EuroSciCon

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Pharmaceutics and Novel Drug Delivery Systems

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Theme: Exploring the future of Pharma Industry through Pharma research, Nanomedicine and Drug Delivery Systems

Abstract

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Puzzling polymorphic behavior of active pharmaceutical ingredients

Peter Karpinski,
Qlife Inc, USA
USA

Statistically, 85% APIs exhibit (pseudo)polymorphism, and 50% of APIs have multiple forms. The capability to reliably manufacture specific stable (pseudo)polymorphs is an integral part of the API development process. This is accomplished by a thorough and systematic process involving the polymorph discovery stage, polymorph detection, and analytical characterization of the properties of the form(s) discovered. In the world of polymorphs confusing results are standard. Nonetheless, the ultimate goal is to select the most thermodynamically stable form and be able to manufacture it consistently. The preferential nucleation and growth of specific (pseudo)polymorphs over others is possible through careful control of environmental conditions, such as temperature, supersaturation, rate of crystallization, seeding, type of solvent(s), etc.

- **Antiproliferative and antioxidant effect of polar hemp (Cannabis sativa L.) extracts**

Peter Karpinski,
Qlife Inc, USA
USA

A significant part of high added value materials are produced by batch precipitation or crystallization. The properties of such materials are largely determined by the way the batch process was conducted. Therefore, in order to obtain crystalline material of desired properties consistently, the entire precipitation/crystallization process must be carefully controlled. In the mid-1990's, this author introduced the concept of *in-situ* seeding that simplifies the design and control of batch precipitation/crystallization and gives the results comparable with the conventional seeding approach.

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Challenges and opportunities in controlling drug substance properties

Peter Karpinski,
Qlife Inc, USA

In order to control drug substance (DS) properties one has to select an optimal form (specific polymorph or hydrate of free form, salt, or co-crystal) and be able to consistently manufacture it with the same particle size (PS), particle size distribution (PSD), and crystal surface attributes. The use of automated and robotic systems in salt/co-crystal and polymorph screening, and in early crystallization development experimentation, facilitates DS form selection. Ultimate properties of DS are largely determined by the way the batch precipitation or crystallization processes are conducted, and to obtain crystalline material of desired properties consistently, these processes must be carefully controlled.

Targeting polymorphs and hydrates in manufacturing of APIs

Peter Karpinski,
Qlife Inc, USA

Successful manufacture of an active pharmaceutical ingredient (API) in a correct form requires a thorough understanding of API properties and in-depth knowledge of crystallization and downstream processing unit operations, as well as significant scale up efforts. Whenever practicable, for API manufacture, a seeded, cooling crystallization is typically considered as the most reasonable approach. The supersaturation profile has a profound effect on the nucleation and growth processes and the resulting CSD of API and its control during crystallization is necessary

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Evaluating a novel drug delivery system for oral amoxicillin

Nadeem Ahmed,
Advanced Product Design Services Inc.., Canada

Antibiotic resistance is one of the major concerns for clinicians engaged in the management of infectious diseases. One of the major reasons for antibiotic failure is the lack of optimum serum concentration. The pharmacokinetics (PK) and pharmacodynamics (PD) features indicate that intermittent infusion of antibiotics is inefficient in ensuring clinical cure. Intermittent infusion results in short half-life and ineffective serum concentrations. Hence, continuous infusion of antibiotics has attracted much attention. Extended release drug delivery systems have been documented for ensuring optimum serum concentrations. Gastrointestinal therapeutic system (GITS) is one such system which is used for the

Drug delivery systems – the regulated unregulated products

Fabio Cirillo,
Avanti Europe AG, Switzerland

Drug Delivery Systems, also regulated as Combination Products in the USA, have been in the focus of development teams. Navigating the regulation, however, is not as easy as it seems as major parts of drug delivery systems are still unregulated and leave vast room for interpretation. With the advent of the MDR, this gap gets somewhat closed. Explore, discuss and learn a possible way of implementing the demanded risk-based approach for product development and understand the focus areas of the Regulators for novel and advanced drug delivery systems, connected to cloud services and interacting with smartphones and health care providers. Especially the connected and smart systems add complexity to the development and a rock-solid strategy to navigate the regulation should be implemented to optimally make use of data and intelligence derived from connected systems.

