5th SCIENTIFIC FEDERATION CONFERENCE
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World Congress & Expo on

Pharmaceutics & Drug Delivery Systems

April 21-22, 2016, Dubai, UAE

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ABOUT SCIENTIFIC FEDERATION

The Scientific Federation is expert-driven and initiated to organize and facilitate proficient international scientific conferences worldwide with associating the world class researchers. The Scientific Federation is establishing outstanding, direct communication between the researchers whether they are working in the similar field or in interdisciplinary research activities. The Scientific Federation provides an international forum for the appearance and discussion of cutting edge research in the science, medical, clinical, technology, engineering, life sciences and their related researches. In this regard, meet Inspiring Speakers and Experts at our universal meetings inclusive all scientific conferences, workshops and symposiums annually on Science, Technology, Medical, Pharma, Clinical, Engineering and Business. Scientific Federation is provider of information, solutions to enhance the performance and progress of science, medical, health, clinical, engineering and technology professionals, and is empowering them to make better decisions, deliver better care, and sometimes make groundbreaking discoveries, that advance the boundaries of knowledge and human progress.

WHO WE ARE?

We are exploring the research to the world through the world-class scientists.

"Imagination is more important than knowledge. Knowledge is limited. Imagination encircles the world."

- Albert Einstein

Now-a-days, the science and technology is growing in rapid way in all aspects of medical, clinical, physics and pharma. In this regard, we are taking into the step to transform the technology and research through the world class professionals, to get awareness worldwide by organizing the international conferences. Which may also lead to helpful in maintain the peaceful collaboration between the countries.

Our devoted team is very much proficient to organize the international conferences, and they are having much experience and expertise in this aspect.

WHAT WE DO?

The Scientific Federation was established with an aim to organize standard and productive conferences across the globe to bring world class researchers on a unique platform and to explore the interdisciplinary research activities. The Scientific Federation promote discussions and the free exchange of innovative thoughts at the research frontiers of the science, medical, health, clinical, engineering and technology.

We promise that every conference is significant for our partners, the professionals attending, as well as the sponsors and the associations. Scientific Federation collaboration ensures responsibility to the peak standards of service, punctual delivery, reliability and open communication.

The Scientific Federation Conferences provides a valuable means of disseminating information and ideas in a way that cannot be achieved through the usual channels of communication and presentations at large scientific meetings.

Team devoted to Scientific Federation, offers expertise with broad environment familiarity and associations with an array of convention centers, vendors, and hotel chains to contribute to your core. Scientific Federation encourage and promotes organizations of all types and sizes to contact Scientific Federation at (contact@scientificfederation.com)

WHY SCIENTIFIC FEDERATION?

Scientific Federation conferences are covering a broad range of research in the Science, Technology, Medical, Pharma, Clinical and Engineering. Attending a Scientific Federation Conferences are immense access to ground-breaking research presentations and discussions, and the informal atmosphere and smaller size of a conferences provides the best break to

develop collaborations, get innovative ideas and opportunity for your own work - and plan for the subsequent stage of your scientific career.

All researchers, including post docs and graduate students, are encouraged to attend the Scientific Federation conferences in their respective research field. All conferences offer the opportunity to exploit your knowledge by submitting a poster for the poster sessions.

B2B meetings will be arranged during the conference time and this is the best platform to develop new partnership & collaborations worldwide.

FOR ATTENDEES

Thank you! We are pleased you are joining us at a Scientific Federation Conferences.

Your meeting was planned by devoted volunteers from your obedience and Scientific Federation staff. We have worked hard to make sure it is the most tremendous conference you attend this year! During the time period, you will have lots of time for networking and recreation with members of your Scientific Federation attendees. All sessions are informal and intended to provide abundant time for discussion.

The Scientific Federation meetings are

- *Created by professionally for scientists*
- *Forums to discuss pre-publication research at the forefront of your field*
- *Informal communities of experts in the field*
- *Held in isolated locations to diminish diversions and exploit time for debate and networking*

A detailed program and as well as information about the site, travel, poster guidelines, and other details for your meeting is accessible on our web site. Refer to the respective conference site with your research interests.

For any further queries you can directly contact through email to the respective conference secretary.

SCIENTIFIC FEDERATION MISSION

Our Mission is to bring inspiration and innovation to every researcher in the world. We create a platform to interact and share their research. We will be a destination for researchers and maintain a pleasant relationship.

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Our vision is to create a home environment for researchers across the globe.

ASSOCIATIONS/COLLABORATIONS

- *Exploring and visualize worldwide*
- *A great opportunity to network with your peers*
- *A way to interact with world class professionals*
- *The opportunity to expand collaboration*
- *Amplified trademark awareness through an additional channel*
- *Closer business relationships*
- *Providing advantages to the members through a variety of first-rate organizations to connect to the world*

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Upcoming Conferences

SCIENTIFIC FEDERATION UPCOMING CONFERENCES

International Congress & Expo on Biotechnology and Bioengineering
September 26-28, 2016 Los Angeles, USA

Global Summit on Obesity & Diet Management
September 26-28, 2016 Los Angeles, USA

World Congress & Expo on Dementia & Neuroscience
September 26-28, 2016 Los Angeles, USA

Global Congress & Expo on Materials Science & Nanoscience
October 24-26, 2016 Dubai, UAE

World Conference & Expo on Petrochemistry & Natural Resources
October 24-26, 2016 Dubai, UAE

World Congress and Expo on Immunology
October 24-26, 2016 Dubai, UAE

World Summit and Expo on Food Technology & Probiotics
November 21-23, 2016 Dubai, UAE

International Conference on Biopolymers & Polymer Chemistry
November 21-23, 2016 Dubai, UAE

Global Virology Congress & Expo
November 21-23, 2016 Dubai, UAE

2nd Global Nanotechnology Congress and Expo
December 01-03, 2016 Las Vegas, USA

2nd World Congress and Expo on Oncology & Radiology
December 01-03, 2016 Las Vegas, USA

2nd World Congress on Nursing & Healthcare
December 01-03, 2016 Las Vegas, USA

2nd Global Summit and Expo on Dental & Oral Diseases
March 27-29, 2017 Kuala Lumpur, Malaysia

2nd World Congress & Expo on Pharmaceutics & Drug Delivery Systems
March 27-29, 2017 Kuala Lumpur, Malaysia

Global Conference and Expo on Vaccines Research
March 27-29, 2017 Kuala Lumpur, Malaysia

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Keynote Forum
Day 1

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The role of intestinal microbiota in the characterization of natural drug pharmaceutical preparations in the treatment of major depressive disorder

Jun Wang, Libby Ward, Giulio M. Pasinetti
Icahn School of Medicine at Mount Sinai, USA
Geriatric Research and Clinical Center, James J. Peter Veterans Affairs Medical Center, USA

A number of recent human studies indicate that psychosocial stressors increase peripheral cytokine production and may be an important factor in the development of major depressive disorders (MDD). Subsets of patients with MDD have higher levels of multiple inflammatory markers, including the cytokine Interleukin 6 (IL-6). The nucleus accumbens (NAc) plays a central role in brain reward circuits, and synaptic plasticity of the NAc is critical for resilience to stress-induced depression/anxiety. Using a model of repeated social defeat stress (RSDS), we demonstrated that stress-mediated long-term disruptions in NAc medium spiny neuron (MSN) synaptic plasticity and induction of IL-6 in the periphery are key factors contributing to depression/anxiety phenotypes. We found that dietary supplementation with a novel pharmaceutical polyphenol-rich preparation undergoes gastrointestinal microbiota metabolism to become bioavailable in the circulation to promote resilience to depression/anxiety phenotypes in the RSDS model. We found that treatment significantly promotes resilience to RSDS-induced depression/anxiety phenotypes, compared to vehicle-treated control mice. In particular, we found that the treatment improved social interaction ratio compared to vehicle-treated control mice (1.8±0.8 vs. 1.1±0.4, $p<0.05$) associated with significant reduction in inflammatory IL-6 circulatory levels. These changes were associated with an improvement of anhedonia, as assessed by sucrose preference test following chronic social stress (74.3±14.4% vs. 31.9±24.8%, $p<0.01$). Our studies strongly support the role of the intestinal microbiome in contributing to the benefits of a novel dietary polyphenol pharmaceutical preparation in promoting resilience to stress-induced depression/anxiety. Ongoing characterization of the commensal gut microbes responsible for improved bioavailability of dietary polyphenols will allow the development of second generation probiotics as a drug treatment to attenuate MDD.

Biography :

Giulio Maria Pasinetti is the Saunders Family Chair and Professor of Neurology (Mount Sinai) and Director of Basic and Biomedical Research and Training (VA). His research on co-morbidities influencing neurodegeneration has made him a top expert in his field. His principal focus is the prevention of neurodegenerative disorders even before the disease becomes symptomatic. He is the recipient of many awards, including the Faculty Council Award for Academic Excellence (Mount Sinai), the Dana Alliance for Brain Research award, and the Zenith award (Alzheimer's Association). Dr. Pasinetti is the recipient of over 30 grants from federal and philanthropic support and has published over 300 manuscripts.

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Targeted Drug Delivery of CNS Active Drug

R N Saha
BITS Pilani Dubai Campus, UAE

New insight of diseases and pharmacokinetic information have made drug deliver totally different. It is no more just delivery of drugs, as objectives are totally different. Present approaches of design of delivery systems are more challenging and expectations are much higher. Nonselective distribution of drugs from conventional deliver systems makes dose requirement high and lead to severe side effects or toxic effects, especially in cancer chemotherapy and CNS therapy.

Application of nanotechnology in drug delivery, has found to modify pharmacokinetic profile and make selective distribution which can lead to decreased dose, lesser or no side effects and better therapy and patient complience. Treatment of CNS disorders or brain cancer is highly challenging due to poor brain permeation or nonselective distribution. Recent studies of CNS active drugs and anticancer drugs for deliver to brain produced higher BBB permeation or direct delivery to brain via nasal route. In vivo pharmacokinetic and biodistribution studies in animal models produced highly encouraging results.

Biography :

Ranendra N Saha, Director of BITS Pilani Dubai Campus and also Shri B K Birla and Sarala Birla Chair Professor, studied Pharmacy at Jadavpur University, Kolkata, India and has 34 years of teaching and research experience. He has developed and transferred numbers of technology on drug delivery systems, granted patent, commercialized designed products. He is recipient of several awards including “Best Pharmacy Teacher of India Award” in 2005, “Pharmacy Professional of the year” 2013. He has visited several universities and research institutes of USA, Canada, Syria, etc on invitation, delivered invited lectures to international conferences. He is visiting Professor at Kathmandu University, Kathmandu, Nepal. He has guided about 25 doctoral students and about 100 M.Pharm students.

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Advanced Drug Delivery: Nano-targeted delivery for Therapeutic and Imaging

Shaker A. Mousa
The Pharmaceutical research Institute, USA

Targeted delivery of drug incorporated nanoparticles, through conjugation of tumor-specific cell surface markers, such as tumor-specific antibodies or ligands can not only enhance the efficacy of the anticancer drug but also reduce the unwanted toxicity of the drug. Additionally, multifunctional characteristics of the nano-carrier system would allow for simultaneous imaging of tumor mass, targeted drug delivery and monitoring. A summary of recent progress in nanotechnology as it relates specifically to nanoparticles and anticancer drug delivery will be reviewed. Nano Nutraceuticals using combination of various natural products provide a great potential in cancer management. Additionally, various Nanomedicine approaches for the detection and treatment of various types of clots organ specific delivery, vascular targeting, and vaccine will be briefly discussed.

Learning Objectives:

Highlight the Role of Nanobiotechnology and other enabling technologies in the followings:

1. Targeted Drug Delivery
2. Early detection (Imaging)
3. Targeted Delivery of Chemotherapy for optimal efficacy and safety
4. Nano synthesis and assembly of various platforms for Targeted Delivery

Biography :

Mousa was appointed as an endowed tenure Professor and Executive Vice President and Chairman of the Pharmaceutical Research Institute (PRI) in 2002 and Vice Provost for Research at ACPHS as of 2010. PRI is dedicated to education, research, and pharmaceutical services, focusing on drug discovery and drug development. Previously, Dr. Mousa was at was a senior Scientist and fellow at DuPont Pharmaceutical Company for 17 years where he served as a Working Group chair of several drug discovery programs from 1993-2001. He is also holds Adjunct Professor Appointments at Rensselaer Polytechnic Institute, SUNY Albany, and SUNY Buffalo. He is a Visiting Professor of Bioethics at Albany Medical College and a Visiting Scholar at Johns Hopkins University. He holds more than 350 US and International Patents discovering novel anti-angiogenesis strategies, antithrombotics, anti-integrins, anticancer, and non-invasive diagnostic imaging approaches. His has published more than 1,000 journal articles, book chapters, published patents, and books as editor and author. His research has focused on diagnostics and therapeutics of angiogenesisrelated disorders, thrombosis, vascular and cardiovascular diseases using various technology platforms. In his role as the leader of PRI, Dr. Mousa works with scientists and students to identify novel strategies for unmet medical needs. At PRI, Dr, Mousa and his staff have developed partnerships with other academic research centers in New York State's Capital Region as well as academic and industrial centers nationally and worldwide. Dr. Mousa received his BS in Pharmacy from Alexandria University, College of Pharmacy & Pharmaceutical Sciences with distinction ranking number 1 on a class of over 500 Pharmacy students then he was appointed a member of the faculty where he received his MSC in Biochemical Pharmacology. Then he finished his PhD from Ohio State University, College of Medicine, Columbus, OH and Post-doctoral Fellowship, University of Kentucky, Lexington KY. He also received his MBA (Management) from Widener University, Chester, PA. He is a fellow of the American College of cardiology (FACC), fellow of the National Academy of Clinical Biochemistry (FACB), and Fellow of the American Heart Association (FAHA).

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In Vivo Anti-tumor Activity of Osmotically Released Bioactive Interleukin-2 from Poly (Diol-co-Tricarballylate) Biodegradable Elastomeric Implants

Husam Younes[1], Somayeh Zamani[1], Wael Kafienah[2], David Morgan[2]

[1]Qatar University, Qatar

[2]University of Bristol, United Kingdom

New biodegradable elastomeric poly (decane-co-tricarballylate) [PDET] matrices loaded with IL-2, which utilize the osmotic-driven controlled release mechanism, were designed and tested in vivo in an attempt to overcome the drawbacks of the IL-2 systemic administration and the other stability/bioactivity challenges facing its delivery and formulation.

Elastomer synthesis was achieved by polycondensation reaction between tricarballylic acid and alkylene diols, followed by acrylation and photocuring. IL-2 loaded implantable microcylinders were prepared by intimately mixing lyophilized IL-2 powder with the acrylated prepolymer prior to crosslinking. A group of 6 to 8 week old BALB/c mice were subcutaneously (SC) injected with 1×106 Renca-HA tumor cells on the back of the neck between shoulders. The following day, few mice were also injected sc at the site where they had received the tumor cells with: a) repeated doses of 1.07 µg IL-2 in 50µl Hank Balanced Salt Solution at various time points, b) a single dose of 20 µg IL-2 in 50µl HBSS, c) various types of biodegradable elastomer cylinders; impregnated with or without 20 µg recombinant mouse IL-2, or d) sham inoculated as controls. The growth of the tumor was evaluated by daily measurements. Statistical analyses of performed using 2-way ANOVA.

The cell based bioactivity assay for IL-2 showed that the released IL-2 retained more than 94% of its initial bioactivity for 28 days. In all mice that received only Renca-HA cells, tumors developed after 11 days and continued to grow until they reached a maximum tumor volume. This was also true for control mice that were also sham inoculated. Similarly, tumors also developed in all mice that received blank cylinders, suggesting that the sc presence of these cylinders regardless of its composition does not inhibit tumor growth. Strikingly, in all of the groups of mice that were given Renca-HA cells followed by cylinders loaded with IL-2, only one mouse per group developed a tumor. Whereas, although their appeared to be a slight delay in tumor, all mice that received a single 20 µg dose of IL-2 shown tumor growth. The data clearly suggested that controlled sc delivery of bioactive IL-2 at the site of tumor inoculation is sufficient to prevent tumor growth in vivo. The presented studies report preliminary in vivo data that provides proof of principle for the therapeutic anti-cancer efficacy of intratumoral sustained-release of IL-2 from loaded cylindrical biodegradable elastomeric implants.

Biography :

Husam Younes is a graduate of the Faculty of Pharmaceutical Sciences at the University of Alberta (UA) in Edmonton, Alberta, Canada. He received his BSc (Pharm) in 1992 followed by MSc (Pharmaceutical Technology) in 1995. He worked as a Technical Manager in the Pharmaceutical Industry in Palestine and Jordan then completed his PhD from UA in 2002. Between January 2003 and June 2007 he was appointed as an Assistant Professor at the School of Pharmacy, Memorial University of Newfoundland, St. John's, Canada. In August 2007, Dr. Younes moved to Qatar to start his new career as the Founding Chair of Pharmaceutical Sciences department in the new Pharmacy Program at Qatar University. He is currently an Associate Professor of Biopharmaceutics at the College of Pharmacy and the founder of the new Pharmaceutics and Polymeric Drug Delivery Research Laboratory. He previously worked in the pharmaceutical industry and as a senior consultant to Newfoundland Health Department in Canada. He also served on the Panel of Examiners of the Pharmacy Examining Board of Canada. His main research is in the areas of controlled drug release, biomaterials, tissue engineering and synthesis of novel biodegradable polymers designed for localized and targeted delivery of therapeutic proteins in cancer therapy. Research from his laboratory was supported by the National Sciences & Engineering Research Council (NSERC) in Canada and currently by Qatar National Research Foundation in Qatar and has been documented in numerous patents, peer-reviewed publications, books chapters, abstracts and conference proceedings. Dr. Younes supervised graduate students and postdoctoral fellows in his lab and acted as an editorial board member and a reviewer for many pharmaceutical and drug delivery journals.

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UMP and uridine as potential medicines for the prevention of oxidative stress. The role of the mitochondrial atp-dependent potassium channel in this prevention

Galina Mironova
Institute of Theoretical and Experimental Biophysics, Russia

A number of recent human studies indicate that psychosocial stressors increase peripheral cytokine production and may be an important factor in the development of major depressive disorders (MDD). Subsets of patients with MDD have higher levels of multiple inflammatory markers, including the cytokine Interleukin 6 (IL-6). The nucleus accumbens (NAc) plays a central role in brain reward circuits, and synaptic plasticity of the NAc is critical for resilience to stress-induced depression/anxiety. Using a model of repeated social defeat stress (RSDS), we demonstrated that stress-mediated long-term disruptions in NAc medium spiny neuron (MSN) synaptic plasticity and induction of IL-6 in the periphery are key factors contributing to depression/anxiety phenotypes. We found that dietary supplementation with a novel pharmaceutical polyphenol-rich preparation undergoes gastrointestinal microbiota metabolism to become bioavailable in the circulation to promote resilience to depression/anxiety phenotypes in the RSDS model. We found that treatment significantly promotes resilience to RSDS-induced depression/anxiety phenotypes, compared to vehicle-treated control mice. In particular, we found that the treatment improved social interaction ratio compared to vehicle-treated control mice (1.8±0.8 vs. 1.1±0.4, $p<0.05$) associated with significant reduction in inflammatory IL-6 circulatory levels. These changes were associated with an improvement of anhedonia, as assessed by sucrose preference test following chronic social stress (74.3±14.4% vs. 31.9±24.8%, $p<0.01$). Our studies strongly support the role of the intestinal microbiome in contributing to the benefits of a novel dietary polyphenol pharmaceutical preparation in promoting resilience to stress-induced depression/anxiety. Ongoing characterization of the commensal gut microbes responsible for improved bioavailability of dietary polyphenols will allow the development of second generation probiotics as a drug treatment to attenuate MDD.

Biography :

Galina D. Mironova received Ph.D degree in Biochemistry from Alma-Ata State Medical School in 1966 and Doctor Science degree in Biophysics from Institute of Theoretical and Experimental Biophysics RAS in 1985. She is the head of laboratory of mitochondrial transport of the Institute of Theoretical and Experimental Biophysics RAS, Pushchino, Russia. She has published more than 125 papers in reputed journals. Her current research interests center on the mitochondrial ion transport, cardioprotection and neurodegradation. She is the professor in Pushchino State University and given lectures on Cytopathology.

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Scientific Sessions

Session 1

Recent Innovations in Drug delivery technology
Drug Targeting
Nanotechnology in Drug Delivery Systems
Drug discovery and medicinal chemistry

Title:	Targeted delivery of anti-tuberculosis drugs using peptide-based carriers **Kata Horvati**, Eotvos L. University, Hungary
Title:	Development of ATRA nanoparticles to improve the treatment of acute myeloid leukemia **Hany Ibrahim**, Université de Toulouse, France
Title:	The Relationship between Physicians and the Pharmaceutical Industry: Some Ethical Considerations **Eike-Henner W. Kluge**, University of Victoria, Canada
Title:	What effect did supplementing with Iron and vitamin B12 singly and in combination have on morbidity among 6 to 9 years old rural primary school children in Kilifi County, Kenya? **Priscilla Monyangi Nyakundi**, Kenya Medical Research Institute, Kenya
Title:	Antiatherosclerotic and Antidiabetic Potential of Desert Medicinal plants: A Therapeutic Approach **Ashok Purohit**, J.N.V. University, India
Title:	Fluorescein Hydrzones as Novel Non-intercalative Topoisomerase IIα Catalytic Inhibitors with Low DNA Toxicity **Afm Motiur Rahman**, King Saud University, Saudi Arabia
Title:	Transdermal Iontophoresis: A Non-Invasive Drug Delivery Approach for Alzheimer's Disease **Sevgi Gungor**, Istanbul University, Turkey
Title:	Site specific tailored polymeric nanoparticles based on tumor endothelium and tumor cells for enhanced antitumor drug delivery **Madhu Gupta**, Shri RawatPura Sarkar Institute of Pharmacy, India
Title:	Gel Trial Formulation of Tinospora cordifolia (Willd.) Miers. Stem Ethanolic Extract and Evaluation of its Anti-Inflammatory, Wound-healing and Skin Irritation Activities **Alyssa Marie P. Hizon**, University of Santo Tomas, Philippines
Title:	Phospholipids complex: A significant tool for Enhancement of Bioavailability of phytoconstituents **Vikas Sharma**, Shri RawatPura Sarkar Institute of Pharmacy, India
Title:	Endotoxin-Induced Uveitis and New Treatment Alternatives (TNF-alpha agonists) **Avni Murat Avunduk**, Pamukkale University, Turkey
Title:	Antitumor activity of transferrin-modified- artemether lipid nanospheres in cancer cell lines **Eltayeb Suliman Elamin Abbas** , Omdurman Islamic University, Sudan

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Targeted delivery of anti-tuberculosis drugs using peptide-based carriers

Kata Horvati

Eotvos L. University, Hungary

The great surviving ability of *Mycobacterium tuberculosis (Mtb)* is based on (i) the capability to transform into a stage of dormancy in which the bacillus is shielded by an extremely robust cell wall and rendering itself phenotypically resistant to chemotherapy; (ii) mutations in the genome to encode enzymes that can modify and inactivate drug molecules and (iii) the capacity to modulate macrophages and evade phagocytic digestion mechanisms. The most challenging factor in fighting tuberculosis (TB) is the ability to kill intacellular *Mtb* and to deliver effective anti-TB drugs into host cells.

Recently, new anti-TB drugs were identified in our laboratory using novel HTS *in silico* docking methods[1]. A set of the new compounds shows relevant *in vitro* effect on susceptibile and multiresistant form of *Mtb*. To achieve enhanced cellular uptake and intracellular killing activity, a new lipopeptide-based delivery scaffold was designed based on the sequence of machrophage targeting tuftsin peptide[2]. Drug-peptide conjugates were encapsulated into poly(lactic-co-glycolic acid) PLGA nanoparticles to improve bioavailability and sustained release. The antitubercular efficacy of the orally administered new formulate was proved in a guinea pig infectious model of TB and diagnostic autopsy revealed that no significant malformations on the tissues occurred after treatment[3].

This study was supported by Hungarian Scientific Research Fund OTKA (104275, 115431) and Bolyai János Research Fellowship of the Hungarian Academy of Sciences.

