. The presentation will present the most suitable approach to get a reliable 3D model.

Biography

Dr. Muhammed Tilahun Muhammed studied Pharmacy at Ankara University, Türkiye, and graduated in 2012. He then did his master's degree in the Department of Biomedical Engineering at Middle East Technical University. He received his PhD degree in Biotechnology in 2020 from Ankara University. He worked as a lecturer at Süleyman Demirel University Faculty of Pharmacy from 2016 to 2021. He has been working as an Assistant Professor at the same institution since 2022. He has published more than 40 articles in SCI(E) journals.

Natassa Pippa*, Aggeliki Siamidi, Marilena Vlachou

Section of Pharmaceutical Technology, Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Panepistimioupolis Zografou, 15771 Athens, Greece

Design and development of controlled release systems: Versatility in drug formulation

Controlled-release drug delivery systems exhibit a gamut of benefits, including improved therapeutic efficacy, reduced side effects, improved patient compliance, and optimized medicine use. For this reason, there is versatility in drug formulation for controlled release purposes. The aim of this lecture is to present two examples of drug delivery platforms with controlled release properties. The first example deals with the design and development of low- and medium-viscosity alginate beads loaded with Pluronic® F-127 nanomicelles. The properties of alginate beads, such as mechanical strength, swelling behavior, and drug release kinetics, were influenced by the encapsulation of the nanomicelles, which exhibited a size around 120 nm with low polydispersity and high stability over time. A model drug, Acetyl Salicylic Acid (ASA), was also encapsulated in the mixed beads, and ASA's release studies were performed[1]. The medium-viscosity alginate beads showed a slow-release profile of the ASA, while the low-viscosity alginate beads showed fast release properties. In the second example, Omeprazole's (OME) development, design, and release kinetics from solid dosage forms have been studied[2]. These formulations were tested for stability in buffer solutions with a pH of 4.5 and for rate of disintegration in an environment similar to the small intestine (pH of 6.8). The outcomes were contrasted with those of the well-known brand product Losec®, whose use has both many advantages and disadvantages. The study employed Thermogravimetric Analysis (TGA) and differential scanning calorimetry (DSC) to investigate the release kinetics of different dosage forms and offer insights into the interactions between the active ingredient and the excipients. In conclusion, the use of pre-formulation techniques such as thermal analysis and the investigation of the interactions between the formulation's components play a key role in the mechanistic explanation of the release profile of the encapsulated active substances when different formulations are involved.

Audience Take Away Notes

- Controlled release drug delivery systems
- Hybrid systems composed of micelles and hydrogels
- The importance of pre-formulation studies

Biography

Natassa Pippa (Pharmacist, MSc, PhD) is Assistant Professor in the Department of Pharmaceutical Technology, National and Kapodistrian University of Athens. Her research is focused on pharmaceutical technology and specifically the design and development of nanoparticles (liposomes, micelles, hydrogels, etc.) for the delivery and targeting drugs. She has published more than 120 scientific papers in peer-reviewed journals (Scopus h-index 21; Google Scholar h-index 22), 15 chapters in scientific books, and is the editor of five scientific books. She has been selected as a speaker at national and international conferences and has presented more than 100 published presentations (oral/poster).

Neha Agarwal
Department of Chemistry, Navyug kanya Mahavidyalaya (University of Lucknow), Uttar Pradesh, India

Pharmaceuticals in the environment: Boon or bane

Pharmaceuticals are essential to ensure the high standards of human health and wellbeing. Extensive and uncontrolled usage under different classes such as antibiotics, analgesics, antipyretics, antidepressant, anticonvulsants, beta-blockers, and steroids, etc. pose high environmental and human health hazards when accumulated in the environment and ecosystem. In recent years pharmaceutical ingredient accumulation as emerging pollutants, intermediates and raw materials in the environment has received great attention all over the world due to their frequent detection in aquatic environments as subclasses of organic contaminants. Human health is directly or indirectly affected by pharmaceutical effluents especially in the vicinity of pharmaceutical industrial zones due to greater probability of contamination in areas of proximity including drinking water. Latest epidemiological studies predicted the possibility of relative risks of brain disorders increasing due to paracetamol exposure. The study of potential impacts of the toxicity of pharmaceutical byproducts on environment and human health is a matter of keen concern. Traditional treatment methods of wastewater are not sufficient for the eradication of active pharmaceutical ingredients and their metabolites from aquatic environments; whereas advanced treatment techniques are not sustainable because of energy consumption, high operational cost, efficiency and efficacy. Therefore, the appropriateness for extensive pharmaceutical production and its rational usage must be checked at the source including a shift to the production of better biodegradable pharmaceuticals in the long run for “sustainable pharmacy.”

Audience Take Away Notes

- An understanding of the accumulation and toxicity associated with the overuse and release of pharmaceuticals in the environment.
- Present and future challenges associated with their accumulation in different environmental matrices.
- Knowledge of various sources of accumulation of commonly used drugs in environment, their serious post effects on health and remediation techniques.
- Further research areas and treatment techniques for a safe and healthy environment and can work for developing sustainable and green environment.
- This research can serve as a career option for expanding both future research and teaching.

Biography

Dr. Neha Agarwal is currently working as Assistant Professor in Department of Chemistry, Navyug Kanya Mahavidylaya, University of Lucknow, India. She had completed her Ph.D. from the University of Lucknow. She has qualified UGC-CSIR-NET Chemical Science and GATE-Chemical Science. She has published 4 patents, many research papers in highly reputed scopus indexed journals, edited many books with Nova Science Publishers, Benthem Science Publishers, Springer Nature, CRC Press, Anu Books International Publishers, and authored two text books for undergraduate students. She is an active member of various National and International bodies and also the editorial board member of various international, referred and peer reviewed journals. Her research interest includes the study the environmental impacts of vast variety of organic pollutants such as pharmaceuticals, dyes, pesticides and to find out economically viable treatment techniques which degrade these pollutants and achieve a green and sustainable environment.

Panagiotis Mallis
Hellenic Cord Blood Bank, Biomedical Research Foundation Academy of Athens

Mesenchymal stromal cells as therapeutic tools in immune disorders: Promising evidence from in-vitro results

Background: Mesenchymal Stromal Cells (MSCs), a multipotent stem cell population which can efficiently be obtained from different tissue sources, exert key specific regenerative and immunomodulatory properties. However, MSCs require priming through binding of IFN-γ to the receptor IGFR1, for the induction of their immunomodulatory properties. Moreover, the mediated immunomodulation by MSCs can be exerted either through direct contact (cell-cell interaction) or the paracrine production of anti-inflammatory biomolecules. Due to the great tolerabily and low immunogenecity that MSCs exhibited when allogeneically administrated, these stem cells are currently used in a great number of clinical trials (>1300 studies, worldwide), including mostly their application against autoimmune diseases, Graft Versus Host Disease (GvHD) and cancer. In addition, clinical grade MSCs were evaluated for the efficient regulation of acute immune responses and Cytokine Release Syndrome (CRS) in COVID-19 patients. Besides their beneficial effects, MSCs share different regenerative and immunoregulatory potential, among the different tissue origins, which may hamper their immunomodulatory properties.

Aim: The aim of this study was the evaluation of the functional properties of MSCs obtained either from fetal and adult origin, to possibly desipher their immunomodulatory potential.

Methods: MSCs derived from the human Wharton's Jelly (WJ, n=20) tissue and Bone Marrow (BM, n=20) were isolated, cryopreserved, expanded, and characterized according to the criteria outlined by the International Society for Cell and Gene Therapies (ISCT). WJ (n=20) and BM-MSCs (n=20) were stimulated with a culture medium containing IFN-γ (50 ng/ μl), 1% penicillin-streptomycin, and 1% L-glutamine for 48 h. The quantification of IL-1Ra, IL-6, IL-10, IL-13, TGF-β1, VEGF-a, FGF, PDGF, and IDO was performed using commercial ELISA kits. The expression of HLA-G1, G5, and G7 was also evaluated in WJ and BM-MSCs. WJ and BM-MSCs were co-cultured in 96 transwell plates with M0 macrophages, to evaluate their immunoregulatory properties, through the polarization effect. The determination of the HLA alleles of the MSCs was performed using the Next Generation Sequencing (HLA Holotype 11 loci, Omixon Inc., MiSeq, Illumina). The frequencies of the HLA alleles were estimated using the machine learning algorithms in R language.

Results: Thawed WJ and BM-MSCs exhibited a spindle-shaped morphology, successfully differentiated to "osteocytes", "adipocytes", and "chondrocytes", and in flow cytometric analysis were characterized by positivity for CD73, CD90, and CD105 (>95%) and negativity for CD34, CD45, and HLA-DR (<2%). Moreover, stimulated WJ and BM-MSCs were characterized by increased cytoplasmic granulation, in comparison to unstimulated cells. The HLA-G isoforms (G1, G5, and G7) were successfully expressed by the unstimulated and stimulated WJ-MSCs. On the other hand, only weak expression of HLA-G1 was identified in BM-MSCs. Stimulated MSCs secreted high levels of IL-1Ra, IL-6, IL-10, IL-13, TGF-β1, FGF, VEGF, PDGF, and IDO in comparison to unstimulated cells ($P<0.05$) after 12 and 24 h.Importanty, MSCs from both sources achieved

to induce the M_2 macrophage polarization, under in vitro conditions. The most frequent HLA alleles were determined, to identify potential association with the MSCs immunomodulatory properties.

Conclusion: The results of this study showed that WJ-MSCs have greater immunoregulatory potential in terms of paracrine factors secretion, compared to the BM-MSCs. Taking into consideration the data presented herein, well-defined WJ-MSCs could be used as Advanced Therapeutic Medicinal Products (ATMPs) and alternative treatment option for severe immune disorders. In this way, a stem cell bank with MSCs lines could be established, in order to serve better the purposes of the precision medicine.

Biography

Panagiotis Mallis gained his bachelor's degree (BSc) in Biomedical Sciences from the University of West Attica in 2010. In 2013, he received his master's diploma (MSc) and in 2018, received his PhD in Tissue Engineering and Regenerative Medicine from the Medical School of National and Kapodistrian University of Athens. Currently, Mallis Panagiotis serves as affiliate researcher at the Hellenic Cord Blood Bank (HCBB). Panagiotis Mallis has extensive experience in Mesenchymal Stromal Cell (MSCs) isolation and in vitro manipulation. His current research involves the investigation of MSCs' immunoregulatory/immunosuppressive properties and their application in tissue engineering and regenerative medicine approaches.

Mr. Pratip K. Chaskar*, Rakesh R. Somani
Department of Pharmaceutical Chemistry, D Y Patil Deemed to be University School of Pharmacy, Nerul, Navi Mumbai, Maharashtra, India

Unveiling green chemistry: Exploring sustainable practices

The forthcoming presentation will delve into the fundamental tenets of Green Chemistry, highlighting key methodologies such as Phase Transfer Catalysis (PTC), Ionic Liquids (IL), Sonochemistry, and Microwave Irradiation (MWI). These cutting-edge approaches epitomize the evolution of sustainable practices in chemical synthesis, offering both theoretical insights and practical applications.

Green Chemistry, often referred to as sustainable chemistry, embodies the ethos of minimizing the environmental impact of chemical processes while maximizing efficiency and safety. At its core, Green Chemistry seeks to design chemical products and processes that reduce or eliminate the use and generation of hazardous substances.

One pivotal aspect of Green Chemistry is Phase Transfer Catalysis (PTC), a technique that facilitates the transfer of reactants between immiscible phases by employing a catalyst. By leveraging a catalyst, typically a quaternary ammonium salt or crown ether, PTC enables reactions to proceed efficiently under mild conditions, thereby reducing energy consumption and waste generation. This approach has found widespread application in organic synthesis, pharmaceuticals, and polymer chemistry.

