3rd World Congress on

NATURAL PRODUCTS CHEMISTRY AND RESEARCH

&

12th WORLD PHARMA CONGRESS

October 16-18, 2017 Budapest, Hungary

Scientific Tracks & Abstracts

Day 1

Sessions:

Day 1 October 16, 2017

Natural Products | Natural Products Chemistry | Pharmacognosy & Phytochemistry | Mass Spectroscopy | Methods of Chromatography | Natural Products Research & Drug Discovery Agriculture Chemistry | Natural Products Research to Medicine

Session Chair
Euis Holisotan Hakim
Institut Teknologi Bandung, Indonesia

Session Introduction

Title: **Anti-inflammatory effects of a PPAR-γ agonistic phthalimide analogue**
Jee H Jung, Pusan National University, South Korea

Title: **Anti-inflammatory activityof *Euphorbia tithymaliodes L.* ethanol extract in lipopolysaccharide-stimulated RAW264.7 macrophages**
Seong Gu Hwang, Hankyong National University, South Korea

Title: **New cytotoxic diels-alder type adducts from root cultures of *Morus alba var. shalun***
Rizki Fitriani, Bandung Institute of Technology, Indonesia

Title: **STVNa, A promising medicine for cardiac protection**
Wen Tan, Guangdong University of Technology, China

Title: **Self-medication, practiced globally is an important public health problem**
Dnyanesh Limaye, University of Hannover, Germany

Title: **Isolation of Lycopodium alkaloids from Thai and Philippine *Huperzia squarrosa* and syntheses of *Huperzine A* derivatives via amidation reaction**
Thanasan Nilsu, Chulabhorn Royal Academy of Science, Thailand

Title: **Polydatin displays antitumour activity against murine melanoma *in vitro* and *in vivo***
Maria Pia Fuggetta, Istituti Fisioterapici Ospitalieri, Italy

Title: **Multifunction of saffron and its component**
Yukihiro Shoyama, Nagasaki International University, Japan

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Anti-inflammatory effects of a PPAR-γ agonistic phthalimide analogue

Jee H Jung, Mingzhi Su, Jiafu Cao, Jin Huang, Sen Liu, Dong-Soon Im and **Jin-Wook Yoo**
Pusan National University, South Korea

Previously, we isolated a new compound paecilocin A as a PPAR-γ binding molecule from the jellyfish-derived fungus *Paecilomyces variotii*. Based on the molecular framework of paecilocin A, a series of phthalimide analogues were synthesized and evaluated for PPAR-γ binding activity. In a subsequent screening for competitive binding activity, 4-hydroxy-2-(4-hydroxyphenethyl) isoindoline-1,3-dione (PD1) showed good PPAR-γ agonistic activity. Since one of the functions of PPAR-γ is suppression of inflammatory responses, the present study aimed to investigate anti-inflammatory activity of PD1. Transcriptions of mRNA were determined by reverse transcriptase-PCR. Inflammatory protein expressions were determined by ELISA and Western blot method. In Lipopolysaccharide (LPS)-stimulated murine macrophage RAW264.7 cells, PD1 suppressed the induction of pro-inflammatory factors including inducible Nitric Oxide Synthase (iNOS), Nitric Oxide (NO), Cyclooxygenase 2 (COX-2), Tumor Necrosis Factor α (TNF-α), interleukine 1β (IL-1β), and interleukine 6 (IL-6) in both mRNA level and protein level. In parallel, PD1 enhanced expression of anti-inflammatory factors such as arginase-1 and interleukine 10 (IL-10). PD1 simultaneously suppressed LPS-evoked Nuclear Factor kappa B (NF-κB) p65 subunit phosphorylation in macrophages. The anti-inflammatory mechanism of PD1 is proposed to be via inhibition of NF-κB pathway. In subsequent *in vivo* animal experiment employing carrageenan-induced acute inflammatory paw edema model, PD1 showed significant reduction in paw swelling. Histological analysis of tissue sections revealed reduction of cellular infiltration of immune cells in PD1-treated groups. These findings suggest that PD1 may serve as an anti-inflammatory lead.