Biography :

Kata Horvati has completed her Ph.D in 2009 from Eotvos Lorand University, Budapest. She spent research stays in University of Palermo and University of Cape Town supervised by prominent scholars in tuberculosis research. She has published more than 20 papers in reputed journals mainly in the field of tuberculosis. As a principal investigator she was awarded with a national research grant which provides a financial support for her independent project.

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Development of ATRA nanoparticles to improve the treatment of acute myeloid leukemia

Hany IBRAHIM[1], Héléna BOUTZEN[2], Jean-Emmanuel SARRY[2], Christian RECHER[3], Jean-Pierre SOUCHARD[4], Jalloul BOUAJILA[4], Sophie CAZALBOU[1]

[1]Université de Toulouse, CIRIMAT, France

[2]IUCT, INSERM, Toulouse

[3]Hématologie, IUCT, Oncopôle, Toulouse

[4]Université de Toulouse, France

The ATRA (all-trans retinoic acid), by reprogramming the differentiation of the blasts of promyelocytic acute leukemia (APL) allowed in combination with anthracyclines, to switch the prognosis of this group of patients with a APL survival rate of 35% at 5 years to over 90%. In contrast, levels necessary to achieve efficacy on other types of acute myeloid leukemia remain unreachable clinically, because of poor stability and bioavailability thereof of this compound. The nanotechnologies using the albumin as carrier/vector allow, further to intravenous administration, to direct the drug to cancer cells thereby limiting its degradation.

The obtained nanoparticles present a homogeneous particle size distribution less than 150 microns. The studies conducted by X-ray diffraction highlight an "amorphization" of the ATRA without appearance of additional phase resulting in an increase of its solubility in an physiological environment. In addition, stability tests have shown that the drug encapsulated in albumin nanoparticles exhibits a significantly enhanced stability thereby facilitating its use.

The release kinetics achieved in vitro highlight a slowed release of ATRA contained in the nanoparticles until obtain a sustained release when the albumin is combined with glutaraldehyde.

The combination of two types of nanoparticles allows to envisage a controlled release (rapid and prolonged). Furthermore, depending on the manufacturing process used (nano-homogenization or nano-precipitation), it is possible to obtain spherical or trapezoid nanoparticles (Fig 1a and b) which increase their plasma half-life.

Thus, the use of protein nanoparticles will allow to increase the solubility, stability and bioavailability of the ATRA. The targeting of cancer cells will allow to increase the intracellular concentration while limiting side effects. This new pharmaceutical form may allow to extend the indication of ATRA to other types of AML.

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The Relationship between Physicians and the Pharmaceutical Industry: Some Ethical Considerations

Eike-Henner W. Kluge

University of Victoria, Canada

It is a common complaint that the pharmaceutical industry's behaviour in providing product-biased information to physicians, patient-directed advertising and the use of clinical evaluation packages is ethically objectionable, and that a majority of ethical failings in the interaction between physicians and the pharmaceutical industry are the direct result of the industry's actions. This paper takes a brief look at whether such industry-focussed criticism is always justified in light of the distinct mandates of the two parties and considering that physicians are the gatekeepers for access to medications. It concludes with the suggestion that while moral (and legal) infelicities in the interrelationship between physicians and the industry do occur, it should never be forgotten that "it takes two to tango."

Biography :

Eike-Henner W. Kluge (PhD, U. of Michigan) was the founding Director of the Canadian Medical Association's Department of Ethics and Legal Affairs, the first expert witness in medical ethics recognized by Canadian courts and was awarded the Medal in Bioethics of the Royal Society of Canada. He is a professor at the University of Victoria and active as a consultant to federal and provincial ministries of health. He has testified before Parliamentary and Royal Commissions and has published extensively on health-related ethical and legal matters. He is the author of the International Medical Informatics Association's Code of Ethics.

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What effect did supplementing with Iron and vitamin B12 singly and in combination have on morbidity among 6 to 9 years old rural primary school children in Kilifi County, Kenya?*

Priscilla Monyangi Nyakundi[1], Yeri Kombe[1] & Anselimo N. Makokha[2]

[1]Kenya Medical Research Institute,

[2]Jomo Kenyatta University of Agriculture and Technology. City: Nairobi, Country: Kenya.

Text This was a double blind placebo controlled clinical field trial of supplementing 6 to 9 years old rural primary school children of both sexes with Iron and vitamin B12 singly and in combination for three months consecutively and reviewed them at 3 and 6 months from start of supplementation. By random selection children were supplemented in four groups: 81 were on Iron alone, 81 were on Iron combined with vitamin B12, 80 were on vitamin B12 alone and 80 were on placebo. Data was collected using questionnaires at baseline, 3 and 6 months follow up.

Study approvals by Kenya Pharmacy and Poisons Board, Kenya Medical Research Institute Scientific Steering and Ethical Review Committees, Ministry of Public Health and Sanitation and Ministry of Education.

Results: A total of 322 children 46.0% (148) boys and 54.0% (174) girls were recruited. Overall baseline prevalence of sicknesses was 37.0% (119) of which 43.9% (65) was in boys and 31.0% (54) was in girls. At 6 months from start of supplementation the overall sickness prevalence was 6.5% (21) of which 2.0% (3) were boys and 2.9% (5) were girls. By supplemental group those that were on Iron alone had sickness occurrence reduce from 30.9% (25) at baseline to 0.0% (0) at 6 months review; those on Iron combined with vitamin B12 had their sickness prevalence reduce from 34.6% (28) at baseline to 3.7% (3) at 6 months assessment; those on vitamin B12 alone had morbidity reduction from 41.3% (33) to 2.5% (2); and placebo group sickness prevalence reduced from 38.8% (31) to 3.8% (3) at 6 months.

Conclusion: 1. Morbidity in primary school was 37% pre-intervention, 2. Giving of Iron alone reduced morbidity from 30.9% to 0.0% at 6 months, and was followed up closely by vitamin B12 alone at 2.5%.

Recommendation: All primary school age children should be given Iron combined with vitamin B12 supplements especially in low income areas**.**

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Antiatherosclerotic and Antidiabetic Potential of Desert Medicinal plants: A Therapeutic Approach

Ashok Purohit

J.N.V. University, INDIA

Recently, considerable attention has been directed towards the utilization of eco-friendly, bio-friendly traditional medicine to meet health care need. WHO also emphasized the utilization of alternative form of medicine from plant origin. The present study was carried out to determine the antiatherosclerotic effect of feeding of various extracts of *Cappris deciduas, Prosopis cineraria* and *Acacia senegal* in cholesterol fed rabbits.In the present study hyperlipidaemia was induced through atherodiet feeding to rabbits caused increase in serum cholesterol and LDL cholesterol levels by nine fold and 14 fold respectively. Simultaneous feeding of atherodiet and *Capparis deciduas* fruit,floor,shoot and bark extracts caused significant reduction in the serum cholesterol and LDL. The maximum reduction was observed in fruit and flower extract (61% and 58%) . Similar results were observed in *Prosopis cineraria bark* (75%) and *Acacia senegal* seed(85%) extracts. The use of these extracts could be useful in the management of cardiovascular disease in which atherosclerosis is important. In other set of experiment screening of various exracts of ,*Azardirachta indica*, *Capparis decidua*, *and Bougainvilllea* for evaluation of diabetic therapeutics was done.. The adult albino rats were used for animal model and diabetes induced by intera-peritoneal releasing of streptozotocin (STZ). The results of various parts of *Azadirachta indica* (bark, seed oil and leave) were shown 69% and 33% reductions in sugar levels when compared with control rats. Similarly, *Capparis decidua* fruit extract (50%ETOH) and *Bougainvillea spectabilis* (flower, leaves and bark) extracts showed significant reductions. Supportively, histopathology of pancreas showed degrees of improvements by treatments of screened plant extracts. In conclusion, when all results of biochemistry and histopathology were compared in relation to percentage reductions of blood sugar levels and improvements of pancreatic histo-architectures can illustrated that *Capparis decidua* ,*Bougainvillea spectabilis* and *Azadirachta indica* showed promising results and can prove to be very useful in the management of the diabetic epidemic.

Biography :

Ashok Purohit,M.Sc,Ph.D, working as Professor , Department of Zoology,Jai Narain Vyas University, Jodhpur. I have Published 75 paper in national and International research Journals. Under my supervision 19 student got Ph.D. degree. At present 7 scholars are working for their Ph.D. degree. From last 30 year I am working on plant products in relation to control diabetes and atherosclerosis, completed many research projects. I was two time Head of the Department.

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Fluorescein Hydrzones as Novel Non-intercalative Topoisomerase IIα Catalytic Inhibitors with Low DNA Toxicity

A. F. M. Motiur Rahman
King Saud University, Saudi Arabia

A series of fluorescein hydrzones were synthesized in three steps with 86–91% overall yields. Topo-I and IIα-mediated relaxation and cell viability assay were evaluated. Among them one compound inhibited 47% topo-I (camptothecin, 34%) and 20% topo-II (etoposide 24%) at 20 μM. Another one derivative inhibited 61% topo-II (etoposide 24%) at 20 μM. Both compounds were further evaluated to determine their mode of action with diverse methods of kDNA decatenation, DNA-topo cleavage complex, comet, DNA intercalating/unwinding and topo IIα-mediated ATP hydrolysis assays. One functioned as a non-intercalative dual inhibitor against the catalytic activities of topo I and topo IIα. Other one acted as a topo IIα specific non-intercalative catalytic inhibitor. Also activated apoptotic proteins as it increased the level of cleaved capase-3 and cleaved PARP in dose- and time-dependent manner. The dose- and time-dependent increase of G1 phase population was observed by treatment of compound along with the increase of p27kip1 and the decrease of cyclin D1 expression.

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Transdermal Iontophoresis: A Non-Invasive Drug Delivery Approach for Alzheimer's Disease

Sevgi Güngör

Istanbul University, TURKEY

Transdermal iontophoresis is a physical technique used to enhance the transport of drugs across skin *via* application of low level of electric current (<0.5 mA/cm2). Iontophoresis has shown to be a potentially emerging technique for the delivery of drugs across skin. It provides a relatively non-invasive alternative to achieve controlled drug delivery. Alzheimer's disease (AD) has become an important health problem as a result of increased elderly population worldwide. AD is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks. To maintain the mental functions and to treat symptoms of AD, acetylcholinesterase inhibitors (donepezil, rivastigmine and galantamine) and NMDA receptor antagonists (memantine) are widely used. Currently, these drugs except rivastigmine has been administered with oral route in Alzheimer's disease treatment. But, AD patient's compliance to the conventional oral therapy could be poor due to risk factors such as memory loss and high incidence of dysphagia. Thus, transdermal iontophoretic delivery could be an ideal therapeutic approach overcoming all limitations of oral route. In our current research, we have explored the feasibility of delivering drugs used in AD treatment *via* transdermal iontophoresis. Constant, direct current, anodal iontophoresis of drugs across dermatomed pig skin was performed *in vitro*. The effect of donor vehicle, single ion effect and drug concentration were examined. Overall the results demonstrated that transdermal iontophoretic drug delivery could be considered as a convenient strategy to achieve therapeutically required input rate for the effective management of AD.

Biography :

Sevgi Güngör received her Ph.D from the Istanbul University, and worked as a post-doctorate fellow at the Istanbul University (Istanbul, Turkey). She then held the position of academic scientist at the University of Bath (Bath, UK). She is currently employed in Istanbul University as Associate Professor of Pharmaceutical Technology Department. Her research focuses on the optimisation of topical and transdermal systems and the enhancement of skin permeation of drugs with chemical enhancers, colloidal nanocarriers, and iontophoresis. She has published nearly 30 papers in peer reviewed scientific journals and 7 book chapters in international books. She has given more than 50 oral and poster presentations at international conferences.

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Functionalized Polymeric Nanoparticles for CD13 Receptor Mediated Dual-Targeting Carrier For Site Specific Antitumor Drug Delivery

Madhu Gupta

Shri Rawatpura Sarkar institute of Pharmacy, India

Some specific type of tumor cells and tumor endothelial cells represented CD13 proteins and act as receptor for NGR motifs containing peptide. These CD13 receptors can be specifically recognized and bind through the specific sequence of cyclic NGR (cNGR) peptide and presented more affinity and specificity towards them. The cNGR peptide was conjugated to the PEG terminal end in PLGA-PEG block copolymer. Then, the ligand conjugated nanoparticles (cNGR-DNB-NPs) encapsulating docetaxel (DTX) was synthesized from preformed block copolymer by emulsion/solvent evaporation method and characterized for different parameters. The various studies such as *invitro* cytotoxicity, cell apoptosis and cell cycle analysis presented the enhanced therapeutic potential of cNGR-DNBNPs. The higher cellular uptake was also found in cNGR peptide anchored NPs into HUVEC and HT-1080 cells. However, free cNGR could inhibit receptor mediated intracellular uptake of NPs into either types of cells at 37°C and 4°C temperature, revealing the involvement of receptor-mediated endocytosis. The *in-vivo* biodistribution and anti-tumor efficacy studies indicated that targeted NPs have higher therapeutic efficacy through targeting the tumor specific site. Therefore, the study exhibited that cNGR-functionalized PEG-PLGA-NPs could be a promising approach for therapeutic application to efficient antitumor drug delivery.

Biography :

Madhu Gupta is an Assistant professor in the Shri Rawatpura Sarkar Institute of Pharmacy, Datia M.P. India. She has about 08 years of research experience and teaching experience. She is pioneer scientist in the field of nanotechnology and drug delivery field. She has judiously exploited bioligands for targeting of bioactives and drug moiety. She has over 17 research publications to her credit published in journals of high scientific impact and contributed 08 chapters in various renowned books and to several international and national books. She is a recipient of various oral and poster presentation in International and National conferences held in India and abroad. She is an acclaimed academician and researcher of high repute. She serves on the potential reviewer of various high repute journals. She is widely visited scientist and delivered invited/popular/keynote addresses in national conferences in India.

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Perception of Filipino Community Pharmacists in Manila on Pharmacy-Based Immunization Program

Princess Camile L. Cruz, Alyssa Marie P. Hizon, Emjay Mark M. Joson, Jan Thereese C. Salas, Justine C. Tanael, Sarah Celine S. Tolentino, and Renz Kenneth G. Cadiang

University of Santo Tomas, Philippines

Immunization is one of the paramount achievements in public health during the 20th century since it is a preventive measure against vaccine-preventable and infectious diseases (Centers for Disease Control and Prevention). Increasing cases of vaccine-preventable diseases and low vaccination rates among adults had led the pharmacists in other countries to become key players in disease prevention by expanding their roles in the administration of vaccines.

In the Philippines, vaccine-preventable diseases continue to escalate. Moreover, vaccination among adults remains to be uncovered in the Expanded Program on Immunization of the Department of Health (Robles, 2015). Thus, the Philippine Pharmacists' Association and Food and Drug Administration tailored a plan to implement a program authorizing FDA-trained community pharmacists to administer vaccines. This study aimed to describe the perceptions of the selected Filipino community pharmacists in Manila regarding the administration of adult vaccines. Through convenience and random sampling, a total of 300 questionnaires were distributed to licensed community pharmacists in the City of Manila and only 263 questionnaires returned which gave a response rate of 87.67%. A 5-point Likert scale was used to measure their perception in each category. The collected data were encoded and analyzed using Statistical Package for the Social Sciences (SPSS) version 19. Spearman's Rank-Order Correlation, Mann-Whitney U Test, Kruskal-Wallis ANOVA and Fisher's Exact Test were the biostatistical analyses used.

Results showed that more than half of the respondents supported (69%) the pharmacy-based immunization program. Most community pharmacists agreed on the statements regarding the competence of the pharmacist to immunize (mean = 4.19 $\pm$ 0.564), the increased accessibility of vaccinations to the community (mean= 4.10 $\pm$ 0.582), the positive effects of the program to their professional services (mean = 3.71 $\pm$ 0.535) and the readiness of their pharmacy (mean= 3.72 $\pm$ 0.793) to adapt the program. In conclusion, community pharmacists conveyed a high acceptance level towards pharmacy-based immunization program.

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Phospholipids complex: A significant tool for Enhancement of Bioavailability of phytoconstituents

Vikas Sharma

Shri RawatPura Sarkar Institute of Pharmacy, India

Over the past century botanical products was established the biological and health promoting activities. Most of the biologically active constituents of plants are polar or water soluble molecules. However, water soluble phytoconstituents (like flavonoids, tannins, glycosidic aglycones etc) are poorly absorbed either due to their large molecular size which cannot absorb by passive diffusion, or due to their poor lipid solubility; severely limiting their ability to pass across the lipid-rich biological membranes, resulting poor bioavailability.

Phytosomes are recently introduced herbal formulations that are better absorbed, and as a result produce better bioavailability and actions than the conventional phytomolecules or botanical extracts. Phytosomes are produced by a process whereby the standardized plant extract or its constituents are bound to phospholipids, mainly phosphatidylcholine producing a lipid compatible molecular complex. This phyto-phospholipid complex, phytosome resembles a little cell. The term "phyto" means plant while "some" means cell-like. Phytosomes exhibit better pharmacokinetic and pharmacodynamic profile than conventional herbal extracts. The phytosome technology creates intermolecular bonding between individual phyto molecules and one or more molecules of the phospholipid, phosphatidylcholine. Phytosomes have the capacity to deliver the standardized plant extracts and phytoconstituents through several routes of drug administration. The phytosome technology has been effectively enhanced the bioavailability of many popular herbal extracts including milk thistle, Ginkgo biloba, grape seed, green tea, hawthorn, ginseng etc and can be developed for various therapeutic uses or as dietary supplements. Only a few natural drugs have been formulated and are available in the market as phytosomes.

Biography :

Vikas Sharma is a Research Associate and Associate Professor Shri RawatPura Sarkar Institute of Pharmacy, Datia. He has about 12 years of research experience and teaching experience. He is pioneer scientist in the field of herbal drug delivery, antigen delivery by nanocarriers and immunology and exploiting this opportunity for investigation on Phytochemical and Pharmacological Aspects of Some Vrashya Rasayan Herbs therefore enable us to achieve the goal of efficacious and specific treatment for a vast array of field. He has over 30 research publications to his credit published in journals of high scientific impact and contributed 05 chapters.

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Endotoxin-Induced Uveitis and New Treatment Alternatives (TNF-alpha agonists)

Avni Murat Avunduk

Pamukkale University, Turkey

A single injection of endotoxin, at a site distant from the eye induces anterior uveitis in some laboratory animals. This phenomenon is called as endotoxin-induced uveitis (EIU). EIU is considered as an exellent laboratory model for investigating newer therapeutic approaches in anterior uveitis. Tumor necrosis factor- α (TNF-α) play a crucial role in EIU, since intraocular injection of TNF-α into rat eyes induced acute uveitis that closely resembled the response to LPS and it is found in aqueous samples of animal models of uveitis as well as patients having uveitis. Thus, TNF- α antagonists might be powerful treatment alternatives in refractory uveitis entities, which do not respond to conventional therapeutics. If there is any beneficial effect of a TNF-α antagonist on EIU this effect should most probably occur early in the course of EIU, since TNF-α plays a crucial role in the early phases of EIU. The currently commercially available anti-TNF-[alpha] agents are infliximab, adalimumab and etanercept. All of three drugs were successfully used in the treatment of systemic inflammations such as rheumatoid arthritis (RA) and Crohn's disease and their role for the control of refractory uveitis have been increasingly appreciated.

Infliximab has been reported to be effective in controlling inflammation in about 80% of refractory uveitis entities. However, repeated infusions in 4–8 weeks intervals are often necessary to obtain good clinical results.

Infliximab is especially effective in ocular complications of Behcet's disease. The response to infliximab is rapid in this disease.

Adalimumab is administrated as a subcutaneous injection in 2-weekly intervals. However, there have been very few studies present in the current literature about its use on clinical uveitis. I have found only one report about its use in Behcet's disease and three small studies in childhood uveitis. All of four studies reported beneficial effects.

Etanercept is given twice weekly as a subcutaneous injection. Etanercept seems to be less effective than the other two agents in the treatment of uveitis. This fact is linked to its relatively weak binding compared to other agents.

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Antitumor activity of transferrin-modified- artemether lipid nanospheres in cancer cell lines

Eltayeb Suliman Elamin Abbas

Omdurman Islamic University, Sudan

Diverse lines of research show that the cellular response to artemether (ART) is multi-factorial in nature. The cytotoxicity of ART is specific to cancer cells because most of them over expressed; transferrin receptors and have high level of intracellular iron and ART is mainly toxic after; interaction with iron ion. Our aim is to investigate the effect of some formulation characteristics on; the cytotoxicity of ART in C6 and MCF-7 cells lines. In this study, the cytotoxicity of ART-loaded; anionic, cationic or neutral (transferring modified) lipid nanospheres was studied by MTT and; apoptosis tests. Characterizations of apoptosis were done. The effect on the mitochondria and the; nucleus was qualitatively characterized after using different types of cell tracker dyes. The cellular; uptake, accumulation and distribution of the formulations were characterized after loading; different hydrophobic fluorescence probes instead of ART. The relation between the; accumulated amount of ART and its cytotoxicity was defined. Our study shows that ART can be highly toxic to the tumor cells if accumulated in a large amount in the cell. Lipid nanosphere containing tween80 and transferrin can highly accumulate ART in brain cells and can be; formulated as a promising potent, safe and inexpensive drug carriers for brain tumors.

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Scientific Sessions

Day 2

Session 2

Vaccine Drug Delivery Systems
Current Issues of Pharmaceutics
Management of QA/QC in Pharmaceutical Industry
Regulatory Issues in Pharmaceutics and Novel Drug Delivery

Title:	Extemporaneous Compounding, Dispensing and Administration of Transdermal Preparations **Alfred T. Reiman,** University at Buffalo School, USA
Title:	Study of concomitant drugs using machine learning QSAR analyses to facilitate brain penetration of morphine **Yoshihiro Uesawa**, Meiji Pharmaceutical University, Japan
Title:	Circadian clock: at long last we can look forward to ending a time of finding novel anticancer strategies **Benedetto Grimaldi**, Fondazione Istituto Italiano di Tecnologia (IIT), Italy
Title:	Solvent Exchange-Induced In Situ Forming Gel Comprising Polymer and antimicrobial Drugs for Periodontitis Treatment **Thawatchai Phaechamud**, Silpakorn University, Thailand
Title:	Pharmacokinetics and antitumoral efficacy of absorbable microspheres pre-loaded with Irinotecan delivered into the metastatic liver tumours from colo-rectal cancer(TANDEM-IRI) **Bogdan Valeriu Popa**, Clinical Emergency Hospital Bucharest, Romania
Title:	Social innovations and e-health business models in multi-side markets **Vivian Vimarlund**, Jönköping University, Sweden
Title:	Information Governance: Managing Big Data by Utilizing Technology to Achieve Regulatory-Compliance, Satisfy Legal Requirements & Effectively Collaborate in the Pharmaceutical Industry **Ray Thomas**, IBM Corporation,USA
Title:	Drug Warming Technology for Faster and Less Painful Administration of High Viscosity Drugs **Harshal Shah**, Cambridge Consultants,USA
Title:	Drug delivery in asthma and chronic obstructive pulmonary disease management: Role of aerosol therapy **Mohammed Shamssain,** Ajman University of Science and Technology, United Arab Emirates
Title:	T Regulatory Cells as a Theraputic Target in management of Patients with Type1 DM **Abdel Basset EL Essawy,** Ras AlKhaimah Meidcal Health and Science University , UAE
Title:	The antifungal caspofungin increases moxifloxacin activity against Staphyloccocus aureus biofilms by inhibiting N-acetylglucosamine transferase activity **Wafi SIALA,** Catholic University of Louvain , Belgium
Title:	Local Infiltration Anaesthia (LIA) and Novel Technique for Effective Pain Relief following Elective Primary Hip and Knee Replacement-Innovative Study **Mohammad Salhab,** Chapel Allerton Hospital, UK
Title:	Antibody-Proteases as a Novel Biomarker and thus a potential Druggable Target to Monitor and to Manage Demyelination **Sergey Suchkov,** I.M. Sechenov First Moscow State Medical University, Russia

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Extemporaneous Compounding, Dispensing and Administration of Transdermal Preparations

Alfred T. Reiman

University at Buffalo School of Pharmacy and Pharmaceutical Sciences, USA

The utilization of transdermal medications is global common practice. To date many agents have been formulated, brought to clinical trial, and now do exist as marketable, commercially available, transdermal dosage forms. Unfortunately, in terms of patient care, many drug substances which do possess qualifying physiochemical properties, are not commercially available in transdermal form, this being largely due to practical marketing issues. The properly equipped pharmacist however can help to bridge this gap by employing the use of extemporaneous compounding methods. For low volume prescription demands at the pharmacy practice level, such traditional methods are capable of producing, in reasonable time, custom, made-to-order gels and patch systems. Where higher quantity demands are encountered, the system can become cumbersome and a hindrance to efficient pharmacy operations. In order to address this need, a robotic, semi-automatic manufacturing system is being developed for use in community and institutional based pharmacy. This work in progress is being conducted at the State University of New York at Buffalo, School of Pharmacy and Pharmaceutical Sciences. In addition to meeting the special needs of individual patients, the compounding pharmacist can be a valuable resource to investigators through the provision of prototype transdermal dosages. By making robotic automation available at the pharmacy practice level, the investigator, as well as the patient, may be more adequately served.