Ionic Liquids (IL) represent another cornerstone of Green Chemistry, offering a versatile solvent platform with unique properties such as low volatility, high thermal stability, and tunable polarity. These molten salts, composed entirely of ions, have emerged as green alternatives to traditional organic solvents due to their negligible vapor pressure and recyclability. Ionic Liquids play a vital role in various processes ranging from biomass conversion and catalysis to electrochemistry and separation technologies.

Sonochemistry harnesses the power of acoustic cavitation to drive chemical reactions, offering a green route to synthesis through the generation of highly reactive species such as free radicals and hot spots. Ultrasonic irradiation induces cavitation bubbles in liquid media, leading to localized heating and pressure differentials that accelerate chemical transformations. This sonochemical activation enables the synthesis of complex molecules under mild conditions, minimizing energy input and enhancing reaction rates.

Similarly, Microwave Irradiation (MWI) has revolutionized chemical synthesis by enabling rapid and selective heating of reaction mixtures through dielectric heating mechanisms. Microwave irradiation exploits the ability of polar molecules to absorb electromagnetic radiation, converting it into thermal energy. This efficient heating method promotes homogeneous heating throughout the reaction vessel, facilitating faster reaction kinetics and higher yields. Moreover, MWI allows for precise control over reaction parameters such as temperature and pressure, thereby enabling greener and more sustainable synthesis routes.

Audience Take Away Notes

- **Understanding of Green Chemistry Principles:** The audience will gain a comprehensive understanding of the fundamental principles of Green Chemistry, including its importance, objectives, and strategies for minimizing environmental impact in chemical processes. This knowledge equips them with a framework for designing and implementing sustainable practices in their own research or industrial projects

- **Proficiency in Advanced Synthetic Techniques:** Attendees will learn about cutting-edge synthetic methodologies such as Phase Transfer Catalysis (PTC), Ionic Liquids (IL), Sonochemistry, and Microwave Irradiation (MWI). By grasping the theoretical underpinnings and practical applications of these techniques, they will be able to incorporate them into their work to streamline synthesis, improve efficiency, and reduce waste generation
- **Application in Research and Industry:** The insights gained from the presentation can directly benefit the audience in their research endeavors or industrial applications. They will be equipped with innovative tools and approaches to address chemical synthesis challenges more sustainably, leading to cost savings, enhanced productivity, and a reduced environmental footprint in their respective fields
- **Potential for Interdisciplinary Collaboration:** The research presented may serve as a catalyst for interdisciplinary collaboration among faculty members from different departments or institutions. By exploring the intersections of Green Chemistry with other fields such as materials science, engineering, and environmental science, researchers can leverage synergies to advance knowledge and address complex societal challenges collaboratively
- **Facilitation of Design and Process Optimization:** The adoption of Green Chemistry principles and advanced synthetic techniques can simplify and expedite the design process for chemical products and processes. By integrating sustainable practices from the outset, designers can streamline operations, minimize resource consumption, and enhance overall process efficiency
- **Enhanced Accuracy and Reliability:** Incorporating innovative methodologies like PTC, IL, Sonochemistry, and MWI into chemical design and synthesis can improve the accuracy and reliability of experimental outcomes. These techniques offer precise control over reaction parameters, leading to reproducible results and facilitating the development of robust, scalable processes
- **Promotion of Environmental Stewardship:** By embracing Green Chemistry principles and sustainable synthetic techniques, the audience contributes to broader efforts towards environmental stewardship and corporate social responsibility. Implementing greener practices not only benefits individual projects but also contributes to a collective movement towards a more sustainable and environmentally conscious chemical industry

Biography

Mr. Pratip K. Chaskar completed his B. Pharmacy degree in 2008, followed by the attainment of his Master's degree in 2010. Presently, he is on the verge of submitting his PhD dissertation at D Y Patil Deemed to be University located in Nerul, Navi Mumbai, Maharashtra, India. With a prolific academic career, he has authored over 30 research and review articles in esteemed journals.

Preeti Sharma[1*], Pradeep Kumar[1], R S Rao[2]
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Telomere length, inflammatory markers and oxidative stress in pre-eclamptic women

Introduction: Preeclampsia (PE) is pregnancy related syndrome which is mainly by gestational hypertension with proteinuria. it affects 2 to 10 % of pregnant women. Improper maternal spiral artery remodelling leads to decreased perfusion to the placenta. Hypoxic placental organ may release micro vesicles(apoptotic cell/ atheromatous plaques), which promotes exaggerated inflammation causing increased CRP, IL 6, TNF alpha, and Oxidative Stress (OS) markers (MDA) into circulation.

Aim: Aim is to find out relationship between the telomere length, markers of inflammation, and Oxidative Stress in preeclamptic women.

Methods: A case-control study included PE cases (n=90) and controls (n=70). RT-PCR measured Relative Telomere Length (RTL) as a T/S ratio. Serum levels of Malondialdehyde (MDA) and C-Reactive Protein (CRP) by using competitive ELISA and Uric Acid (UA) levels by autoanalyzer.

Results: RTL is significantly (p=.000) reduced in PE compared to control. MDA, CRP, and Uric acid levels significantly (p=.000) increased in cases than in control. Telomere length decreased with the rise in BP, and CRP, MDA, and UA levels increased significantly with an increase in BP. Therefore, we planned to explore the association between telomere length, inflammation, and oxidative stress with every ten mmHg increase in BP.

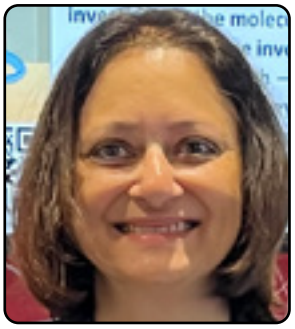
Conclusion: Increasing BP by ten mmHg led to shorter Telomere Length and increased MDA, CRP, and UA levels. Therefore, increasing BP is associated with shorter telomere length, oxidative stress, and inflammation in PE.

Audience Take Away Notes

- The current study concludes with an association of RTL, MDA, GSH, ET1, IL6, TNF alpha, CRP and Uric acid in PE patients. A positive association was seen for RTL, MDA, GSH, ET1, IL6, TNF alpha, CRP and Uric acid levels with increasing BP.
- Therefore, this study may provide link between oxidative stress and inflammation with a reduction in telomere length that leads to the pathophysiology of PE.
- We suggest based on our study, antioxidants and anti-inflammatory drugs may help in reducing incidence of preeclampsia.

Biography

Motivating and talented Biochemistry Professor, driven to inspire students to pursue academic and personal excellence. Exceptional track record of research success with multiple published articles. Dr. Preeti Sharma is currently working at Autonomous State Medical College, Fatehpur, UP, India, deeply involved in teaching and research. Her area of research has been interdisciplinary including Drug Metabolism, Pharmacokinetics and Inflammatory Markers, Immunology. She has more than 140 publications with high citation and few in phase of communication. She also wrote 2 books, and guided and coguided many MD and Ph.D students. She is member of various professional bodies and has participated and presented number of papers in national and international conferences. She is frequently invited as international speaker. She is awarded with many international and National Scientific Awards for exceptional contribution to research & teaching.



Priya Hays, MS, PhD
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Clinical decision making in advanced and metastatic breast cancer cases between PARP inhibitors and CDK4/6 inhibitors

Background: PARP inhibitors and CDK 4/6 inhibitors have been studied extensively as model targeted agents for advanced and metastatic breast cancer with hormone receptor positive/HER2 negative molecular subtype, the most common in the patient population. Both agents have been evaluated extensively in clinical trials for clinical efficacy and toxicities and studies have proposed recommendations to overcome resistance. A comparison of the agents within each class is presented.

Method: A pubmed search was conducted using the keywords PARP inhibitors and Breast Cancer and CDK 4/6 inhibitors and Breast Cancer and PARP inhibitors and Hormone Receptor Positive Tumors and PARP inhibitors and Toxicity and BRCA1/2 mutation testing and HR+/HER2- Advanced Breast Cancer.

Results: A number of factors, including molecular subtype, genomic characteristics, risk factors such as adverse events and potential for resistance, and evidence for desired clinical outcome must be considered in this decision making process, most impacted by the presence of the BRCA mutation and hormone receptor status and the prognostic and predictive potential of each agent. Specifically, PARP inhibitors, olaparib, talazoparib, and veriparib, should be administered if the patient is positive for the BRCA1/2 mutation. If BRCA test is negative, the three main lines of CDK 4/6 inhibitors, abemaciclib, pablociclib, ribociclib, should be considered for HR+/HER2- molecular subtypes, and the latter patient group should be subdivided into premenopausal and postmenopausal categories. If CDK 4/6 agents are not efficacious in first line settings in combination with aromatase inhibitors, there is evidence that genomic testing for the BRCA gene could be conducted in the clinical setting post treatment and subsequently a PARP inhibitor could be administered.

Conclusion: This presentation explicitly compares these therapies for HR+/HER2- subtypes, and the finding of BRCA testing in the post clinical setting has not been proposed before after the non-efficacious administration of CDK 4/6 in second line settings.

Audience Take Away Notes

- In a clinical scenario of locally advanced and metastatic breast cancer cases, a decision making algorithm is proposed
- The research presented will assist the audience in deciding between PARP inhibitors and CDK 4/6 inhibitors for HR+/HER2- molecular subtypes
- Drug developers would benefit from the discussion of adverse events and drug resistance in the presentation

Biography

Priya Hays, M.S., Ph.D. is an accomplished science writer, having written and published five books as well as having authored over twenty publications in journals as varied as the Bulletin of Science, Technology and Society, L'Esprit Createur, Interdisciplinary Literary Studies, Genetics in Medicine, Journal of Clinical Investigation and Studies, and Preventive Medicine, Epidemiology and Public Health. She is served as Guest Editor for a volume on cancer immunotherapies in the Cancer Treatment and Research series. Her most recent book is a compilation of papers entitled "A Dialectical Mind: Essays in Literary Studies, Science and Medicine" published by Eliva Press. She completed her postdoctoral research fellowship in the Division of Hematology/Oncology, Department of Medicine, at Dartmouth Medical School. She has an A.B. with Honors from Dartmouth College in Biochemistry and Comparative Literature, an M.S. in Genetics from the University of California, Davis, and a Ph.D. in Literature from the University of California, San Diego.

Raja Chakraverty
Department of Critical Care Medicine, IPGME&R, Kolkata-700020, India

Impact of implementation of antimicrobial stewardship (AMSP) and infection prevention and measures (IPC) on MDRO profiles in a tertiary care hospital of India

The study was conducted to gather information to assess the extent of impact of Antimicrobial Stewardship (AMSP) practices on antimicrobial prescribing patterns and bacterial resistance profiles among indoor patients across ten ICU and non-ICU departments at the Institute of Postgraduate Medical Education and Research, Kolkata. The study protocol was submitted to the Institutional Ethics Committee of the institute and it was approved unanimously. A modified version of the patient Case Record Form (CRF) proposed by WHO-AMSP scale was adopted for validation using standard methodologies. Data from indoor patients were collected prospectively from June, 2022 till October, 2023. The use of antimicrobials was categorized as empiric, prophylactic or targeted/culture driven. The WHO-AWARE classification of antimicrobials was used to classify systemic antimicrobials being prescribed to patients. Study data was archived and analyzed using software such as SPSS 20.0 (IBM), Jamovi and Med Calc 8 (Belgium).Total number of beds covered annually was 2972 and the number of patients on antimicrobials was found to be as high as 98.57%. Relatively higher numbers of patients were found to be on two or more antimicrobials predominantly from WATCH and RESERVE categories. Interestingly, among nosocomial CLABSI and CAUTI rates were 22.05% and 22.11% respectively with a relatively lower proportion of SSIs 0.88%. Mortality relatedness to infection was found to be 48.62%. The overall compliance rate to hospital antibiotic policy was found to be 72.51% while culture was sent in nearly 59% of the patients surveyed. Rationality assessment and prospective audit and feedback of antimicrobials was performed which is under analysis. This preliminary study resulted in acquisition of data not only related to resistance profiles of microbial pathogens to antimicrobials but also yielded data about determinants of hospital acquired infection including surgical site infections which may aid policy makers to formulate newer antimicrobial guidelines in the state and country based on such definitive findings.