Biography

Jee H Jung has his expertise in isolation, structure elucidation, and biological evaluation of new compounds from marine organisms. In recent years, his research was focused on the study of bioactive compounds from marine invertebrate-derived microorganisms. Further studies on optimization of lead compounds by docking simulation-based analogue synthesis and enhancement of bioavailability by nanoparticle formulation are also his major research interests.

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Anti-inflammatory activity of *Euphorbia tithymaliodes* L. ethanol extract in lipopolysaccharide-stimulated RAW264.7 macrophages

Seong Gu Hwang[1], Theresia Galuh Wandita[1], Seong Hyeon Bae[1] and **Joseph Dela Cruz[2]**
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[2]University of the Philippines Los Banos, Philippines

Euphorbia tithymaloides L. is native plant growing in tropical and subtropical areas of Asian countries. It has been known as traditional medicine with a wide range of healing properties such as anti-oxidant, anti-inflammatory, anti-hemorrhage, anti-diabetic, antibiotic, and anti-tumoral. It contains some bio-active compounds such as beta-sitosterol, cycloartenone, octacosanol, oxime, etc. In earlier *in-vitro* study, octacosanol has reduced the expression of mRNA or protein of pro-inflammatory cytokines. This study is aimed to evaluate the anti-inflammatory activity of *Euphorbia tithymaloides* L. ethanol extract (ETE) in RAW264.7 macrophages. Anti-inflammatory activity was studied by treating RAW264.7 murine macrophages cells with increasing concentration of the ETE extract (50, 100, 200, and 400 µg/ml). Lipopolysaccharide (LPS) was used to activate the cells. CCK-8 assay and Griess reagent were used to examine the cell viability and Nitric Oxide (NO) production, respectively. The result shows increasing concentration by 200 µg/ml increases cell proliferation then declines. On the other hand, Nitric Oxide (NO) production decreases with the increase of concentration of the extract. Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was used to measure the mRNA expression of pro-inflammatory cytokines. Western blotting was also done to examine the effect of ETE extract on the protein expression of RAW264.7 murine macrophages cells. It has been shown that increasing concentration decreased the mRNA expression of IL-6, iNOS, COX-2, TNF α, IFN γand NF-kB, as well as protein expression. In conclusion, the results support the empirical use of *Euphorbia tithymaloides* L. ethanol extract as an anti-inflammatory medicine.

Biography

Seong Gu Hwang has completed his higher qualification from Hankyong National University, Korea and currently working in Department of Animal Life and Environmental Science, Hankyong National University, Korea.

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Notes:

Rizki Fitriani, American Journal of Ethnomedicine, 4:2
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New cytotoxic diels-alder type adducts from root cultures of *Morus alba* var. *shalun*

Rizki Fitriani
Bandung Institute of Technology, Indonesia

Morus is one genus of plants belonging to *Moraceae* family that has important economic and medicinal value. The leaves of some *Morus* plants are indispensable food for silkworm, while their root bark has been used for treatment of diabetes, arthritis, and rheumatism. Previous phytochemical investigation showed that this genus produces a variety of phenolic compounds including stilbenes, 2-arylbenzofurans, flavonoids, and Diels-Alder adducts. Diels-Alder type adducts are the unique ones due to their complex and fascinating structures. Some of these compounds showed important and various bioactivities, such as cytotoxicity, antioxidant, antimicrobial, anti-inflammatory, and antiviral. The source of biologically important secondary metabolites was obtained conventionally from the intact plants. However, recent development in plant biotechnological approach has shown the possibility of plant tissue cultures as an alternative source for producing bioactive secondary metabolites. Therefore, the isolation and characterization of secondary metabolites from *Morus alba* var. *shalun* root cultures were implemented in this research. Three new Diels-Alder type adducts (1-3) together with two known Diels-Alder type adducts (4-5) were isolated from the EtOAc extract of liquid medium and MeOH extract of *Morus alba* var. *shalun* root cultures. The structures of the isolated compounds were elucidated based on a comprehensive analysis of spectroscopic data, including 1D, 2D, and MS data. Compound 1-5 exhibited significant cytotoxicity against murine leukemia P-388 cells with IC_{50} values 0.7, 0.7, 2.0, 1.7, and 0.6 μg/mL respectively. These results demonstrate the potency of compound 1-5 as the lead compounds for anticancer agent.