Biography :

Alfred T. Reiman, male, professor of pharmacy practice, graduated from the pharmacy department, University at Buffalo in 1998. He worked for Children's Hospital of Buffalo and Millard Fillmore Hospital 1998-2002, the State University of New York at Buffalo, Department of Pharmacy Practice, 2000-date. Since 2002, he became supervising pharmacist, laboratory curriculum coordinator, laboratory operations coordinator, research pharmacist, and primary compounding pharmacy lecturer. He was selected as recipient of the esteemed Robert M. Cooper award in 1998, the Faculty Teaching Award in 2012 and elected Outstanding Teacher of the Year 2003-2006. Prior to pharmacy practice, 1979-1995, he worked as an electrical engineer with specialization in the fields of digital hardware/software design and robotic motion control systems. In addition to academic pharmacy practice, he is a prolific designer of microprocessor based devices for general use in community and institutional pharmacy.

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Study of concomitant drugs using machine learning QSAR analyses to facilitate brain penetration of morphine

Yoshihiro Uesawa

Meiji Pharmaceutical University, Japan

Introduction: Morphine is a substrate of P-glycoprotein (MDR1), which is expressed in the blood brain barrier and regulates the excretion of drugs from the brain to the blood. On the other hand, morphine-6-glucuronide (M-6-G), an active metabolite of morphine, is a substrate of organic anion transporting peptide (OATP), a membrane transport protein. It is thought that appropriate control of these transporters can increase the analgesic effect of morphine and decrease the dose required. Therefore, seed compounds for concomitant drugs with morphine were investigated to identify compounds that can prohibit the elimination of morphine by MDR1 and allow the uptake of M-6-G by OATP.

Methods: Compounds with properties similar to OATP1A2 substrates and MDR1 inhibitors were extracted from drug interaction databases. Structural and physicochemical properties were calculated based on chemical structures to construct Quantitative Structure-Activity Relationship (QSAR) prediction models. The models were constructed using machine learning techniques, such as deep-learning, random-forest, support-vector-machine, boosting-tree, and artificial-neural-network-ensemble (ANNE) methods. Model prediction validities were validated with an external verification method. The models for both transporters were adopted to locate seed compounds from a chemical compound database to ensure that the morphine reached the brain effectively.

Results and Discussion: Deep-learning and ANNE were suitable methods for prediction model construction. These models enabled the selection of compounds with the dual properties of high MDR1 inhibition and low OATP substrate.

Biography :

Yoshihiro Uesawa received his Ph.D. degree from the Graduate School of Pharmaceutical Sciences, Kyoto University, Kyoto, Japan, in 1992. He is an Associate Professor at Meiji Pharmaceutical University, Tokyo, Japan. His major areas of research include computational toxicology, pharmaceutical interactions between medication and food, analyses of quantitative structure-activity relationships (QSAR), machine learning, and data mining. In January 2015, he was one of the winners of the "Tox21 DATA Challenge 2014," organized by NIH, USA.

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Circadian clock: at long last we can look forward to ending a time of finding novel anticancer strategies

Benedetto Grimaldi

Fondazione Istituto Italiano di Tecnologia (IIT), Italy

We recently obtained the first evidence that the pharmacological targeting of a circadian regulator may be an innovative anticancer strategy. We found that a number of cancer cell lines and primary tumors predominantly express the circadian nuclear receptor REV-ERBβ. This receptor plays an unexpected role in sustaining cancer cell survival when the autophagy flux is compromised. Accordingly, genetic inhibition of REV-ERBβ sensitizes to cytotoxicity induced by chloroquine (CQ), an autophagy inhibitor that is currently evaluated in numerous cancer clinical trials. These observations suggested that a combinatorial inhibition of both REV-ERBβ and autophagy may offer an innovative pharmacological approach to induce cytotoxicity in cancer cells. Following this idea, we identified a chemical compound, ARN5187, with inhibitory activity toward both REV-ERB-mediated transcriptional regulation and autophagy. Further structure-activity relationship (SAR) analysis on ARN5187 identified analogs that decreased the viability of different cancer cells at concentrations from 5 to 50 times lower than CQ.

Notably, ARN5187 analogs and CQ have a similar effect on autophagy inhibition. Many cancer cells require high micromolar concentrations of CQ to block autophagy *in vitro*, yet such levels are rarely achieved in patients. Although improved lysosomotropic agents have been synthetized, the homeostatic roles of lysosome and autophagosome in normal tissue impose carefully consideration of potential side effects in healthy organs. Consequently, the fact that dual REV-ERBβ/autophagy inhibitors have greater cytotoxicity than CQ, but similar autophagy inhibitory activity, supports their future development as novel anticancer agents with a potential improved therapeutic index.

Biography :

Benedetto Grimaldi obtained his PhD under the supervision of Dr. Paola Ballario (University of Rome, La Sapienza, Italy), an expert in the study of epigenetics and signal transduction, Benedetto Grimaldi transitioned into a postdoctoral fellowship under the mentorship of Prof. Sassone-Corsi (University of California, Irvine, USA), a leader in the field of circadian clock, metabolism and epigenetics. He is Senir Researcher the "Istituto Italiano di Tecnologia (IIT)", Italy, where he pursues a line of research focused on the study of "clock-related pathologies", and on the identification and evaluation of novel molecules with "clock modulator" activity for therapeutic applications.

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Solvent Exchange-Induced *In Situ* Forming Gel Comprising Eudragit RS-antimicrobial Drugs for Periodontitis Treatment

Thawatchai Phaechamud, Jongjan Mahadlek, Purin Charoensuksai

Silpakorn University, Thailand

Local drug delivery to periodontal pocket for periodontitis treatment has been recently interesting. Antibiotic-loaded *in situ* forming gel has been commercialized for this purpose. Eudragit RS (ERS), a quaternary polyacrylate positively charged polymer, exhibits a very low permeability and swells in aqueous media independently of pH without dissolving. Owing to its high solubility in *N*-methyl pyrrolidone (NMP) it was interesting to apply as polymer matrix for solvent-exchanged *in situ* forming gel. The aim of this research was to prepare *in situ* forming gels prepared from Eudragit RS to deliver the antimicrobial agents (doxycycline hyclate, metronidazole and benzyl peroxide) for periodontitis treatment. The solvent exchange between NMP and an external aqueous simulated gingival crevicular fluid stimulated the dissolved Eudragit RS transforming into the opaque rigid gel. Antimicrobial agent-loaded-ERS systems exhibited Newtonian flow which their syringeabilities were acceptable. The higher-loaded Eudragit RS promoted the more prolongation of drug release because of the retardation of water diffusion into the precipitated matrix. Antimicrobial activities against *Staphylococcus aureus, Escherichia coli, Candida albicans, Streptococcus mutans* and *Porphyrommonas gingivalis* depended on type of drugs and test microorganisms. Doxycycline hyclate loaded-Eudragit RS systems showed these activities greater than the others however all of them could inhibit all test microorganisms. Thus the solvent exchange-induced *in situ* forming gels comprising Eudragit RS-antimicrobial drugs exhibited potential use as localized delivery systems for periodontitis treatment.

Biography :

Thawatchai Phaechamud has completed his Ph.D at the age of 30 years from Chulalongkorn University. He is the academic staff at Faculty of Pharmacy, Silpakorn University, Nakhon Pathom, Thailand. He concentrates the research works on controlled drug delivery systems, herbal preparation and pharmaceutical material sciences.

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Pharmacokinetics and antitumoral efficacy of absorbable microspheres pre-loaded with Irinotecan delivered into the metastatic liver tumours from colo-rectal cancer (TANDEM-IRI)

Bogdan Valeriu Popa

Clinical Emergency Hospital Bucharest, Romania

Liver chemoembolization is based on the vascularity of the liver: hepatic artery supplies ~ 20% of liver blood, oxygenated (clean blood),meanwhile portal vein supplies ~ 80% of liver blood, deoxygenated blood which contains products of metabolism/toxins etc. Liver chemoembolization with particles(DEB-TACE) consists of a mixture among millions of absorbable microspheres (Embozene TANDEM,CeloNova Biosciences) and Irinotecan,a chemotherapic drug with cytotoxic effect.

The lecture emphasizes the pharmacokinetics of liver chemoembolization with smallest dimension particles in the world -40 μ – loaded with Irinotecan,which is delivered inside the tumour and transformed into the hepatic cell,by an enzyme(carboxilysterase) in a very active metabolite(SN38).The size of microspheres is tightly calibrated (40 μ +/- 10) and it will be maintained after delivery in tumoral tissue.

The mean serum Irinotecan levels remains near C_{max} for 180 minutes after chemoembolization: 351.4+/-49,7 at 30 minutes and 329.0+/-48.2 at 60 min(Tanaka et al). Serum levels of Irinotecan and SN38 levels are proportional to the drug dose and do not reflect the number of microspheres used to deliver the dose.

The method is proved to be safe and an effective treatment of liver metastases from colorectal cancer according to the last international clinical trials.

Biography :

Bogdan Popa is Associate Professor and Chairman at University of Medicine and Pharmacy "Carol Davila" Bucharest,Romania and Head Department Diagnostic and Interventional Radiology at Clinical Emergency Hospital "Floreasca" Bucharest. He completed his Ph.D.in 2005 at the same university. He is EMEA expert (Europe,Middle East,Africa) in liver chemoembolizations with TANDEM loaded microspheres and international trainer in endovascular treatment of primary and secondary malignant liver tumours. His experience in the field of Interventional Vascular Radiology got him the position of President of Romanian Society of Interventional Radiology and invited speaker at many conferences.

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Social innovations and e-health business models in multi-side markets

Vivian Vimarlund

Jönköping University, Sweden

Many countries in Europe develop strategies to foster the use of eHealth services and social innovations (European Commission, 2012) .However, despite the fact that business models are perceived as an important part of the strategy used to achieve a sustainable implementation and use of social innovations, there is no generic models that allow to capture the effects of a multi-side market in which enterprises, industries and public organization participate. Further, business models are usually connected to an organization ability to focus on value- creation and to the ability to develop cost- effectiveness at the organizational level. In a multi-side market as e-health there are several challenges that has to be over-win to develop sustainable business models that create and increase the market for e-health but that at the same time supported social innovations developed in close collaboration between industry, individuals and organizations. In this presentation, Issues such as: challenges when developing business models for social innovation, pre-requisites a multi-side market demands as well as constrains the market for social innovations and e-health services has today will be discussed. Examples from current innovation project will be presented.

Biography :

Vimarlund is Professor in e-health and in Informatics. She has a wide experience on management and leadership. Academic leadership is practiced as academic leader of the informatics research group, Director of the Research Center (CENIT/IS) at Jönköping International School (JIBS), as a Member of the American Medical Informatics (AMIA) Mentorship programme, and as the scientific leader of a series of research projects with focus on implementation, business models and social innovations.

Vimarlund is also the co-director of the master programme Software Engineering and Management at LiU, the coordinator of the national eHealth network in Sweden.

Professor Vimarlund has since 1989 conducted research within the area of Health Informatics with special focus on issues such as: a) Methods and models to evaluate the impact of the implementation and use of IT-based innovations in healthcare. b) Business models for Public Information Systems and Electronic Markets c) E-health services implementation.

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Information Governance: Managing Big Data by Utilizing Technology to Achieve Regulatory-Compliance, Satisfy Legal Requirements & Effectively Collaborate in the Pharmaceutical Industry

Ray Thomas Jr.,

IBM Corporation, USA

Big Data is the concept of enormous amounts of "wild" information within an enterprise. The exponential growth of this varied information, when left untamed, results in high cost, increased risks, and decreased value. Information Governance is a strategic framework that ensures effective and efficient management of enterprise information, which enables an organization to reach its goals (e.g., achieve regulatory-compliance and satisfy legal requirements). The Pharmaceutical Industry is: i) very litigious due to competitive-litigations based on patent infringement, and consumer-litigations based on products liability; ii) highly regulated due to U.S. Food & Drug Administration (FDA) oversight; and iii) inherently collaborative due to the extensive teamwork required to achieve FDA-approval and licensure. Each of the three (3) above-mentioned general use cases call for an Information Governance framework including technical mechanisms that enable pharmaceutical companies to tame their Big Data in order to decrease cost, reduce risks and increase the value of enterprise information. This session will include an in-depth discussion on Information Governance best practices and use cases particular to regulatory-compliance, legal requirements, and secure content-collaboration in the Pharmaceutical Industry.

Biography :

Ray is a seasoned attorney. He holds a Juris Doctorate (J.D.) from Cleveland-Marshall College of Law, a Master of Laws (LL.M.) from American University, Washington College of Law, and 2 data privacy certifications (CIPP/US, CIPM) with the International Association of Privacy Professionals. Previously, he served as Adjunct Assistant Professor at Howard University School of Law. He is the Global Subject Matter Expert (Legal & Data Privacy) for IBM Corporation. He lectures extensively throughout the world and consults corporate executives on regulatory-compliance matters to assist them in defining and enhancing Information Governance processes and practices to reduce business cost and risks.

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Drug Warming Technology for Faster and Less Painful Administration of High Viscosity Drugs

Harshal B. Shah

Cambridge Consultants,USA

Majority of chronic autoimmune and immune deficiency disease such as Ruhemtoid Arthritis, Multiple Schelrosis, Ulceretive Colits are treated by bioligcs and monoclonal antibodies. Most of these therapies are self administered by patients on daily/weekly basis. mABs and biologics are inherently viscous and the requirement to refrigerate it before administration increses the viscosity of the drug at the time of administration even higher. As a result, injecting such highly viscous drugs results in to longer injection time and/or use of high gauge needles, both of which increases the pain and discomfort for patients.

Heating these highly viscous drugs before administering to reduce its viscosity seems an obvious choice. However heating these biologics would posses a risk of compromising stability and chemical structure of the formulation. Heating the drug content evenly is another challenge.

Advance modeling, computational fluid dynamics analysis and active heat mapping technologies could resolve these challenges alogn with careful consideration on engineering and design aspects of the injector device. Based on the data generated from the internal research, a viscous biologic can be heated with uniform temperature distribution and 60% lower injection time along with 30% reduction in needle gauge can be achieved. This findings could help improve life of millions of patients living with autoimmune and immunodeficicy diseases.

Content Comments:

The talk will focus on some statistics on prevelance of this pain and discomfort issue, and research on advanced analytical methodologies to acheie even heating of biologics without compromising stability and improvements achieved due to this research efforts

Biography :

Harshal has mechanical engineering degree from Nirma Institute of Technology in India and MBA from Syracuse University in New York. He has over 10 years of experience focused on advance pharmaceutical technologies and drug delivery device engineering. Currently he serves as Vice President in Global Medical Technology Division at Cambridge Consultant.

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Drug delivery in asthma and chronic obstructive pulmonary disease management: Role of aerosol therapy

Mohammed Shamssain

Ajman University of Science and Technology, UAE

Asthma, chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF) are all pulmonary diseases that are characterized by chronic inflammation and an increase in mucus production. This presentation discusses some of the different treatment options that are currently available for asthma and COPD and the considerations that need to be taken into account to produce new therapies for the treatment of chronic respiratory diseases. Inhaled therapy is the cornerstone of asthma and COPD management in that it optimizes the delivery of the medication to the site of action. The effectiveness of inhaled therapy is affected by the correct choice of the device and proper inhalation technique. This influences the drug delivery and distribution along the bronchial tree, including the most peripheral airways. In this context, accumulating evidence supports the contribution of small airways in asthma, and these have become an important target of treatment. The "ideal inhaler" does not exist, and not all inhalers are the same. Advances in technology has highlighted these differences, and have led to the design of new devices and the development of formulations characterized by extrafine particles that facilitate the distribution and deposition of the drug particles along the respiratory tract. In addition, efforts have been made to implement adherence to chronic treatment, which translates into clinical benefit. The optimal control of asthma depends on the drug that is selected, the device that is employed and the removal of factors that reduce patient's adherence to therapy. Whilst oral drugs may be easier to administer, they are more prone to side-effects due to higher bioavailability. Inhaled compounds may show reduced bioavailability, but face their own unique challenges; thick mucus in the respiratory tracts of asthma, CF and COPD patients can act as a physical barrier that impedes drug delivery. Mucus also contains a high number of enzymes and proteases that may degrade compounds before they reach their site of action. When treating pulmonary diseases such as asthma, COPD and CF, inhalation may be the best route of administration due to the rapid clinical response and the high doses of drug that can be administered to the disease site with limited off-target effects. However, a number of considerations need to be taken into account when designing new inhaled therapies. Particle size, particle charge and solubility and physical characteristics of particles need to be considered as well as the ability of these particles to withstand the defense barriers presented by the lung itself. Inhaled compounds must also be able to withstand degradation by ectoenzymes within the lung. A final consideration is their ability to penetrate the thick mucus often associated with respiratory diseases. Inhaled therapies may need to be administered alongside mucolytic drugs to aid penetration through mucus. Getting all of these factors to successfully align can lead to successful drug deposition within the lung followed by drug elimination without any systemic side effects. In conclusion: when designing new inhaled therapies enzymatic degradation in the lung lumen should be taken into account.

Biography :

Mohammed Shamssain completed his Ph.D from Loughborough University, UK, then he worked in academic field at many universities world wide including north Africa, Ireland, USA, South Africa, and the United Kingdom. He hold a position of Associate Professor in the College of Pharmacy and Health Sciences, Ajman University of Science and Technology, Ajman, UAE. His research areas are respiratory pathophysiology, epidemiology, asthma and COPD therapeutics and management.

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T Regulatory Cells as a Theraputic Target in management of Patients with Type1 DM

Abdel Basset EL Essawy

Ras AlKhaimah Meidcal Health and Science University , UAE

T-regulatory cells (Tregs) play a fundamental role in the creation and maintenance of peripheral tolerance. Deficits in the numbers and/or function of Tregs may be an underlying cause of human autoimmune diseases including type 1 Diabetes Mellitus (T1D), whereas an over-abundance of Tregs can hinder immunity against cancer or pathogens. The importance of Tregs in the control of autoimmunity is well established in a variety of experimental animal models. In mice, manipulating the numbers and/or function of Tregs can decrease pathology in a wide range of contexts, including autoimmunity and it is widely assumed that similar approaches will be possible in humans. T1D, the most prevalent human autoimmune disease, has been a focus of interventions either through direct and indirect *in-vivo* proliferations or through adoptive transfer of the *in-vitro* generated antigen specific and nonspecific T reg. Some challenges still need to be addressed, including a more specific phenotype marker for Tregs; the reproducibility of satisfactory animal results in human and the reconcile of discrepancies between *in-vitro* and *in-vivo* studies. In this article, we will highlight the role of Tregs in autoimmune disease in general with a special focus on T1D, highlighting progress made and challenges ahead in developing Treg-based therapies.

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The antifungal caspofungin increases moxifloxacin activity against *Staphyloccocus aureus* biofilms by inhibiting *N*-acetylglucosamine transferase activity

Wafi SIALA

Catholic University of Louvain, Belgium

Biofilms play a major role in *Staphylococcus aureus* pathogenicity but poorly respond to antibiotics. We show that the antifungal caspofungin improves the activity of the fluoroquinolone moxifloxacin against biofilms grown *in vitro* (96-well plates or catheters) or *in vivo* (mouse subcutaneous model of implanted catheters). The degree of synergy among different clinical isolates was inversely proportional to the level of expression of *ica* operon, the products of which synthesize poly-*N*-acetyl-glucosamine polymers, a major constituent of the biofilm matrix. *In vitro,* caspofungin inhibited the activity of IcaA, for which BLAST and ClustalW analyses revealed homology with β-1-3-glucan synthase, the caspofungin pharmacological target in fungi. This inhibition destructured the matrix, reduced the biofilm content in exopolysaccharides, and increased moxifloxacin penetration within the biofilm. This study describes for the first time a bacterial target for caspofungin. In a broader context, it highlights the interest of pharmacological inhibitors of IcaA for biofilm-related infections.

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Local Infiltration Anaesthia (LIA) and Novel Technique for Effective Pain Relief following Elective Primary Hip and Knee Replacement-Innovative Study

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[3] University of Leeds, Uk

Background: Acute pain control following elective primary total knee replacements (TKRs) and total hip replacements (THRs) is often poor and is associated with long term chronic pain syndrome. Moderate to severe pain is often reported in the first 48 hours following surgery requiring different pain modality management strategies such as patient controlled analgesia and multimodal drug analgesia. The Local Infiltration Anaesthetic (LIA) technique is currently an established technique to tackle perioperative pain relief; however, studies have reported conflicting evidence so far. In a recent review of 29 studies investigating the use of LIA in TKR, LIA emerged as a safe technique with improved pain control (Gibbs DMR 2012). We have developed the LIA technique to include an intra-articular catheter allowing an infusion of Novel Mixture (NM) to be infused continuously postoperatively.

Aims and Objectives: In this study we report on our experience using LIA in addition to the Novel Technique and Proprietary NM developed in Leeds-Bradford and infiltrated at 4-5 mls/hour for 48 hours post surgery.

Materials and Methods: Between October 2013 and October 2015, 62 patients undergoing primary TKR were prospectively followed up. Three groups of patients were studied. All patients studied had spinal anaesthesia (SA) with 300-400mcg diamorphine.

Group 1. GA. No LIA and no NM. 20 patients.

Group 2. SA plus NM for 48 hours post operatively with catheter placed anteriorly under the patella. 21 patients.

Group 3. SA plus LIA plus NM for 48 hours post operatively with catheter placed posteriorly in the knee joint. 21 patients.

Between June 2011 and July 2014, 173 consecutive patients undergoing primary THR using the posterior approach were also prospectively followed up.

Group 1. GA only. 31 patients,

Group 2. SA only. 37 patients,

Group 3. SA plus LIA_1 only. 38 patients,

Group 4. SA plus LIA_2 only, 34 patients,

Group 5. SA plus NM for 48 hours. 33 patients.

Demographics reveal similar distribution between the two groups in terms of age and sex.

Results and complications: The patients without LIA or NM required more morphine in the first 12 hours

postoperative period than the other groups. Seventy percent (n=14) of these group 1 patients required 10mg morphine following TKR compared to only 2% (n=1) of patients requiring 10mg of morphine when LIA and NM were used. The increased morphine requirement continued for 48 hours postoperatively in group 1, whereas none of the patients in groups 2 or 3 required morphine after 36 hours. Statistical analysis revealed no difference of morphine requirements with different catheter placement. Fewer patients suffered from nausea and vomiting or urinary retention in the group with LIA and NM (*p-value* <0.05, Mann-Whitney test). There were no infections DVT or other complications in any of the groups.

Conclusion: This study demonstrates that patients following TKR treated with LIA and NM for 48 hours after required significantly less morphine during this time. This benefit was most marked in the first 24 hours after surgery and the benefit was maintained for 48hours. Fewer patients required opiate analgesia when LIA plus NM was used compared to the other groups. The highest significance was at 0-12 hrs for patients requiring up to 20mg morphine usage ($\chi 2(2) = 46.713$, $p = 0.000$); and 0-12hrs for patients requiring 30mg morphine usage ($\chi 2(2) = 46.310$, $p = 0.000$).

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Antibody-Proteases as a Novel Biomarker and thus a potential Druggable Target to Monitor and to Manage Demyelination

Sergey Suchkov

I.M. Sechenov First Moscow State Medical University, Russia

Abs against myelin basic protein/MBP endowing with proteolytic activity (Ab-proteases) are of great value to monitor demyelination at either of the stages (clinical and subclinical ones) to illustrate the evolution of MS resulting in demyelination, axon loss and development of disability. The activity of the Ab-proteases markedly differs between: (i) MS patients and healthy controls; (ii) different clinical MS courses; (iii) EDSS scales of demyelination to correlate with the disability of MS patients to predict transformation prior to changes of the clinical course, i.e., changing of a remitting type (moderate) into the secondary progradient type (aggressive) prior to changing in a pattern of the clinical manifestations.

