

# Pharmacy & Biopharma 2017



3<sup>rd</sup> International Conference on

BIOPHARMACEUTICS AND BIOLOGIC DRUGS  
&

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August 31-September 01, 2017 Philadelphia, USA

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## Poster Abstracts

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**Harmaline interaction with D2 signaling in tremor and attenuation of sensory-motor activity in mice**

Xiping Zhan

Howard University, USA

Essential tremor is one of the most common neurological disorders characterized by uncontrollable shaking and tremors throughout the body. Well known to affect adults, it can also affect children. Harmaline induced tremor is an established animal model for human essential tremor, but its underlying mechanism and effects on mood behavior are still elusive. This study aims to use pharmacological and behavioral methods to investigate the pharmacology in harmaline-induced tremor and the auditory startle response. Mice tremors and auditory startle responses were recorded by the Kinder Startle Monitor System. Harmaline (12.5 mg/kg) reliably induced tremor, and that can be attenuated by ethanol (1.5 mg/kg) and sulpiride (20 mg/kg). In addition, it caused the startle response to decrease significantly. Prepulse inhibition and gap responses also decreased upon harmaline injection and increased the following day, but not significantly from the controls. Supplemental administration following recovery can significantly attenuate gap detection without affecting prepulse inhibition. Our data confirms the frequency of the tremor was from 10-15 Hz, and the ethanol effect, which indicates validity as novel tremor assay. We also found that harmaline attenuates the auditory startle reflex by causing the reflex and gap detection to be suppressed, but did not affect prepulse inhibition significantly. These findings suggest harmaline not only specifically modulates sensory-motor integration, but also the timing of gap detection. Our data provides additional information that D2 receptors are involved in harmaline-induced tremor.

**Biography**

Xiping Zhan has his expertise in Neuropharmacology. His lab uses multiple interdisciplinary approaches to study neural circuits and underlying functional implications. He applies behavior measures to evaluate the neuropharmacology of small molecular drugs on tinnitus, tremor or mood behavior, and uses patch clamping or single unit *in vivo* recording to address the molecular mechanisms. In addition, he uses human iPS cell derived dopamine neurons to model pharmacology in human. He has been focused on tinnitus and tremor for years in research and teaching.

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**Evaluation of *keytruda* for metastatic non-small cell lung cancer****Dewilka Simons**

Temple University School of Pharmacy, USA

*Keytruda* (Pembrolizumab) is the only anti-PD-1 treatment approved for first-line combination with pemetrexed and carboplatin and/or as monotherapy for the treatment of metastatic non-small cell lung cancer (mNSCLC) in appropriate patients. Lung cancer is the second most common form of cancer in both men and women and NSCLC accounts for 80%- 85% of all lung cancers. The 5-year survival rate for metastatic lung cancer is <18.1%. Cancer immunotherapy works by enhancing or allowing the immune system to recognize and destroy cancer cells. Clinical responses targeting the programmed cell death-1 (PD-1) pathway have shown promise in improving survival while maintaining a relatively tolerable toxicity profile. Combination therapy with pemetrexed and carboplatin received accelerated approval based on tumor response rate and progression-free survival in clinical trials. In combination therapy, the use of *Keytruda* is irrespective of PD-L1 status. The use of *Keytruda* in the first-line monotherapy setting requires to have high expressions of PD-L1 with a tumor proportion score (TPS)  $\geq 50\%$  in which the TPS must be determined by an FDA-approved test. The monotherapy indication received approval based on overall survival and progression-free survival data in clinical trials.

**Biography**

Dewilka Simons is currently a third-year Pharmacy student at Temple University School of Pharmacy in Philadelphia. She has received her BS in Life Science from the Pennsylvania State University in 2014 with an emphasis in cultural studies. Her interests are transplant therapy, critical care and infectious disease in immunocompromised patients and patient education. She is the Vice President of the Interdisciplinary Health Advocacy (IDHA) a student run organization that promotes interprofessional patient outreach. She hopes to pursue PGY-1 and PGY-2 residency in solid organ transplant upon graduation.

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**Development and optimization of pH responsive crosslinked polymeric microparticulate system for solubility enhancement of Rosuvastatin calcium (RST)****Sajid Bashir**

University of Sargodha, Pakistan

**Statement of the Problem:** Low solubility in water as well as biological media leads to poor bioavailability that reflects sub-therapeutic response even at low doses. Rosuvastatin calcium (RST) is a synthetic lipid lowering agent of statin group that is widely used for the treatment of hyperlipidemia. It belongs to BCS-II and has crystalline nature. It presents solubility issues and poor bioavailability i.e. 20% with gastric media leading to patient non-compliance. These properties lead towards high cost of product as well as wastage of pharmaceutical resources.