Biography

Rizki Fitriani has completed her Master's degree in Natural Products Chemistry from Bandung Institute of Technology. She is currently a Doctoral Candidate at the same university. Her research interests focus on natural products isolation and their structural characterization, as well as bioassay on the isolated pure compounds.

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Wen Tan, American Journal of Ethnomedicine, 4:2
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STVNa, a promising medicine for cardiac protection

Wen Tan
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Cardiac ischemia or hypertrophy involves multiple mechanisms and may lead to heart failure. Few medicines are now available for effective treatment. STVNa, derived from Stevia, has been shown beneficial effects in protection of acute cardiac ischemia. Our recent studies demonstrated that in animals with chronically coronary occlusion, consecutive oral treatment of STVNa significantly ameliorated the deterioration of cardiac function with reduced area of infarction and apoptosis. Long-term treatment of STVNa in Transverse Aortic Constriction (TAC) rats also protected the heart from fibrosis and hypertrophy remodeling and improved both cardiac systolic and diastolic function. In isoproterenol treated ventricular myocytes, STVNa reduced hypertrophy, inhibited the increases in cytosol calcium or ROS, and preserved contractility and mitochondrial membrane potential. Proteomic analysis, cell biochemistry and electrophysiological studies indicated that STVNa protected the heart against fibrosis and remodeling of metabolite and electrophysiology during ischemia and/or reperfusion injury or hypertrophy.

Biography

Wen Tan is a Professor and Dean at Institute of Biomedical and Pharmaceutical Sciences, Guangdong University of Technology, Guangzhou, China. He has his expertise in "Thousand Talents" plan in China (2012). Professor Tan earned his medical degree at HB Medical School in China and earned his PhD. from University of Nebraska Medical Center in USA. After post-doc trainings at Harvard Medical School, he joined Howard Hughes Institute& Columbia University in USA as an associate research scientist and research assistant professor. In late of the nineties, he returned to China as a founder of a pharmaceutical research company which has successfully registered more than ten generic & innovative drugs for China market since.

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Self-medication, practiced globally is an important public health problem

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Introduction: Self-medication, practiced globally is an important public health problem. Research studies have indicated inappropriate self-medication results in adverse drug reactions, disease masking, antibiotic resistance and wastage of healthcare resources.

Objectives: The objective of the study is to explore overall self-medication and antibiotic self-medication prevalence among students of university students in Karachi, Pakistan along with probable reasons, indications, and sources of advice for self-medication.

Methods: A descriptive, cross-sectional, questionnaire-based study was carried out among students from University of Karachi, Pakistan during the time period of September to November 2016. Pretested questionnaire was distributed to 320 students and the collected data was analyzed using IBM SPSS version 24.

Results: From 320 students, 311 (83 male and 228 female) students participated in the study giving a response rate of 97%. Prevalence of self-medication was 66%. Belonging to higher monthly family income group was associated with likelihood of self-medication. Antibiotic self-medication prevalence was 39%. Lack of time (39%), and old prescription (35%) were the main reasons for self-medication. Pharmacy shop (75%) was the main source for self-medication. In case of antibiotics, 44% students changed the dosage of antibiotic and 50% students stopped antibiotics after the disappearance of the symptoms.

Conclusion: Antibiotic self-medication (39%) and self-medication with other drugs among university students of Karachi is a worrisome problem. Our findings highlight the need for planning interventions to promote the judicious use of general medicines as well as that of antibiotics.

Biography

Dnyanesh Limaye is currently working as a Faculty III at Hochschule Hannover Germany. He is a fellow of Information and Design from University of Applied Sciences and Arts, Hannover, Germany. He has his expertise in Self-medication practices among university students from Karachi, Pakistan.

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Isolation of *Lycopodium* alkaloids from Thai and Philippine *Huperzia squarrosa* and syntheses of Huperzine A derivatives via amidation reaction

Thanasan Nilsu[1], Sakornrat Thorroad[2], Apiwan Jamruksa[1], Sirikan Deesiri[1], Somsak Ruchirawat[1,2] and **Nopporn Thasana[1,2]**
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Statement of the Problem: *Lycopodium* alkaloids are quinolizine, pyridine and pyridone alkaloids isolated from club mosses (Lycopodiaceae). The most notable alkaloid from this group is huperzine A, which is a potent reversible Acetylcholinesterase (AChE) inhibitor. Studies on *Lycopodium* alkaloids from club mosses in Southeast Asia are deficient. This work aimed to phytochemically investigate club mosses native to Thailand and the Philippines.