The sequence-specificity of Ab-proteases demonstrates 5 sites of preferential proteolysis to be located within the immunodominant regions of MBP. Those sites are located within the immunodominant regions; and two of them falling inside the sequence covering a 81-103 segment and its 82-98 subsegment as well, with the highest encephalitogenic properties to be attacked by the Ab-proteases in MS patients with the most severe (progradient) clinical courses.

In remission-type courses, Ab-proteases attack low-immunogenic sites presumably. In progradient courses, Ab-mediated proteolysis is prevailed on highly-immunogenic sites. The activity of Ab-proteases was first registered at the subclinical stages 1-2 years prior to the clinical illness. Low-active Ab-proteases (to target 43-68 and 146-170 sites) in persons at risk (at the subclinical stages), and primary clinical and MRT manifestations observed were coincided with the activity to have its mid-level reached. And registration in the evolution of highly immunogenic Ab-proteases to attack 81-103 and 82-98 sites predominantly would illustrate either risks of transformation of subclinical stages into clinical ones, or risks of exacerbations to develop. The activity of Ab-proteases in combination with their sequence-specificity would confirm a high subclinical and predictive value of the biomarkers as applicable for personalized monitoring protocols.

Of similar value is MMP-9, which would act on many inflammatory substrates, and thus is suspected of contributing to the progression of MS, in particular. Upregulation of MMP-9 increases the permeability of the blood brain barrier (BBB), facilitates the infiltration of leukocytes into the CNS, and causes myelin sheath degradation and neuronal damage. Those observations would consider MMP-9 as a potential drug target for MS.

Of tremendous value in this sense are Ab-proteases directly affecting the physiologic re-modeling of tissues with multilevel architectonics (for instance, myelin). By changing sequence specificity of the Ab-mediated proteolysis one may reach reduction of a density of points of the negative proteolytic effects within the myelin sheath and minimizing scales of demyelination.

Drugs approved for MS management to reduce the frequency of exacerbations or slow disability progression are referred to as disease-modifying drugs (DMDs). In this sense, further studies on targeted Ab-mediated proteolysis may provide a supplementary targeted drug to control demyelination and thus the disability of the MS patients.

Biography :

Dr Sergey Suchkov, MD, PhD was born in 11.01.1957, a researcher-immunologist, a clinician, graduated from Astrakhan State Medical University, Russia, in 1980. Suchkov has been trained at the Institute for Medical Enzymology, The USSR Academy of Medical Sciences,National Center for Immunology (Russia), NIH, Bethesda, USA, and British Society forImmunology to cover 4 British university facilities.

Since 2005, Dr Suchkov has been working as Professor of I.M. Sechenov First Moscow State Medical University and of A.I.Evdokimov Moscow State Medical & Dental University. From 2007, Suchkov is the First Vice-President and Dean of School of PPPM Politics and Management of the University of World Politics and Law. In 1991-1995, Dr Suchkov was a Scientific Secretary-in-Chief of the Editorial Board of the International Journal"Biomedical Science" (Russian Academy of Sciences and Royal Society of Chemistry, UK) and TheInternational Publishing Bureau at the Presidium of the Russian Academy of Sciences. In 1995-2005, Suchkov was a Director of the Russian-American Program in Immunology of the Eye Diseases.Dr Suchkov is a member of EPMA (European Association of Predictive, Preventive and Personalized Medicine,Brussels-Bonn), a member of the NY Academy of Sciences, a member of the Editorial Boards for Open Journal of Autoimmunity, EPMA J., Jacobs J. of Biomarkers and Personalized Medicine Universe. Dr Suchkov is known as a co-author of the Concept of post-infectious clinical and immunological syndrome, co-author of a concept of abzymes and their impact into the pathogenesis of autuimmunity conditions, and as one of the pioneers in promoting the Concept of PPPM into a practical branch of health services.

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Poster Presentations

Title:	Effect of vegetable oils on co-encapsulating of two antioxidant and anti-UV actives into nanostructured lipid carriers **Raluca Stan**, University POLITEHNICA of Bucharest, Romania
Title:	Toxicokinets of combination statin-digoxin to Mother Teresa University Hospital at Cardiology Clinic from 2011 to 2012 **Rudina Prifti**, Albanian University, Albania
Title:	Studies on the vascular effect of four plant species (Rosmarinic acid, Sclareol, Manool and Cubebin) in normotensive and hypertensive rats **Paulo Roberto B Evora**, University of São Paulo,Brazil
Title:	Microspheres prepared using both a low cost modified hydrophobic congealable disperse phase method and a fusion method to taste mask rifampin for treatment of tuberculosis in sanctuary elephants **Anthony Capomacchia**, Lebanese American University, Lebanon
Title:	Gel Trial Formulation of Tinospora cordifolia (Willd.) Miers. Stem Ethanolic Extract and Evaluation of its Anti-Inflammatory, Wound-healing and Skin Irritation Activities **Nicole Eileen M. Bagon**, University of Santo Tomas , Philipines
Title:	Electrically assisted transdermal drug delivery of ovalbumin **Ahlam Zaid Alkilani**, Queen's university of Belfast, UK

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Effect of vegetable oils on co-encapsulating of two antioxidant and anti-UV actives into nanostructured lipid carriers

Raluca Stan, Gabriela Badea, Ioana Lacatusu, Nicoleta Badea
University POLITEHNICA of Bucharest, Romania

The use of biologically active compounds from various medicinal herbs as functional ingredients in food, cosmetic and medical applications is gaining growing interest in the last few years, mostly for providing naturally derived actives that manifest mild features and low side effects. The present study aims to evaluate the effect of two kinds of vegetable oils, *e.g.* pomegranate seed oil and wheat germ oil on co-encapsulating of a natural flavonoid – Naringenin (*Nar*) together with a UVA filter – Diethylamino hydroxybenzoyl hexyl benzoate into vegetable oil-based nanostructured lipid carriers (NLCs). The type of lipid nanocarriers has influenced the antioxidant properties determined by chemiluminescence and TEAC assays. The most effective scavenging systems have proved to be the Nar-UVA-NLC, by capturing 93% of short-life free oxygen radicals and around 60% of long-life ABTS cation radicals. The coupling of *Nar* and UVA filter into the same lipid nanocarriers has led to improved UV absorptive properties of hydrogel formulations when compared with those formulations based on NLC which encapsulate a single active, *Nar* or UVA filter. At concentrations of 25 and 50 μg/mL the nanocarriers have shown no cytotoxicity and the presence of *Nar* inside the nanocarriers has increased the cell viability of L929 murine fibroblast cell line.

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Toxicokinets of combination statin-digoxin to Mother Teresa University Hospital at Cardiology Clinic from 2011 to 2012

Msc Rudina Prifti and Kleva Shpati

Albanian University, Albania

Introductions: Drug drug Intercations (DDIs) are a risk factor for advrse drug reactions. Statins are concomitantly treated with a variety drugs in Cardiology clinics for manies deseases such miocardial infarction, dislipidemia, diabetus hypertension, etc. Interactions with statin can lead to rabdomyiolises, as well myialgia , weekness, dizzise etc. Statins are all biotransformd by CYP3A4, the most abudant CYP isoenzyme, which mtabolized most drugs indergoing CYP-associated biotransformation. The Intercations invole P-glycoprotein (p-gp) too e.g interactions between statin and digoxin. Toxikokinetic of statin relected by adverse evnts due to this comittement drugs in polypharmaci medications we shown in our study dyring the years 2011-2012 at Cinical Cardiology at "Mother Teresa" Hospital

Materials and methods: The data were received from written files from Cariology Clinic to mother Teresa Univrsity hposital . Varialbles were tested wth SPSS 15 significance level of adjusted for multiple testing according to Bonferroni-Holm. We have include 200 hospitalized patients with statin treated an other comorbidies. The mai n desease of their hospitalizations was Mocardial Infarction and othe comorbidement like as dislipidemia, Arterial Hyprtentions , Diabetus mellitus Type II were a considerable number of prescribed medicines were evident.

Results: 200 patients selected and controll for statin userer the combinations had a total drug-intercations. Interacting drugs were statin - digoxin were 8 from all of them were. The side efect were detected such as aritmia and it was stoped the statin treatment. 3 other cases has continued with this combnation but the side efects weren't a risk for patients and the combination has continued. The patients were complains for headache, weekness and gastro-intestinal disorders.

Conclusion: CYP 3A inhibitors are the most frequent cause for potential interactions with statin. The side efect reported for those patients were weekness, myialgia, gastro-intestinal disorders etc.It si important to teach clinicians about the most frequenty observed drug-statin interaction and how this interact can be avoided. The combinations statin – digoxin when the problems were cardiovascular one were discontinued.

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Studies on the vascular effect of four plant species (Rosmarinic acid, Sclareol, Manool and Cubebin) in normotensive and hypertensive rats

Paulo Roberto B. Evora, Andrea Carla Celotto, Agnes Afrodite S. Albuquerque, Marco Tulio Menezes de Carvalho, Debora Ribeiro Campos, Ariadne Santana e Neves Monteiro

University of São Paulo, SP, Brazil

Introduction. High blood pressure (HBP) is a common cardiovascular disease that affects millions of people worldwide. There are several ways to treat hypertension, such as the use of angiotensin converting enzyme inhibitors (ACE). In recent years, it has been demonstrated the inhibitory effect of some plant species on the ACE and NO/cGMP pathway. Plant species have been considered, among other effects, prominent sources for new drugs for the arterial blood hypertension treatment, however; its effects are relatively little studied in the cardiovascular system.

Rosmarinic acid. Considering these facts, we carried out experiments, whose objectives were to verify if the RA has an effect on BP through inhibitory activity on ACE and compare its potential effectiveness to the classical ACE inhibitor (captopril) in normal and hypertensive rats. From the results obtained in these studies, we concluded that the RA has shown promise in reducing BP in hypertensive animals, proved to be selective, since, unlike captopril, did not promote BP reduction in normotensive group. The BP reduction obtained from dose-response curve for Ang I suggests a possible inhibitory activity and / or modulation of HR on ACE in vivo. Probably, besides the possible effect on ACE, the RA may be involved in endothelial vasodilator activity, by activating NO, PGI2 and EDHF pathways and, antioxidant activity. However, more studies should be performed to support such possibilities

Sclareol and Manool. The diterpenes are synthesized in plants located in plastids, but can also be synthesized by certain insects and marine organisms. Many studies have shown that many diterpenoid classes exert the significant effect on the cardiovascular system. These studies suggest that metabolites class as a promising source prototype for the development of new agents in the cardiovascular therapy. We investigate in vitro ("organ chambers") and in vivo (blood pressure dose responses), the mechanisms involved in cardiovascular effect (in vitro and in vivo) of the diterpenes esclareol and manool in normotensive and hypertensive rats. The analysis of the effect of diterpenes caused a significant reduction on blood pressure in both groups. The nitric oxide synthase inhibitors and soluble guanylate cyclase were as efficient as the removal of endothelium, to inhibit the diterpenes-induced relaxation with potential use in the treatment of hypertension,

Cubebin. Cubebin, the most abundant lignan in Piper cubeba, has been described as having several effects as trypanocidal, antimycobacterial, antispasmodic, antimicrobial, anti-inflammatory, and analgesic. We investigated the vasorelaxant effect produced by (-)-cubebin in isolated rat aortic rings pre-contracted with phenylephrine (Phe), and the possible mechanism involved in this event was evaluated. (-)-Cubebin was found to exert a vasorelaxant effect irrespective of the presence of endothelium, which was abolished by pretreatment with L-NAME and ODQ, but not with indomethacin. In addition, (-)-cubebin was able to reduce Phe contraction in the case of intact rings. These results suggest that (-)-cubebin promotes vasorelaxation via NO/cGMP pathway in rat aorta, without prostacyclin involvement.

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Microspheres prepared using both a low cost modified hydrophobic congealable disperse phase method and a fusion method to taste mask rifampin for treatment of tuberculosis in sanctuary elephants

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[3]The, Lebanese American University, Lebanon

Purpose: The proposed research describes novel, taste-masked drug formulations to treat captive elephants and other animals for Tuberculosis (TB). Elephants reject the most commonly used medicines because of bad taste and smell, and other considerations; therefore a masked formulation was developed. TB is rapidly becoming a severe global problem among captive elephants that contract the disease then transmit it to handlers, visitors at zoos, the circus, and wild populations of elephants and other animals. Treating elephants is difficult because of their discriminating tastes, lingual dexterity and large size, outright refusal of foodstuffs and individualpersonality and behavior. As an air borne disease close proximity is not required for infection.

Transdermal administration was considered, especially in African elephants because of their large ear surface area. This approach was abandoned because of the dose size, about 50 grams daily. The latter is probably too large an amount to achieve clinically efficacious blood levels, considering expected microgram per square centimeter drug throughput for transdennal permeation using the ear. A solid drug release device implanted und er the skin was also considered but the idea discarded because of possible infections subsequent to surgical implantation. The presence of TB in captive elephant populations validates the proposed research as a first line chemical drug defense against the spread of TB in animals and humans until biological methods such as vaccines are developed. These considerations lead to a more detailed examination of the best possible system for oral drug delivery in an elephant population, and to evaluation of the hydrophobic congealable disperse phase method for preparing microparticles, for the following reasons: Low material cost, relatively easy preparation, good drug entrapment in the microparticle matrix with little or no drug surface residue (to eliminate taste), no volatile organic solvents em.ployed, and good rn.icroparticle drug release characteristics.

The process allows for slightly water soluble drugs like Rifampin (in the unionized form) to be encapsulated while avoiding the routine use of toxic, environmentally dangerous solvents.

Methods: White beeswax melt, surfactant, Rifampin and various polymers were emulsified in a heated, stirred, aqueous external phase then cooled with ice-cold water causing the wax droplets to congeal into solid microparticles. The microparticles were collected by vacuum filtration washed, dried. Alternatively, the initial melt with drug and adjuvants was cooled into solid bars then milled to form microparticles. Microparticles from both preparations were sieved into size fractions, weighed, particle size distribution and drug loading determined.

The process was scaled up from 1.33 g Rifampin to 212g; wax, 2g to 544g; dispersion system reduced by factor of 32, reducing aqueous waste per run to about l.2L thus increasing efficiency. A single batch may be prepared in less than 30 minutes. The fusion method is even quicker to prepare.

Drug release from. the microparticles was detennined by an in vitro dissolution test using a modified USP Apparatus I and analyzed spectrophotometrically.

Results: Size distributions were normal bell curve or biphasic depending on process conditions. Microparticle yield and drug loading ranged from 90-95%. Each remained high for both laboratory (g) and scaled-up (kg) batches. Drug release depended on polymer additives, and could be demonstrated as controlled release of 6 hours to immediate release of 1.5 hours. Controlled release particles exhibited Higuchi model for drug release which could be reversed by adding polymers like PEG and maltodextrin to counter the controlled release characteristics of the wax matrix. Veterinarians at the Elephant sanctuary wanted an immediate release product but with taste masking capabiiity and low cost. Wax provides low cost taste masking but controlled release. The addition of specified quantities of PEG and/or rn.altodextrin allowed the matrix to be riddled with pores as the water soluble polymers were dissolved from. within the matrix by dissolution or body fluids thus providing both taste masking and immediate release. Microparticles were fed to elephants as free flowing on foodstuffs, encapsulated in gelatin capsules to further mask taste, or in trapped in laboratory prepared chocolate bars. The latter have proven so far to be the most acceptable to the elephants.

Conclusion: A taste masking oral delivery system was developed to deliver Rifampin over a time period of 1.5 - 6 hours dependent on process conditions and polymer additives.

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Gel Trial Formulation of *Tinospora cordifolia* (Willd.) Miers. Stem Ethanolic Extract and Evaluation of its Anti-Inflammatory, Wound-healing and Skin Irritation Activities

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Tinospora cordifolia (Menispermaceae), commonly known as "Makabuhay", is known for its immense application in the treatment of various diseases in the traditional ayurvedic literatures. This medicinal plant, which is found in most or in all islands of the Philippines has wide array of physiological roles, thereby signifying the versatility of the plant. However, there was no scientific evidence justifying the use of *T. cordifolia* as an anti-inflammatory and a wound-healing gel formulation. Thus, this study was initiated to formulate, characterize and evaluate the effectiveness of crude ethanolic stem extract incorporated in a gel base, in concentrations of 5% (w/v) and 10% (w/v) as a wound healing and anti-inflammatory gel preparations. Seven gel formulations were prepared and the physical attributes were observed to identify one formulation with desirable characteristics. The viscosity, pH, spreadability, consistency, and homogeneity of the selected formulation were examined. Both gel concentrations were assessed using incision wound model in Sprague-Dawley rats and formalin-induced rat paw edema method, which showed significant increase in tensile strength ($p<0.05$) of the wound compared to Curiosin gel and decrease in mean paw size ($p<0.001$) of the rats compared to Voltaren as reference drugs, respectively. The 10% gel concentration has more enhanced wound healing and anti-inflammatory activity compared to the 5% gel concentration exhibited in both tests. In parallel, Scratch and Patch tests in albino rabbits were performed to determine primary skin irritation effect. Both 5% and 10% *T. cordifolia* gels exhibited negligible irritant property, thus, they can be used safely as topical preparation to treat wounds and inflammation.

Biography :

Nicole Eileen M. Bagon, a constant dean's lister, is currently studying at University of Santo Tomas - Faculty of Pharmacy. She is an active member of UST Lingkod E.R., a public health-oriented organization in UST that promotes awareness and develops emergency care in both hospital and community settings.

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Electrically assisted transdermal drug delivery of ovalbumin

A. Zaidalkilani[1], R. Thakur[2], R.F. Donnelly[2]

[1]Zarqa university, Jordan

[2]Queen's university of Belfast, UK

The poor oral bioavailability of proteins requires that they be administered mainly by parenteral routes. Moreover, the short plasma half-lives of these drugs means they typically require repeated injection, leading to poor patient compliance. These factors have lead to the search for novel delivery methods, such as transdermal administration through intact skin. Skin is an appealing site for systemic delivery of active pharmaceutical ingredients. However, the *stratum corneum*, which is the outermost layer of the skin, acts as the principal barrier for penetration of most drugs. Therefore, microneedle (MN) arrays will be combined with iontophoresis (IP) in order to enhance delivery of drugs across the skin.

The primary aim of this study was to evaluate the ability of super swelling hydrogel MN arrays coupled with IP to facilitate the transdermal delivery of a model protein, OVA from electro-responsive patch. Super swelling hydrogel forming MN arrays, containing aqueous blends of 20% w/w Gantrez® S97 and 7.5% w/w PEG 10,000 were prepared by diluting the 40% w/w Gantrez® S97 stock solution and mixing it with the required amount of PEG 10,000 solution and subsequently 3% w/w Na_2CO_3 added. Electro-responsive patches containing OVA were prepared using a casting method, from aqueous blends containing 10% w/w Gantrez® AN139 and 5% w/w tripropylene glycol methyl ether (TPM). The drug reservoir film mediated electrically responsive drug delivery was physically and electrically characterized using a suite of techniques, such as thermal analysis (mDSC), tensile testing (texture analyzer). Altering patch formulation e.g. changing the casting gel pH produced substantial alteration in physicochemical properties of films. The feasibility of super swelling hydrogel MN arrays to deliver OVA form electro-responsive patch was evaluated *in vitro*. *In vitro* OVA delivery experiments were performed using the Franz cell apparatus. All samples were analysed using ELISA. The *in vitro* OVA permeation experiments indicated that super swelling hydrogel MN arrays with electro-responsive OVA loaded patch capable of providing a sustained transdermal OVA delivery over a 24 hours period. Furthermore, the synergistic effect of MN and iontophoresis arrays led a two-fold enhancement in the cumulative amount of insulin permeating across neonatal porcine skin after 6 hours. In addition, it was found that the electrically responsive nature of these super swelling hydrogel MN and patches led to a dramatic increase in OVA transport when such systems were combined with IP.

Biography :

Ahlam Zaid Alkilani is an Assistant Professor at faculty of Pharmacy, Zarqa University, Zarqa, Jordan. Now she is a head of pharmaceutical science department. She completed her Ph.D. in drug delivery and pharmaceutical technology at the Faculty of Pharmacy, Queen's university of Belfast, Belfast, United Kingdom in October 2013. She has published more than 6 papers in reputed journals.

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Lipoplexes and polyplexes as delivery systems for nucleic acids and recombinant proteins: an overview of advances, opportunities and challenges

Abdelatif Elouahabi
Director of R&D Pharmaceuticals, Morocco

Over the last decades, dramatic advances have been made in understanding the molecular events leading to inherited and acquired diseases. This enabled design of radically innovative therapeutic and prophylactic medicines based on recombinant nucleic acids and proteins. However, efficient delivery systems have been limiting advances of these novel medicines from exploratory research to clinical developments.

Cationic liposomes (lipoplexes) and cationic polymers (polyplexes) have emerged as promising delivery systems for nucleic acids (plasmid DNA, mRNA & siRNA) or recombinant proteins (therapeutic proteins & vaccinating antigens). Despite limited success have been achieved when applying these systems to cure genetic inherited diseases, substantial progress have been made for delivery of siRNA and recombinant vaccines. For instance, a vaccine candidate against tuberculosis using lipoplexes as delivery system have reach phase-II clinical stage and siRNA delivered in lipid-based particles is being tested in phase-III for Transthyretin-mediated amyloidosis (ATTR) indication.

Basic research efforts aimed at understanding the molecular and cellular mechanisms of these delivery systems have been advancing in parallel. Critical steps in the drug transfer process have been identified which could help rational design of more potent and safer systems. Robust analytical tools and manufacturing processes are today needed before products can reach the market.

In this talk, mechanistic, preclinical/clinical and manufacturing aspects of lipoplexes/polyplexes will be reviewed.

Biography :

Abdelatif Elouahabi has completed his Ph.D. from the Free University of Brussels and postdoctoral studies from University of Pittsburgh. He has worked for more than 10 years in the pharmaceutical industry. He is the founder and Director of R&D pharmaceuticals, a CRO project proposing animals models for late stage preclinical testing. He has published more than 20 papers in peer-reviewed journals and was co-leader of a work package in the EC-founded framework, NanoBioPharmaceutics (2006-2010).

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Rabid and Sensitive Ultra-Performance Liquid Chromatography Coupled Tandam Mass Assay for Busulfan in Plasma

Abubakr Suliman Elgorashi[1], Salaman A..Alfadel[2], Abdalla Alturki[2]

[1]Ahfad University for Woman, Sudan

[2]King Abdullah International Medical Research Center, Saudi Arabia

A sensitive, rabid and specific assay for detection of busulfan (anti neoplastic agent) in human plasma was developed and validated. Chromatographic separation was performed on ultra-performance liquid chromatography (UPLC) C_{18} 1.7 µm, 2.1 x 50mm column. Protein precipitation with acetonitrile was used for plasma sample preparation. Busulfan and internal standard (IS) tolbutamide were detected as ammonium adducts.

Waters XevoTQ UPLC system coupled with triple quadrupole MS/MS equipped with an electrospray ionization source, operated in the positive ion mode was used, and the quantification was performed in the multiple reaction monitoring mode with mass-to-charge (m/z) transitions at 247.08 for parent and 151.03 for daughter, and 271.18 for parent and 90.99 for daughter for busulfan and tolbutamide (IS) respectively. The conditions were set as follows: collision energy 10 V for busulfan and 34 V for IS, capillary voltage 4.0 kV, dwell time 50ms, sheath gas flow 12 L/min at 300°C, desolvation gas flow 700 Litre/hour at 500°C, cone voltage 18 for busulfan and 24 for tolbutamide. The injected volume was 5µL and the data was analyzed using Masslynx 4. One-way analysis of variance and regression analysis were used to evaluate with-in and between-run precision, line fitness, linearity, homoscedasticity and uncertainty of the method. calibration curves were linear up to 2000 ng/m with a significant correlation ($p>0.05$and r^2 of 0.99). Intra-day and inter-day coefficients of variation of the assay were < 2.5% .The limit of detection was 0.05 ng/ml.

This method was used to analyze busulfan plasma concentrations for therapeutic drug monitoring and bioequivalence studies.