Audience Take Away Notes

- Antimicrobial Resistance research in India
- Infection prevention and control
- Antimicrobial Stewardship and its feasibility in LMICs

Biography

Dr. Raja Chakraverty serves as an ICMR Scientist co-ordinating research on Antimicrobial Resistance and based at the Department of Critical Care Medicine at IPGME&R, Kolkata. He is a well-known biomedical scientist who studied Pharmaceutical Technology at the UG, PG and Doctoral level. He has 11 years of rich teaching and research experience. Dr. Chakraverty has been awarded many accolades for Best Paper awards at National Seminars and has travelled to countries for academic discourses and invited orations. Dr. Chakraverty is a prolific writer who has published around 60 high impact articles in indexed journals and several book chapters and one book. Dr. Chakraverty is also a leading Editor for various journals. He is also a life member of the Indian Pharmacological Society.

Rayhan Shahid Shanavas[1,2*], Panya Ajay[3], Triveni Yarraboyena[3], Ravi Pigil[3]

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UPLC method development and validation for the estimation of Sulbactam and Durlobactum in pharmaceutical dosage form

Infectious diseases especially associated with multidrug resistant pathogens in critically ill patients is an area of global research and concern for healthcare professionals across both private and public sector. Sulbactam and Durlobactam have been approved as a combination drug, called Xacdura, recently for the treatment of Hospital-Acquired Bacterial Pneumonia (HABP) and Ventilator-Associated Bacterial Pneumonia (VABP) caused by Acinetobacter baumannii-calcoaceticus complex and is commercially available currently only in the US and China. With 1 million cases of drug-resistant Acinetobacter infections seen globally year-on-year leading to potentially about 300,000 deaths, we expect rapid investments in the development of follow-on drugs, even though the primary patents expire between 2033-2035. Currently there is no pharmacopeia method for this combination which can aid in quantification or purity testing to aid these pharmaceutical development efforts. Accordingly, we have developed an Ultra-Performance Liquid Chromatography (UPLC) method for the simultaneous estimation of Sulbactam and Durlobactum. The best chromatographic separation was obtained when the HSSC18 column (1.7µm; 2.1 x 100mm) was used with 0.01N KH2P04: Methanol in 70:30 v/v ratio as mobile phase at an injection volume of 3µL, and run rate of 0.3mL/min. Sulbactam and Durlobactam eluted at 1.77 and 1.33 minutes respectively. The described method shows high precision, sensitivity, resolution, accuracy, linearity and robustness as well as reliability. The method was specific as none of the known or unknown impurities expected during the degradation experiments, conducted across different conditions, were seen to be eluted during the same window as the chosen drugs. The described method is expected to accelerate the development and commercialization of the formulations of these drugs with higher efficiency, lower cost and faster run rate.

Audience Take Away Notes

- Given the importance of the antibiotic resistance and the need for these drugs globally, the audience gets to understand the detailed validated methodology to simultaneously quantify the parent drugs and detect any impurities accelerating the drug registration and approval in many countries
- Deployment of QbD approach to simultaneously detect two drugs yielding a new scalable and economic UPLC method
- The diverse parameters, per ICH guidelines, that get validated before deploying any analytical chemistry method in drug discovery and development.

Biography

Rayhan S. Shanavas is a senior at Oakridge International School, UNICEF Ambassador of his school, and the co-founder of The Synapse Foundation. He is committed to building a more equitable society by understanding healthcare disparities and innovating with other change leaders. Access to pharmaceutical drugs is one such critical healthcare challenge that he is focussing on by evaluating drug development and approval value chain and bottlenecks that need to be solved for. He has worked with senior authors on this project by evaluating the therapeutic landscape, available methods, analyzing and validating the data from optimized methods against the required specifications.

Ruchika Bajaj
Department of Bioengineering and Therapeutic Sciences, University of California San Francisco, San Francisco, California, USA

Understanding ABC transporters to navigate human diseases

Membrane proteins constitute 30% of the genome in organisms and are involved in numerous physiological processes. ABC transporters is a class of membrane proteins which are ubiquitously present in all organisms, bind and hydrolyze ATP to power the solute transport and are associated with several human diseases like multidrug resistance in cancer, macular degeneration, cystic fibrosis, retinitis pigmentosa etc. ABC transporters consists of two Transmembrane Domains (TMDs), which form the permeation pathway and Nucleotide Binding Domains (NBDs) to bind and hydrolyze ATP and follow alternating access mechanism. Bacterial ABC transporters like binding-protein-independent mutant of maltose transporter, MalG511 from E.*coli* and FtsEX-PcsB from S. *pneumoniae* have been characterized biochemically and biophysically to study mechanism and future higher resolution studies. Structure-function relationships were studied in mammalian ABC transporters, bovine MRP4 and human P-glycoprotein. High resolution cryoEM structures of bovine MRP4 in three different states (apo state, nucleotide bound state and substrate bound state) are determined which revealed the architecture, asymmetry of NBDs, interpreted functional effects of genetic variants, located substrate binding site, deciphered associated conformational changes in catalytic cycle of bovineMRP4. Structure based drug designing and targeting MRP4 in context of cancer and cardiac diseases will be helpful to the field of medicine. Oral excipients were screened against P-gp using calceinAM fluorescence assay and digoxin flux assay were found to be inert for their effect on P- glycoprotein. beta-Cyclodextrin and light green SF yellowish were found to be inhibitory at high macromolecular range in digoxin flux assay. This information will be helpful in preparing novel generic formulations. Additionally, the meta-analysis study provides an overview of the revolutionizing field of structural biology of ABC transporters.

Audience Take Away Notes
Audience will learn about the ABC transporters, their function and how these sciences can be used for human welfare

Biography
Ruchika has BSc (H) Biochemistry from University of Delhi and MSc. Biotechnology from Indian Institute of Technology Roorkee, India and received her PhD from Purdue University where she was trained as a Membrane Protein Biologist. Afterwards, she pursued her postdoctoral training at UCSF. She focused on ABC transporters all the way in her scientific training. She is very much passionate in elucidating in mechanistic underpinning of membrane proteins using biochemical, biophysical and structural biology approaches, which could help to rationally design novel pharmacological tools to modulate the function of membrane proteins altered in disease.

Dr. Rudra Pratap Singh Rajput[1*], Dr. H. V. Gangadharappa[2], Dr. Deepak Kumar Dash[1]

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Preparation and evaluation of herbosome of herbal plant of *Lawsonia inermis L.* for topical application

Background: *Lawsonia inermis L.* (Lawsone) was reported to contain carbohydrates, proteins, flavonoids and phenolic compounds, alkaloids, terpenoids. The plant has also been reported to have hepatoprotective, anti-inflammatory, antiviral, antifungal and anticancer properties. Lawsone has low bioavailability because it is less soluble in water and it is rapidly eliminated from body.

Objectives: The aim of this study was to prepare and evaluate the herbosome containing lawsone.

Methods: The herbosomes (P_1–P_4) containing different molar ratios (1:1, 1:2, 2:1 and 2:2) of lawsone and soya lecithin were prepared by the anti-solvent precipitation technique. Further it was evaluated for % yield, particle size analysis, % EE and characterized by FTIR, DSC and SEM. Antifungal activity of herbosome of lawsone was evaluated on Candida albicans (NCIM 3471) fungi by using ketoconazole as standard drug. The optimized herbosome was further proceeded for herbosome gel using different polymers. Then, ex-vivo permeation study in vivo anti-inflammatory activity was carried out on male wistar rats.

Results: The herbosome of lawsone P_1 showed better % yield, drug content, particle size and entrapment efficiency as compared to other herbosomes. The Infra-Red (FT-IR) and Differential Scanning Calorimetry (DSC) studies revealed that there was no interaction between the plant drug and phospholipids. SEM data showed that herbosome of lawsone P_1 has irregular size vesicles consisting of soya lecithin and it was found to be intercalated in the lipid layer. Antifungal activity of herbosome P_1 (1:1) showed the better zone of inhibition as compared to P_2 (1:2), drug lawsone and standard drug ketoconazole till 3 days. The ex-vivo permeation study of herbosme gel of lawsone (PG4) through excised rat skin showed 92.91% of drug permeation up to 6 h. The in vivo anti-inflammatory activity of gel of herbosome of lawsone showed significant anti-inflammatory activity as compared to gel of drug lawsone at 4 h ($P<0.001$).

Conclusion: Furthermore, Herbosome of Lawsone has shown the potent ex-vivo permeation study and significant in vivo anti-inflammatory activity as compared to plant drug against microbial infection (C. albicans). This may conclude that it have the effective potential to treat skin infections.

Keywords: Herbosome, Lawsone, Soya lecithin, Topical Application.

Biography

Dr. Rudra Pratap Singh Rajput completed Ph.D at JSSAHER, Mysuru (Karnataka) in 2018. Further, He joined as Assistant Professor in Jeypore College of Pharmacy, Odisha in Aug, 2018 and continued his academic profession in Columbia institute of Pharmacy, Raipur since 29th April, 2019 to 17th Feb, 2022. Further He joined to Royal College of Pharmacy, Raipur on 18th Feb, 2022 and continuing till date. He has supervised 8 degree and 7 post graduation students to accomplish project dissertation work. He has more than 33 publication in SCI(E) indexed reputed journals. He also received an International Travel grant from ICMR, New Delhi to present his work on international platform. He actively participated in various national and international conferences. At latest, he has organized successfully two different National conferences sponsored by Department of Biotechnology, New Delhi and AERB, Mumbai.

Sergey Suchkov[1-6*], Roger D. Kamm[9], Shawn Murphy[7,8], Holland Cheng[10], Noel Rose[7,8,11]

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The promise of nanotechnology in personalized & precision medicine: Drug discovery & development being partnered with nanotechnologies via the revolution at the nanoscale

A new systems approach to subclinical, predictive and/or diseased states and wellness resulted in a new Hi Tech trend in the healthcare services, namely, ***Personalized and Precision Medicine (PPM).***

Meanwhile, despite breakthroughs in designed-driven research that have led to an increased understanding of PPM-based disease, the translation of discoveries into therapies for patients and pre-illness persons-at-risk has not kept pace with medical need. It would be extremely useful to integrate data harvesting from different databanks for applications to thus provide more tailored measures for the patients and persons-at-risk resulting in improved outcomes and more cost effective use of the latest healthcare resources including diagnostic (e.g., companion ones and theranostics), preventive and therapeutic (targeted ones) etc.

Biodesigners, biotechnologists and biomanufacturers are beginning to realize the promise of PPM, translating to direct benefit to patients or persons-at-risk. For instance, companion diagnostics tools and targeted therapies and biomarkers represent important stakes for BioPharma, in terms of market access, of return on investment and of image among the prescribers. So, developing medicines and predictive diagnostic tools requires changes to traditional clinical trial designs, as well as the use of innovative (***adaptive***) testing procedures that result in new types of data. Making the best use of those innovations and being ready to demonstrate results for regulatory bodies requires specialized knowledge that many clinical development teams do not have. The areas where companies are most likely to encounter challenges, are data analysis and workforce expertise, biomarker and diagnostic test development, and cultural awareness. Navigating those complexities and ever-evolving technologies will pass regulatory muster and provide sufficient data for a successful launch of PPM, is a huge task. So, partnering and forming strategic alliances between researchers, biodesigners, clinicians, business, regulatory bodies and government can help ensure an optimal development program that leverages the Academia and industry experience and FDA's new and evolving toolkit to speed our way to getting new tools into the innovative markets.