Methodology: Whole plants of *H. squarrosa* collected from Thailand and the Philippines were extracted with methanol. The methanolic extracts were subjected to acid-base extraction. The obtained alkaloidal fractions were further purified through column chromatography.

Findings: *H. squarrosa* from Thailand yielded four alkaloids. Two known *Lycopodium* alkaloids were identified to be huperzine A (1) and 12-epilycodoline N-oxide (4). Squarrosine A (2) was a new fawcettimine-type *Lycopodium* alkaloid which possessed intramolecular hydrogen bonding. (R)-2-piperidineacetic acid (5) has never been reportedly isolated. This alkaloid was speculated to derive from precursors of *Lycopodium* alkaloids. From Philippine *H. squarrosa*, huperzine A (1) and pyrrolhuperzine A (3), a new lycodine-related *Lycopodium* alkaloid bearing a rare pyrrole moiety, were isolated. Semi-synthetic approaches to pyrrolhuperzine A (3) were achieved to confirm its structure elucidation, and two plausible biogenetic pathways from huperzine A (1) to pyrrolhuperzine A (3) were proposed. Furthermore, huperzine A (1) was chemically transformed into three amide derivatives (6-8). The newly isolated and semi-synthetic alkaloids were assayed for their anti-AChE activities. Huperzine A derivatives 6 and 7 exhibited strong AChE inhibition.

Conclusion & Significance: Thai and Philippine *H. squarrosa* contained high amount of Huperzine A (1) (0.014% and 0.13%, respectively). The synthesis of pyrrolyl derivative of Huperzine A has been accomplished for the first time.

Biography

Thanasan Nilsu is doing his PhD in Applied Biological Sciences at Chulabhorn Graduate Institute, Chulabhorn Royal Academy of Science, Bangkok, Thailand. He has been working on the isolation of *Lycopodium* alkaloids from Thai club mosses and derivatization of huperzine A. His research also includes pharmacological evaluation of natural and synthetic compounds in mammalian cell culture.

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Notes:

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Multifunction of saffron and its component

Yukihiro Shoyama
Nagasaki International University, Japan

We confirmed that crocin prevented N-SMase activation, ceramide production and JNK phosphorylation. Exploration of the crocin's preventive mechanism in oxidative stress-induced cell death revealed that the activities of GSH reductase. These results strongly support the importance of the proposed GSH-dependent inhibitory mechanism in oxidative stress-mediated cell death. The effects of saffron extract and crocin on improving ethanol-induced impairment of learning behaviors of mice in passive avoidance tasks has been reported. Based on these results, it became evident that saffron extract and crocin prevent the inhibitory effect of ethanol on Long-Term Potentiation (LTP) in the denatate gyrus *in vivo*. We examined the sleep-promoting activity of crocin by monitoring the locomotor activity and electroencephalogram after administration of crocin to mice. Crocin (30 and 100 mg/kg) increased the total time of non-REM sleep by 60 and 170%, respectively, during a 4-h period from 20:00 to 24:00 after its intraperitoneal administration at a lights-off time on 20:00. Furthermore, the anti-cancer activities against colon cancer cell lines, skin and colon cancers in mice are also discussed.

Biography

Yukihiro Shoyama worked in MGH in Boston as a Post-doc in 1975. During 1978 to 1991, he worked as an Associate Professor and as a Full Professor during 1991 to 2007 in Kyushu University. During these periods he was the Director of Pharmacognosy Department, the Director of Herbal Garden, and held Deanship (2004-2006). He moved to Faculty of Pharmaceutical Sciences, Nagasaki International University as a Full Professor from 2007. He was the President of Japanese Society of Pharmacognosy (2007-2008) and Vice Chairperson of Specialty Committee of Traditional Chinese Medicine, Pharmaceutical Chemistry of World Federation of Chinese Medicine Societies (2012-2020). His research interests are marijuana studies like structure elucidation of biosynthetic enzyme protein by x-ray analysis, monoclonal antibodies against over 40 natural bioactive products, biotechnology of medicinal plants and bioactive natural products like saffron resulting in approximately 400 original papers and over 200 review articles.