Biography :

Abuakr Suliman Elgorashi Sudanese national has completed his PhD from school of pharmacy Wales university and currently he is the dean school of pharmacy at Ahfad Univerity for Women, Sudan. He is the professor in physical pharmacy and pharmacokinetics. He has published more than 40 papers in reputed journals in different fields of pharmacy including drug delivery and drug analysis. He has a great experience in pharmacy education teaching and research. He worked as research scientist at king Abdalla International Medical Research center. He is a consultant and advisor for different Pharmaceutical plants.

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Approaches to Develop Solid Oral Formulations of Poorly Soluble Compounds Containing a Low Melting Surfactant

Aditya S Tatavarti
Merck Research Laboratories, USA

Two distinct approaches to formulate poorly soluble compounds with Vitamin E TPGS, a waxy and low melting surfactant, are described. The first approach includes application of an extrusion-spheronization (ES) process towards developing solid dosage forms with a high drug load and a relatively high TPGS load, wherein the process complications arising from high energy processes are mitigated. The second approach examines the viability of developing film coated tablet formulations with intermediate drug load and a relatively high TPGS load, via a high shear wet granulation process, without the use of hydroalcoholic or cryogenic means. Using the ES approach, multiparticulates with seventy five percent loading of a poorly soluble model compound (MK-A) could be formulated as an encapsulated product. The extrusion spheronization process also appeared to result in more intimate API: surfactant mixing, potentially resulting in improved bioperformance. In the second approach, feasibility of developing a wet granulated tablet formulation was evaluated using a multivariate design. Impact of critical variables such as levels of TPGS, hydroxypropyl cellulose (binder) and Prosolv (extragranular filler) on product quality attributes was studied. The potential impact of temperature elevation during processing was assessed through a heated die fitted onto a compaction simulator. Bilayer tabletability was also assessed in combination with a secondary non-TPGS formulation. TPGS levels significantly impacted tensile strength (TS), disintegration time and dissolution. Heat sensitivity studies demonstrated that extragranular Prosolv potentially provided a 'heat shielding' effect thereby minimizing the TS reduction upon exposure to higher temperatures. Acceptable interfacial strength of bilayer tablets was achieved and tablets could be coated without the need for hydroalcoholic solutions. The study demonstrates the feasibility of two distinct techniques in developing solid dosage forms containing a low melting, waxy surfactant.

Biography :

Tatavarti is a Principal Scientist in the Oral Formulation Science and Technology group at Merck Research Laboratories. He has more than 11 yrs. of industry experience with expertise in the areas of immediate and modified release, solubility enhancement and differentiated complex dosage form development. He is the author/co-author of more than 25 published manuscripts, patent applications and abstracts. He holds a PhD in pharmaceutical sciences from the University of Maryland and conducted doctoral research in the area of microenvironmental pH modulation in controlled release systems. Since joining Merck, he has worked across various indications, but has dedicated majority of his time towards designing and advancing complex delivery systems, in the NCE and PVE space, for HIV treatment.

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Discovery of new Gyrase B inhibitors via structure Based Modeling

Afaf Hasan Al-Nadaf
Mutah University College of Pharmaceutical Science, Jordan

Bacterial infectious diseases become a life threatening which cause death of around 2 million people around the world. Gyrase B is an essential enzyme in the prokaryotes which became an attractive target for antibacterial agents. In our study, we implemented a wide range of docking configurations to dock 120 inhibitors into the binding pocket of Gyrase B enzyme (PDB code: 4GEE). LigandFit docking engines and six scoring functions were utilized in the study. Furthermore, the ligands were docked in their ionized and unionized forms into the hydrous and anhydrous binding pocket. We used docking-based Comparative Intermolecular Contacts Analysis (db-CICA) which is a novel methodology to validate and identify the optimal docking configurations. Three docking configurations were found to achieve self-consistent db-CICA models. The resulting db-CICA models were used to construct corresponding pharmacophoric models that were used to screen the National Cancer Institute (NCI) list of compounds. In-vitro study represents antibacterial activities for twelve hit molecules with the most active having IC_{50} of 20.9 μM

Biography :

Afaf H. Al-Nadaf is an Asscioate prof. in Medicinal chemistry and Drug Discovery, has completed here Ph.D at 2010 from Jordan University. She is a registration consultant for generics in JFDA.

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Electrically assisted transdermal drug delivery of ovalbumin

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The poor oral bioavailability of proteins requires that they be administered mainly by parenteral routes. Moreover, the short plasma half-lives of these drugs means they typically require repeated injection, leading to poor patient compliance. These factors have lead to the search for novel delivery methods, such as transdermal administration through intact skin. Skin is an appealing site for systemic delivery of active pharmaceutical ingredients. However, the *stratum corneum*, which is the outermost layer of the skin, acts as the principal barrier for penetration of most drugs. Therefore, microneedle (MN) arrays will be combined with iontophoresis (IP) in order to enhance delivery of drugs across the skin.

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Biography :

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Development and in vitro evaluation of Floating ranitidine microparticulates

Mohamed A. ETMAN[1], Engy Mahmoud[2], Sally Galal[1] and Aly H.Nada[3]

[1] University of Alexandria, Egypt

[2]European Egyptian Pharm Ind. (EEPI), Egypt

[3]Kuwait University, Kuwait

Rapid and inconsistent GIT transit could results in reduced drug efficiency and the need for frequent dose administration, which usually result in patients' incompliance. Ranitidine hydrochloride (RH), as a model drug is freely soluble, moisture sensitive drug with a short biological half-life (~2.5-3 hours) and narrow absorption window in the initial part of the small intestine. The present study aims at development of ranitidine floating multiparticulates (RFM) using melt granulation technique and investigation of the effect of lipids and additives on the physicochemical properties. Compritol 888 ATO, glyceryl behenate, Cutina HR, hydrogenated castor oil, Cutina GMS, glyceryl monostearate, and beeswax will be used as lipids and ethyl cellulose, Povidone K 90 and Aerosil 200 as release modifiers. The effect of preparation method and additives, as well as storage for 6 months at 40°C, on floating and release characteristics were evaluated. Size distribution indicated that the prepared formulations exhibited reasonably small floating microparticulates; More than 90% of the prepared microparticles are less than 710µm. Hausner ratios and Carr's compressibility indices ranged from 1.17 to 1.289 and 14.54 to 22.4 % respectively, and angle of repose (≤40°), indicating good flow properties. RFM containing Compritol showed a relatively higher release properties compared to hydrogenated castor oil. Increasing the proportion of the fatty component was accompanied by retardation in RH release. The tested additives (PVP, ethylcellulose, Aerosil) resulted in different degrees of retardation of drug release. The %- floating of RFM was almost 100% in all formulations with the exception of formulations prepared using glyceryl monostearate. FT-IR and DSC indicated the compatibility of the excipients with RH. Stability results revealed insignificant change in RFM properties over 6 months.

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Novel Rho kinase inhibitors block melanoma invasion and inhibit metastasis

Amine Sadok
Institute of Cancer Research, UK

Melanoma cells can either migrate in an elongated mesenchymal fashion or in a rounded, "amoeboid" mode. Rho GTPase effector Rho-kinase (ROCK) plays a central role in the regulation of tumour cell migration and impact on several components of the metastatic process, including local invasion and cell proliferation. I hypothesised that potent inhibition of ROCK would impair all modes of melanoma cells movement leading to a decrease in metastatic dissemination. I've characterised a novel series of compounds that exhibit strong potency toward inhibition of ROCK activity in vitro and in cells. Using these highly potent ROCK inhibitors, I have established that ROCK-driven actomyosin contractility is needed for both types of movement as I showed that these compounds inhibit melanoma cells movement both in vitro and in vivo, irrespective of the genetic background/mode of migration of the melanoma cell lines I tested. I also showed that these compounds efficiently inhibit experimental and spontaneous metastasis of melanoma cells, or when treatment starts after metastases have arisen.

Biography :

Amine Sadok is currently a senior post-doctoral fellow in the laboratory of Prof Chris Marshall at the Institute of Cancer Research in London. Amine has a strong interest in understanding the molecular mechanisms that regulate the invasion and metastatic dissemination of tumour cells to delineate novel therapeutic targets. He graduated, as an engineer in biotechnology, from the University of Carthage (Tunisia) and completed a PhD in oncology at the University of Aix Marseille (France). As part of his PhD, Amine uncovered a novel role for oxidative signalling in the control of colorectal cancer cells migration and response to therapy. During this time Amine published several papers and won many awards, including a doctoral fellowship from the Ministry of Higher Education and Research in France, a teaching fellowship from the University of Aix Marseille and the Young Researcher Fellowship from the French Association of Cancer Research (ARC). More recently, Amine was awarded the Marie Curie long term Intra-European Fellowship and the Institute of Cancer Research dean's Award for his work on the identification of novel therapeutic targets for melanoma dissemination.

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Nanotechnology and Regulatory Gimmicks: A Step Towards Harmonization

Anjali Singh
Jamia Hamdard University, India

The development, performance and regulatory authorization of nanotechnology-based therapeutics (NBT) essentially encompassing agents for drug delivery as well as diagnostics are critically dependent on their physiological behaviors which in-turn relies on high-resolution particle characterization. Proposing consistent characterization techniques can accelerate translational dynamics from the development of a nanotech product to a marketable nanotech product, which serves as the chief glitch to the inability of nanomedicines to effectively seep clinical settings. Physico-chemical heterogeneity of nanomaterials as well as the limited control over precise particle dimensions has formed an informal scientific consensus worldwide that nanomaterials should be characterized via recognized criterions before conducting any in vitro experiments that involve biological entities. This specifically entails for nanotech products fabricated for drug delivery as the significance of long-term biodistribution and mass balance studies to understand the nanoparticle accumulation profile is crucial to assess its safety and efficacy. In view of this, current and anticipated upsurge in the assembly of nanotech-based products, FDA had formed a Nanotechnology Task Force in 2006 to determine the critical regulatory issues regarding nanomaterials for future approvals and all allied departments have developed guidance documents to address to any specific requirements. Anticipating a US$130.9 billion market by 2016, owing to a projected 10% pharmaceutical market share solely held by nanomedicines, the medical regulatory agencies of the EU along with Japan, and Canada have felt the need for sharing and discussing the global academic, industrial, and regulatory experience and perspectives in the field of nanotechnology.

Biography :

Anjali Singh has completed her Masters in Pharmacy in Pharmaceutics in 2012 (Gold medalist) and currently pursuing her Ph.D from Jamia Hamdard University since 2012. Her research work included fabrication of monolithic controlled delivery nanoparticles for Thymoquinone and Resveratrol. Her PhD research encompasses biomarker exploration for gallbladder cancer in two city-based hospitals. She has published 6 international peer-reviewed papers (**citations: 91**) in reputed journals and currently have 3 papers under review.

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Regulatory challenges in drug delivery: Pharmaceutical pricing and affordability

Anthia Zammit

Republic of Malta, USA

We are unfortunately subject to an optimistic bias when we evaluate how, and to what extent, drugs and other medical therapies will become available and accessible to patients on the global level in which pharmaceutical enterprises operate. In developed countries, the pricing and affordability of medicines is a controversial issue that highlights health and economic inequalities, and great challenges for the future. According to the New York Times article Lawmakers Look for Ways to Provide Relief for Rising Cost of Generic Drugs (November 24th 2014), "the cost of many generic medications has increased so much over the past year that prices for many common generic drugs in the USA have surpassed those of their brand-name equivalents in other developed countries". The issue of unaffordable healthcare is rendered more challenging with technological advances and the demographic growth of the geriatric population, including those with cancer and cardiac disease. Legislation can be instrumental in the creation of equitable solutions. The EU member state's management of healthcare access and drug entry; the implementation of regulatory requirements aimed at ensuring quality, safety, and efficacy of medicines and vaccines for human use; and the European Transparency Directive (Council Directive 89/105) which defines procedural requirements for pricing and reimbursement of medicinal products will be discussed. These issues must be taken into account since few of the hundreds of drugs in clinical development ever reach the stage of final approval, having failed to produce the anticipated results expected by the investigators. These trials can take up to 20 years to complete, and several billion dollars to reach the stage of approval or denial by the regulatory agency involved. When failing to demonstrate viability, pre existing expenditures are allowed to be passed onto the price the pharmaceutical company charges patients. In the cancer industry for example, most new drugs require the patient or insurance company to pay 50-100,000 dollars for a course of treatment which may not offer more than several months of improvement in the clinical response. It is essential that the legislators in each of the countries where the drug is to be introduced be able to negotiate a fee arrangement where the patient will not be denied treatment and the drug company be compensated reasonably for development costs.

Biography :

Anthia served as legal counsel to the Healthcare Business Section of the Malta Chamber of Commerce, Enterprise, and Industry, and as a member of the European Patients' Forum (EPF) Policy Advisory Committee. EPF is a not-for-profit non-governmental-organization that represents the interests of an estimated 150 million patients in public health and health advocacy across Europe. She worked at the Office of the CEO of Malta's national competent authority, the Medicines Authority (the "Malta FDA"). The Medicines Authority is established by the Medicines Act (Chapter 458 of the Laws of Malta, transposing European Directive 2001/83) to protect and enhance public health through the regulation of medicinal products and pharmaceutical activities. Anthia also worked as Associate at a leading business and tax law firm in Malta. Anthia's profile was enhanced by her role representing private and publicly-listed companies during their global expansion in established and emerging markets; business development; contract negotiation; medicinal product launches; drug and vaccine licensing (centralized, decentralized and mutual recognition procedures); regulatory affairs; regulatory compliance; good manufacturing practice (EU-GMP); good distribution practice (EU-GDP); pharmacovigilance; data privacy; pricing & reimbursement; and marketing. She is passionate about preventive healthcare, and interested in legislation as a means of increasing global access to safe medicinal products and vaccines. She is regularly invited as keynote speaker at high-level global conferences on invitation of the European Commission to discuss healthcare delivery; medical practice; digital health; e-health; mobile-health technologies and systems; personalized medicine; youth health; global business development in life sciences; international harmonization of regulatory requirements of pharmaceuticals for human use, and other topics. Anthia received an LL.B (Bachelor of Laws) and an LL.D (Doctor of Laws) from the University of Malta. Her doctoral thesis *Pharmaceutical Law in the EU and USA: The Impact on Public Health and the Pharmaceutical Industry,* earned her the European Commission (DG Health and DG Research) and World Health Organisation Regional Office for Europe's Young Gastein Scholarship. Anthia is admitted to the practice of law in the Republic of Malta (a member state of the European Union), and is certified as a Legal Consultant by the Supreme Court of the State of New York, U.S.

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Molecular Modelling Studies of Synthesized Pentacyclo-Undecane Lactam Peptides as Potential HIV-1 Wild type C-SA Protease Inhibitors

B.Honarparvar and H.G. Kruger

University of KwaZulu-Natal, South Africa

Increasing numbers of HIV infected patients along with severe treatment-associated complications and related deaths make the AIDS pandemic [1]. These inhibitors reduced the virus proliferation and this success made the HIV aspartic protease the prime target for AIDS therapies [2]. In this study, we present the first account of pentacycloundecane (PCU) lactam-peptide based HIV protease inhibitors with nanomolar activity against the resistance-prone wild type C-South African HIV-protease (C-SA). NMR and molecular docking were employed to determine a logical correlation between the inhibitory concentration (IC50) results and the 3D structure of the corresponding inhibitors in solution. NMR investigations indicated that the activity is related to the chirality of the PCU moiety and its ability to induce conformations of the coupled peptide side chain. In addition, docking studies confirmed the observed EASY-ROESY results and the experimental IC_{50} activity profile of the considered inhibitors. Due to theoretical importance of nuclear quadrupole resonance data [3] for characterization of molecular dynamics, DFT calculations are carried out to obtain electronic structure properties. The studies reported in this work were undertaken to establish whether the DFT-based quantities could be used to derive a rational structure-activity relationship for these inhibitors. These findings open up useful applications for this family of inhibitors, considering the vast number of alternative disease related proteases that may exist.

Keywords: Pentacycloundecane (PCU) peptides; HIV protease inhibitor; Inhibitory concentration (IC_{50}); Molecular docking.

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Pharmacogenetics of Angiotensin converting enzyme (ACE) gene polymorphism and response to ACE inhibitor Enalapril from Aseer region of Saudi Arabia.

Bander Assiri , Murali M, Gauthaman Karunakaran

King Khalid University, Saudi Arabia

Background: Hypertension is a common disorder associated with increased cardiovascular morbidity and mortality. Genetic polymorphisms accounts for the interindividual variability and abnormal response to antihypertensive drugs. Candidate gene and genome-wide approaches have identified common genetic variants associated with response to antihypertensive drugs. Predicting the effect of a particular antihypertensive agent in an individual patient is difficult. There is no currently available pharmacogenetic test to guide hypertension treatment in clinical practice. Several studies show that the insertion/deletion (I/D) polymorphism of the angiotensin-converting enzyme (ACE) gene has been associated with hypertension in various populations

Objective : To evaluate the relationship between the Insertion /Deletion polymorphism of the ACE gene on the mean difference in systolic blood pressure (SBP) and diastolic blood pressure (DBP) among ACE-inhibitors users and controls.

Methods: Population based case control design with a total of 25 newly diagnosed hypertension patients and 25 healthy subjects were recruited in this study after getting their informed consent Blood pressure were recorded from 0 to 8 weeks of treatment with enalapril . Genotyping of the I/D polymorphism of the ACE gene were identified on the basis of polymerase chain reaction (PCR) amplification of the respective fragments from intron 16 of the 59 ACE gene and size fractionation and visualization by electrophoresis. Genotype frequencies in control and hypertensive groups were compared by Chi-square analysis.

Results: Our Results showed ACE (I/D) gene polymorphism was seen to be in Hardy–Weinberg equilibrium and showed significant allelic and genotypic association between cases and controls to enalapril Monotherapy ($P<0.01$).

Conclusion: This research will form a molecular marker for hypertension in the study population and baseline information for subsequent molecular studies.

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Study the various biochemical parameters of liver to find out the effect of methanolic extract of fruits of sechium edule against paracetamol induced liver damages

B. R. Sarkar and B. K. Dey

Assam Down Town University, India

Liver diseases remain as one of the serious health problems. However we do not have satisfactory liver protective drugs in allopathic medical practice for serious liver disorders. Herbal drugs play a role in the management of various liver disorders most of which speed up the natural healing processes of the liver. Numerous medicinal plants and their formulations are used for liver disorders in ethno-medical practice as well as traditional system of medicine in India. This plant is evaluated for their hepatoprotective action in light of modern medicine.

The hepatoprotective effect of Methanolic extract of *Sechium edule* commonly known as Chayote from Cucurbitaceae family by Paracetamol induced liver damage in albino rats. The methanolic extract of *Sechium edule* was studied for their hepatoprotective effects on Paracetamol induced liver damage on Wistar albino rats. The degree of protection was measured by changes in biochemical parameters (SGPT, SGOT, ALP, Total Bilirubin, and Total protein). The effects of methanolic extract of *Sechium edule* were comparable to that of standard drug, silymarin. These results indicate that the *Sechium edule* could be useful in preventing chemically induced acute liver injury. From this study, it can be concluded that the methanolic extracts of *Sechium edule* possesses significant protection against chemical driven liver damages.

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The potential role of Toll like receptor 4 in regulating α-SYN expression

Carmela Conte, Tommaso Beccari, Giuseppina Mariucci

University of Perugia, via del Giochetto, Italy

The etiology and pathogenesis of Parkinson's disease (PD) are still unclear. However, multiple lines of evidence implicate Toll Like Receptor 4 (TLR4) as a concurring factor in inflammation and neuronal death. Conversely, in a model of atypical parkinsonism, TLR4 can promote α-SYN clearance and to be associated with a neuroprotective mechanism.

The current study aims to establish the potential role of TLR4 in acute 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine-HCl (MPTP) mouse model of PD by using TLR4-deficient mice ($TLR4^{-/-}$) and their wild type littermates (WT). Seven days post-MPTP intoxication, mice were sacrificed and the brains were dissected to isolate cerebral cortex, striatum, hippocampus and midbrain region.

Immunohistochemical analysis of tyrosine hydroxylase-positive neurons (TH^+) was carried out in Substantia Nigra pars compacta (SNpc). TH and α-SYN mRNA levels were determined in all brain regions by real time PCR. α-SYN and TH protein levels were evaluated in midbrain region by western blotting analysis. MPTP treatment induced a significant depletion of nigral TH^+ neurons in both WT and $TLR4^{-/-}$ mice. Moreover, we found that WT and $TLR4^{-/-}$ mice showed a different basal pattern of midbrain TH and α-SYN expression. TLR4-deficient mice showed lower TH protein levels than WT in midbrain region. Conversely, the midbrain from TLR4-deficient mice exhibited higher α-SYN protein levels compared to the same region from WT mice. Interestingly, high α-SYN mRNA levels were observed in all other brain regions from $TLR4^{-/-}$ mice.

These findings suggested a role for TLR4 as a negative regulator of α-SYN expression. Further investigation are needed to clarify the cross-talk between TLR4 and α-SYN and the involvement of TLR4 in the pathogenesis of Parkinson's disease.

Biography :

Carmela Conte graduated in Biological Sciences from the University of Perugia, Italy. PhD in Medical Embryology. She has completed the postdoctoral studies and research fellow from University of Ferrara, ITALY. She is specialist in chemistry and food technology. Current position: Research and Assistant Professor of Biochemistry and Molecular Biology at University of Perugia.

The main research activities concerns studies of the pathogenic mechanisms involved in the neurodegenerative process, with particular reference to Parkinson's disease: animal and cellular models for defining the molecular mechanisms that underlying the neuronal death.

She has pubished more than 30 papers in reputated international journals.

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Evidenced based potentials of croton membranaceus in management of prostate enlargement and cardiovascular diseases

Daniel Kwame Afriyie

Ghana police hospital, ghana

Croton membranaceus (CM) is a medicinal plant which has been used for decades in the management of BPH and its related cancers in Ghana.

Acute toxicity studies showed it was non toxic. Sub chronic studies of the aqueous extract of CM in Sprague-Dawley(S-D) rats at doses at 30, 150 and 300 mg/kg confirmed it was non toxic. Subchronic studies found significant decrease in triglycerides and VLDL ($p<0.01$) in 150 and 300 mg/kg dose groups. Significant decrease of skeletal and heart muscle markers in the high dose group were observed with respect to LDH ($p<0.001$), CK-MB ($p<0.05$) and CK-total ($p<0.01$). Histological examination of the heart, liver and kidney in the treated groups showed no alterations. *In vitro* and *in vivo* studies in BPH cells and rats showed it had genotoxic and cytotoxic activity. Aqueous extract of CM on BPH cells (*in vitro*) induced dose-dependent staining of the nuclear chromatin, significant DNA fragmentation with G0/G1 sub-diploid cells, loss of the mitochondrial membrane potential, upregulation of the mRNA and protein levels of Bax, but levels Bcl2 did not change significantly. Therefore, induction of mitochondria-dependent apoptosis of BPH-1 cells may be a possible mechanism of action of CM. In vivo studies in S-D rat BPH models showed that, it reduced stromal and epithelial growth, subsequently shrinking the prostate. Observational study in BPH patients revealed shrinkage of prostate and improved quality of life, using the ethanolic root extract of *Croton membranaceus*.

These findings validate anecdotal evidence of CM efficacy in BPH management.

Biography :

Daniel Kwame Afriyie holds a Fellowship in Clinical Pharmacy from the West Africa Postgraduate College of Pharmacists, MPhil in Pharmacology from the University of Ghana Medical School, Honorary Fellow of Ghana College of Pharmacy. Has been working for the past 20 years at Ghana Police Hospital, and currently the Director of Pharmaceutical Service and is an Assistant Commissioner of Police. His research interest is in rational drug use, microbial resistance, and medicinal plants used for prostate cancer and BPH. He has published more than 12 papers in peer reviewed journals, and an editorial board member of the Pharmaceutical Society of Ghana.