Healthcare is undergoing a transformation, and it is imperative to leverage new technologies to support the advent of PPM.

Both PPM and PPM-guided and driven nanotechnologies are new to medical practice, which are being integrated into diagnostic and therapeutic tools to manage an array of medical conditions. On the other hand, PPM is a novel and individualized concept that aims to customize therapeutic management based on the personal attributes of the patient. Novel nanomedicines are employed in the treatment of several diseases, which can be adapted to each patient-specific case according to their genetic profiles.

Nanotechnology is used in conjunction with advanced tools such as OMICS technologies to achieve more personalized therapeutic, diagnostic, and predictive strategies. Clinical application of theranostics would enable subclinical detection and preventive treatment of diseases. PPM has thus become an interdisciplinary challenge where nanotechnology-enabled theranostic approaches may indeed become a key driver in harmonizing the needs of the various stakeholders by allowing cost-effective delivery and monitoring of drug efficiency and safety, and close-meshed high-quality data collection.

For instance, nanoparticles and nanocarriers have been developed to overcome the limitations of free therapeutics and navigate biological barriers - systemic, microenvironmental and cellular - that are heterogeneous across patient populations and diseases. Overcoming this patient heterogeneity has also been accomplished through precision and nanodrug-based therapeutics, in which personalized interventions have enhanced therapeutic efficacy. So, the integration of nanotechnology into the PPM-driven healthcare industry holds immense potential for the future, whilst covering: (i) cancer treatment: (ii) diagnostic tools; (iii) tissue regeneration etc. This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM to elicit the content of the new trend.

Meanwhile, it is necessary to to develop new methods or strategies to discover and to create new drugs. With the support of nanotechnology, the solubility, absorption and targeting of traditional drugs were greatly improved by modifying and fabricating with various types of nanoparticles to some extent, though many shortages remain. For instance, candidate proteins associated with disease development and progression might provide novel targets for new targeted therapeutic agents and biomaterials, or aid the development of assays for disease biomarkers and identification of potential biomarker-target-ligand (drug) tandems to be used for the targeting. Latest technological developments facilitate proteins to be more thoroughly screened and examined in the context of drug discovery and development.

The latter means that advancements in nanobiomedicine have played a crucial role in driving the PPM-guided revolution. With the ability to engineer and manipulate materials at the nanoscale, biodesigners have been able to develop innovative solutions for diagnostics, drug delivery, and imaging. So, the Grand Change and Challenge to secure our Health and Wellness are rooted not in Medicine, and not even in Science! Just imagine WHERE?! In the upgraded Hi-Tech Culture!

Biography

Sergey Suchkov was born in the City of Astrakhan, Russia, in a family of dynasty medical doctors. In 1980, graduated from Astrakhan State Medical University and was awarded with MD. In 1985, Suchkov maintained his PhD as a PhD student of the I.M. Sechenov Moscow Medical Academy and Institute of Medical Enzymology. In 2001, Suchkov maintained his Doctor Degree at the National Institute of Immunology, Russia. From 1989 through 1995, Dr. Suchkov was being a Head of the Lab of Clinical Immunology, Helmholtz Eye Research Institute in Moscow. From 1995 through 2004 -a Chair of the Dept for Clinical Immunology, Moscow Clinical Research Institute (MONIKI). In 1993-1996, Dr. Suchkov was a Secretary-in-Chief of the Editorial Board, Biomedical Science, an international journal published jointly by the USSR Academy of Sciences and the Royal Society of Chemistry, UK. At present, Dr. Sergey Suchkov, MD, PhD, is: The Russian University of Medicine, Moscow, Russia. The Russian Academy of Natural Sciences, Moscow, Russia. Member, New York Academy of Sciences, USA. Member, New York Academy of Sciences, USA. Secretary General, United Cultural Convention (UCC), Cambridge, UK. Dr. Suchkov is a member of the: American Chemical Society (ACS), USA; American Heart Association (AHA), USA; European Association for Medical Education (AMEE), Dundee, UK; EPMA (European Association for Predictive, Preventive and Personalized Medicine), Brussels, EU; ARVO (American Association for Research in Vision and Ophthalmology); ISER (International Society for Eye Research); Personalized Medicine Coalition (PMC), Washington, DC, USA.

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Development and evaluation of prolonged-release Dutasteride transdermal delivery system

Benign Prostatic Hyperplasia (BPH), an enlargement of the prostate affecting older men, leads to urinary complications. Oral administration of Dutasteride (DTS) is a common treatment, but it poses challenges for the elderly, including difficulty in taking the medication by mouth, sexual side effects, and the need for daily intake. To address these issues, this study aimed at exploring transdermal delivery systems for DTS, offering a non-invasive alternative with potential benefits such as prolonged drug delivery, and improved patient comfort and compliance. Transdermal patches were prepared using a solution casting method and employing ethylene vinyl acetate as backing layer and Eudragit® RL as drug-loaded film. Triethyl citrate was used as plasticizer, and a 1:1 mixture of Capmu® PG-8-70 NF and Captex® 170 EP was incorporated, in different concentrations, as Penetration Enhancers (PEs). All patches underwent extensive characterization, evaluating parameters such as thickness, weight variation, drug content, folding endurance, and more. Further, the physicochemical properties of the drug and patches were assessed through FTIR, DSC, TGA, XRPD, and SEM analyses. In vitro release and permeation studies were performed using Franz diffusion cells and apparatus. Strat-M® membrane was used for the permeation studies as a highly reliable predictor of human skin permeation. Patches prepared with PEs demonstrated higher drug release than those without PEs. The permeation studies demonstrated increased drug permeation in patches with lower polymer content. The optimal formulation, labelled as patch I, demonstrated an impressive 58.05% drug permeation over a 14-day period, suggesting its potential for sustained DTS delivery and a viable two-week treatment option. This research offers a promising alternative to oral administration, addressing the challenges associated with DTS treatment for BPH. The transdermal patches, characterized by their smooth, clear, and flexible nature, present advantages in terms of patient comfort and convenience. The findings highlight the feasibility of formulating extended-release transdermal patches containing DTS, utilizing Eudragit® RL polymer along with penetration enhancers. Overall, this study opens avenues for improving therapeutic efficacy and patient adherence in the treatment of BPH.

Audience Take Away Notes

- The audience would appreciate the formulation and optimization strategy used in the transdermal delivery of such highly lipophilic drug, which normally pose challenges in drug delivery across the skin
- This research could be used for the information from this study to enhance BPH treatment strategies; they can consider incorporating the transdermal delivery system, into their research or treatment protocols for patients with BPH, thus offering a potential alternative to oral administration, addressing challenges faced by elderly patients, such as difficulty in taking medications by mouth and unwanted sexual side effects, and improve patient outcomes
- The study opens avenues for further research in the field of transdermal drug delivery. Researchers can build upon these findings to explore additional formulations, delivery systems, or combination therapies for BPH treatment or other treatments. This may lead to continuous improvements in therapeutic efficacy and patient adherence

- The research offers valuable insights that other faculty members could potentially use to expand their research or integrate into their teaching. They can use the study's strategies and methodology as a foundation to explore and develop transdermal delivery systems for other drugs or medical conditions. The specific use of Eudragit® RL polymer, Capmul® PG-8-70 NF, and Captex® 170 EP can inspire further studies on the application of these materials in different drug delivery systems
- Hopefully, the interdisciplinary nature of this research can encourage collaboration between faculty members from different departments. This collaboration could lead to more comprehensive studies that address both pharmaceutical and clinical aspects

Biography

Dr. Shereen M. Assaf is a distinguished pharmaceutical sciences professor. After receiving her PhD from the University of Strathclyde, Glasgow, in 1992, she joined the faculty of pharmacy at Jordan University of Science and Technology. She has nine years of administrative experience and extensive contributions to academia. She is also a consultant and committee member at the Jordanian Food and Drug Administration since 2012. Her research focuses on designing pharmaceutical dosage forms, specializing in microencapsulation, nanocarriers, liposomes, and polymeric drug delivery systems across various administration routes.

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Design and assessment of transdermal delivery system containing Levodopa-loaded nanoparticles

Levodopa, an essential precursor of dopamine, was widely used to address motor disorders in the early stages of Parkinson's disease. However, its effectiveness was hindered by a short plasma half-life, enzymatic conversion in the systemic circulation, limited absorption in the upper small intestine, and difficulties in swallowing, particularly common in Parkinson's patients. To overcome these challenges, transdermal delivery of levodopa was explored in this study. The research focused on formulating and characterizing levodopa-chitosan nanoparticles and subsequent integration into transdermal patches. Ionic gelation was employed to prepare the nanoparticles, and their essential attributes, including particle size, zeta potential, encapsulation efficiency, and loading capacity, were evaluated. The transdermal patches were crafted using a film casting technique, incorporating Eudragit® RL as the drug reservoir and ethylene-vinyl acetate as the backing layer. The patches underwent thorough assessment for thickness, weight, drug content, flexibility, drug release, and permeation. Further analyses involved Fourier transform infrared spectral analysis, differential scanning calorimetry analysis, thermogravimetric analysis, and X-ray diffraction for both the nanoparticles and patches. Scanning electron microscopy was employed to observe the morphology of the nanoparticles and their uniform distribution within the polymeric film. A chitosan to tripolyphosphate weight ratio of 3:1 was identified as optimal for subsequent analyses and transdermal preparation. The selected nanoparticles exhibited favorable characteristics, with a size of 141.44 nm, a polydispersity index of 0.29, a zeta potential of 27.30 mV, an encapsulation efficiency of 49.21%, and a loading capacity of 20.40%. The patches, assessed for thickness, weight, and drug content, demonstrated the reproducibility of the solvent casting method. Physicochemical characterization confirmed the absence of interaction between the nanoparticles and Eudragit® RL, and SEM images validated the uniform distribution of nanoparticles in the polymeric film. In vitro permeation studies revealed that nanoparticles enhanced the drug permeation, and patches loaded with nanoparticles exhibited significantly higher permeability than those with pure drug. Notably, the transdermal patches demonstrated prolonged drug permeation compared to free nanoparticles, offering potential advantages in reducing the frequency of applications and enhancing patient compliance.

Audience Take Away Notes

- This study addresses challenges in transdermal drug delivery, discussing how these were addressed and overcome
- The findings could spark new research on levodopa-loaded nanoparticles for targeted brain delivery, potentially eliminating the need for combining therapy with carbidopa
- Valuable for researchers in nanotechnology or transdermal drug delivery, this work offers practical solutions to common issues
- Interesting discoveries in this study suggest promising avenues for future research
- The work outlines a systematic design and approach to optimize the properties of levodopa-loaded nanoparticles and their skin delivery

Biography

Dr. Shereen M. Assaf is a distinguished pharmaceutical sciences professor. After receiving her PhD from the University of Strathclyde, Glasgow, in 1992, she joined the faculty of pharmacy at Jordan University of Science and Technology. She has nine years of administrative experience and extensive contributions to academia. She is also a consultant and committee member at the Jordanian Food and Drug Administration since 2012. Her research focuses on designing pharmaceutical dosage forms, specializing in microencapsulation, nanocarriers, liposomes, and polymeric drug delivery systems across various administration routes.