**Methodology & Theoretical Orientation:** Aqueous free radical polymerization technique was adapted to prepare polymeric microparticles. Resultant lyophilized products were characterized for entrapment efficiency, FTIR, thermal analysis i.e. DSC & TGA, SEM, TEM, sol-gel fraction, PXRD, zeta size and zeta potential, swelling behavior, solubility studies, dissolution studies and pharmacokinetic evaluation. Release data was subjected to kinetic models to find out best fit model and mechanism of release of RST from micro-particles.

**Findings:** A highly stable, biocompatible and non-toxic polymeric network containing methacrylic acid as monomer was successfully developed. pH dependent swelling and ultimate higher drug release (85.74%) was seen at basic pH. 9.59 folds increased solubility of RST was proved when compared to the pure drug. Amorphous nature of RST within the microparticles was confirmed by PXRD. Compatibility among ingredients was confirmed by FTIR studies.

**Conclusion & Significance:** RST loaded hydrogel microparticles were prepared and optimized successfully to improve solubility. At pH 6.8 a marked increase in solubility of RST was seen. A rapid release and improved bioavailability of RST was offered by this newly prepared polymeric carrier system. These cheaper, non-toxic and biocompatible matrices can be used for solubility enhancement of other hydrophobic drugs.

**Biography**

Sajid Bashir has expertise in solubility and bioavailability enhancement of hydrophobic drugs and has devotedly enhanced solubility of various drugs by utilizing various techniques including the introduction of hydrogel microparticles in solubility enhancement in his Doctorate degree. Currently, he is working on nanocomposite hydrogels.

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# Accepted Abstracts

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**Quercetin ameliorates the hepato-renal toxicity induced by *Echis coloratus* snake venom in rats****Abdulrahman K Al Asmari, Rajamohamed Abbasmanthiri, Nasreddien Mohammed Abdo Osman, Sara Abdulrahman Al Asmari and Faiz Saeed**  
Prince Sultan Military Medical City, Saudi Arabia

The application of new drugs derived from plant resources were being investigated and explored by scientists since long ago, for snakebite treatment, as an alternative to anti-venom therapy, that has several limitations. Flavonoids, the naturally produced antioxidants, are abundantly available in plants, and are largely consumed in daily diet, recently. The aim of this study is to investigate and evaluate the potential effects of the flavonoid (quercetin) on envenoming of albino rats by sub-lethal venom (3.84 mg/kg, i.p.) doses of *Echis coloratus* (*Ec*) viper crude venom. Quercetin (30 µM/kg, i.p.) doses were administered to evaluate their beneficial effects on the induced venom hepato-renal toxicity by assessing and measuring selected stress biomarkers. Results were obtained by biochemical studies of tissues and sera after sacrificing the animal groups. Significant increase levels of AST, ALT, ALP and creatinine were observed. Histopathological damage of the tissue's architecture and rise in the liver and kidney MDA levels were also significant. In conclusion, the reversal effects of modulation of the biochemical parameters and histological damage are attributed to the potential protective effects that ensued after administration of the quercetin. However, further studies are warranted to facilitate that quercetin ameliorates the toxicity induced by *Ec* snake venom in experimental animals.

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**Vancomycin loaded super paramagnetic MnFe<sub>2</sub>O<sub>4</sub> nanoparticles coated with PEGylated chitosan to enhance antibacterial activity****Akbar Esmaeili and Sepideh Ghobadian Pour**  
Islamic Azad University, Iran

**Background & Aims:** Increasing prevalence of antibiotic-resistant and failed-treatment make more investigations to deal with these problems. Hence new therapeutic approaches for effective treatment are necessary. Ferrite super paramagnetic nanoparticles have potentially antibacterial activity.

**Methods:** In this study we prepared MnFe<sub>2</sub>O<sub>4</sub> super paramagnetic nanoparticles as core by precipitation method and used chitosan crosslinked by glutaraldehyde as shell, then modified with PEG to increase stability of particles against RES.

**Results:** Chitosan coating not only improves the properties of ferrite nanoparticles but also has antibacterial activity. FT-IR confirmed this surface modification XRD and SEM were developed to demonstrate particle size and characteristics of crystal structure of these nanoparticles. Final particle size was reported approximately 25 nm. Magnetic properties of nanoparticles were evaluated by VSM. Actual drug loading and releasing were examined by (UV-Vis) spectroscopy method.

**Conclusions:** We employed liquid broth dilution method to assessment antibacterial activity of nanoparticles against microorganisms. Significant antibacterial effect against gram negative bacteria was developed.