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Anti-Cyclooxygenase 1 and 2 Activities of the Different Stem Extracts of Tinospora cordifolia (Willd.) Miers. (Menispermaceae)

Barretto, Danielle P.[1], Alava, Paul James A.[1], Alcausin, Denise Anne R.[1], Andal, Mary Iris M.[1], Bautista, Calvin EJ R.[1], Ong, Kurt Kaizer Y.[1], Castillo, Agnes L.[1,2]

[1]University of Santo Tomas, Philippines

[2]Research Center for the Natural and Applied Sciences, Manila

Tinospora cordifolia or "Makabuhay" is a large, glabrous, deciduous, and climbing shrub that can be found in some regions in Asia. The crude extract of Makabuhay contains secondary metabolites specifically phenols and flavonoids. The water extract of Makabuhay significantly inhibits acute inflammatory response evoked by carrageenan. Its mode of action appeared to resemble that of nonsteroidal anti-inflammatory agent and its effect was comparable with indomethacin. With these, the researchers wanted to determine the anti-inflammatory activities of the different stem extracts of Makabuhay, through the inhibition of cyclooxygenase 1 & 2 (COX) correlated with its flavonoid and phenolic content. The dried stem of Makabuhay was subjected to percolation using ethanol and sequential extraction using hexane, ethyl acetate and butanol. The extracts collected were then subjected to phytochemical screening, Folin-Ciocalteau method for the determination of the total phenolic content (TPC) and Aluminum chloride Colorimetric Assay for the determination of the total flavonoid content (TFC). Lastly, the Cayman COX Inhibitor Screening Assay kit was used for the determination of the anti-inflammatory activity of the different stem extracts through the measurement of prostaglandin F2α produced by stannous chloride reduction of COX-derived prostaglandin H2. Its COX inhibition was quantified through enzyme immunoassay (EIA). Phytochemical screening confirmed the presence of tannins and flavonoids, higher alkaloids, phenols and steroids in all of the extracts. Only hexane and butanol showed the presence of anthrones and anthraquinones. TPC showed ethyl acetate extract to have the most phenolic content with a GAE (mg/g plant sample) of 8.4 ± 0.7 and TFC showed ethanol with the most flavonoid content with a QE (mg/g plant sample) of 10.4 ± 0.7. For COX 1 inhibition, the IC50 (pg/mL) for ethanol, hexane, ethyl acetate, and butanol are 441.021, 1.2x1026, 2.0x1028, and 3.5x1027, respectively. In terms of COX 2 inhibition, the IC50 (pg/mL) for ethanol, hexane, ethyl acetate, and butanol are 35,662, 2.7x10-26, 274252, and 900,938 respectively.

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Anti-Dementia Property of *Mussaenda philippica* A. Rich (Rubiaceae) Leaf Extracts on Scopolamine-Induced Sprague-Dawley Rats

Eilleen P. Sagun

University of Santo Tomas, Philippines

Dementia is the decline in memory caused by progressive brain cell death. Despite the increasing prevalence rate of dementia, treatment is still unavailable. Leaf extracts of *Mussaenda philippica* A. Rich, an endemic Philippine plant, were used to determine its effects on the memory of Sprague-Dawley rats. The antioxidant property, total phenolic and flavonoid count of the leaf extracts were also determined. Memory tests specifically, Y-maze and 8-arm radial maze were done. One-way Analysis of Variance (ANOVA) was used to analyze the results of the memory tests. Results showed that methanolic and ethanolic extracts exhibited the greatest radical scavenging property ($p=0.219$). The ethanolic extract contains a significant higher flavonoid than the three extracts ($p<0.05$). There was no significant difference in the phenolic count of the extracts [$F = 0.333$, $p = 0.802$]. Thin Layer Chromatography confirmed the presence of flavonoids, phenols and alkaloids in the ethanolic extract. No toxic and lethal effects were observed on rats. Results on the Y-maze showed that the rats treated with NSS and scopolamine gave a lower % arm alternation($p<0.05$) compared to the other groups. For the % working error memory no significant difference was observed among the groups ($F=0.770$, $p=0.589$). The rats treated with the extract and Piracetam have shown a significantly less mean % reference memory error compared to the NSS-treated group ($p<0.05$). Scopolamine-induced Dementia and 200 mg/kg gave the longest time to complete the maze. In conclusion, *Mussaenda philippica* A. Rich leaf extracts may be used as a memory enhancer but, needs further studies. Use of other methods in inducing dementia is highly recommended.

Biography :

Eilleen Sagun is taking BS Pharmacy at the Faculty of Pharmacy, University of Santo Tomas.

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Improving the efficiency of a General Hospital pharmacy in Greece through the implementation of Kanban System

Eleftheria Mitka

Democritus University of Thrace, Greece

This paper records and analyzes how to implement a Kanban System in a pharmacy of a General Hospital in Greece, and investigates the pharmacy's improvement in terms of cost-efficiency services, through the implementation of recommendations of ABC-XYZ analysis. Its role is gradually upgraded to strategic advisor to pharmacy's administration in lean management and its significant contribution in developing new strategic inventory management policies-systems approach for the current economic environment of financial crisis is shown. The main research questions of the study are: The verification of the necessity of analysis of stock requirement, item stock prices and demand and the substantial percentage of the stocked drugs that can be procured using the Kanban System result in a cost-effective management of inventory of this public institution in health services industry, the investigation of degree of existence of an adequate internal system of making orders of medications and consumable health material, any deviation from L. 108/93 (Gazette 50/ B/ 7-4-1993) model and the measurement of effectiveness of cost savings and operational advantages applied in General Hospital. The research process was carried out through a combination of fundamental and secondary research. The secondary issues include the theoretical background of review of Lean Management, Forms of Kanban System and waste and if L. 108/93 is implemented. The main themes cover the actual structure of administration of the hospital studied, strategic inventory issues and the results of ABC-XYZ analysis applying Microsoft Excel that was performed based on real consumptions of medications and health material codes.

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Enhanced identification of transcriptional regulatory relationships in breast cancer using saga

Emmanuel S. Adabor

Ghana Institute of Management and Public Administration, Ghana

Identification of functional causes and contributing mechanisms of disease is a pre-eminent aim in biomedical research. Cancer, like other diseases associated with organs, is not completely understood as it is characterized by complex genetic changes involving multiple mutated genes. In this work, we recover transcriptional regulatory relationships among genes for molecular insights into the etiology of breast cancer. We use a novel search approach: Simulated Annealing with a Greedy Algorithm (SAGA) structure learning in Bayesian Networks. A compendium of probe level microarray data from human breast epithelial cells of patients was subjected to the Robust Multiarray-Average (RMA) procedure for normalization and background correction. A subset of only relevant probe-set identifiers of the genes in breast cancer in the data was extracted from the resulting expression matrix with a LISP code. This subset was supplied to a Bayesian Network inference learning algorithm in which SAGA was used to uncover new regulatory relationships from the data. The learning algorithm revealed 70 predictions of direct regulatory signaling relationships in breast cancer. Prominent among the predicted signaling relationships include that between the cyclin-dependent kinases regulatory subunit 1 (CKS1B / CDC28) and tumor suppressor protein (TP53) and also that between Cullin 1 (CUL1) and ring-box 1 (RBX1), E3 ubiquitin protein ligase. These transcriptional regulatory relationships involve genes that are directly involved in dysregulation of cell proliferation and cell cycle that are associated with cancers.

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Television advertising of selected medicinal products in Poland and in the United States – a comparative analysis of selected television commercials

Ewa Wiśniewska[1], Aleksandra Czerw[1], Marta Makowska[2], Adam Fronczak[1]

[1]Medical University of Warsaw, Poland

[2]University Of Life Sciences, Poland

The aim of the analysis was to establish the differences between television commercials of OTC drugs broadcast in Poland and in the U.S. The study covered 100 commercials of medicinal products of various producers applied to treat a variety of symptoms and diseases. The analysis demonstrated that there are both similarities and differences. The differences concerned e.g. spot length, the time of placement of a brand name and the diversity of advertising slogans. The most significant similarities concerned applied manipulation techniques, locations featured in commercials and the choice of actors.

Biography :

Wiśniewska Ewa graduated in Public Health (specialty: Management in Health Care) at the Medical University of Warsaw. She is a law student at Kozminski Univeristy and student activist in students' associations and research groups. She has just started research work.

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Effect of leaf extract of *Vernonia amygdalina* on the contractility of an isolated mammalian heart

Godfrey S. Bbosa[1], Robert Lubajo[2], Aloysius Lubega[1] & John Kateregga[2]

[1]Makerere University College of Health Sciences, Uganda
[2]Makerere University College of Veterinary Medicine, Uganda

Vernonia amygdalina is a common herb in Uganda with numerous medicinal properties. It commonly used by various communities in the country in management of hypertension (high blood pressure) though no scientific evidence documented for its effectiveness. Study determined effect of ether, methanol, aqueous and total crude leaf extract of *V. amygdalina* on rate and force of contractility of an isolated rabbit heart using Langendorff Heart Perfusion Methods. Acetylcholine and adrenaline were used as controls. Heart rate was determined by counting number of beats per minute. Force of heart contractility was determined using peak heights generated on kymogram after each dosing. Data was analyzed using SPSS Ver.16 and anova was used to compare means. P-value of less than 0.05 was considered statistically significant. There was reduction trend in both rate and force of contractility of isolated rabbit heart with increase in concentration of methanol, ether, aqueous and total crude leaf extracts similar to acetylcholine used as a negative control. Methanol and aqueous extracts caused cardiac arrest at a dose of 250mg/ml. Findings provide evidence for increased use of herb by local communities in management of high blood pressure.

Biography :

Bbosa completed his Ph.D (Medicine – Clinical Pharmacology) at Makerere University College of Health Sciences, Kampala-Uganda. Currently he is working as a Faculty member in the Department of Pharmacology & Therapeutics, Makerere University College of Health Sciences. He has more than 30 publications in peer reviewed Journals.

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'New' Limitations of the Bioequivalence Concept – a regulatory view on bioequivalence issues for specific drugs and drug products

Henrike Potthast

Federal Institute for Drugs and Medical Devices, Germany

The concept of bioequivalence has been successfully used for generic applications for marketing authorization (MAA) since decades. Respective guidelines have been developed in almost all jurisdictions and are even partly harmonized. However, technological developments allowed more complex drugs to arrive on the market, like e.g. liposomal formulations and/or targeted products. Meanwhile a number of these medications have reached the end of data protection period and generic companies seek to get respective MAAs. While it is widely agreed that biosimilars need more than the usual pharmacokinetic bioequivalence investigation as performed for chemically defined drugs, the situation is not so clear and undisputed regarding liposomal drugs and orally applied drugs to be locally acting in the gastro-intestinal tract.

The presentation aims to address current regulations and discussions on such specific products with respect to generic applications mainly from a European perspective. Possibilities and limitations how to employ the bioequivalence concept will be discussed including additional proposals in order to allow the necessary conclusion on therapeutic equivalence.

Biography :

Henrike Potthast is working as a biopharmaceutics expert at the German agency since 2002 and has particular responsibilities for internal and external issues on bioequivalence/bioavailability and biowaiver. Before joining the agency she was employed at the Central Laboratory of German Pharmacists (ZL, Eschborn, Germany). Her activities there comprised research projects in pharmacokinetics, bioavailability, bioequivalence, in-vitro dissolution, and cell culture (Caco-2) investigations. She is member of the EMA Pharmacokinetics Working Party (PKWP) and the EUFEPS Network Steering Committee on Bioavailability and Biopharmaceutics. She is teaching in extension studies "Master of Drug Regulatory Affairs (MDRA)" at Bonn University, and is a Temporary Advisor to WHO.

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Discovery of new human epidermal growth factor receptor-2 (HER2) inhibitors for potential use as anticancer agents via ligand-based pharmacophore modeling

Hiba Zalloum

The University of Jordan, Jordan

To discover potential antitumor agents directed toward human epidermal growth factor receptor-2 HER2/ErbB2 overexpression in cancer, we have explored the pharmacophoric space of 115 HER2/ErbB2 inhibitors. This identified 240 pharmacophores which were subsequently clustered into 20 groups and cluster centers were used as 3D-pharmacophoric descriptors in QSAR analysis with 2D-physicochemical descriptors to select the optimal combination. We were obliged to use ligand efficiency as the response variable because the logarithmic transformation of bioactivities failed to access self-consistent QSAR models. Two binding pharmacophore models emerged in the optimal QSAR equation, suggesting the existence of distinct binding modes accessible to ligands within the HER2/ErbB2 binding pocket. The QSAR equation and its associated pharmacophore models were employed to screen the National Cancer Institute (NCI) and Drug Bank databases to search for new, promising, and structurally diverse HER2 inhibitory leads. Inhibitory activities were tested against HER2-overexpressing SKOV3 Ovarian cancer cell line and MCF-7 which express low levels of HER2. *In silico* mining identified 80 inhibitors out of which four HER2 selective compounds inhibited the growth of SKOV3 cells with IC_{50} values < 5μM and with virtually no effect in MCF-7 cells . These lead compounds are excellent candidates for further optimization.

Further screening on different breast cancer cells with different HER2 expression patterns has been done.

Biography :

Hiba Zalloum is a Researcher in Hamdi Mango Center for Scientific Research at the University of Jordan, She holds a Master degree in Chemistry from The University of Jordan. Her practical research dealt with the synthesis, chelation and sorption properties of chelating polymers. Recently, her research interest is turning to molecular modeling and drug discovery field.

She has 15 publication, 13 ISI-published articles, 2 book chapters and running now 6 funded research projects

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Harnessing the Revolution of Site-Specific Genome Engineering Technologies to Create a Resistant Immune System for HIV cure

Hind Fadel

Mayo Clinic College of Medicine, USA

The therapeutic triumph of antiretroviral therapy (ART) converted HIV disease from a nearly invariably fatal disease to a manageable condition. Nevertheless, considerable limitations are evident: the need for life-long adherence to daily pill ingestion, expense, drug toxicities, and resistance. Even in patients on ART, chronic inflammation persists that harms the cardiovascular, renal, hepatic and neurologic systems. Earlier hopes that ART would enable us to "treat our way out" of the pandemic are now acknowledged as unrealistic. Fundamentally different approaches are sought. Our increased understanding of HIV-1 pathogenesis, and the evidence for one bona fide cure in the "Berlin Patient" have led researchers to view cure as a realistic and feasible *yet highly challenging goal*. The accelerating revolution in site-specific genome engineering technologies such as transcription activator-like effector nucleases (TALENs) and clustered regularly interspaced short palindromic repeats/CRISPR associated protein 9 (CRISPR/Cas9) allows us to envisage effective curative gene therapy approaches. Our work aims to target two vulnerabilities of HIV: (i) eliminating host dependency factors HIV-1 requires, and (ii) editing host restriction factors that HIV-1 has evolved to evade in order to restore their ability to restrict HV-1. Our goal is to generate resistance to HIV infection in hematopoietic stem cells (HSC) with potential for translational applications for curative HIV-1 therapies. Developing HSC-mediated therapeutics in this disease can also advance related applications to other infectious, autoimmune and hematologic diseases.

Biography :

Hind Fadel has completed a fellowship in Infectious Diseases, a PhD in Virology and Gene therapy and postdoctoral studies at the Mayo Clinic. She is an Assistant Professor at the Mayo Clinic College of Medicine. She is a member of the Division of Infectious Diseases in the Department of Medicine, and of the Department of Molecular Medicine. Dr. Fadel is a physician-scientist, committed to a career in basic and translational HIV research, virology and gene therapy with federal grant from NIH supporting her work.

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Critique of Inhalable Nanocomposite Microparticles: Preparation, Characterization and Optimization

Ibrahim Elsayed[1,2*] and Mohamed Hassan Hany AbouGhaly[1,3]

[1]Cairo University, Egypt

[2]Gulf Medical University, UAE.

[3]Pudure University, USA

Nanocomposite microparticles are intelligent carriers utilized for pulmonary drug delivery. This carrier is composed of nanoparticles encapsulated the drug and those nanoparticles are dispersed in microstructures of biodegradable rapidly disintegrating polysaccharides. Upon administration, the inhaled microparticles could reach deeply and deposit within lung due to their adjusted aerodynamic particle size. After that, nanoparticles would release into the biological fluids in lungs and retained in site for prolonged time due to their resistance to immunological opsonization, engulfment and digestion. Nanocomposite microparticles could be prepared by spray drying, spray freeze drying, spray drying fluidized bed granulation or dry coating techniques. The selection of the included excipients, preparation technique and optimization of the operational parameters play a significant role in determination of the aerodynamic particle size, redispersability of nanoparticles, morphology, yield, moisture content, flowability and the in vitro drug release. Moreover, the in vivo behavior of this novel carrier could be optimized and traced through studying the output of the previous researches which tested the lung deposition of the inhaled particles and the biological activity of the encapsulated drug. Finally, nanocomposite microparticles were found to be superior over both nanoparticles and microparticles and could be a promising carrier for pulmonary drug delivery.

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Progesterone release from biodegradable PLGA microspheres

Ignacio M. Helbling, Carlos Busatto, Diana Estenoz, Julio A. Luna

Fine Chemical Laboratory - CCT CONICET-SANTA FE, , Argentine

Biodegradable microspheres have been studied extensively for drug delivery purposes. They provide several advantages compared to conventional pharmaceutical dosage forms, including: (i) the possibility to accurately control the drug release rates over extended periods of time, (ii) easy administration and (iii) complete biodegradation. Poly(lactic-co-glycolic acid) copolymer (PLGA) is widely used because of its biocompatibility, long clinical experience, controllable degradation characteristics and possibilities for sustained drug delivery. In the present contribution, PLGA-based microspheres loaded with progesterone were prepared by the oil-in-water emulsion technique. Size exclusion chromatography (SEC), differential scanning calorimetry (DSC) and nuclear magnetic resonance (NMR) were used to evaluate polymer degradation during microspheres preparation. In addition, the effect of progesterone encapsulation on microspheres size was analysed. In vitro release studies were carried out in phosphate buffer at 37°C. The effect of particle size and hormone load on the release kinetics were studied. Scanning electron microscopy (SEM) was employed to observe morphological changes of particles after delivery assays. Results showed that microspheres preparation conditions do not induce significant PLGA degradation. In addition, the hormone load (0-40% w/w) does not modify the initial particle size. Microspheres with smaller size presented two release phases. Increasing the hormone load from 20 to 40 % w/w, the release rate in the burst phase increase from 17 to 45 10^{-2} mg mg^{-1} days $^{-1/2}$. Microspheres with large size presented three release phases. The burst effect was low (approximately 8.7 10^{-2} mg mg^{-1} days $^{-1/2}$) and the hormone release takes place over a more extended period of time.

Biography :

Ignacio Marcelo Helbling, biotechnologist graduated from Universidad Nacional del Litoral in 2008 and PhD in Biological Sciences graduated from Universidad Nacional del Litoral in 2012. He worked for Laboratorio Productor de Fármacos Medicinales S.E. Pcia. Santa Fe (Santa Fe, Argentine) for one year and actually he works in Fine Chemical Laboratory (Santa Fe, Argentine). He is Assistant Researcher of CONICET (Consejo Nacional de Investigaciones Científicas y Técnicas, Argentine). He has published 9 papers in reputed journals, 1 book chapter and has served as a referee for 44 manuscripts at the request of reputable journals.

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Nano Anti-cancer Drugs: Targeted Medication

Imran Ali

Jamia Millia Islamia, India

Normal chemotherapy of cancers has not achieved good status due to many side effects and incapability to cure cancer at late stages. Therefore, nano anticancer drugs are in growing stage; with few available in the clinical use. These are safe drugs as targeting only cancer parts of the body and also called as targeted drugs. Some nano medication in the market is carboplatin, cisplatin, 5-fluorouracil, bleomycin, dactinomycin, doxorubicin, paclitaxel, 6-mercaptopurine, topotecan, etoposide and vinblastin. These drugs are prepared using polymeric, liposomal, dendrimers and micelles inorganic materials. These drugs have special drug delivery to the targeted sites. Lecture wills highlights the importance, preparation, mechanism and future perspectives of anti-cancer nano drugs.

Biography :

Imran Ali is a world recognized academician and researcher. He completed his Ph.D. at the age of 28 years from Indian Institute of Technology Roorkee, Roorkee, India. Prof. Ali is known globally due his great contribution in anti-cancer and chiral drugs development and water treatment. He has published more than 250 papers in reputed journals including papers in Nature and Chemical Reviews of more than 41 impact factors. He has also five books published by Marcel Dekker, Inc., USA; Taylor & Francis, USA; John Wiley & Sons, USA; John Wiley & Sons, UK; Elsevier, The Netherlands. His citation is 8,050 with H index 31.

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Quercetin in association with moderate exercise training restores diabetes-induced vascular damage in rat carotid arteries

Irina C. Chis [1,*], Mihai Socaciu [2], Remus Moldovan [1], Simona Clichici [1]

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Diabetes mellitus is a chronic endocrine-metabolic disorder associated with increased risk of cardiovascular diseases due to vascular dysfunction caused by an impairment of endothelium-dependent relaxation (EDR). Quercetin is a natural flavonoid with multiple pharmacological effects including reducing oxidative stress and improvement vascular function. Exercise training has the effect in restoring endothelial function to diabetics by inhibiting inflammation and oxidative/nitrosative stress and by restoring NO bioavailability in vessels wall.The aim of the present study was to investigate the synergistic effects of Quercetin and moderate exercise training in restoring diabetes-induced vascular damage in rat carotid arteries.

Diabetic rats that performed exercise training were subjected to a swimming training program (1 hour/day, 5 days/week, 5 weeks). The diabetic rats received Quercetin (30 mg/kg body weight/day) for 5 weeks. At the end of the study, were performed ultrasound (US) evaluation of carotid arteries and carotid arteries rings were isolated from all experimental rats. The US procedures aimed to obtain morphological (2D), vascular (color Doppler and pulsed Doppler) and angiospecific functional data (CEUS). The effect of Quercetin in association with moderate exercise training on carotid arteries elasticity and EDR in response to acetylcholine in isolated phenylephrine-preconstricted arteries segments in the presence of indometacine was studied. In sedentary untreated diabetic rats EDR was significantly decreased - maximal relaxation (% of KCl) of carotid arteries and cause morphological and functional changes in carotid arteries. Quercetin in association with moderate exercise training restored normal EDR in carotid arteries segments and elasticity of carotid arteries from diabetic rats. These findings suggest that Quercetin in association with moderate exercise training protects vascular endothelial function in diabetic rats.

Biography :

Irina Camelia CHIŞ, lecturer in the Physiology Department of University of Medicine and Pharmacy "Iuliu Haţieganu", Cluj-Napoca, Romania, PhD in Medical Sciences, specialist in Laboratory Medicine and Internal Medicine. I am researcher at the Physiology Department of University of Medicine and Pharmacy "Iuliu Haţieganu", Cluj-Napoca, Romania. My actual research field is the exploration of the pathophysiological mechanisms underlying the development of the endothelial dysfunction in diabetes mellitus, as well as the implications of oxidative and nitro-oxidative stress in the development of this disease. I published the results of my research in extenso papers in ISI (6), and BDI (32) reputed journals.

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Young/middle-aged hypertensive subjects with or without type-2 diabetes, the sympathetic nervous system, and treatment implications

John M Cruickshank

Independent Cardiovascular consultant (Oxonian Cardiovascular Consultancy), UK

Hypertension in young/middle-age is underpinned by increased sympathetic nerve activity (SNA), particularly in the presence of type-2 diabetes (DM2). High levels of plasma norepinephrine (noradrenaline) and beta-receptor density (in lymphocytes), independent of blood pressure (BP), are associated with a high risk of cardiovascular events (including myocardial infarction (MI)). This has important treatment implications, whereby anti-hypertensive agents that increase SNA, e.g. thiazide-type diuretics, dihydropyridine calcium blockers, and angiotensin receptor blockers (ARBs), do not reduce (and may actually increase) the risk of cardiovascular events and MI in younger/middle-age hypertensive subjects. Beta-blockade is at least as effective as ACE-inhibition in preventing cardiovascular endpoints in the treatment of younger/middle-age hypertension with DM2 over a 10 year period, and is significantly superior in preventing all-cause death after 20 years follow-up.

Biography :

Dr John Cruickshank is a retired cardiologist. He qualified at Pembroke College, Oxford. His cardiological training was at Southampton University and he was a senior lecturer at the Royal Brompton and National Heart Hospital London. He has over 200 medical publications. He has written 8 medical text books, the best known being "Beta-blockers in Clinical Practice 1994"; "The Modern role of beta-blockers in cardiovascular medicine, 2010"; "Essential Hypertension 2013". He continues to lecture all around the world, on topics related mainly to hypertension, the sympathetic nervous system, and appropriate treatment.