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Peptide-modified micelles and liposomes: carriers for xenon hyper-cest mri of blood brain barrier endothelial cells

Margitta Else Anna Dathe,
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Diagnostics and treatment of the brain is a particular challenge. We developed a micelle forming and lipid binding lipopeptide (P2A2) which selectively recognizes human brain capillary endothelial cell (HBMEC), the major components of the blood brain barrier (BBB).Here we present the development of lipopeptide-modified micellar and liposomal carriers for the selective transport of cryptophane-A (CrA) into HBMECs. Chemical exchange saturation transfer with hyperpolarized Xenon nuclei (Hyper-CEST) allows highly sensitive detection of supramolecular cages such as CrA in non-invasive

SIRT1 siRNA loaded cationic liposomes showed enhanced cell death of prostate cancer cells with different p53 expression patterns

Bilge Debelec Butuner,
Ege University, Turkey

Sirtuin 1 (SIRT1) is a histone deacetylase (HDAC) from Sirtuin family. High expression of SIRT1 induces activation of DNA repairing factors eventually leading either tumor suppression or tumor development in cellular context dependent manner. Most of the chemotherapeutics induce apoptosis by creating DNA damage in tumor cells. However, SIRT1-activated repair of the chemotherapeutic-induced DNA damage results in decreased apoptosis and finally chemotherapy resistance. Therefore, inhibition of SIRT1 is a promising strategy both in anticancer therapy and preventing chemotherapy resistance.

CBD and thc content of cannabıs genotypes of turkey

Selim Aytaç,
Ondokuzmayıs University, Turkey

In this study, the detection of the village population for many years cultivated in Turkey in order THC and CBD content was produced in 2018. In the study, 8 village populations collected from the producers in 2014 harvest year, 1 village population gathered in 2015 harvest year, 34 hemp (C. Sativa L.) genotype obtained from Gene Bank of the Aegean Agricultural Research Institute of the Ministry of Food, Agriculture and Livestock and 3 cultivars brought from abroad including a low THC (Uso-31, Ferimon 12 and Santhica 27). Totally 46 genotype was used this research. Nine populations obtained from producers; they have produced themselves for many years. Populations were collected legally from producers engaged in fiber production.

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The important ıntTerms of health of flax (*Linum usitatissimum L.*)

Sahane Funda Arslanoglu ,
Ondokuz Mayis University, Turkey

The flax is one of the oldest known cultivated plants of the World that that benefited from seeds and fibers. It is an important nutrient because of the rich α-linolenic acid (ALA, omega-3 fatty acid), lignans, short chain polyunsaturated fatty acids, soluble and insoluble fibers, phytoestrogenic lignans (secoisolariciresinol diglycoside-SDG), waxy and mucilage compounds, protein and antioxidant compounds. In addition, the seed contains components effective in reducing cardiovascular disorders, diabetes, digestive system, urinary tract disorders, osteoporosis, cancer, arthritis, autoimmune and neurological diseases. Seed protein content varies between 20-30%, of which approximately 80% consists of globulins (linine and conlinin) and 20% glutelines

Healing from nature; *Trachystemon orientalis (L.) G. Don*

Sahane Funda Arslanoglu ,
Ondokuz Mayis University, Turkey

There are many plant species in Anatolia that are believed to be a source of healing, consumed and collected from nature. One of them is *Trachystemon orientalis* (L.) (Boraginaceae), which grows in beech and oak forests in moist, organic matter high, shaded areas in North Anatolia (Black Sea Region). The genus *Trachystemon* D.Don is represented by one species in Turkey. *Trachystemon orientalis* (L.) G.Don which is distributed in various habitats in the Black Sea region in Turkey. Its local names are Kadırayak, Kaldirik, Deve pancarı, Ispıt, Zılbıt, Zıbıdık, Acı hodan, Doğu hodanı, Tamara. *T. orientalis* is an edible plant that flowering branches, rhizomes, leaves, petioles, young stems are sold in the in bazaar (open markets) in Black Sea region as vegetable until beginning of February end of June.