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**Synthesis and biological activity evaluation of 2-(5-substituted-1-((piperazino) methyl)-2-oxoindolin-3-ylidene) N-substituted-hydrazinecarbothioamides****Amol Kulkarni**

Siddhant College of Pharmacy, India

Various 5-substituted-2-(1-((piperazino) methyl) 2-oxoindolin-3-ylidene) hydrazine carbothioamide and 5-substituted-2-(1-((piperazino) methyl)-2-oxoindolin-3-ylidene)-N-(phenyl-4-substituted) hydrazine carbothioamide derivatives were synthesized. The compounds were screened for cytotoxicity against human HeLa and CEM T-lymphocytes as well as murine L1210 cells. Several of these compounds were endowed with low micromolar 50% cytostatic concentration (IC<sub>50</sub>) values, and some were virtually equally potent as melphalan. The most potent inhibitors against the murine leukemia cells (L1210) were also the most inhibitory against human T-lymphocyte (CEM) tumor cells. Derivative 2-(1-((piperazino) methyl)-2-oxoindolin-3-ylidene)-N-(4-methoxyphenyl)hydrazinecarbothioamide 5c emerged as the most potent cytostatic compound among the tested compounds. All derivatives showed antiviral activity against HeLa cell cultures (IC<sub>50</sub> 11–20 μM). The encouraging cytostatic and antiviral activity data provides an adequate rationale for further modification of these molecular scaffolds.

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**PhcrTx1, novel marine peptide acting on acid-sensing ion channels and its isolation and characterization****Armando Alexei Rodríguez Alfonso**  
Hannover Medical School, Germany

Acid-sensing ion channels (ASICs) are H<sup>+</sup>-gated Na<sup>+</sup> channels that belong to the ENaC/degenerin superfamily of sodium channels. ASICs are involved in sensory perception, synaptic plasticity, learning, memory formation, cell migration and proliferation, nociception, and neurodegenerative disorders, among other processes, therefore those molecules that specifically target these channels are of growing pharmacological and biomedical interest. Sea anemones produce a large variety of ion channels peptide toxins. However, those acting on ligand-gated ion channels, including acid-sensing ion channel (ASIC) toxins, remain poorly explored. PhcrTx1 is the first compound characterized from the sea anemone *Phymanthus crucifer*, and it constitutes a novel ASIC inhibitor. This peptide was purified by liquid chromatographic techniques, followed by biological evaluation on ion channels of isolated rat dorsal root ganglia (DRG) neurons using patch-clamp techniques. PhcrTx1 partially inhibited ASIC currents (IC<sub>50</sub> 100 nM). The N-terminal sequencing yielded 32 amino acid residues, with a molecular mass of 3477 Da by mass spectrometry. No sequence identity to other sea anemone peptides was found. Interestingly, the bioinformatics analysis of cys-pattern and secondary structure arrangement suggested that this peptide presents an inhibitor cystine knot (ICK) scaffold, which has been found in other venomous organisms such as spiders, scorpions, and cone snails. Our results show that PhcrTx1 represents the first member of a new structural group of sea anemones toxins acting on ASIC. Also, this peptide constitutes a novel template for the development of drugs against pathologies related to ASICs function.

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**Biosimilars: Challenges in safety and risk management****Asif Mahmood**  
Pfizer, USA

Advances in biotechnology have ensured a world of opportunities for biosimilars to enter the market and serve the needs of patients in a cost-effective manner. However, Pharmacovigilance and risk management for biosimilars present a significant challenge that arise from their unique characteristics as biologics as well as from their differences with the reference innovator products. Traditional PV processes may not incorporate sufficient provisions to meet the particular requirements for biosimilars. While a biosimilar and its reference drug can show similar efficacy, it can exhibit a different safety profile with respect to the nature, seriousness, or incidence of reported adverse events (AEs). Therefore, there is a need to clearly identify the specific product associated with the AE. Hence, product naming is an important consideration for biosimilars traceability. The potential for immunogenicity represents an important safety concern with all biologics, including biosimilars. The nature and severity of immunogenic reactions may differ from those observed for the reference innovator and immunogenicity data from the reference product may not be directly extrapolated to the biosimilar. Given the relatively small number/size of clinical trials required for regulatory approval of biosimilars, full characterization of the immunogenicity profile of a biosimilar may not be established at the time of regulatory approval. Continued post-marketing surveillance of biosimilars is critical for effective risk management. Also, the unique nature of biosimilars requires a labeling approach that combines data on the reference product with data specific to the biosimilar due to differences in their source materials, manufacturing processes and impurities. Finally, the safety specifications in the RMP of a biosimilar should include the identified and potential risks of the reference innovator product as well as risks identified from studies on the specific biosimilar product.