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Solubility enhancement of gliclazide using hydrotropy and mixed hydrotropy

Jyotsana R. Madan and Virendra J.Kamate

Savitribai Phule Pune University, India

Gliclazide (GLZ) is a BCS Class II , oral antihyperglycemic agent which shows dissolution rate limited absorption. GLZ is used in treating non-insulin dependent diabetes mellitus. The aim of this research was to provide fast dissolving tablets of Gliclazide using the phenomenon of hydrotropy. Hydrotropy is a novel, safe and effective way to enhance solubility of poorly aqueous soluble drugs.

Aqueous solubility of GLZ was enhanced with the help of hydrotropic solubilization technique which provided a good enhancement in solubility. By using single hydrotropic agent the highest solubility of GLZ was obtained in 40% sodium benzoate solution. In order to decrease the concentration of individual hydrotropic agent further we used mixed hydrotropy.

Mixed hydrotropic blend of sodium salicylate and sodium benzoate in the ratio of 25:15 gave the highest solubility enhancement for GLZ. Solid dispersions of drug in hydrotropic blend were prepared and evaluated for drug content and micromeritic properties. The values of compressibility index, hausner ratio and angle of repose indicate that the flow character of the solid dispersion is good and no aid is needed to increase the flow properties, hence it can be used for direct compression of tablets. FTIR, X.R.D. and D.S.C. studies of the prepared solid dispersions were also performed which indicated absence of any complex formation between drug and hydrotropic agents.

The hydrotropic solid dispersion of GLZ was further used to prepare fast dissolving tablet by direct compression using Sodium starch glycolate as superdisintegrant and Mannitol as a diluent. Based on the *in vitro* dispersion time (49 secs)and wetting time (33 secs) tablets were found to facilitate faster dispersion in the mouth. Based on *in vitro* dissolution studies, tablets of optimised batch show 86% cummulative drug release within 14 mins.

It was concluded that the concept of mixed hydrotropy is an emerging field which can serve as a milestone for solubility enhancement and therefore deserves an urgent attention of scientific community to assess its efficiency and applicability.

Biography :

Jyotsana R.Madan has completed M.Pharm in Pharmaceutics from Gujarat University and her Ph.D. from GB Technical University, Lucknow, India. She has more than 18 years experience in research and teaching . She has published more than 23 papers in reputed journals and is a recognised PG and Ph.D. guide of Savitribai Phule Pune University, India.

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Budesonide loaded microspheres, experimental design and optimization

Liljana Makraduli

Replek Farm Ltd. Skopje, Republic of Macedonia

Calcium-alginate microspheres loaded with the active substance Budesonide and coated with chitosan were developed. Several different formulations were prepared and several responses were followed: particle size, dissolution at pH 1.2, dissolution at pH 7.4, production yield. Factorial design was applied aiming to obtain suppressed dissolution at pH 1.2 and sustained release at pH 7.4. The optimization was performed by using central composite design. Microspheres with size range of 5 to 11 mm were produced. With the study it was shown that Design of Experiments could be successfully used in planning the experimental design, performing series of well-selected experiments and gaining the most informative combination out of the given factors. It is a science based and effective approach to analyze and optimize a given formulation; in contrast to the most frequently used "trial and error" approach when the experiments are first performed and the gained data are analyzed afterwards.

Biography :

Liljana Makraduli is currently completing her PhD thesis at the "Ss Cyril and Methodius University" Skopje, Macedonia. She is R&D Director at Replek Farm Ltd, Skopje, Macedonia. She is Expert in Pharmaceutical Technology; Specialization at the "Faculty of Pharmacy", "Ss Cyril and Methodius University" Skopje, Macedonia. She participated in two scientific projects financed by the Ministry of Education of Republic of Macedonia and by the NATO Science for Peace Programme. She participated in more than 20 Workshops, Forums, Congresses and Symposia with published scientific work. Her paper "Factorial design analysis and optimization of alginate-Ca-chitosan microspheres" was published in Journal of Microencapsulation.

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Polyelectrolyte-drug ionic complexes as nanostructured drug carriers to design solid and liquid oral delivery systems

María Eugenia Olivera

Ciudad Universitaria, Argentina

Aqueous dispersions of acid or basic polyelectrolytes (PE) loaded with ionizable drugs (D) of opposite charge are characterized by a high degree of counterionic condensation. In solid state, these PE-D complexes are stable amorphous materials that, in many cases, quickly swell reverting to the original dispersion in the presence of aqueous fluids. Such systems exhibit a set of unique properties. Among them, the reversibility of the PE-D association modulates the release of D when dispersions are in contact with biological fluids. Besides, some of them exhibit interesting bioadhesive properties. By compaction of solid complexes swellable PE-D matrices (SPDM) are obtained. Kinetics and rate of D delivery from SPDM can be modulated by changes in their composition to satisfy the design of extended delivery systems. Among the factors that control the delivery of D, the rate of swelling, complex dissociation of ionic pairs and further diffusion of D, as well as hydrogel layer erosion, are mainly involved. PE-D complexes formulated as matrices, multiparticulate or dispersed systems play an important role in the design of drug delivery systems.

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Safety in Drug Delivery with Electronic Medication Information Management Systems

Maryam Varzeshnejad- Morteza Masoumi

Isfahan University of Medical Science, Iran

Introduction: The medication management process is complex, involving multiple stages and a variety of health care team members. Electronic medication management systems evidentially offer significant benefits, including reduced medical errors, better compliance, time saving, cost saving and better drug safety.

Methods and Materials: Electronic Medication Information system developing and data collection were conducted during the following 3phases:1- design and develop drug decision support system, 2- design and develop drug care documentation system,3-design and develop an electronic nursing medication information management system ,to be used in the neonatal intensive care unit.

Results: The of this project led to the design and development of an electronic nursing medication information management system for the neonatal intensive care unit which enables nurses to carry out medication care and documentation with minimal error and the least possible time.

Discussion and Conclusion: The system has some advantages that seem more practical, compared to similar systems. As a result, the nurses are able to identify and prevent a lot of medication errors, save his/her time in drug care documentation and take major steps toward promoting neonatal safety.

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Pharmacological Activities of Culinary-Medicinal Mushroom, *Auricularia auricula-judae*

Md. Ahsanur Reza

Patuakhali Science and Technology University, Bangladesh

Pharmacological efficacies of solvent extracts of Culinary-Medicinal Mushroom, *Auricularia auricula-judae* were studied. The 70% ethanol extract (AAE) (70% ethanol + 30% water) were fractionated with dichloromethane, ethyl acetate and butanol and water successively. Antitumor and antihyperlipidemic activities of solvent extracts were examined both in vivo and in vitro. A dose-dependent antitumor activity of all solvent extracts of AAE were shown against both murine P388D1 macrophage and Sarcoma 180 and human NCI H358 (Bronchoalveolar cancer) and SNU1 (Gastric cancer) cell lines. These cytotoxic effects were confirmed by the MTT and SRB assays. On the basis of IC_{50} values, dichloromethane fraction (DCM) exhibited strong cytotoxic activity than other fractions. The potent antitumor effect of DCM was found against solid tumor in BALB/c mice and negative control of splenomegaly and higher spelic index. Apoptosis of tumor cells were induced by down-regulation of Bcl-2 and over-expression of p53 on the presence of DCM. The principal components of DCM were 5,11,17,23-Tetrakis (1,1-dimethyl)-28-methoxypentacyclo (65.85%) and diazane (6.17%) those are identified by Gas Chromatography Coupled Mass Spectroscopy (GC-MS) analysis. DCM also has anti-oxidant and anti-inflammatory activities. The differentiation and adipogenesis of murine 3T3-L1 cells were suppressed by AAE and DCM with decrease expression of adipogenic (PPARγ and C/EBPα) and lipogenic (LPL and FAS) genes, while AAE was shown stronger activity than DCM. The plasma triglycerides, cholesterol, LDL, glucose, transaminase enzymes were reduced, while elevated HDL and decreased atherogenic index by feeding of AAE. It also improved the hepatic steatosis in male C57BL/6 mice. These findings suggest that it might be used as functional feed additive for reducing the risk of cardiovascular diseases, hepatic steatosis, tumor growth and enhancing anti-oxidant and anti-inflammatory activities.

Biography :

Md. Ahsanur Reza gained his first degree in Doctor of Veterinary Medicine (D.V.M.) and MS in Physiology from Bangladesh (Bangladesh Agricultural University). Later I awarded PhD in Veterinary Functional Medicine (Major in Pharmacology) from Republic of Korea (Kyungpook National University). After a short period of graduation, I joined at a government veterinary college as Lecturer. I later entered into the Department of Physiology and Pharmacology at Patuakhali Science and Technology University (PSTU), Bangladesh in 2008 and now Chairman of said I have published more than 20 papers in pair review journals. Research interests in veterinary medicine and medicinal properties of natural products.

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Aerosil Gel , a promising base for transdermal formulation: Formulation, Characterization, In Vitro and In-Vivo Evaluation Of Diclofenac - Aerosil Gel.

Abdullah K. Alkindi; Abd Elazim A. Ali; Mohammad W. Islam

Ajman University for Science and Technology, UAE

There has been an exponential rise exploring the possibility of the use of orgenogels as a drug delivery vehicle. These organogell formulations are getting more popular because of their stability and providing controlled released rather than other semisolids preparations. In the present investigation Aerosil, also known as colloidal silicon dioxide, were gelled with a nonpolar vehicle (Liquid paraffin) and investigated to their possible efficaciousness as olegenous ointment bases, considering the hydrophilicity, viscosity and polarity in the preparation of gel from colloidal silicon dioxide.

In vitro diffusion cell experiment was designed to demonstrate the rate of release of diclofenac sodium from two topical vehicle i.e. (1) 8% and (2) 10% Aerosil gelI, loaded with diclofenac sodium through cellophane membrane and animal skin was monitored spectrophotometrically. These parameters include the rheological behavior of the gels including *Appearance/Clarity; pH; homogeneity and grittiness, Spreadability/ Stickiness/ Tackiness, Extrudibility, Viscosity, and Drug content.* Compatibility studies were carried out using *FT-IR spectroscopy.*

In vitro drug diffusion and ex vivo penetration study using rat abdominal skin studied showed the drug permeation was slow and steady and also penetrated through rat abdominal skin membrane, which could possibly permeate through human skin. The in vitro release kinetics studies revealed that there were no significant changes in the peak pattern of IR spectra of pure diclofenac sodium, which implies that there was no chemical incompatibility between drug and excipients used in the formulations. Using the tail flick method, a significant analgesic activity in rats was observed as compared to the control value. The Aerosil gel formulation loaded with 1% diclofenac sodium assessed for irritancy test on New Zealand rabbits, indicated that the gel formulation was associated with no skin irritation throughout the entire observation period.

Having macromolecules of very high molecular weight, 8% diclofenac sodium Aerosil gel based formulation maintained for longer period of time and has wider prospects for topical preparations, remained unabsorbed on the skin thus it can be used for various topical dosage forms for external application. We conclude that 8% diclofenac sodium, Aerosil based gel formulation can be successfully utilized for the sustained delivery of diclofenac via transdermal route.

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Synthesis of Effective and Safe New Antimicrobial Derivatives of Hydroquinoxaline-2,3-diones Under Al Baha Conditions

Mostafa A. Hussein *, Fergany Abdel Hamid El Gamal

Al-Baha University, Saudi Arabia

The study relied on highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* a causative agent of human respiratory tract and skin infections. Also hospital-acquired infections and resistant fungi such as *Candida albicans* a causative agent of oral and genital infections.

The above-mentioned bacteria and fungi are among the highly resistant microbes to the available antimicrobial agents especially due to the effect of low oxygen level and low pressure of Al Baha governorate on the bioavailability of such antimicrobial agents. On the other hand, and newly designed and synthesized derivatives is considered a virgin area of study to pharmaceutical and medicinal chemists. Moreover, antimicrobial (antibacterial and antifungal) resistance is a serious and growing phenomenon in contemporary medicine. This research project involves design and synthesis of new derivatives of octahydroquinoxaline-2,3-dione derivatives through two steps reaction. This protocol involves the formation of N,N-disubstituted cyclohexane-1,2-diamine derivatives (la-l) through reductive alkylation reaction from 1,2-cyclohexanediamine and different carbonyl compounds in the presence of sodium cyanoborohydride. The second step involves fusion of the intermediate compounds (la-l) with diethyl oxalate affording the target new compounds. Consequently, the chemical structures of the new 1,4-disubstituted octahydroquinoxaline-2,3-dione derivatives will be elucidated depending upon different spectral data (IR, UV, and NMR) as well as the elemental methods of analyses. The preliminary antimicrobial and MIC activities of the newly synthesized derivatives will be investigated in comparison to chloramphenicol and cotrimazole as reference drugs respectively.

Moreover, the study aims to optimize a rapid, sensitive and selective high performance liquid chromatography (HPLC) method for the simultaneous quantification of octahydroquinozaline-2,3-dione derivatives in rabbit plasma. The Validation of the method will demonstrate its Specificity (selectivity), limit of detection (LOD), precision, repeatability or reproducibility , linearity and working range. In addition, accuracy (bias), absolute and relative recoveries and stability of octahydroquinozaline-2,3-dione derivatives in plasma and working solutions will be carried out.

The method will be applied for determination of the pharmacokinetic parameters and the absolute bioavailability of the prepared octahydroquinozaline-2,3-dione derivatives in rabbits after both Intravenous and oral administration. Statistical analysis of data will be performed using ANOVA computerized system.

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Fabrication and Characterization of Folic Acid-Grafted-Thiomer Enveloped Liposomes for Enhanced Oral Bioavailability of Docetaxel.

Muhammad Farhan Sohail

Quaid-i-Azam University, Pakistan.

The present study was aimed to develop a hybrid nanocarrier (NC) system with enhanced membrane permeability, bioavailability and targeted delivery of Docetaxel (DTX) in breast cancer. Hybrid NC's based on folic acid (FA) grafted thiolated chitosan (TCS) enveloped liposomes were prepared with DTX and evaluated in-vitro and in-vivo for their enhanced permeability and bioavailability. Physicochemical characterization of NC's including particle size, morphology, zeta potential, FTIR, DSC, PXRD, encapsulation efficiency and drug release from NC's was determined in vitro. Permeation enhancement and p-gp inhibition was performed through everted sac method on freshly excised rat intestine which indicated that permeation was enhanced 5 times as compared to pure DTX and the hybrid NC's were strongly able to inhibit the p-gp activity as well. Invitro cytotoxitiy and tumor targetting was done using MDA-MB-231 cell line. The stability study of the formulations performed for 3 months showed the improved stability of FA-TCS enveloped liposomes in terms of its particles size, zeta potential and encapsulation efficiency as compared to TCS NP's and liposomes. The pharmacokinetic study was performed in vivo using rabbits. The oral bioavailability and AUC_{0-96} was increased 10.07 folds with hybrid NC's as compared to positive control. Half-life ($t_{1/2}$) was increased 4 times (58.76 hrs) as compared to positive control (17.72 hrs). Conclusively, it is suggested that FA-TCS enveloped liposomes have strong potential to enhance permeability and bioavailability of hydrophobic drugs after oral administration and tumor targeting.

Biography :

Muhammad Farhan Sohail is a PhD scholar at Quaid-i-Azam University, Department of Pharmacy; Nanodrug delivery. He is working as research assistant in functional nanomaterials group at LUMS Pakistan and visiting post graduate faculty member at Riphah International University Pakistan. He has published 04 papers in international journals and 02 are under peer reviews. Besides that he is national and international trainer with IFRC/PRCS for youth as agent of behavioral change initiative, First aid and Disaster response. He has represented Pakistan as youth memeber at manay National and International forums.

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Development and Characterization of Edaravone nanoparticles

Namita Giri

University of Missouri, USA

In a healthy body, a physiological balance is maintained between ROS (reactive oxygen species) and antioxidants. Disruption of this balance towards overabundance of ROS leads to the condition called oxidative stress (OS). OS resulted from an imbalance between prooxidants (free radical species) and the body's scavenging ability (antioxidants) affects entire reproductive lifetime of a woman and even thereafter (i.e. menopause). ROS affect multiple reproductive processes and serve as key signal molecules in physiological processes. However, they also have a role in the pathological processes involving female reproductive tract. The efficacy of antioxidant supplements in disorders of female reproduction involved with OS hasn't still been proved. The ROS levels exceeded the scavenging capacity of the physiological system need to be lowered, so the balance between prooxidants and antioxidants can be maintained. An efficient free radical scavenger drug, Edaravone, will be used to lower the up-normal level of ROS. Edaravone has been proved to reduce or prevent the oxidation process of exposed tissue environment.

Nanoparticles containing Edaravone were developed and optimized using design of experiment (DOE). The formulations were characterized for size, surface charge, polydispersity, entrapment efficiency, drug loading and yield. Nanoparticles exhibited an average size range between 200 nm to 250 nm with low polydispersity. Free radical scavenging capacity and cytotoxicity of the nanoparticles were also evaluated using vaginal epithelial cell line, VK2/E6E7. A design of experiment (DOE) strategy was successfully applied to achieve the optimal carrier with high entrapment efficiency and drug loading. Vaginal delivery of these Edaravone nanoparticles may serve as an excellent platform against ROS induced disorders of female reproductive system.

Biography :

Namita Giri, a researcher in the field of Pharmaceutical Sciences born in central part of India. She has been in Pharmaceutical Sciences field for more than 14 years. She graduated with master of Pharmaceutical biotechnology from Dr. H.S Gour University Sagar, India. Currently she is pursuing her interdisciplinary PhD in pharmaceutical Sciences with chemistry s co-discipline at University of Missouri Kansas City, United States of America. She is working on nanotechnology based strategies/approaches for microbicides delivery for the prophylaxis and treatment of HIV-1 infection. She is a doctoral candidate actively involved in student organizations representing her school.

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Integrating QbD and BioRAM for generic products

Naseem A Charoo[1, 2], Rodrigo Cristofoletti[3,4]

[1] AlFalah Life Sciences Pvt. Ltd., India.

[2] Zayn Pharmceuticals, C/O AESK Inc. British Virginia Islands.

[3] Brazilian Health Surveillance Agency (ANVISA), Brazil.

[4] Goethe University, Germany.

A case study for integrating quality by design (QbD) and BioRam(biopharmaceutics risk assessment) in the development of a conventional immediate release generic dosage forms is provided. Quality target product profile (QTPP) enlisting patient needs vis a vis desired clinical effect was derived from RLD (reference listed drug product) label. Drug substance was thoroughly characterized and dissolution method developed. The drug was determined to be a BCS (Biopharmaceutics Classification System) class I. Prototype formulation similar to RLD (fit for the purpose) was prepared to understand dissolution release kinetics. Simulations were performed using Advanced Dissolution, Absorption and Metabolism (ADAM) model to compare fraction of dose absorbed and discern effect of particle size on drug dissolution. Risk assessment was performed to identify critical quality attributes (CQA's). Parameter profile index and good compressibility index of 5.3 and 5.1, respectively, and Amidon's process selection criteria supported direct mixing process. Lactose/pregelatinized starch ratio of 1.7-3.0 ensured > 85% in vitro drug release in 10 min with coefficient of variation of less than 4 for capsule weights. The cumulative fraction absorbed vs time profiles derived from ADAM model were superimposable for test and reference formulations. Risk due to lubrication and filling operation was determined to be non critical. ADAM model was successfully used to predict formulation specific effects on drug absorption. The clear and precise understanding of product vis a vis patient needs and performance criteria for chosen formulation approach was used to construct design space and formulate control strategy.

This case study should help to integrate the QbD and BioRAM for generic formulations and improve confidence in biowaivers based on invitro dissolution studies for BCS class I drug candidates.

Biography :

Naseem Ahmad Charoo has completed his Ph.D in 2004 from Jamia Hamdard University, New Delhi. He is the Project director of Zayn Pharmaceuticals, an upcoming pharmaceutical Co. in United Arab Emirates. He started his carrer with Ranbaxy Research Laboratories. He has worked in Premiere pharmaceutical organizations in Africa, and Malaysia. He has published more than 22 papers in reputed journals.

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Preclinical evaluation of herbal formulation for its effect on Female sexual function.

N. S. Vyawahare[1], S. S. Sadar[1] and Rajendran. R[2]

[1]Pad. Dr. D. Y. Patil College of Pharmacy, India

[2]CEO and Founder Green Chem Domlur, India

Sexual relationships is important social and biological relationships in human life. This physiological instinct, so essential to the survival of the species, is one of the mainsprings of human motivation, and its disappointment is closely related to happiness or misery. Normal sexual function involves biological, psychological and interpersonal influences. The impairment of sexual ability has unpredictable personal, social and biological consequences. Female sexual dysfunction (FSD) which is more common than male sexual dysfunction is recurring reduction in drive, aversion to sexual activity, difficulty becoming aroused, inability to reach orgasm, and pain during sexual intercourse.

The purpose of this study was to evaluate the effects of herbal formulation on altered sexual behavior in female rats.

An overectimized female rats who qualified base line test were selected for the study. These rats were subjected to hormonal priming. The study was documented for three sets of parameters using runway methodology and copulatory test at three different interval. The run time, proximity time, core proximity time and retreats in runway model while various proceptive and receptive parameters in copulatory test were recorded as a direct evaluation. In addition, various male incides were also recorded as a indirect parameters. The conclusion was extrapolated as a collective effects on these parameters.

The study documented that herbal formulation at the dose of 400 mg/kg showed significant improvement on 21st day of treatment.

The result also recorded on 11th and 31st day, formulation did not show significant and any further improvement as compared to 21st day result.

Biography :

N. S. Vyawahare, the Principal of Pad. Dr. D. Y. Patil College of Pharmacy, Akurdi has attained his Ph. D from Amravati University, in 2008. With 14 years teaching experience, he has gained many accolades as a presenter of multiple research papers in National and International Symposia in India and abroad, as a Resource person of national and international conferences, as author of five prestigious Book Publications and more than seventy Research Publication and as recognition to this magnanimous research contribution, he has been bestowed with the prestigious: "Society's Young Scientist Award", by the Society of Science and Environment.

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Spectroscopic, DFT, antioxidant, anti-hemolytic and cytotoxic studies on Zn(II), Cd(II) and Hg(II) complexes of 4-acetylpyridine carbohydrazone

O. A. El-Gammal*, G. M. Abu El-Reash and A. H. Radwan

Mansoura University, Egypt

A new series of Zn(II), Cd(II) and Hg(II) complexes of 4-acetylpyridine carbohydrazone (H_2APC) have been prepared and characterized by elemental analyses, spectral (IR, UV-visible, mass and ^{1}HNMR) as well as thermal measurements. The spectroscopic data confirmed that the ligand behaves as a neutral bi-dentate in all complexes. An octahedral geometry is proposed for Hg(II) complex and a tetrahedral one for Cd(II) and Zn(II) complexes. The bond length and angles were evaluated by DFT method using material studio program for all complexes. The thermal behavior and the kinetic parameters of degradation were determined using Coats-Redfern and Horowitz-Metzger methods. The antioxidant (DDPH and ABTS methods), anti-hemolytic and cytotoxic activities of the compounds have been screened. Zn(II) complex showed the highest antioxidant activity using ABTS and DPPH methods followed by H_2APEC. With respect to in vitro Ehrlich ascites assay, H_2APEC exhibited highest cytotoxic activity followed by Zn(II) complex.

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Phytochemical and antimicrobial screening of root extracts of *carica papaya*

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[1]University of Ilorin, Ilorin

[2]Olabisi Onabanjo University, Nigeria.

Resistance to antimicrobial agents have been on increase in recent time due to a number of factors. There is the need to explore new agents to address the rising failure of some of the existing antimicrobials to therapy. This work is designed to confirm the folklore claim of the antimicrobial activity of the root extract of the plant Carica papaya. The antimicrobial activity of ethanolic extract of male Carica papaya (EMCP), female species (EFCP) collected at 8.00a.m were tested against some selected bacteria (5) strains and fungal (1) organisms.The antimicrobial activity were evaluated using cup plate nutrient agar diffusion method. The roots of the plant were also screened phytochemically for the presence of secondary metabolites. The antibacterial and antifungal activity of EFCP appear to have similar MICs with EMCP against all organisms tested. The exception is that of Proteus mirabilis where EFCP at MIC 62.5mg/ml was outstanding in that it exhibited broader activity compared with EMCP.The Extracts of both EMCP and EFCP contains Saponin, Flavonoid, Tannins in pronounced amount. They also contain Akaloids, anthraquinones, anthocyanide in moderate amount. The antimicrobial activity of EMCP and EFCP was comparable with that of ciprofloxacin and clotrimazole that were used as reference standards.