Traditional uses of Berberis sp. in Anatolia

Sahane Funda Arslanoglu ,
Ondokuz Mayis University, Turkey

The *Berberidaceae* family consists of 12 genera and 200 species. These are perennial herbaceous or bush form. That they contains berberine alkaloid which gives yellow color in woody parts. In Turkey, *Berberis vulgaris, Berberis integerrima, Berberis crataegiana, Berberis cretica* species naturally grown. The roots, bark, leaves and fruits of *Berberis sp*. is consumed as food, jam, molasses, sweet and tea in Anatolia.

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Ultrasensitive pulse-induced electrochemical sensor for cancer cell detection and drug delivery

Ruey-an Doong,
National Tsing Hua ,
University, Taiwan

Facile and efficient detection of cancer cells at their preclinical stages is one of the central challenges in cancer diagnostics. A direct, rapid, highly sensitive and specific biosensor for detection of cancer biomarkers is desirable in early diagnosis and prognosis of cancer. In this work, a pulse-triggered ultrasensitive electrochemical sensor has been fabricated using Angiopep conjugated with gold nanoparticles coated carbon sphere (Agp@Au-C) self-assembly approach. Introducing the external electrical pulse during the cancer cell accumulation step on the sensing electrode, it shows higher affinity towards cancer cells due to the expanded surface of the cancer cells, increasing the limit of detection compared to conventional electrochemical sensors.

The perspective and concern of apply chinese medicine in cancer care and new drug development

Tsai-Ju Chien,
Taipei City Hospital ,
Taiwan

In recent decade, Chinese herb has raised researchers' attention for the efficacy in clinical cancer care. Many patients in China adopt TCM as a complementary therapy and TCM do have benefit in improving chemotherapy related side effect, such as oral mucositis, fatigue and anorexia, etc. Accordingly, may researchers start to pay attention to Chinese herb and keen to develop new drug from Chinese herb.However, there are some concerns a in applying TCM in cancer care and also limitations in developing new drug from Chinese Medicine.

Membrane interactivity shared by different drugs that act on membrane-associated receptor, ion channel and enzyme: a tool for screening lead compounds

Hironori Tsuchiya,
Asahi University
,Japan

Lipids are no longer a structural component to constitute biomembranes but a critical factor to modulate the activity of membrane-associated proteins. Besides directly acting on functional proteins, receptor-, ion channel- and enzyme-acing drugs are presumed to interact with membrane lipids because of their common amphiphilic structure. In order to obtain insights into the drug target and mechanism, we studied the membrane interactivity of different drugs that act on representative receptor, ion channel and enzyme. Unilamellar vesicles were prepared with phospholipids and cholesterol to mimic the lipid composition of neuronal membranes.

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Chemomodulatory effect of betanin against paracetamol and diclofenac induced neurotoxicity and endocrine disruption in rats

Tarek K. Motawi,
Cairo University.
Egypt

Paracetamol and diclofenac are two of the most popular analgesics and anti-inflammatory medications. Despite of their several therapeutic benefits, their over consumption led to subsequent cellular damage. Their cytotoxicity is attributed to reactive radical generation. Betanin has antioxidant and anti-inflammatory properties. The protective effects of betanin against paracetamol or diclofenac induced neurotoxicity or endocrine disruption has not been investigated before. Therefore, this study aims to explore the protective potential of betanin against paracetamol or diclofenac neurotoxicity and endocrine disruption in a rat model.

Curcumin loaded microemulsion for brain targeting

Jayvadan Patel,
Sankalchand Patel University

This study was aimed at designing a successful mucoadhesive microemulsion system to accomplishsuperior brain uptake of curcumin through intranasal route. Mucoadhesive microemulsion ofcurcumin (MMEC) was prepared using screened oil, surfactant and co-surfactant by Box-Behnkendesign and was evaluated for mucoadhesion, stability and naso-ciliotoxicity study. A comparativebrain uptake of curcumin via nasal route was studied by performing bio-distribution study in Swissalbino rats. The result showed that all formulation variables i.e., amount of Capmul MCM (X1),Smix (Accenon CC: Transcutol P) (X2) and % of aq. Polycarbophil (X3) had a significant effect ($p<0.05$) on the responses. Developed MMEC was stable and non-ciliotoxic with 66.74 nm ± 3.46 and98.58 % ± 1.21 as average globule size and drug content, respectively.