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**Effects of microbubble size on ultrasound-induced transdermal delivery of high-molecular-weight drugs**

Chih-Hung Wang, Taiwan

Ai-Ho Liao, Taiwan

Transdermal drug delivery can be assisted and enhanced by sonophoresis with ultrasound (US)-aided microbubbles (MBs). The conventional transdermal delivery of a wide range of high-molecular-weight drugs is limited by the outermost layer of the epidermis, with the stratum corneum representing the main barrier to penetration across the skin. The present study determined the different effects of various sizes of MBs that underwent US exposure to enhance the transdermal delivery of high-molecular-weight drugs. The effects of US-mediated MBs of different sizes (1.4, 2.1, and 3.5  $\mu\text{m}$ ) and ascorbyl tetraisopalmitate (VC-IP, a cosmetic ingredient for skin lightening) on enhancing skin transdermal delivery were demonstrated both *in vitro* and *in vivo*. The results indicated that the US power intensities of a 3 W/cm<sup>2</sup> penetration depth in the US group combined with 3.5- $\mu\text{m}$  MBs and penetrating VC-IP (U+3.5) were 34% and 14% higher than those in the US group combined with 1.4- $\mu\text{m}$  MBs and penetrating VC-IP (U+1.4) and US combined with 2.1- $\mu\text{m}$  MBs and penetrating VC-IP (U+2.1), respectively, for the agarose phantoms; the corresponding increases for pigskin were 37% and 19%. In terms of the skin permeation of VC-IP, the VC-IP concentrations in the U+3.5 group were 23% and 10% higher than those in the U+1.4 and U+2.1 groups, respectively. The whitening effect (luminosity index) of mouse skin in the U+3.5 group significantly increased by 28% after 1 week and 34% after 2 weeks, while it tended to stabilize after 3 weeks (45%), in C57BL/6J mice over a 4-week experimental period. In conclusion, to the best of our knowledge, this is the first study to demonstrate that US combined with MBs of different sizes can produce different degrees of skin permeability to enhance the delivery of high-molecular-weight drugs like VC-IP for skin brightness without damaging the skin.

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**Design, synthesis and biological evaluation of novel antiproliferative agents****Dinesh Kumar**

Guru Nanak Dev University, India

4,6-diarylpyrimidones as constrained chalcone analogues have been synthesised in the present study. The synthesised compounds were evaluated against a panel of human cancer cell lines. Striking selectivity was displayed by the compounds against MiaPaCa-2 (Pancreatic) cell lines while PC-3 (prostate) and A-549 (lung) cell lines were almost resistant to the exposure of the test compounds. Compound SK – 25 exhibited remarkable cytotoxicity against MiaPaca-2 cell line with an IC<sub>50</sub> value of 1.95  $\mu$ M and was found to induce apoptosis evidenced through phase contrast microscopy, DAPI staining and mitochondrial membrane potential loss. The cell phase distribution studies indicated that the apoptotic population increased from 1.79% in control sample to 30.33% in sample treated with 20  $\mu$ M compound SK-25.

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**Nanoparticles: A novel approach to drug development, targeting and therapeutic monitoring****Douglas Taylor**

Harrisburg University, USA

**Statement of the Problem:** Currently, for most cancers, diagnostic tests are too expensive and invasive; primarily detect late-stage cancers exhibit too many false negatives/positives to be reliably used. Traditional tissue biopsies provide limited value due to access and availability of samples. Further, cancers that have spread often differ from the primary and tumor cells change in response to treatment. Based on these heterogeneities, traditional biopsies can only provide a limited window into the dynamic genetic and translational changes occurring in tumors, resulting in an ineffective view of tumor progression and metastasis.

**Methodology & Theoretical Orientation:** Liquid biopsies, or blood-sample tests can generate actionable information by analyzing circulating components released from the tumor. The most common version of the liquid biopsy comprises either circulating tumor cells (CTC) or fragments of tumor cell-derived DNA (cell-free DNA or cfDNA). Since CTCs are markers of metastatic disease, they have limited application for initial diagnosis or identification of early stage disease. cfDNA is generated from necrosis and apoptosis and are thus the product of cell death, from both normal and tumor cells. Analysis of cfDNA provides limited information about tumor cells not affected by specific therapies. In contrast, using our proprietary technology, it is now possible to enrich for circulating exosomes (50-200 nm vesicles), released specifically by tumor cells.

**Findings:** From these cancer specific exosomes, the transcriptome and proteome of the tumor cells can be defined. By detecting and quantifying genomic alterations reflected in tumor exosomes, these can provide real-time information on tumor progression, therapeutic targets and treatment effectiveness. We have developed an IVD cancer platform based on our discovery and characterization of exosomes derived from biofluids, including blood, saliva, cerebrospinal fluid and urine. These exosomes mirror protein and RNA components present in the tumor cell that released them.

**Conclusion & Significance:** Analysis of proteins and RNA cargoes of exosomes derived specifically from the tumor provides critical information in identifying and monitoring tumor type and stage, as well as predicting and monitoring responses to therapy and targets for therapy.