Shripriya Kalbhavi
Lynbrook High School, San Jose, California, United States of America

A novel method of active medication delivery via microneedles using a Belousov-zhabotinsky oscillating hydrogel

Despite the widespread use of hypodermic needles in intradermal medication delivery, they remain a source of pain and trauma in patients young and old. The research introduces a novel approach to active medication delivery using microneedle arrays, utilizing the high swellability of Belousov-Zhabotinsky oscillating hydrogels. The patch has several essential elements, including an innovative hammock design, a sink, and an oscillating hydrogel that undergoes dynamic swelling and shrinking. The oscillating hydrogel is a mechanical force within the patch, facilitating precise medication delivery through microneedles into the subdermal skin. Several types of hydrogels were synthesized with different catalysts, such as 5-acrylamide-1,10-phenanthroline, 1,10-phenanthroline ferrous sulfate, and iron(5-acrylamide-1,10-phenanthroline)bis(1,10-phenanthroline) sulfate, to test the effectiveness of various hydrogel particle sizes, from microgels to solid gels. A base of n-isopropylacrylamide was used as a pre-polymer, along with a BIS-crosslinker. Still, the initiator was changed to influence the particle size of the gels, and the gels were characterized underneath a microscope as well. A customized plexiglass prototype was constructed to measure the pressure generated by the oscillation of the gels. It was discovered that the solid gel generated the most pressure at 8 millimeters of mercury and displaced the hammock by 0.625 centimeters, showing the utility of oscillating hydrogels in a microneedle patch to deliver medication. The proposed system offers a potential long-term, reusable solution, and a disposable, short-term method, potentially applicable in a hospital setting or for use by patients in a non-clinical setting. The focus on oscillating hydrogels aligns with patient-friendly drug delivery, showcasing their unique capabilities in autonomous and pain-free administration of a diverse range of medications, promising oscillating hydrogels and microneedles in revolutionizing drug delivery.

Audience Take Away Notes

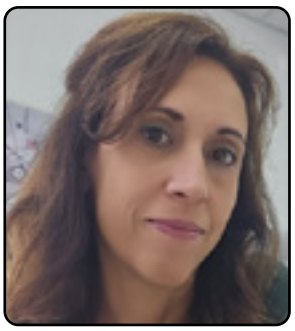
- This presentation serves the purpose of bringing awareness to needle phobia, which is a very common fear that people have, but there have not been many efforts to address this problem as the hypodermic needle has not been changed in design for hundreds of years. Also, it is difficult for many people to self-administer medication, so there is also a need for more autonomous medication delivery systems
- There is still scope for active medication delivery. Traditional forms of active medication delivery that include some sort of external force acting upon the vessel of delivery are typically painful and uncomfortable for the end user or patient. On the other hand, passive medication delivery methods, such as transdermal patches, often rely on natural diffusion. This leads to many limitations, such as the size of the medication that can be delivered using the drug delivery method. Microneedles with active force can be a possible solution to this problem
- The prototype that has been prepared can showcase the ease and accessibility of use. It is not only quite wearable in daily life, but it is also easy to use and activate, potentially being a short-term vaccination option or a long-term medication administration method for patients all over the world
- Also, the use of the Belousov-Zhabotinsky oscillating hydrogel could make it more cost-effective for

active medication delivery. Using the hydrogel could not only prolong the drug delivery and control the dosage and intervals accurately, but it could also be less expensive than other methods that use more hard-to-procure technology. BZ oscillating hydrogels are quite an untapped field

- The microneedle patch is also an environmentally friendly solution as it is reusable and sustainable, contributing significantly less plastic pollution to the environment compared to traditional syringes and needles. It could prevent much waste from the healthcare industry compared to other methods of drug delivery

Biography

Shripriya Kalbhavi is an incoming sophomore at Lynbrook High School in San Jose, California. She is interested in biology and chemistry and enjoys researching and developing solutions to scientific problems in society. She is passionate about medication delivery methods and was awarded the title of America's Second Top Young Scientist in October 2023 for her research on active medication delivery via microneedles and BZ oscillating hydrogels, having ownership of a patent for the same invention. She is also the host of the Famous Personalities podcast, which aims to honor female scientists, and the founder of the Junior Medicine Professionals Initiative.



Stella Kafkala
Genepharm Pharmaceutical Company, Greece

Gastrointestinal performance simulation system for the analysis of Eltrombopag formulations

Eltrombopag olamine is the active substance of the innovator product Revolade, which is indicated for the treatment of chronic immune (Idiopathic) Thrombocytopenic Purpura (ITP) and acquired Severe Aplastic Anemia (SAA).

The molecule of eltrombopag acquires 6 protonatable sites as described by Meloun et al, leading to the existence of 6 ionic forms in solution, depending on the pH and ionic strength of the environment that the molecule meets. Due to the complexity of performance in solution, the predictability of in vivo behaviour of eltrombopag through the conventional in vitro methods involves several challenges, and the selection of a successful candidate as a bioequivalent developed product is not easily achieved. The present paper describes the use of a Gastrointestinal Performance Simulation System (GTPS) to overcome such challenges.

Biography

Stella Kafkala has studied Chemistry at the National and Kapodistrian University of Athens, Greece, with an MSc in Food Chemistry in 2002. She has worked in the pharmaceutical industry since 2003, both in Analytical Development and Regulatory Departments. She has been an external lecturer for the Pharmacy Department of Aristotle University of Thessaloniki since 2018, in the Industrial Pharmacy Post graduate Course. In parallel she is a candidate PhD student at the same school, in cooperation with the pharmaceutical industry she is currently occupied in, as an Analytical Development Director.

Suresh P.K.
Department of Biomedical Sciences, VIT, Vellore, Tamil Nadu, India

Natural plant-based extract-mediated cell death induction potential in human cancer cells - In vitro and *in silico* strategies for drug development

Extracts from plant sources have been mined for their anti-cancer potential. The n-butanolic extract of the leaves of A.muricata exhibited a higher cytotoxic potential in MDA-MB-435s & HaCaT cells in comparison with normal hepatic cells. The free radical scavenging potential correlated with the presence of total phenolics. The methanolic A.muricata leaf extract exhibited free radical scavenging potential and was better than the aqueous version in terms of protecting DNA from H_2O_2-mediated damage. Sodium arsenite ($NaAsO_2$)-induced toxicity was decreased following their treatment of WRL-68 hepatocyte cells as well as erythrocytes with the methanolic and aqueous extracts of A.muricata (methanolic extract better than the aqueous version).

Extracts (hot and cold non-polar petroleum ether and chloroform extracts) from the bark of O.indicum were more cytotoxic in MDA-MB-231 than in WRL-68 cells. The hot petroleum ether extract exhibited better anti-metastatic potential and was better in inducing apoptosis in MDA-MB-231 than in the MCF-7 cells. Comparison of the hot and cold versions of the ethyl acetate extracts of the bark of O.indicum (hot and cold) was done with the latter showing more cytotoxicity to MDA-MB-231 than to the WRL-68 cells. Also, this cold extract induced apoptosis in MDA-MB-231 as well as in the MCF-7 cells. The cold extract exhibited an ability to inhibit the migration of MDA-MB-231 cells.

The different extracts (hot and cold chloroform extracts) of the rhizome of R.emodii extracts exhibited antioxidant properties; were cytotoxic to the MDA-MB-231 (in comparison with WRL68 cells) and MCF-7 cells and also caused apoptosis. The hot chloroform extract performed well in MDA-MB-231 cell migration inhibition assay. The chloroform extracts were analysed for the presence of bioactive principles. Again, the toxicity and cell death induction capabilities of the antioxidant ethyl acetate extracts (hot and cold) of the rhizome of R.emodii were analysed. Higher toxicity was exhibited by the hot ethyl acetate extracts in MDA-MB-231 cells in comparison with WRL-68 cells. Apoptosis induction was higher in the MDA-MB-231 cells than in MCF-7 cells and the extracts exhibited anti-metastatic potential. Again, the analytical data seemed to indicate the involvement of polyphenolics in these phenomena. The petroleum ether R.emodii rhizome extracts (hot and cold) exhibited cytotoxicity (in comparison with WRL68 cells) and increased cell death in MDA-MB-231 cells (in comparison with MCF-7 cells) with the involvement of CPP32/caspase-3. Using an in silico experimental flow, good affinity values were obtained following the docking of bioactive principles of R.emodii with proteins involved in ER signaling pathway-mediated cell death (unpublished data).

Molecular docking (with human caspase-6 proteins) showed that there was good binding affinity of ligands (identified based on chromatographic profiling of crude and soxhleted extracts of the seeds of *L.sativum*), to human caspase-6 proteins, apart from synergy in cytotoxicity and cell death (in caspase-3-deficient MCF-7 cells) with these two types of methanolic extracts and quercetin.

Finally, our *in vitro/in silico* experimental flow, when extended to mine for ligand-based information, will enable us to select the best bioactive principle-target combination for verification using advanced *in silico* and higher order *in vitro* cancer model systems.

Audience Take Away Notes

- Bioprospecting for natural molecules with anti-cancer potential involves multiple steps (including screening and identification of key bioactive principles with cytotoxic and cell death induction potential (resistance to cell death is a hallmark feature of cancer). The audience will be able to learn and understand the experimental flow that is involved in this process of generating pre-clinical data (as a fundamental first step in the proof-of-concept strategy) for drug development
- They can better visualize the experimental design as well as comprehend the rationale behind the selection of different assays to verify and demonstrate the cytotoxic and cell death induction potential of extracts from different plant sources. This approach can help them in possibly identifying and networking with mentos who can train them in the experimental and in silico aspects of this process
- This research could be used by other faculty to expand their research or teaching, especially those involved in drug development (experimental and in silico) and allied areas
- It will possibly provide a road-map, especially for generating and verifying cancer cell line-based data using a combination of in silico and experimental approaches. Specifically, the selection of different plant sources with bioactive potential should give the drug developer a head-start
- The information discussed should be useful, in terms of possibly fine-tuning the investigators experimental design (this design can then be tested, if they have the infrastructure and provision for consumable-related recurring expenditure) to carry out the cell death-related experiments (in vitro and/or in silico experiments)
- Other benefits
- Opportunities for networking on a global level -opportunities for synergizing to expediting the process of drug development and also aid in the inter-laboratory validation of standardized assays

Biography

Suresh P.K. is a Professor Higher Academic Grade in the School of Biosciences and Technology, VIT, Vellore, India. He has 23.75 years of teaching and research experience in Biomedical Sciences, Biotechnology and Environmental disciplines. Suresh received his masters and Ph.D. in SIUE, IL, USA and the University of Cincinnati, OH, USA. He was a PDF at the University of Texas at Austin and Rutgers University, USA. P.K. Suresh has authored/co-authored 67 publications (h-index -17; citation index - 892). He has been a resource person and coordinator in FDPs and in International Conferences. He is working on drug development and delivery systems.

Tarek Aboul-Fadl
Department of Medicinal Chemistry, Faculty of Pharmacy, Assuit University, Assuit 71526, Egypt

Tetrahydro-(2H)-1,3,5-Thiadiazine-2-Thione (THTT), a versatile carrier system for targeting cell cycle checkpoint pathways with potential anticancer activities

Cancer remains a global health threat despite advances in research and technology. According to International Agency for Research on Cancer, the cancer burden will increase by about 77% by 2050, further straining health systems, people and communities. Although cancer chemotherapy has progressed in major strides in recent years, there is still an unmet need for new anti-cancer agents with good potency, diminished toxicity and able to treat tumors that are resistant to currently known drugs. In recent years, cell cycle and checkpoint pathways regulation are offering new therapeutic approaches against cancer. Targeting the cell cycle holds promise but further optimization is necessary to fully exploit it as an anti-cancer strategy across diverse malignancies. Tetrahydro-(2H)-1,3,5-Thiadiazine-2-Thione (THTT) nucleus has been verified for its anticancer activities. It has been postulated that the anticancer activities of THTT is mainly based on their role as carrier system generating the active species in the biosystem. Furthermore, Preliminary biological evaluation revealed that THTT carrier system possess notable cell growth inhibitory activity by disrupting the cell cycle with enhanced selectivity against cancer cells, suggesting the potential for the development of new selective cell cycle inhibitors. Encouraged by the above and in continuation of our synthetic work on THTT it seemed interesting to prompted to develop THTT as a new class of carriers to these active species of molecules.