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In-vivo evaluation of an oral solid self nano-emulsifying drug delivery system (S-SNEDDS) for embelin, an herbal active ingredient from Embelia Ribes

Jayvadan Patel,
Sankalchand Patel University

Embelin with wide range of medicinal properties is a highly lipophilic and water insoluble benzoquinone molecule found in Vidanga which suffers from erratic bioavailability. The objective of the present investigation was to prepare solid self nano-emulsifying drug delivery system (S-SNEDDS) of embelin and study its pharmacokinetic parameter in an animal model to assess its bioavailability. SNEDDS of embelin was formulated using capryol 90 as oil, acrysol EL 135 as surfactant and PEG 400 as cosurfactant.

A commercial herbal drug prior to intramuscular ceftriaxone injection for monitoring of cholestasis, intestinal absorption of lipid soluble substance and to increase efficacy for treatment of intestinal bacterial infection

Tapas K. Sar,
West Bengal University of Animal and Fishery Sciences,

The study was aimed to use a commercial herbal product with a single intramuscular injection of ceftriaxone by evaluating its disposition and intestinal absorption as the drug undergoes maximum hepatic clearence. Six goats (3 males and 3 females) were administered with a single intramuscular injection of 50 mg kg^{-1} ceftriaxone with 1 hour prior oral dosing of 1.9 gm of a commercial herbal drug (Fibrosin®) as it helps to prevent antimicrobial resistance in bacteria to antibiotics. Blood samples were collected at scheduled time intervals and analyzed for ceftriaxone concentration.

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Packaging challenge for biosimilar products

Anupam Chanda,
Alembic
Pharmaceuticals Ltd

Presently Packaging plays a significant role for Biosimilar product. The process of selecting materials and the type of packaging also offers an opportunity for the Packaging scientist to look for new biological delivery choices. Most injectable protein products were supplied in some sort of glass vial, prefilled syringe, cartridge. Those product having high Ph content there is a chance of "delamination "from inner surface of glass vial. With protein-based drugs, the biggest issue is the effect of packaging derivatives on the protein's three-dimensional and surface structure. These are any effects that relate to denaturation or aggregation of the protein due to oxidation or interactions from contaminants or impurities in the preparation.

Effective hybrid nanopaticulate system approached for synergistic drug delivery for solid tumor management

Madhu Gupta,
Delhi
Pharmaceutical
Science and
Research
University

Efficient dual targeted chemotherapy is an attractive approach for killing the tumor cells and tumor endothelial cells, while sparing the normal tissue. Herein, we investigated whether encapsulation of paclitaxel (PTX) within polymer–lipid hybrid nanoparticles conjugated with kNGR (PLNs-kNGR) achieved this goal in a subcutaneous tumor induced Balb/c mice bearing HT-1080 tumor model with nanocarrier-modified biodistribution and toxicity. The dual targeted PLNs-kNGR was prepared by modified nano-precipitation technique combined with self-assembly and evaluated for different parameters.

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Graph theoretical analysis, In silico modeling, prediction of ADME and synthesis of Novel 2-(methyl/phenyl)-3-(4-(5-substituted-1,3,4-oxadiazol-2-yl) phenyl) quinazolin-4(3H)-ones as NMDA receptor inhibitor

Theivendren Panneerselvam,
Karavali College of Pharmacy

A variety of novel 2-(methyl/phenyl)-3-(4-(5-substituted-1,3,4-oxadiazol-2-yl)phenyl) quinazolin-4(3*H*)-ones have been synthesized by treating 3-(4-(5-mercapto-1,3,4-oxadiazol-2-yl)phenyl)-2-(methyl/phenyl)-quinazolin-4(3*H*)-one with a variety of secondary amines. KEGG (Kyoto Encyclopedia of Genes and Genomes) database and Cytoscape software were used in graph theoretical analysis for identification of drug target i.e., NMDAR (N-methyl-D-aspartate receptors). The observed reports of *in silico* modeling and ligand based toxicity, metabolism prediction studies were encouraging us to synthesize of title compounds and evaluate their antiepileptic effects