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**Formulation and evaluation of liquid crystalline nanoparticles of artemether and lumefantrine for the treatment of malaria****Vandana Chaudhary<sup>1</sup>, Shakir Hussain<sup>2</sup> and Vijay Bhalla<sup>1</sup>**<sup>1</sup>SGT College of Pharmacy, India<sup>2</sup>Sidhi Vinayak College of Science, India

Liquid crystalline nanoparticles of artemether and lumefantrine were prepared by using glyceryl monooleate, oleic acid, poloxamer 407, ethanol and water. The optimization of liquid crystalline nanoparticles was achieved by response surface methodology (BBD). 17 trials were prepared making use of artemether, lumefantrine and oleic acid in varying concentration and GMO, poloxamer, ethanol and water were kept constant. Out of these F9 formulation was found best formulation. The selection was made based on particle size and entrapment efficiency of artemether and lumefantrine. Optimized formulation (OF1) contained particle size in the range of 193.5-194 nm (PDI 0.10) indicated that particle size was uniform. Entrapment efficiency of artemether and lumefantrine were found 85% and 95.5%. Release study of artemether and lumefantrine revealed that the drugs were released in a remarkably controlled manner up to 72 hrs. Physical and chemical stability study revealed that the optimized formulation (OF9) was physically and chemically stable.

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**Novel nitroimidazole analog as a potent anti-tuberculosis agent****Gurleen Kour**  
CSIR, India

New compounds against tuberculosis are urgently needed to combat the crisis of drug resistance in tuberculosis (TB). We have identified a novel nitro-dihydro-imidazooxazole (NHIO) analog, as a new anti-tubercular agent with a MIC of 0.21  $\mu\text{M}$  against H37Rv. Physicochemical properties, drug metabolism and pharmacokinetics (DMPK) were studied for the compound. Physicochemical parameters were determined *in silico*. Lipophilicity was determined experimentally as octanol-PBS partition coefficient ( $\log P$ ). Passive and active permeability of the compound was determined by PAMPA and Caco-2 cell permeability analysis, respectively. Plasma protein binding was found by rapid equilibrium dialysis. The compound was found to be stable *in vitro* in liver microsomes with very low intrinsic clearance. The compound exhibited very good lipophilicity ( $\log P$ ) which makes it optimal for oral administration. The compound showed a low solubility and permeability and high plasma protein binding. However, it was highly stable in rat liver microsomes with very low intrinsic clearance. It was found to be non-hepatotoxic and did not induce any significant DNA damage at high concentrations up to 50  $\mu\text{M}$ . The compound did not have any inhibitory effects on human CYPs 1A2, 2C9, 2D6, 3A4 and 2C19 up to concentrations of 50  $\mu\text{M}$ , which is an important attribute for a TB-drug. The compound showed satisfactory *in-vivo* pharmacokinetic properties and a good oral bioavailability of 46.5%. The results insinuate that the novel NHIO analog should undergo further development as a potential treatment for tuberculosis.

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**Development and cytotoxicity evaluation of respirable nanomicelle carriers for delivery of tretinoin by jet nebulizer****Maryam Rezaeizadeh, Abbas Pardakhty and Hamid Forutanfar**  
Kerman University of Medical Sciences, Iran

**Background & Objectives:** Lung cancers are serious and lethal problems in cigarette smoking patients. Direct deposition of cytotoxic drugs to the site of neoplasm (lungs) and avoiding the systemic side effects and drug interactions are some benefits following inhalation of anticancer agents which can be an effective and safe alternative to systemic administration. The aim of present study is to prepare and characterize chitosan-stearic acid conjugate nanomicelles for encapsulation of all-trans retinoic acid (ATRA).

**Methods:** Water soluble chitosan was grafted to stearic acid (SA) chains via 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide mediated coupling reaction. The chemical structure of depolymerized chitosan (DC)-SA copolymers and degree of amino substitution was determined by <sup>1</sup>H NMR. ATRA loaded micelles were prepared by film hydration, solvent evaporation and dialysis method. The physicochemical properties and formation of polymeric micelles were studied by dynamic light scattering and fluorescence spectroscopy methods. Nanomicelle size and zeta potential and ATRA entrapment efficiency were determined and the cytotoxicity of the formulations was also evaluated on A549 cell line by MTT assay. ATRA-loaded micelles were also characterized for their nebulization efficiency and retention of ATRA in the micelles after nebulization.

**Results:** ATRA was loaded in nanomicelles with entrapment efficiencies more than 70%. Nanomicelles possessed positive charges with mean particle sizes of less than 300 nm. The IC<sub>50</sub> of ATRA nanomicelles showed increased cytotoxic potential of drug. Transmission electron microscopy (TEM) revealed the spherical shape of prepared nanomicelles. The nebulization efficiency was up to 89% and the fine particle fraction (FPF) varied from 38% to 47%. The micelles had enough stability to remain encapsulation of the drug during nebulization process.

**Conclusions:** The results exhibited the potential of DC-SA micelles as a suitable carrier for delivery of ATRA by different routes of administration, specially the pulmonary route via jet nebulization.