Audience Take Away Notes

- Development of new Drug Delivery System
- Potential of Structure based drug design for drug discovery and development
- How to improve the activities of the current clinically approved drugs
- Opening the windows for global scientific collaborations
- Improvement of the accuracy of drug design and providing new information to assist in solving drug design problems

Biography

Prof. Tarek Aboul-Fadl has completed his PhD in Medicinal Chemistry from Assiut University, Egypt (1994) under the channel system and joint supervision scheme between Assiut University and Josai University/Japan. He performed his postdoctoral training as a postdoctoral research fellow and scientist of Pharmaceutical and Medicinal Chemistry at University of Vienna, Austria (1997- 1998), Friedrich-Alexander-Universität, Erlangen-Nürnberg, Germany (1999 and 2013) and University of Utah, USA (2001-2002 and 2004-2005). He has over 88 publications and 4 patents that have been cited over 2266 times, and his publication H-index is 25(google_scholar), 23(Scopus). He was awarded ACDIMA Research Award for the Best Scientific Research in Arab World, 2012. He was listed in the World's 2% Top-Cited Scientists by Stanford University for three successive years (2021-2023).

Teresa Carvajal
Agricultural and Biological Engineering Department, College of Agriculture and Engineering, Purdue University, West Lafayette, IN, USA

Surface chemistry and particle interactions in materials and their impact on powder performance

Surface and physico-chemical properties are critical in formulation and in processes involving the handling, processing, packaging, shelf-life and bioavailability of medicines. In this presentation, we will explore and discuss the intricate ways in which interactions at the surface chemistry of biomaterials and multicomponent systems dictate powder behaviour. Highlighting how the role of surface interactions, environmental conditions (%RH) can help or hinder powder flow through promoting particle agglomeration, mixing, and suppressing electrostatic charge on particle cohesion, adhesion to processing equipment, and friction between particles. This comprehensive analysis can deliver a fundamental insight into the critical factors for identifying powder behaviour problems. By understanding these interactions, we aim to formulate targeted strategies to enhance powder performance such as flow properties, prevent undesirable agglomeration, thereby overcoming formulation, processing, manufacturing, stability, release, dissolution and bioavailability challenges.

Audience Take Away Notes

- To be aware of characterization tools and have another insight of the information these provide.
- The audience may wish to explore further on the topic and perhaps, if appropriate, implemented it in their job.
- This research could be utilized by other faculty to expand their research and teaching.
- By having a robust understanding of their systems, it is possible to do it right first- time.
- It is designed to improve design accuracy and provide new insights for design problems.

Biography
M. Teresa Carvajal is a Faculty Member at the Agricultural and Biological Engineering at Purdue University. She worked in the pharmaceutical industry, Roche, Bayer and Transave for a total of 14 years prior to joining Purdue. She graduated with a MS in Physical Pharmacy, from the University of Arizona, USA and with a PhD in Powder Pharmaceutical Technology at the University of Bath, UK. Tere's research group on material sciences focuses on microstructure, surface/ interface interactions and energetics, and their impact on powder bulk properties during formulation, processing and manufacturing. She has authored or co- authored more than 70 peer reviewed articles.

Vyacheslav R. Shulunov
Institute of Physical Materials Science of the Siberian Branch of the Russian Academy of Science, Ulan-Ude, Buryatia, Russia

Breakthrough, fast, precise and inexpensive 3D bioprinting of organoids and blood vessels

The calculated specifications of Roll Porous Scaffold (RPS) are orders of magnitude superior to all currently dominant 3D bioprinters in speed, volume, and print density without the use of expensive equipment and components: print density of 10–15 μm cells up to ~1.5×10^8 cells/mL. The use of 360 and 1200 dpi inkjet printheads immediately enables biomanufacturing with 10–30 μm cells in a single organoid with performance >1.8 L/hour for 15 μm layer thickness. The spongy bioresorbable ribbon for RPS technology is designed to solve the problems of precise placement, leakage and increasing in the number of instantly useable cell types. RPS based on widely available components and opens up new ways to improve healthcare without sending 3D bioprinters printers into space. Application of RPS 3D bioprinting are 1) Patch on an organ, a blood vessel for bypass or replacement, regenerative personal medicine, 2) Many parallel tests for targeted therapy, 3) Regularly rejuvenate even from a hundred years with the help of personal Hormone Replacement Therapy derived from printed endocrine glands for each of his DNA excluding rejection, but not creams, tablets, injections.

Audience Take Away Notes

- Parallel testing of new drugs, substances not on animals, but using formed 3D biomodels "organ on a chip"
- Personalized and precision medicine with simultaneous testing of many methods and drugs of treatment, targeted therapy of a specific patient in vitro as if in vivo on 3D compositions of his personal cells and selection of the most effective with the lowest toxicity
- Overcoming the shortage of organs for implantation

Biography
Ph.D Vyacheslav R. Shulunov studied Physics at the Buryat State University and graduated in 1997. He then joined the research group of Prof. Semenov at the Institute of Physical Materials Science of the Siberian Branch of the Russian Academy of Science, Ulan-Ude, Buryatia. He received his Ph.D degree in Thermal Physics and Theoretical Heat Engineering in 2002 from the East Siberia State University of Technology and Management. He has published 4 patents of the Russian Federation, 5 certificate of state registration of the program, 12 Web of Science and Scopus papers – Scopus h-index: 5 (1 co-author in 2 publications).

Yusuke Shimoyama[1]*, Thossaporn Wijakmatee[1], Ryunosuke Akiyama[1], Yasuhiko Orita[1], Yuya Murakami[2]

[1]Department of Chemical Science and Engineering, Tokyo Institute of Technology, Meguro-ku, Tokyo, Japan
[2]Department of Applied Chemistry and Biochemical Engineering, Faculty of Engineering, Shizuoka University, Chuo-ku, Hamamatsu-shi, Shizuoka, Japan

Supercritical microfluidic system for production of nanoparticles and liposomes for pharmaceutical formulation

Pharmaceutical formulation techniques have been developed as achieving controlled-release system and high bioavailability of Active Pharmaceutical Ingredients (APIs). Formation of the pharmaceutical suspension with nanoparticles or liposomes is one of the dosage forms to increase the bioavailability. The nanoparticle of the pharmaceuticals in the suspension can enhance the absorption rate and liposomes can control the release rate and dissolved amounts of APIs. There is an obstacle of the difficulties in the aggregation of the suspended particle and difficulties of liposome size control in the conventional production of the pharmaceutical suspension. Supercritical CO_2 can be applied for material design in pharmaceuticals, cosmetics and food fields because of its nontoxic property and mild temperature operation. Some research groups have developed the fabrication technique of the nanoparticles and liposome using supercritical CO_2, such as rapid expansion of supercritical solution or supercritical anti- solvent.

We have provided a flow-production of the APIs carrier nanoparticles in aqueous suspension using supercritical CO_2 combined with microfluidic system. Supercritical Extraction of Emulsion (SFEE) in the microfluidic system was applied for the fabrication of Polyvinyl Alcohol (PVA) and lipid suspension as a carrier of APIs. Slug flow of supercritical CO_2 and a liquid-phase emulsion can be used for the extraction of oil in the O/W emulsion into supercritical CO_2. The effect of the hydrophobicity of PVA and lecithin on the particle formation in the solution was investigated. This microfluidic SFEE system has been also applied for the lipid-nanosuspension. The microfluidic system using supercritical CO_2 is also used for liposome production (LipTube system). The water in supercritical CO_2 (W/CO_2) emulsion can be formed by a swirl-type micro-mixing at high-pressure condition and the further slug flow of W/CO_2 emulsion and water phase used for the formation of liposome structure.

Audience Take Away Notes

- How to design the microfluidic system using supercritical CO_2?
- How to control the nanoparticle size using supercritical extraction of emulsion?
- How to control the liposome size in LipTube system?

Biography

Yusuke Shimoyama is a Professor and (2016.4) Associate Professor in Department of Chemical Science and Engineering, Tokyo Institute of Technology. (2014.10) Visiting Associate Professor, The University of Tokyo. (2019.4) Visiting Professor, The University of Tokyo. (2011.4) Associate Professor and (2009.4) Assistant Professor in Department of Chemical Engineering, Tokyo Institute of Technology. (2007.9) Assistant Professor, in Department of Chemical Engineering, Kyushu University. (2004.4) Research Fellowship for Young Scientists, Japan Society for the Promotion of Science and Ph.D. in Chemical Engineering, Kyushu University, 2005.

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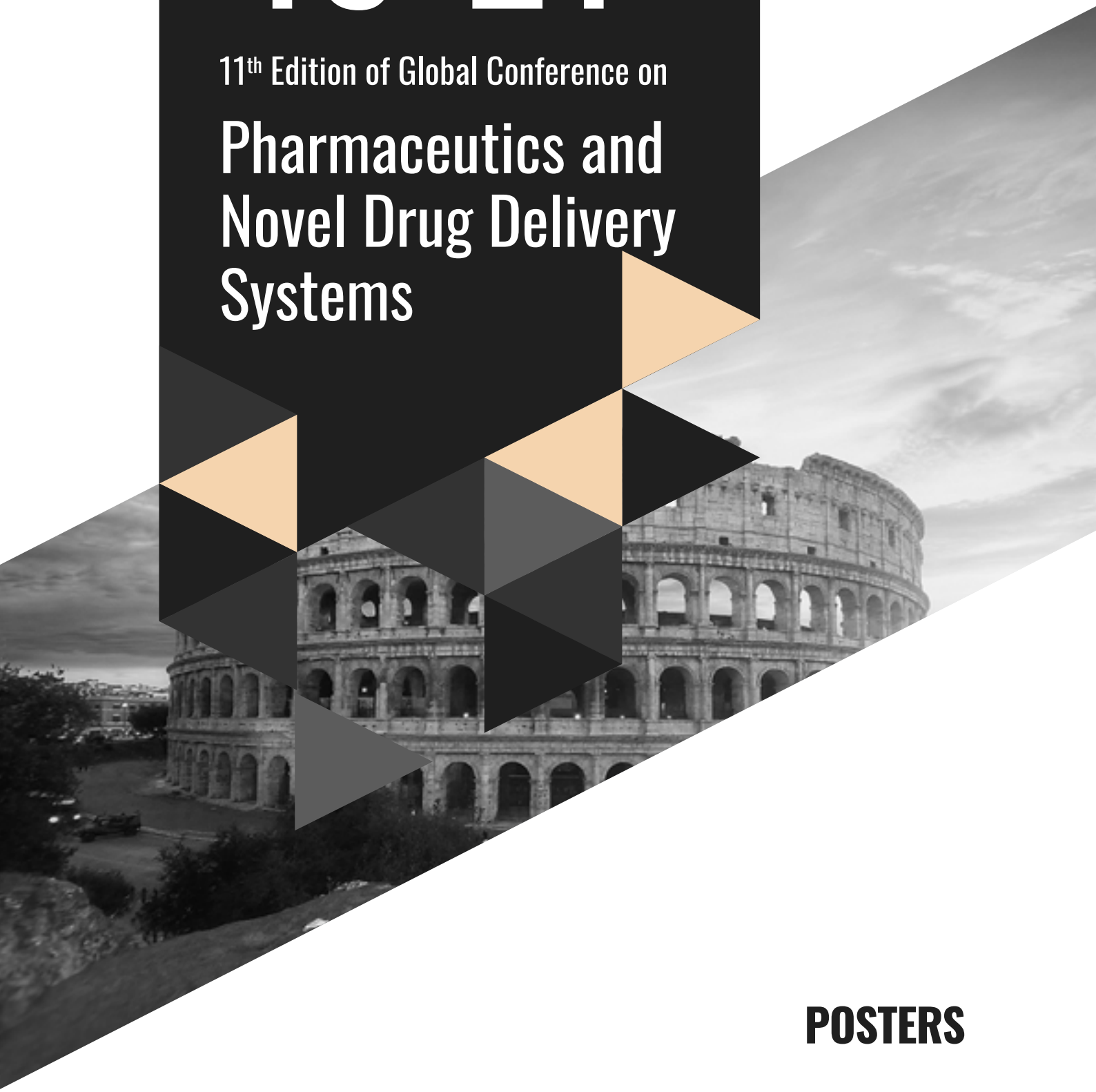