Progression of controlled drug delivery technology

Anil Batta,
Govt.Medical College

Controlled drug delivery technology has progressed over the last six decades. This progression began in 1952 with the introduction of the first sustained release formulation. The 1st generation of drug delivery (1950–1980) focused on developing oral and transdermal sustained release systems and establishing controlled drug release mechanisms. The 2nd generation (1980–2010) was dedicated to the development of zero-order release systems, self-regulated drug delivery systems, long-term depot formulations, and nanotechnology-based delivery systems.

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Waiver of in vivo bioequivalence studies based on biopharmaceutics classification system

Al Awati Nabila,
Brighton University

Instead of conducting expensive and time-consuming in vivo studies to demonstrate whether two pharmaceutical products are equivalent, an in Vitro dissolution test could be adopted as the surrogate basis for the decision.At the beginning, US FDA considered the biowaiver for SUPAC to pharmaceutical products but now it considered for the application to approval of certain orally administered generic products. Biowaiver is considered only for APIs with high solubility and high permeability according to the biopharmaceutical classification system and which are formulated in solid, immediate release (IR) oral formulations

Method of additive modernization of preservation solutions that improved the quality, efficiency and safety transfusion of RBCs

Andrey Belousov,
Laboratory of Applied Nanotechnology of Belousov

This study was devoted to the learning of the use of nanotechnology to correct the functional activity of red blood cells (RBCs) at the storage stages at a positive temperature. It was established that saline NaCl, which had previously been processed by magnetite nanoparticles (ICNB) had a marked membrane-stabilizing effect, inhibits hemolysis and increasing the sedimentation stability of preserved RBCs. The complex analysis of the obtained data allowed to determine the primary mechanisms effect of the saline NaCl, which had previously been processed by ICNB on the preserved RBCs.

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Periodontal muscle training can strength the periodontal support Feet your teeth

Nima Sabzchamanara, National Medical University

Previous research on periodontal structure and function has shown a significant relationship between periodontal tissue and teeth. This study assessed dentist's beliefs about the relative efficacy of the health of periodontal tissue. A total of 505 patients in general pracrice were asked to respond to a list of 25 obligatory nourishment for a child while going to have the first teeth, for its effectiveness in dealing with patient's periodontal health especially include chewing hard food. They were also asked to select the three most effective nutrition for periodontal tissue.

Neoadjuvant chemotherapy in breast cancer

Hojouj Mohammad, Dnipropetrovsk medical academy of Health Ministry of Ukraine

The preoperative, or, as it is often called, neoadjuvant chemotherapy (NAPCT) of operable breast cancer (the breast cancer) with affected regional lymph nodes has in its time replaced preoperative radiotherapy, as it has a number of significant advantages over the latter. The most important advantage of NAPCT is its systemic action, which allows to "catch up" with probable distant micro metastases or circulating tumor cells, while pre-operative radiotherapy has a local effect, and on the systemic level the tumor continues to develop. Despite the fact that with operative breast cancer the time of NAPCT (before or after the operation) does not affect to the long-term results of treatment, the latter becames applicable even for operable breast cancer without affected regional lymph nodes.

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Abstract

Some aspects of medicine distribution in sudan

Abdeen M. Omer,
Occupational Health Administration

The strategy of price liberalisation and privatisation had been implemented in Sudan over the last decade, and has had a positive result on government deficit. The investment law approved recently has good statements and rules on the above strategy in particular to pharmacy regulations. Under the pressure of the new privatisation policy, the government introduced radical changes in the pharmacy regulations. To improve the effectiveness of the public pharmacy, resources should be switched towards areas of need, reducing inequalities and promoting better health conditions. Medicines are financed either through cost sharing or full private.

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