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**Curcumin potentiates the function of human  $\alpha 7$ -nicotinic acetylcholine receptors expressed in SH-EP1 cells**Murat Oz<sup>1</sup>, Eslam El Nebrisi<sup>2</sup>, Keun-Hang Susan Yang<sup>3</sup> and Nadine Kabbani<sup>4</sup><sup>1</sup>Qatar University, Qatar<sup>2</sup>UAE University, UAE<sup>3</sup>Chapman University, USA<sup>4</sup>George Mason University, USA

Effects of curcumin, a biologically active ingredient of turmeric, was tested on the Ca<sup>2+</sup> transients induced by the activation of  $\alpha 7$  subunit of the human nicotinic acetylcholine ( $\alpha 7$  nACh) receptor expressed in SH-EP1 cells. Curcumin caused a significant potentiation of choline (1 mM)-induced Ca<sup>2+</sup> transients with an EC<sub>50</sub> value of 231 nM. The potentiating effect of curcumin was not observed in Ca<sup>2+</sup> transients induced by high K<sup>+</sup> (60 mM) containing solutions or activation of  $\alpha 4\beta 2$  nACh receptors. Notably, the effect of curcumin was not observed when curcumin and choline were co-applied without curcumin pre-incubation. The effect of curcumin on choline-induced Ca<sup>2+</sup> transients was not reversed by pre-incubation with inhibitors of protein C, A, and CaM kinases. Metabolites of curcumin such as tetrahydrocurcumin, demethylcurcumin, and didemethylcurcumin also caused potentiation of choline-induced Ca<sup>2+</sup> transients. Collectively, our results indicate that curcumin directly potentiate the function of the  $\alpha 7$ -nACh receptor expressed in SH-EP1 cells.

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**Antidiabetic activity and phytoconstituents of *Anthocleista nobilis***

Philip F Uzor, Joshua E Ahiabuike, Helen N Ani and Charles O Nnadi

University of Nigeria, Nigeria

The incidence of diabetes mellitus is rising at an alarming rate but the conventional drugs used for its management have many limitations. Herbal medicines are known to be effective and safe for use in its management. *Anthocleista nobilis* G. Don (*Gentianaceae*) is a plant used in the traditional management of diabetes. The present study was therefore designed to establish and hence validate the use of the plant for the management of diabetes. It was also aimed at investigating quantitatively the class of phytoconstituents present in the root and stem bark the plant. Phytochemical studies were done by the standard procedures. The root and stem bark extracts of the plant were investigated for antidiabetic activity in alloxan-induced diabetic rats. The animals were treated orally with 100, 200 and 400 mg/kg of both extracts for seven days. The fasting blood glucose (FBG) of the animals was monitored for seven days. Abundance of terpenoids, alkaloids, flavonoids and tannins were observed in both parts of the plant. Results also showed that the root and stem bark extracts significantly ( $p < 0.001$ ) reduced the FBG of the diabetic animals in a dose related manner. The present study has validated the acclaimed traditional use of *A. nobilis* in the management of diabetes. Terpenoids, alkaloids, flavonoids and tannins could be responsible for the antidiabetic activity of the plant.

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**Transition metal complexes/organometallic compounds as anticancer/anti HIV drugs or in pharmaceutical industry****Prakash Kinthada**

Sri Vidyanikethan Engineering College, India

Cancer is a dreadful disease and any practical solution in combating this disease is of paramount importance to public health. Cancer patients have burdened by drug induced toxic side effects, and no turned to seek help from the complementary and alternative medicine hoping for a better cure. Research on Platinum based drugs and Non Platinum based drugs is a Multi-Million Dollar Industry in USA and there is every need to produce safe drugs for the cure of this monstrous disease. Flavonoids have a long history of use in traditional medicines in many cultures. The phytochemical, curcumin is one of the major dietary flavonoid, belonging to a group of flavonol, Curcumin is a natural polyphenol. It is highly potential molecule capable of preventing and treating various cancers. Various dietary chemo preventive agents, turmeric powder or its extract are broadly used as therapeutic preparations in Indian System of medicine. We provide a summarized synthesis and structural determination of Curcumin Oxime, Curcumin Thiosemicarbazone derivative of Gold (III) complex. The use of these analogs for prevention of cancer tumor progression and treatments of human malignancies. A pharmacologic agent for treating and/or preventing cancer, among other diseases and conditions, and particularly breast, prostate, and pancreatic cancer, in humans and animals. The novel pharmacologic agent is an isoflavonoid or isoflavonoid mimetic covalently attached to a cytotoxic pharmacophore that, preferably has the ability to conjugate with a metal salt to form a more potent metal complex, particularly a Au (III) complex and other complexes of Platinum, Palladium, Ruthenium, Copper etc.