POSTERS

Afonin S.M.
National Research University of Electronic Technology, MIET, Moscow, Russia

Structural scheme of an electro magneto elastic actuator for nanomedical research

An electro magneto elastic actuator is electro magneto mechanical device intended for actuation of mechanisms, systems based on the piezoelectric, electrostriction, piezomagnetic, magnetostriction effects, converts electric or magnetic signals into mechanical movement and force. The piezo actuator is used for nanomedical research in the scanning tunneling microscope. The structural scheme of an electro magneto elastic actuator nanomedical research is constracted by using the equation of electro magneto elasticity and the linear ordinary second-order differential equation of the actuator. An electro magneto elastic actuator is using for nanomedical research in nanobiology, nanotechnology for the reparation of the gravitation, temperature deformations and for the nanoalignment. The problem of building the structural scheme of an electro magneto elastic actuator is solved in difference from Mason's electrical equivalent circuit. The transformation of the structural scheme is obtained under various boundary conditions of the actuator. The matrix transfer function is determined from the set of equations for the structural sheme of the actuator in the control system. The matrix transfer function for the deformation and the structural model of the actuator are used for nanomedical research.

Biography

Sergey Mikhailovich Afonin is a associate professor of National Research University of Electronic Technology, MIET. Graduate of MIET in 1976. Degree PhD received in MIET 1982. Academic title of Senior researcher received in MIET 1991. Aspirant MIET 1976–79, junior researcher MIET 1979–82, senior researcher MIET 1983–93, associate professor at MIET since 1993 to present time. He has published more 200 scientific articles. He won World Championship-2018 in Physics for Electromagnetoelastic Actuators World Cup from Directorate of Physics, International Agency for Standards and Ratings (IASR). He is awarded in 2019 the field of physical research Who's Who Lifetime Achievement: Albert Nelson Marquis Lifetime Achievement. He is recipient Silver medal and two Bronze medals VDNKH Russia.

N. Benahmed*, A. Cheriti,
Phytochemistry and Organic Synthesis Laboratory (LPSO), Tahri Mohamed University–Bechar, Algeria

Influence of some medicinal plants on the crystallization of ammonium-magnesium phosphate hexahydrate (struvite)

Urinary stones (urolithiasis) are a disease resulting from the presence of stones in the kidneys or urinary tract. It constitutes a major problem to public health. Struvite (STR) is among the most important phosphate stones caused this disease, and are one of the risk factors that promote and lead to kidney failure. The precipitation of STR from human urine is influenced by many factors including concentration of Mg^{2+}, NH^{4+}, and PO_4^{3-} ions, and extreme alkalization of urine (pH is above 6.5) by ammonia produced under the effect of the hydrolysis of urea by bacteria producing urease (chronic urinary infection).

Many plants species, described in pharmacopoeias of several countries is used as a remedy for urinary stones. The selection of the Some Algerian Saharan Medicinal Plants was done according to an ethnopharmacological survey on medicinal plants used in the region of the south west of Algeria to cure the urinary tract diseases.

On the first stage, we have studied the crystallisation of struvite “in vitro” without inhibitors. The work was resumed, and this time by crystallization with inhibitors in order to explore the influence of the medicinal plant extracts on the phase of crystallization of struvite.

We have used an optical polarizing microscope to follow the evolution of the size of crystals and aggregates as a function of time. At the end of the experiment, the crystallization precipitate subjected to the spectroscopic analysis IRTF.

The results of the most of the organic and aqueous extracts compared to crystallization without inhibitor have an significant inhibitory effect on the size of crystals and aggregates of struvite.

Biography
Benahmed nacira studied Chemistry at Tahri Mohamed University-Algeria-and graduated as MS in 1999. She joined the research group of Prof A. Cheriti at Phytochemistry and Organic Synthesis Laboratory (LPSO). She prepare PhD at the same institution. She obtained the position of an Assistance Professor class A at Tahri Mohamed University.

Mohammad F. Bayan[1], Saeed M. Marji[1], Mutaz S. Salem[1,2]*, M. Yasmin Begum[3], Kumarappan Chidambaram[4], Balakumar Chandrasekaran[1,5]

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Polymeric-based formulation for intelligent drug delivery

Conventional oral formulations are mainly absorbed in the small intestine. This limits their use in the treatment of some diseases associated with the colon, where the drug has to act topically at the inflammation site. This paved the way for the development of a smart colonic drug delivery system, thereby improving the therapeutic efficacy, reducing the dosing frequency and potential side effects, as well as improving patient acceptance, especially in cases where enemas or other topical preparations may not be effective alone in treating the inflammation. In healthy individuals, it takes an oral medication delivery system about 5 to 6 hours to reach the colon. A colonic drug delivery system should delay or prohibit the medication release during these five to six hours while permitting its release afterward. The main aim of this study was to develop a smart drug delivery system based on pH-sensitive polymeric formulations, synthesized by a free-radical bulk polymerization method, using different monomer and crosslinker concentrations. The formulations were loaded with 5-amino salicylic acid as a model drug and Capmul MCM C8 as a bioavailability enhancer. The characterization, in vitro swelling, and release studies were performed to evaluate the produced formulations and determine the ability of the developed system to retard the drug release at conditions mimicking the stomach and small intestine while triggering its release at conditions mimicking the colon. The polymer-based formulation was found to have promising applicability as a potential smart colonic drug delivery system.

Keywords: 5-Amino Salicylic Acid, Smart Delivery System, Sustainable Polymers, Triggered Drug Delivery, Ulcerative Colitis.

Biography

Professor Mutaz Sheikh Salem is currently working at the Faculty of Pharmacy in Jordan University of Science and Technology. His research interest includes solid phase manipulation of pharmaceutical powders, solubility and dissolution enhancement of poorly water-soluble drugs, bioavailability and bioequivalence evaluation of pharmaceutical products, and development and evaluation of drug delivery systems. Professor Sheikh Salem hod PHD degree from Manchester university, UK, and S Sc in Pharmacy from the university of Bagdad, Iraq.

Rassa Pegahi
UPSA, France

An updated review on the central mechanism of action of Paracetamol (Acetaminophen): Experimental evidence and potential clinical impact

Paracetamol remains the recommended first-line option for mild-to-moderate acute pain in general population and particularly in vulnerable populations. Despite its wide use, debate exists regarding the analgesic Mechanism of Action (MoA) of paracetamol. A growing body of evidence challenged the notion that paracetamol exerts its analgesic effect through Cyclooxygenase (COX)-dependent inhibitory effect. It is now more evident that paracetamol analgesia has multiple pathways and is mediated by the formation of the bioactive AM404 metabolite in the Central Nervous System (CNS). AM404 is a potent activator of $TRPV_1$, a major contributor to neuronal response to pain in the brain and dorsal horn. In the periaqueductal grey, the bioactive metabolite AM404 activated the $TRPV_1$ channel-?mGlu5 receptor-?PLC-?DAGL-?CB1 receptor signaling cascade. The present article provides a comprehensive literature review of the centrally located, COX-independent, analgesic MoA of paracetamol and relates how the current experimental evidence can be translated into clinical practice. The evidence discussed in this review established paracetamol as a central, COX-independent, antinociceptive medication that has a distinct MoA from Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and a more tolerable safety profile. With the establishment of the central MoA of paracetamol, we believe that paracetamol remains the preferred first-line option for mild-to-moderate acute pain for healthy adults, children, and patients with health concerns. However, safety concerns remain with the high dose of paracetamol due to the NAPQI-mediated liver necrosis. Centrally acting paracetamol/p-aminophenol derivatives could potentiate the analgesic effect of paracetamol without increasing the risk of hepatoxicity. Moreover, the specific central MoA of paracetamol allows its combination with other analgesics, including NSAIDs, with a different MoA. Future experiments to better explain the central actions of paracetamol could pave the way for discovering new central analgesics with a better benefit-to-risk ratio.

Biography

Rassa Pegahi earned a Ph.D. in Molecular Biology and brings seven years of hands-on experience in oncology from a hospital environment. Currently, Dr. Pegahi is pursuing her career in the pharmaceutical industry as a specialist in medical affairs & clinical trials.

Riyadh Al- Asady
Department of Chemical and Biological Engineering, The University of Sheffield, UKD

Pharmaceutical continuous manufacturing: The interaction between different units and tablet properties

In a multi-processes pharmaceutical continuous tablet production line such as ConsiGmaTM-25, the quality of the final tablet is a function of different processes and formulation parameters of different units. The effect significance of each unit depends not only on the unit itself but also on the overlapping between different units. In this study, different process parameters of each unit within ConsiGmaTM-25 and Modul P tablet press were changed within a wide range and the effect of this change on the tablet strength was investigated and compared. It was found that some units have more effect than others. In terms of process parameters effect, the tablet press has the highest effect on tablet properties followed by the fluidized bed dryer then twin screw granulator then mill, and blender. The study also covers the effect of formulation parameters such as Liquid-to-Solid ratio (L/S) and using different formulations such as different percentages of excipients which also could affect the tablet strength and whole manufacturing process.

Audience Take Away Notes

- How to control the product quality?
- Tablet manufacturing is widespread in many pharmaceutical industries
- Understanding the relation between critical process/formulation parameters and critical quality attributes is useful in designing the particle and tablet properties

Biography
Dr. Riyadh Al-Asady studied powder technology at the University of Sheffield, UK where he was awarded a PhD in granulation in 2017. He then joined the research group of Prof. Agba Salman (Particle product group) at the University of Sheffield in 2018. He published many research papers in different journals.

Savvopoulos Pantelis
Genepharm Pharmaceutical Company, Greece

Gastrointestinal performance simulation system for the analysis of Eltrombopag formulations

Eltrombopag olamine is the active substance of the innovator product Revolade, which is indicated for the treatment of chronic immune (Idiopathic) Thrombocytopenic Purpura (ITP) and acquired Severe Aplastic Anemia (SAA).

The molecule of eltrombopag acquires 6 protonatable sites as described by Meloun et al, leading to the existence of 6 ionic forms in solution, depending on the pH and ionic strength of the environment that the molecule meets. Due to the complexity of performance in solution, the predictability of in vivo behaviour of eltrombopag through the conventional in vitro methods involves several challenges, and the selection of a successful candidate as a bioequivalent developed product is not easily achieved. The present paper describes the use of a Gastrointestinal Performance Simulation System (GTPS) to overcome such challenges.