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In vitro characterization and pharmacodynamic evaluation of furosemide loaded self nano emulsifying drug delivery systems (SNEDDS)

Pankajkumar Yadav[*1] • Ekta Yadav[1] •Amita Verma[1] • Saima Amin[2]

[1]Sam Higginbottom Institute of Agriculture, Technology & Sciences (SHIATS), India
[2]Hamdard University, India

Poor water solubility is one of the reasons for erratic absorption after oral administration of furosemide (FSM), an antihypertensive loop diuretic. Self nano emulsifying drug delivery system (SNEDDS) is a novel drug delivery system utilized to improve the water solubility, permeability and ultimately bioavailability. FSM solubility was determined in various vehicles oils, surfactants and co surfactants. Self emulsification region for the rational design of SNEDDS formulations were identified by pseudoternary diagrams. Developed formulations were characterized by zeta potential determination, droplet size analysis, dilution test, viscosity determination, in vitro dissolution studies and in vivo pharmacodynamic evaluation. A remarkable increase in dissolution was observed for the optimized SNEDDS when compared with the plain FSM and marketed formulation by in vitro dissolution studies. The pharmacological effect of FSM was improved by SNEDDS formulation as compared to plain FSM. The study confirmed that the SNEDDS formulation can be used as a possible alternative to traditional oral formulations of FSM to improve its bioavailability.

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Development of new drug combinations as a solution to the patent cliff problem currently faced by the pharmaceutical industry

Pierre A. Guertin

Laval University, Canada

Traditionally, the main model of the pharmaceutical industry for developing new drugs has been based on monotherapies, new molecular entities (NMEs), and their underlying one-target-one-disease dogma. As expected, closely related fields such as the cosmeceutical and nutraceutical areas, largely inspired by Big Pharma, have also mainly used that model. However, compelling evidence suggests that the time has come for these sectors of R&D activities to further explore more efficient, cost-effective and reliable approach for innovative products. Among a few approaches proposed in recent years, there is one that is of particular interest–the 'combination drug' also known as the fixed-dose combination (FDC) products approach. It has been generally defined as two or more active ingredientsthat are combined in a single dosage form for either new effects or superior synergistic-like efficacy with less adverse effects. Both the World Health Organization (WHO) and the U.S. Food and Drug Administration (FDA) have recognized the great potential of FDCs for the future of innovation in those sectors. In fact, the development of FDCs has recentlyreceived substantial support for commercialization of new products – that is between three and five years of additional protection and exclusivity. Next-generation FDCs have already been identified.

Biography :

Guertin has completed his Ph.D at the age of 31 years from University of Manitoba and postdoctoral studies from University of Oxford, University of Copenhagen and University of Aix-Marseille. He is the director of the Laboratory on Spinal Cord Injury (Laval University Medical Center) as well as CEO of Nordic Life Science Pipeline, a biotech focusing on the development of combination products. He has published more than 100 publication as original article, review article, patent, and abstract.

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Regulatory control of Medical Devices in India

Ram Chandra Besra

State Drugs Control Directorate, India

Medical devices have been used to treat and diagnose disease since 2000 BC. Today, widely used in all branches of medicine, surgery, and community care. [1] The Medical device industry is a major one, with worldwide sales of more than £110 billion per year. [2] While, Indian Medical device industry has a potential to grow from current $4.4 billion to $7 billion by 2016. [3] A new report predicts the global medical devices market will reach $398.0bn in 2017. [4] Medical devices and related technologies that offer countless benefits and numerous risks, including alarm hazards, exposure hazards from radiation therapy and CT, drug-delivery errors involving the use of infusion pumps, cross-contamination associated with the use of flexible endoscopes, inattention to change management for medical device connectivity, enteral feeding misconnections, surgical fires, needlesticks and other sharps injuries, anesthesia hazards resulting from incomplete preuse inspection, and poor usability of home-use medical devices. [5] So, need to provid consumers with sufficient choice and offering the medical devices that perform safely and efficaciously. Therefore, knowledge of Indian laws and regulatory guidelines related to clinical trial, patent, registration, import, sale, manufacturing and distribution of Medical devices is mandatory before enter into the Indian market.

Biography :

Ram Chandra Besra has completed his M.S.(Pharm.) in Medicinal Chemistry from National Institute of Pharmaceutical Education & Research, Mohali. and Ph.D. (Pharmacology &Therapeutics) at the age of 35 years from Department of Pharmacology and Therapeutics, Rajendra Institute of Medical Sciences, Ranchi University, India. He is the Inspector of Drugs, Govt.of Jharkhand, India. He has long working experience in Industry as Assistant General Manager, in Institution as faculty for Medical and pharmaceutical Sciences, in Research particulary clinical and paraclinical subject. He has published his reserach papers in internationally reputed journals.

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The Perfect Protocol

Richard T Penson

Harvard Medical School, USA

The talk will focus on the IRB's perspective of clinical research. The goal is to navigate regulatory requirements and best practices using real world examples of the key elements of clinical trials in oncology, and the experience of the Harvard hospitals cancer programs. The main focus will be: regulations: guidelines or rules; PI responsibilities; personalized medicine; tissue banking, and conflicts of interest. Patients are motivated to get access to new agents, but our responsibility in their protection, ethical practice, and being able to answer important research questions, while navigating classic, obvious and hidden pitfalls and balancing the priorities of both the investigator and the pharmaceutical industry. Novel design, selected patient populations, and the specifics of the trial conduct are key issues that will be reviewed, as well as how to balance detail and pragmatism, in the nitty-gritty reality of visits and CRFs. The different emphases of Phase I - IV trials will be reviewed, and the unique facets of different trials, particularly the 'umbrella' and 'basket' trials of the new targeted agents. The statistical section has to clearly and reasonably justify the study, and there are newer looming challenges which include: combination studies, social justice and cost effectiveness. Getting it right first time without the burden of multiple amendments is the goal.

Biography :

Richard Penson is Associate Professor of Medicine at Harvard Medical School. Dr. Penson came from St Bartholomew's Hospital, London, in 1997 and his practice is devoted almost exclusively to gynecologic oncology with the majority of patients having ovarian cancer. Dr. Penson sits on the national Gynecologic Oncology Group (GOG) committees for ovarian cancer and quality of life research, and the NCCN Ovarian Committee. Dr. Penson attends on the Bigelow General Medical Service at Mass General, serves as the chairman for panels C, and E of the Institutional Review Board of Dana-Farber/Partners CancerCare.

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Discovery, Development, and Delivery of MDM2 Inhibitors for Cancer Therapy

Ruiwen Zhang

TTUHSC School of Pharmacy, USA

The MDM2 oncogene was initially discovered as a negative regulator of the tumor suppressor p53. There is a MDM2-p53 feedback auto-regulatory loop. In late 1990s and early 2000s, we and others first proposed to target MDM2 for cancer therapy. We were the first to demonstrate that MDM2 knockdown results in significant anticancer activity. In the last two decades, we and others have demonstrated MDM2's oncogenic activity based on p53-dependent and -independent mechanisms. We have identified several novel MDM2-interactive molecules and novel MDM2 regulatory pathways. At least 5 classes of natural product MDM2 inhibitors that exert cancer preventive and therapeutic activities have been discovered in our lab. In the development of MDM2 targeted therapy, most published studies are focused on the MDM2-p53 pathway, inhibiting p53-MDM2 binding. These inhibitors would depend on the expression of wild type p53 in the cancer cells to exert anticancer activity and will have limited efficacy in tumors with mutant p53 or no p53 expression. More recently, we have developed small molecule MDM2 inhibitors with novel mechanisms of action that directly inhibit MDM2 expression and/or induce MDM2 protein degradation, demonstrating significantly improved anticancer activity in variety of cancer models, regardless of p53 status. More interestingly, an oral nano-delivery system for small molecular MDM2 inhibtors has been developed and evaluated in vitro and in vivo. (Supported by NIH/NCI R01 grants CA80698, CA121211, CA112029, and CA 186662.)

Biography :

Zhang obtained his MD with highest honor and PhD in Toxicology from Shanghai Medical University (now Fudan University Shanghai Medical College) and completed his post-doctoral/clinical pharmacology fellowship at University of Alabama School of Medicine (UAB). He joined UAB faculty in 1992 and was Tenured Professor and Cancer Pharmacology Laboratory Director until July 2010, when he joined TTUHSC School of Pharmacy as Tenured Professor and Chair. His research experiences include translational medicine, cancer therapy and prevention, clinical pharmacology and therapeutics, pharmaceutical and toxicological research, with more than 250 publications. Dr. Zhang is a certified toxicologist by the American Board of Toxicology (D.A.B.T.). He is also Editor-In-Chief, Associate Editor-in-Chief, and Associate Editor for 6 SCI journals and Editor Board Member for additional 18 journals. For his outstanding contributions in sciences, Dr. Zhang was elected as a Fellow of American Association for the Advancement of Science (AAAS) in 2009.

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Influence of menstrual cycle on the pharmacokinetics of antibiotics

Sandhya Rani Guggilla, Sarangapani Manda

Kakatiya University India

For several reasons no two individuals can be considered identical and hence individualization of therapy is the current trend in treating the patients.

Influence of menstrual cycle on the pharmacokinetics of Doxycycline. Twelve healthy female volunteers have been included in the study after obtaining written informed consent. The age ranged from 16 to 25 years

Experimental design: The volunteer selection and recruitment will be carried out after obtaining informed consent from each volunteer. The drug administration will be done to each volunteer at 7 a.m along with a glass of water after an overnight fasting on 3rd, 13th and 23rd day of menstrual cycle. These saliva samples will be stored under frozen conditions until HPLC analysis.

Results: In the present study the changes in estrogen levelsduring ovulatory phase have not shown any influence onAUCo-t of Doxycycline. Only AUCo-t of doxycycline showed an increasing trend with increasing levels of estrogen in ovulatary phase, but not in other phases. Eventhough the FSH levels differed significantly among volunteers during different phases FSH does not seem to influence overall pharmacokinetic behavior of Doxycyline during different phases. The present study indicated only the trend that the hormone levels may influence the pharmacokinetic behavior of the Doxycycline.

Conclusion: In the present study the changes in hormones have shown an increasing C-max,increasing AUCo-t of Doxycycline pharmacokinetics significantly in follicular phase than ovulatory and luteal phases among volunteers during different phases.In other pharmacokinetic properties like clearance, biological haif life,volume of distribution,mean residence time the change was not significant.

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Colonic Disposition of Budesonide from liposomal dry powder

Sanjay Kshirsagar

Savitribai Phule Pune University & MET's Institute of Pharmacy, India

The aim of this study was to develop and evaluate the liposome for colon specific drug delivery system for treatment of inflammatory bowel disease (IBD) through oral administration. But colon specific drug delivery system should be capable of protecting the drug en route colon and hence it is filled in enteric coated capsules. Budesonide containing liposomes were prepared by thin film hydration method. The budesonide loaded liposomes were optimized by using statistical design and evaluated for particle size, zeta potential, percent entrapment efficiency (%EE), TEM, *in vitro* and *in vivo studies*. Where, FT-IR, SEM, DSC were carried out for freeze dried liposomes. Particle size and entrapment efficiency of optimized batch were between 285 and 300 nm and 51% and 60%, respectively. *In vivo* and *ex vivo* study indicates higher accumulation of liposomes in colonic region as compared to pure drug showing anti inflammatory activity. Enteric coated capsules delivered the drug after 5 hr lag time.

Keywords: Budesonide, Liposomes, Inflammatory bowel disease, Colon specific drug delivery system

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Nanotechnology for Modulation of Drug Pharmacokinetics and Pharmacodynamics

Sarasija Suresh,

M.S .Ramaiah University of Applied Sciences (MSRUAS), India

One of the major limitations of advances of drug discovery programs is that the newly discovered leads tend to be lipophilic with high molecular weight resulting in poor oral bioavailability, short-half life, extensive tissue distribution and metabolism. More than 40% NCEs are water insoluble, BCS Class II drugs exemplified by erlotinib, tamoxifen, telmisartan. Biotechnological molecules are highly water soluble, but exhibit poor permeability orally and rapid metabolism parenterally. The members of the BCS Class III drugs such as atenolol and metformin exhibit limited absorption window.

Nanotechnology represents a viable option to achieve enhanced drug bioavailability, duration of action, increased efficacy and decreased toxicity. Different approaches can be selected based on physicochemical and physiological factors of drug molecules. Nanocrystals represent a novel, versatile approach for enhancement of therapeutic activity of drug molecules, with a wide range of applications and industrially viability. Nanocrystals are crystalline particles in 200-500 nm size range composed essentially of drug and stabilized by stabilizers. They enhance bioavailability of poorly soluble drugs, enhance efficacy, increase permeation, and improve pulmonary and ocular absorption of drugs. Hybrid nanocrystals confer theranostic applications and offer scope for further functionalization. Nanophospholipid complexes enhance bioavailability of drug molecules, increase circulation time, achieve passive drug targeting and decrease toxicity. This talk summarizes the application of nanotechnology in modulating drug action with emphasis on nanocrystals and nanocomplexes with case studies.

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Optimized production of aceclofenac nanocrystals: a box-behnken design approach

Satyanarayan Pattnaik, Kalpana Swain

Talla padmavathi college of pharmacy, India

Statistical design of experiments for development and further optimization of pharmaceutical products and processes has gained a lot of importance, now a day, in the era of quality by design. In this study we demonstrate optimization of process variables for development of nanocrystals to improve dissolution rate of aceclofenac. Bottom up approach was adopted to obtain pure drug nanocrystals of aceclofenac using different polymeric stabilizers. A Box-Behnken design was used to study the influence of process variables and further optimization was carried out. The physicochemical properties were evaluated including particle size distribution, PXRD, SEM and dissolution studies. The identified process variables influenced the particle size and dissolution velocity of aceclofenac. Methylcellulose (MC) and hydroxypropyl methylcellulose (HPMC) were found very effective in preventing growth of crystals and improving the dissolution of aceclofenac. The optimized aceclofenac nanocrystals showed improved dissolution and reduced particle size.

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The evaluation of supercritical fluid technology as a preparative technique for the manufacture of flurbiprofen-methyl-β-cyclodextrin inclusion complexes: an approach to enhance the solubility and dissolution properties

Shashi Ravi Suman Rudrangi

University of Greenwich, United Kingdom

The aim of this study was to enhance the apparent solubility and dissolution properties of flurbiprofen through inclusion complexation with cyclodextrins. Especially, the efficacy of supercritical fluid technology as a preparative technique for the manufacture of flurbiprofen-methyl-β-cyclodextrin inclusion complexes was evaluated. The complexes were prepared by supercritical carbon dioxide processing and were evaluated by solubility, differential scanning calorimetry, X-ray powder diffraction, scanning electron microscopy and *in vitro* dissolution studies. Computational molecular docking studies were conducted to study the possibility of molecular arrangement of inclusion complexes between flurbiprofen and methyl-β-cyclodextrin. The studies support the formation of stable molecular inclusion complexes between the drug and cyclodextrin in a 1:1 stoichiometry. The results obtained from different analytical studies suggest complete complexation or amorphisation of flurbiprofen and methyl-β-cyclodextrin binary samples prepared by supercritical carbon dioxide processing. *In vitro* dissolution studies showed that the dissolution properties of flurbiprofen were significantly enhanced by the binary mixtures prepared by supercritical carbon dioxide processing. The amount of flurbiprofen released from drug alone was very low with 1.11 ± 0.09% dissolving at the end of 60 min while the binary mixtures processed by supercritical carbon dioxide at 45°C and 200 bar released 99.39 ± 2.34% of the drug at the end of 30 min. The study demonstrated the single step, organic solvent-free supercritical carbon dioxide process as a promising approach for the preparation of inclusion complexes between flurbiprofen and methyl-β-cyclodextrin in solid state.

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HPMC Matrix Film Containing Acetazolamide–Zinc Oxide Nano-Composite for Ocular Drug Delivery

Subrata Mallick, Debabrata Acharya, Rudra Narayan Sahoo

Siksha O Anusandhan University, India.

Glaucoma is a disease leading to progressive damage to the optic nerve resulting in permanent loss of vision. Lowering intraocular pressure (IOP) is the main focus for the treatment of glaucoma. Treatment with acetazolamide helps to reduce IOP, and prevents further eye damage. Gastrointestinal upset and diuresis are the most common symptoms of acetazolamide intolerance after oral administration along with its poor oral bioavailability. To overcome these associated limitations local ocular delivery is advisable particularly for the management of glaucoma. Ocular thin film was prepared by solvent casting method using hydroxypropyl methylcellulose as polymer and triethanolamine as plastisizer incorporating acetazolamide-zinc oxide nano-composite. The film formulations have been characterized by using analytical techniques such as FTIR, DSC, XRD and SEM studies. Absence of significant change of characteristic peak of ACZ in FTIR spectra indicated no major interaction. Presence of shouldering in the region 3200-3400 cm-1 in the FTIR spectra of the formulation indicated H-bond formation with the HPMC. The absence of melting endotherm of DSC thermograms confirmed the almost complete amorphization of drug in film formulations. XRD peaks confirmed the presence of zinc nanoparticle in the amorphous domain of drug in HPMC matrix. SEM analysis exhibited presence of micro and nano rod type drug crystals in the film formulation. Ex-vivo ocular permeation study revealed the sustained permeation of ACZ for 6-8 hours by the film formulations. In conclusion, ACZ-ZnO nanocomposite film might present a promising vehicle for effective sustained ocular drug delivery.

Biography :

Subrata Mallick, currently is the Professor and HOD, School of Pharmaceutical Sciences, Siksha 'O' Anusandhan University, Bhubaneswar, India since 2008. He has 19 years of teaching & research and 14 years of industrial experience. His major research areas of interest are Drug Delivery Systems and Powder Compaction. He has many research publication of full length (50) and conference proceedings accepted and published (67). He is the Editorial Board member of several International Journals of America, Canada, UK, Thailand, India, and invited reviewer of Elsevier, Informa Healthcare, Bentham, Springer, Wiley. He chaired and delivered talk in several scientific programs.

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Synthesis and antidepressant evaluation of compounds containing 4-(1*H*-benzo[*d*]imidazol-2-yl)-*N*-(substituted phenyl)-4-oxobutanamide

Theivendren Panneerselvam[1], **Arumugam Sivakumar**[2],

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[2]VIT University, India

A new synthetic strategy for the synthesis of novel 4-(1H-benzo[d]imidazol-2-yl)-N-(substituted phenyl)-4-oxobutanamide **(3a-i)** analogues is described and evaluated for their antidepressant activity. Reaction of 4-(1H-benzo[d]imidazol-2-yl)-4-oxobutanoic acid **(1)** with 4-(1H-benzo[d] imidazol-2-yl)-4-oxobutanoyl chloride **(2)** furnished novel 4-(1*H*-benzo[*d*]imidazol-2-yl)-*N*-(substituted phenyl)-4-oxobutanamide **(3a-i)**. All the newly synthesized compounds were characterized by IR, ^{1}H-NMR and Mass spectral analysis. The antidepressant activities of synthesized derivatives were compared with standard drug Clomipramine at a dose level of 20mg/kg. The compound **3a** significantly reduced the duration of immobility time at 50mg/kg dose level considered to be highly promising when compared to the standard drug. Molecular docking studies revealed that the computational values obtained after docking calculation are in good agreement with the experimental values.

Biography :

T.Panneerselvam Is working as an Associate Professor in Arulmigu Kalasalingam College of Pharmacy, Krishnankoil, Tamilnadu. He received his PhD degree in 2013 from Acharya Nagarjuna University, Guntur, India and he earned Young Faculty Award 2014 from EET CRS presents Academic Brilliance Award-2014, Noida and has 08 years of teaching experience, scientific research and development. He has published 21 Books and 52 scientific research articles in international and national journals. His research has focused on the **Design, Synthesis, and Analytical/Biological Screening of Novel Heterocyclic Derivatives**.

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Characterization and evaluation of Colicin to inhibit and reduce the growth of *Escherichia coli* K99 in mice

Golestan F[1], Tahamtan Y[2*], Moazamian E[3]

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[2]Razi Vaccine and Serum Research Institute, Iran.

[3]Azad University of Shiraz, Iran.

Colicin produce by colicinogenic *E. coli* (CEC) arenarrow limited spectrum antimicrobial agents that are able to kill or prevent close related strains. The objective of this study was to evaluation effect of Colicintoinduce immunized mice to prevent infection caused by *E. coli*K99. The experiment was conducted into twomice groups (30 in each group) with two weeks old. All mice were administered by streptomycin sulfate prior to treatment to eliminate resident *E. coli*. Group one was orally inoculated with PBS as control and the second was immunized byColicinsolution as immunize group. Both control and immunized group were challenged by 3 LD_{50} of *E. coli* K99 and follow a week.Immunized mice group were not showed severe clinical signs. While diarrhea with different sings of colibaccillosiswas established in control group and infected mice was died. Overuse antibiotics developed serious new types of multi drug *resistance* in human medicine and therefore has limited their use in farm animals. The study indicates the use of Colicin and biotherapy instead of antibiotic is more safe and efficient for control of *E. coli*K99 infection. Immunized mice by Colicin solution protected *E. coli* K99 colonization and reduce fecal shedding. Investigation in livestock for applying Colicin in farm animal is recommended.

Key word: Immunize mice,Colicin, colibacillosis.

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Dual Targeting Peptide-Conjugated Doxorubicin Reverses Drug Resistance in Breast Cancer

Yun Chen

Nanjing Medical University, China

The extended use of doxorubicin (DOX) could be limited due to the emergence of drug resistance associated with its treatment. To reverse the drug resistance, a hybrid peptide, which is chemically synthesized and is composed of two target-binding peptides, was conjugated to DOXO-EMCH, forming a maleimide bridge in this study. The peptides achieved the drug resistance reversal by two different mechanisms. The structures and properties of peptide-DOX conjugate (H24-DOX) was characterized using ^{1}H NMR, ^{13}C NMR, mass spectrometry and HPLC. Their stability was also evaluated. Using MCF-7/ADR cells as an in vitro model system and nude mice bearing MCF-7/ADR xenografts as an *in vivo* model, the ability of these novel peptide-conjugated DOX to reverse drug resistance was accessed as compared with free DOX and our previously developed T10-DOX. As a result, the IC_{50} value for H24-DOX significantly decreased, whereas the percentage of apoptotic cell population increased. The *in vivo* extent of inhibition was more evident in the mice groups treated with H24-DOX, which had DOX primarily accumulated in tumor. These conjugates also showed a longer half life in plasma and cleared much more slowly from the body.

Biography :

Yun Chen now is a full professor of clinical pharmacy, vice dean of School of Pharmacy, Nanjing Medical University. She got her Ph.D. degree at university of Minnesota, USA. Currently, Dr. Yun Chen focuses on the study of multi-drug resistance phenotype and the development of novel peptide-drug conjugate to reverse drug resistance. Her research is supported by the national natural science fund (21175071), the research fund for the doctoral program of higher education of China (20093234120010), the project sponsored by SRF for ROCS, SEM (39) and Jiangsu six-type top talents program (D).

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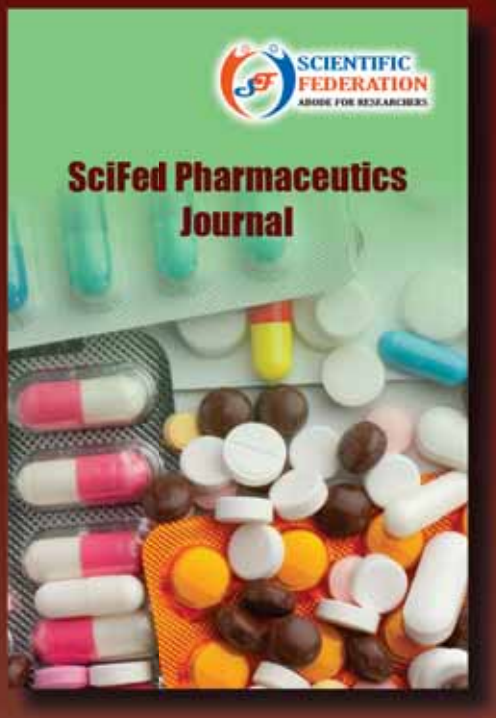

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