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3<sup>rd</sup> International Conference on

BIOPHARMACEUTICS AND BIOLOGIC DRUGS

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5<sup>th</sup> INTERNATIONAL PHARMACY CONFERENCE

August 31-September 01, 2017 Philadelphia, USA

**Inhibition of spermatogenesis with the treatment of 50% methanolic extract of *Maytenus emarginata* leaves in Albino rats****Pratap Chand Mali**

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Since population explosion threatens to human resources contraceptives used to check population. Due to drawbacks and side effects of contraceptives, Scientists are still trying to search a new economic, reversibly effective and safe contraceptive from plants. Many plants have been explored for their fertility regulating properties around the world including India and China in search to discover a male contraceptive agent because humans depend on plant products as sources of herbal therapeutic agents without causing any side effects. The present study was planned to evaluate antifertility and reversible contraceptive activity, therefore, 50% methanolic extracts of *Maytenus emarginata* leaves was prepared according WHO guidelines and administered orally at the dose of 50, 100, 200 mg/kg/body wt/day for 60 days to develop an orally effective and reversible male contraceptive. Results of the present study reveal a significant decline in the sperms motility and density of extract treated rats as compared to control. The weight of seminal vesicles and testes was significant decreased in rats followed extract treatment suggests anti-androgenic effects in rats. Proteins, ascorbic acid, cholesterol and fructose contents in testis and sex accessory reproductive organs, as well as FSH, Testosterone hormones levels were decreased in rats treated with the extract. Histological observation of testes showed degenerative changes in spermatogenesis in the lumen of seminiferous tubules, reduced sperm number might be due to inhibition of spermatogenesis caused reduction of fertility in extract treated rats. It can be concluded that oral treatment of 50% methanolic extract of *Maytenus emarginata* decreased fertility of male rats might be due to the decreased level of proteins, fructose and hormones.

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August 31-September 01, 2017 Philadelphia, USA

**Formulation, design and evaluation of fast dissolving tablets of fexofenadine hydrochloride by lyophilization technique**<sup>1</sup>Rajendra Kotadiya and <sup>2</sup>Bhavin Bhalani<sup>1</sup>Sigma Institute of Pharmacy, India<sup>2</sup>Indukaka Ipcowala College of Pharmacy, India

In the present study an attempt was made to formulate and evaluate fast dissolving tablets containing Fexofenadine HCl as a model drug by Lyophilization technique. Fexofenadine HCl, is a non-sedating anti histamine used in the symptomatic relief of allergic conditions including seasonal allergic rhinitis and urticaria with poor aqueous solubility. The study was aimed to enhance the aqueous solubility and dissolution of drug by developing it into Lyophilized tablets. The Lyophilized tablets were prepared by dispersing the drug in an aqueous solution of highly water-soluble polymers (gelatin, maltodextrose and acacia) with glycine and mannitol. The mixture was poured into the pockets of blister packs and subjected to freezing followed by Lyophilization. Prepared Lyophilized tablets were characterized by XRD, SEM, Mercury porosimetry, solubility, wetting, water absorption ratio, drug content, dissolution and stability studies. Characterizations showed that tablets containing acacia had fast disintegration and higher mechanical strength with improved solubility of Fexofenadine HCl. XRD study revealed that the physical state of drug was unchanged with decreased crystalline structure. A good porous structure was observed for tablets as per SEM. The total porosity, wetting time, water absorption ratio and drug content were found to be 23.27%, 7sec, 80.22 and 97.78%, respectively. Dissolution study showed almost 90% of drug released in 5 minutes. Comparison of selected batch was made with the marketed formulation (MF) where our formulated batch showed 90% drug release in 30 min compared to 7 min for MF. Moreover, tablets were found to be stable over a period of one month as well.

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August 31-September 01, 2017 Philadelphia, USA

**Paradigm shift in classical drug research: Challenges to modern pharmaceutical sciences****Riddhi H Shukla, Rajeshri D Patel, Prakruti R Buch, Tejas P Sharma, Mihir K Raval and Navin R Sheth**  
Saurashtra University, India

Many classical drugs are claimed to have blood sugar lowering properties that make them valuable for people with or at high risk of type 2 diabetes. Vijaysar (*Pterocarpus marsupium*) and Gaumutra (Indian cow urine) both have been shown antidiabetic property since primordial time and both shows synergistic effect in combination for hypoglycaemic activity. The study was undertaken to investigate the hypoglycaemic and anti-diabetic effects of the combination of Vijaysar and Gaumutra which is a classical preparation mentioned in Ayurveda named as Pramehari ark. Rats with Type 2 diabetes which is induced by streptozotocin (STZ, 35mg/kg) given a high-fat diet for one month and compared with normal rats. Diabetic rats showed raised level of body weight, triglyceride (TG), total cholesterol, HDL, LDL, and D-glucose concentration and other serum, cardiac and hypertrophic parameters in comparison of normal rats. After treatment of different doses of drug the level of parameters like TG, total cholesterol, HDL, LDL, and D-glucose concentration found to be decreased in standard as well as in treatment groups. In addition treatment groups also found to be decreased in the level of serum markers, cardiac markers, and hypertrophic parameters. The findings demonstrated that Pramehari ark prevented the pathological progression of type 2 diabetes in rats.