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[3]Institute of Biomedical Sciences, National Chung Hsing University, Taichung, Taiwan; Department of Medical Research, Taichung Veterans General Hospital, Taichung, Taiwan; Rong Hsing Research Center for Translational Medicine, National Chung Hsing University, Taichung, Taiwan

Paeoniflorin effectively inhibit melanoma growth through induce senescence and ER stress converging on the Calpain1/ERK5/P21 axis

Background: Senescence leads to permanent cell-cycle arrest and is a potential target for cancer therapy. Paeoniflorin (PAE) is a monoterpene isolated from Traditional Chinese Medicine (TCM) Paeonia Alba, which has been used as an anti-inflammatory drug in clinical practice with the potential to target senescence in recalcitrant melanoma.

Purpose: To determine whether PAE can induce senescence in melanoma cells in vitro and in vivo and to elucidate the underlying mechanisms.

Methods: SA-β-Gal staining was used to detect the expression of Senescence-Associated β-Galactosidase (SA-β-Gal) in melanoma cells line. DNA damage was examined by the detection of γH_2AX foci. Cancer cell proliferation was determined by colony formation and survival assay in vitro. Transmission Electron Microscope (TEM) was detecting Endoplasmic Reticulum (ER) morphology. ER stress maker expression was estimated by Western blotting. Metastatic tumor growth was determined in mouse model of intraperitoneal or intravenous injection with B16F10. In vivo tumor growth was detected by Positron Emission Tomography/ Computed Tomography (PET/CT) and exterior photography of peritoneal dissection.

Results: PAE-induced B16F10 and A375 cell senescence were determined by increased cell size, flattened morphology, DNA damage as well as the increased expression of senescence associated β-galactosidase. PAE inhibited cell proliferation in melanoma cells in MTT and colony formation assay. ERK5/ P21, the major cell cycle regulators and mediators of senescence, were up-regulated at the protein level in PAE-treated melanoma cell. Further studies demonstrated that PAE induced cell senescence via ER stress and Calpain1/ ERK5/ P21.

Audience Take Away Notes

- We are the first confirm that Paeoniflorin (PAE) can effectively inhibit the growth of melanoma through promote melanoma senescence, causing cell cycle arrest at G2/M.
- We demonstrated that PAE induced ER stress, which can activate Calpain1 and targeting ERK5 for the first time.

- PAE can induce melanoma senescence and ER stress, which correlation with Calpain1/ ERK5/ P21 axis in vitro and in vivo.
- PAE can inhibit the tumor growth in two metastatic melanoma animal models.
- Illumination of PAE is a promising senescence and ER stress-inducing therapeutic drug for recalcitrant melanoma.

Biography

Dr. Liu graduated from Traditional Chinese Medicine at the China Medical University, Taiwan in 2013. She is the visiting staff serving in the Department of Traditional Chinese Medicine at Chang-Bing Show-Chwan Memorial Hospital, Taiwan. Then she joined Ph.D. program in Translation Medicine at National Chung- Hsing University and had become a doctoral candidate. She is committed to the research and development of traditional Chinese medicine for clinical treatment. She had published an article “Attenuation of in vitro and in vivo melanin synthesis using a Chinese herbal medicine through the inhibition of tyrosinase activity” in the Phytomedicine.

Siobhan Fogarty[1*] EVP, Marino Nebuloni[2], Seth Lederman[3] MD, CEO, Bruce Daugherty[3] EVP

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The importance of invitro discriminatory tests in the development of a sublingual dosage form of TNX-102 SL (Cyclobenzaprine HCl) tablets

The formulation of cyclobenzaprine HCl contained in TNX-102 SL has been designed specifically for sublingual administration. Earlier clinical studies indicated that the addition of a basifying agent was necessary for optimal transmucosal absorption. The TNX-102 SL formulation with added dibasic potassium phosphate resulted in higher levels of exposure during the first 2 hours after dosing and less exposure 8 to 24 hours after dosing. Sublingual TNX-102 also reduces exposure to an active, long half-life, main metabolite of cyclobenzaprine (ie, norcyclobenzaprine) as a result of bypassing first-pass hepatic metabolism. The PK profile of TNX-102 SL is optimal for bedtime dosing to improve sleep quality while minimizing daytime somnolence. (see companion abstracts, Daugherty/Nebuloni et al).

The formulation development of a sublingual dosage form of Cyclobenzaprine HCl highlighted the necessity for local absorption and the importance of a local pH effect. The local pH effect was enabled by the development of a eutectic of Cyclobenzaprine HCl and Mannitol. This presentation will describe the formulation development pathway with specific emphasis on the invitro techniques used to assess and control the absorption. It will demonstrate the discriminatory behaviours of typical monograph tests such as;-dissolution and disintegration, and the development and implementation of a specific/unique test;-wetting with a direct correlation to residence of the dosage form at the site of administration. These invitro tests with emphasis on sublingual absorption will challenge the discriminatory behaviour and assess impact of particle size, excipient variation and compression force.

Audience Take Away Notes

- Invitro test selection specific to the route of absorption and the associated critical characteristics required.
- Reduce the reliance on the usual monograph invitro test methods and the need for more specific invitro testing to accelerate formulation and process development.
- This could be applied directly to other local absorption developments such as transdermal, sublingual, buccal, films etc.
- It offers a practical, easy-to-use in vitro discriminatory test method that simplifies formulation and process development.
- It will enhance scale-up and support the development of continuous manufacturing techniques.

Biography

Siobhan Fogarty studied Industrial Chemistry at the University of Limerick, Ireland, graduated with BSc in 1989. She then joined Elan Corporation in Formulation Development and Manufacturing while studying for an MSc in Pharmaceutical Technology to satisfy the requirements of Qualified Persons in 1996. She then joined Glaxo Welcome in UK, Fuisz Technologies, VA, USA, Biovail Corporation, Canada and since 2016 has been part of the product development team at Tonix Pharmaceuticals Inc.

Yuna Tatsumi*, Yasuhiko Orita, Yusuke Shimoyama

Department of Chemical Science and Engineering, Tokyo Institute of Technology, Meguro-ku, Tokyo, Japan

Lipid media with supercritical CO_2 for promoted formation of Itraconazole cocrystals

Pharmaceutical cocrystal is one of the crystal engineering techniques to improve the solubility and bioavailability of Active Pharmaceutical Ingredients (APIs). Cocrystal is a crystal composed of API and other molecules called as coformer. There are many fabrication techniques for cocrystal formations. In particularly, some methods using supercritical CO_2 have been focused on to reduce the use of organic solvents and the safety risk. However, supercritical CO_2 techniques reported so far have an issue that the limited API species are targeted.

To expand the supercritical CO_2 techniques to more API species, this work aims to develop a new method using the combination of supercritical CO_2 and fatty acid (as safe media) and analyze the cocrystallization mechanism by a thermodynamics model with molecular informatics approach. We applied Itraconazole (ITZ), Succinic Acid (SUC) and Linoleic Acid (LA) as model API, coformer and fatty acid, respectively. Itraconazole cocrystal was fabricated successfully by many conventional methods but it was fabricated with using toxic organic solvents. Moreover, we used the Conductor-Like Screening Model (COSMO) as molecular informatics approach for understanding the mechanism of the cocrystal formations.

As a result of experimental approach, fatty acid under high-pressure CO_2 (5 and 10 MPa) significantly promoted the itraconazole cocrystallization compared to those in only fatty acid media or in only high-pressure CO_2 (5 and 10 MPa). The comparative experiment of cocrystallization in the two phase and the homogeneous phase system suggested that fatty acid rich phase including high-pressure CO_2 mainly contributed to the ITZ cocrystallization. Additionally, the calculation based on the thermodynamics model with molecular informatics suggests that fatty acid rich phase with CO_2 could has the higher Gibbs free energy than pure fatty acid phase, which means that fatty acid with CO_2 is more unstable than pure fatty acid. Conclusively, the experimental result supports that the combined system of high-pressure CO_2 and fatty acid is a suitable and safe media to fabricate ITZ cocrystal and the calculation approach is expected to be useful for the design of the media to promote cocrystallization.

Audience Take Away Notes

- How to design the fabrication process of cocrystal using supercritical CO_2?
- Suggest the new cocrystallization in lipid media with supercritical CO_2
- Use of molecular information for design the suitable media for cocrystal formation

Biography

Yuna Tatsumi is the Student of Ph. D. in Chemical Science and Engineering, Tokyo Institute of Technology, Japan, 2022. M. S. in Chemical Science and Engineering, Tokyo Institute of Technology, Japan, 2020-2022.Recent Research Contribution: Research Fellowship for Younger Scientists (DC1), Japan Society for the Promotion of Science, (2023. 4). Researcher grant, Howokawa Powder Technology Foundation, (2024. 4).

Yuxin Liu
Chongqing University Three Gorges Hospital , China

The efficacy, mechanisms, and safety of phyto-based detoxifying agents in the treatment of acute drug and chemical poisoning

Objective: The surge in incidents of acute poisoning from pharmaceuticals and chemicals necessitates the exploration of effective and safe treatment alternatives. This review aims to evaluate the efficacy, underlying mechanisms, and safety profiles of plant-based detoxifying agents in managing acute poisoning cases.

Methods and Materials: This study synthesizes data from various experimental models and clinical trials that investigated the use of phyto-based agents in detoxification. The review focuses on a range of plant-derived compounds, analyzing their biochemical pathways, interaction with toxins, and the resultant therapeutic outcomes. The data collection involved both in vitro studies and controlled human trials to gauge efficacy and safety.

Results: Efficacy: Clinical trials involving 500 patients across three continents demonstrated that silymarin, a milk thistle extract, reduced liver enzyme levels by 40% more effectively than conventional treatments in cases of acetaminophen overdose. In another study, curcumin was found to decrease neurotoxicity in patients exposed to heavy metals, with a 50% improvement in neurologic symptoms compared to baseline.

Mechanisms: Investigations into the biochemical pathways revealed that silymarin enhances glutathione synthesis, boosting the liver's capacity to detoxify. Curcumin, on the other hand, has been shown to chelate heavy metals, facilitating their excretion and reducing oxidative stress in neural tissues.

Safety: In a safety assessment of 200 participants, the use of phyto-based agents resulted in negligible adverse effects, with only a 2% incidence rate, significantly lower than the 15% reported for synthetic antidotes.

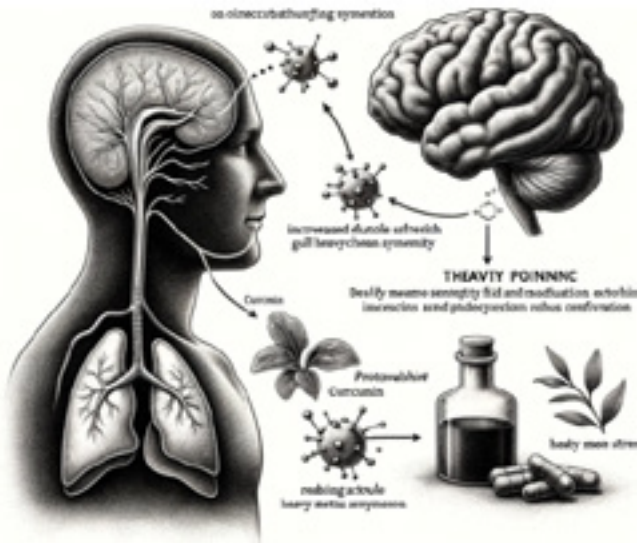

Figure: 1 Phyto-based Detoxifying Agents in the Treatment of Acute Drug and Chemical Poisoning.

Conclusion: Plant-based detoxifying agents offer a promising alternative in the treatment of acute drug and chemical poisoning, exhibiting significant efficacy and favorable safety profiles. The mechanisms through which these agents operate include enhancement of natural detoxification pathways and reduction of oxidative stress. Given their low incidence of adverse effects, further research and development of these phyto-based therapies are warranted to fully integrate them into standard poisoning treatment protocols.

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