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Notes:

Sessions:

Pharmacovigilance | Drug Delivery Systems | Regulatory Affairs

Session Chair
Buket Aksu
Istanbul Kemerburgaz University, Turkey

Session Introduction

Title: **PVG practice: Suggested approach in improving adverse drug reaction reporting and factor perceived may be influencing pharmacovigilance practice among health care providers in Lagos state**

Oyeneye Temitope K, Drug Consult Pharmacy, Nigeria

Title: **Novel drug pharmacology for targeting dopamine signaling in the brain through ghrelin and dopamine receptor heterodimers**

Andras Kern, Scripps Research Institute, USA

Title: **Development and evaluation of sustained release alginate beads for delivery of self-emulsifying resveratrol**

Arpa Petchsomrit, Prince of Songkla University, Thailand

Title: **Quality by Design, advances in pharmaceutical technology**

Buket Aksu, Istanbul Kemerburgaz University, Turkey

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PVG practice: Suggested approach in improving adverse drug reaction reporting and factor perceived may be influencing pharmacovigilance practice among health care providers in Lagos state

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The success or failure of any pharmacovigilance activity depends on the reporting of suspected adverse reactions. ADR reporting with yellow cards has tremendously improved pharmacovigilance of drugs in many developed countries and its use is advocated by the World Health Organization (WHO). ADR reporting among health care workers in Nigerian tertiary institutions is at a very low practice. A cross sectional study was made involving 75 medical doctors, 75 pharmacists and 30 nurses was surveyed with self-administered questionnaire which had undergone some modification to suit Nigerian environment. The questionnaire was validated through scrutiny in the Clinical Pharmacy department of University of Lagos and the zonal head of the NPC in LUTH. The Questionnaire was distributed through various heads of the units and professional acquaintances and was allowed to stay with them so as to allow attending to the question. The questionnaire sought the demographics of the HCPs; the factors they perceived may influence pharmacovigilance practice and suggestion on the possible way to improve ADR reporting. The result gave 95.6% response rate. A majority of the HCPs responds to positive impact in improving ADR reporting and factors militating the practice. Education and training was the most recognized means of improving ADR reporting. Adverse drug reaction reporting among the Nigerian health care professional proves to be inefficient and lack a proper data base documentation. Though, there has however been a slight improvement when compared to previous studies. Social workers and all sectors of the health care system need to be involved. Governments needs to include private hospitals, retails dispensaries and traditional medicine. PV reporting centre should also be at primary health centre, effort must be to train staffs who would flag off the monitoring and documentation of ADR, lack of local expertise in pharmacovigilance could be tackled through developing exchange programmes with NAFDAC and sharing of best practices, there should be established organizers of public health and drug access campaigns in local languages and with regional surveillance stem and creating a specific centre for pharmacovigilance in all hospitals will help the advancement.

Biography

Temitope Oyeneye completed her Graduation at Olabisi Onabanjo University and internship at Lagos University Teaching Hospital in Lagos, Nigeria. Presently, she is working as Pharmacist at Drug Consult Pharmacy, Nigeria. She has years of experience in interpreting a prescription and administration of pharmaceutical drugs in both government hospital and private corporate pharmacy stores.

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Novel drug pharmacology for targeting dopamine signaling in the brain through ghrelin and dopamine receptor heterodimers

Andras Kern
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A major challenge in the field of G-Protein Coupled Receptor (GPCR) drug discovery in CNS is developing specific drugs without side effects. Selection of a drug candidate is traditionally based on canonical signal transduction pathways after expression of the individual GPCRs in heterologous cell lines. However, these assays do not predict the response of target cells in the native tissue; therefore, the desired clinical outcome is often not met. For example, drugs designed for dopamine (DA) receptor subtypes act on all neurons expressing this subtype, but selectivity requires knowledge of a specific target that discriminates between neuronal subtypes. In neurons, the targeted GPCR is frequently not present in isolation, but with other GPCRs. Some GPCRs are capable of forming heterodimers with a specific GPCR partner resulting in cell and tissue specific modification of canonical signal transduction. To achieve more selectivity for regulating DA signaling, our research focused on regulating DA signaling by target neurons that express dopamine receptor (D1R or D2R) and ghrelin receptor (GHSR1a) heterodimers. We exploit the novel concept that in GPCR heterodimers a neutral antagonist of one protomer can modify the function of the partner protomer by an allosteric mechanism. We detected that D2R:GHSR1a and D1R:GHSR1a heterodimers exist in neurons of native brain tissue resulting in allosteric modification of DA signaling. Our results show that dopamine receptor heterodimers in hypothalamus can regulate food intake in animals through D2R:GHSR1a. We found that in hippocampus D1R:GHSR1a heterodimers regulate DA-dependent memory performance. We show DA signaling through these heterodimers is modulated by a GHSR1a antagonist. Hence, treatment with a GHSR1a antagonist provides a selective way of blocking or enhancing DA signaling in neurons expressing the heterodimers without affecting signaling in neurons expressing D1R or D2R alone. These results show potential opportunities for developing more selective therapeutic agents for treating psychiatric disorders involving abnormal DA signaling.