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**Design and evaluation of press coated pulsatile release tablets of prednisolone****Upendra L Patel**

Arihant School of Pharmacy and Bio-Research Institute, India

To formulate and evaluate a press coated pulsatile release tablets of prednisolone using an admixture of hydrophilic polymer, i.e., low substituted hydroxy propyl cellulose (L-HPC) and hydrophobic polymer, i.e., ethyl cellulose (Ethocel 10 cps) to achieve a pre-determined lag time for chronotherapy of rheumatoid arthritis. The press coated pulsatile tablets containing prednisolone in the inner core were prepared by compression coating with L-HPC and Ethocel 10 cps as the outer layer in different ratios. The effect of polymer ratio and weight gain of the outer layer on lag time of drug release was investigated using 32 full factorial design. The parameters determined were tablet hardness, friability, drug content, lag time, *in vitro* dissolution. The release profile of the press coated tablet exhibited a distinct lag time before burst release of prednisolone. Lag time was dependent on the ratio of L-HPC/Ethocel 10 cps and weight gain in outer shell. The lag time was from 1 to 10 hours and could be modulated as it decreased as the amount of L-HPC in the outer layer increased. A surface plots are also presented to graphically represent the effect of independent variables on the lag time. The validity of generated mathematical model was tested by preparing checkpoint formulation. Formulation PCPT7 with L-HPC/Ethocel 10 cps (10:90) and weight gain 300 mg showing predetermined lag time of 5 hours prior to burst release of the drug from the press coated tablet was taken as the optimized formulation.

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**Probucol protects endothelial progenitor cells against oxidized low-density lipoprotein via suppression of reactive oxygen species formation *in vivo***

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Oxidized low-density lipoprotein (Ox-LDL) is a major component of hyperlipidemia and contributes to atherosclerosis. Endothelial progenitor cells (EPCs) play an important role in preventing atherosclerosis and notably decreased in hyperlipidemia. Ox-LDL and Ox-LDL-related reactive oxygen species (ROS) have deleterious effects on EPCs. Probucol as an antioxidant and anti-inflammatory drug reduces ROS production. The present study was to determine if probucol could protect EPCs from ox-LDL *in vivo* and to investigate the potential mechanisms. Ox-LDL was injected into male C57BL/6 mice for 3 days with or without probucol treatment with PBS as control. Bone marrow (BM) fluid, serum, circulating mononuclear cells (MNCs) and EPCs were collected for analysis. The increased extracellular ROS in BM, serum and blood intracellular ROS production in the mice with Ox-LDL treatment in association with a significant reduction of circulating MNCs and EPCs were restored with probucol treatment. A significant increase in the serum Ox-LDL and C-reactive protein and decrease in superoxide dismutase and circulating MNCs and EPCs were observed in hyperlipidemic patients that were effectively reversed with probucol treatment. These data suggested that probucol could protect EPCs from Ox-LDL through inhibition of ROS production *in vivo*.

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**CHO glycosylation mutant cells as potential hosts for production of therapeutic biologics with enhanced efficacy****Zhiwei Song**

Agency for Science, Technology and Research, Singapore

Glycosylation can significantly affect the efficacy of recombinant therapeutics. Glycoprotein drugs require a high degree of sialylation of their N-glycans for a longer circulatory half-life. Mannose-terminated N-glycans can specifically target the proteins to macrophages and dendritic cells via mannose-binding receptors. Removal of core fucose from human IgG1 has been shown to significantly enhance its affinity to FcγRIIIa and thereby dramatically improves its antibody-dependent cellular cytotoxicity (ADCC). Cancer cells generally express glycoproteins with shortened O-glycans. Therefore, recombinant anti-cancer vaccines carrying these short tumor-associated O-glycans are more ideal for triggering specific anti-tumor immune responses. With cytotoxic lectins and the newly-developed genome editing technologies, such as ZFNs, TALENs and CRISPR-Cas9, we have generated more than 20 CHO glycosylation mutant cell lines. Some of these mutant lacks one specific glycosylation genes whereas others lack more than 10 glycosylation genes. With these CHO cell mutants, we have been able to produce highly sialylated EPO, recombinant human β-glucocerebrosidase with mannose-terminated N-glycans (like Cerezyme, but no need for *in vitro* glycan modification) and fucose-free antibodies. Furthermore, these mutant CHO cells can produce recombinant antibodies carrying different N-glycans with highly homogenous structures (90-97%). These are invaluable tools for antibody PK/PD studies on the impact of different N-glycans.

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