Biography

Andras Kern completed his PhD in Genetics at Eotvos Lorand University, Hungary. He is currently working as Staff Scientist and studying the ghrelin receptor signaling in neuronal tissue at Scripps Research Institute (TSRI).

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Development and evaluation of sustained release alginate beads for delivery of self-emulsifying resveratrol

Arpa Petchsomrit and **Ruedeekorn Wiwattanapatapee**
Prince of Songkla University, Thailand

Resveratrol is a polyphenol compound found in grapes and other food products. It exhibits numerous pharmacological activities including anti-oxidant and anti-carcinogenic properties. Therapeutic application of resveratrol is limited due to its low aqueous solubility. The purposes of this study were to develop self-emulsifying resveratrol sustained release alginate beads and assess anticancer activity on gastric cancer cells. Floating alginate beads were prepared by ionotropic gelation method and used calcium carbonate as gas forming agent. Use of different concentrations of sodium alginate, self-emulsifying resveratrol, pore forming agent (Kollicoat® IR), and drying method showed different effects on physical properties and *in vitro* drug release in each bead formulation. All formulations floated immediately and remained floating over 72 h. The optimized formulation consisted of 2% w/v sodium alginate and 15% w/w self-emulsifying resveratrol. Freeze dried beads and oven dried beads showed sustained release profiles and values of cumulative release profiles in 8 h were 97.22% and 84.60%, respectively. Conversely, liquid self-emulsifying resveratrol gave immediate release approximately 80% in first hour and almost completely released (99.75%) in same period. Anticancer activity on AGS cells of both floating self-emulsifying resveratrol beads and liquid self-emulsifying resveratrol (IC50 23.53±0.66 and 23.99±1.05 µg/ml, respectively) were equivalent to that of unformulated powders dissolved in DMSO (IC50 23.75±0.53 µg/ml). Consequently, alginate bead preparation process did not have any effects on pharmacological activity. This study disclosed that floating self-emulsifying beads could enhance the solubility, prolongs drug release, and may have potential for gastric cancer treatment.

Biography

Arpa Petchsomrit is a PhD student at Prince of Songkla University, Songkhla, Thailand. She has her expertise in development and evaluation of liquid and solid dosage form of self-emulsifying drug delivery system for oral application.

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Notes:

Buket Aksu, American Journal of Ethnomedicine, 4:2
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Quality by Design, advances in pharmaceutical technology

Buket Aksu
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Despite continuous innovations in the pharmaceutical industry for developing futuristic new drug products, there has been a repeated set back owing their low quality and manufacturing standards. The studies and tests required to deliver a new drug to patients last up to 15 years, and cost over 800 million $. Even after a drug is invented, its development may fail due to the proven impossibility of its safe manufacture in a large scale and incompliance with the relevant specifications. The length of the approval process and the requirement to start over for a development cycle of any changes due to the stalemates, even product is licensed has led to concerns for many decades. With the consequent growing concerns and criticism, in this regard, in 2002, the current Good Manufacturing Processes (cGMP) was introduced to improve and modernize the rules that regulate the drug manufacturing and quality. Subsequently, in 2005, the guideline Q8 of the International Conference on Harmonization (ICH), which focused on the content of the Module 3.2.P.2 of the Common Technical Document (CTD), was published. The ICH instituted a series of quality guidelines all emphasizing the adoption of systematic principles of Quality by Design (QbD) and Process Analytical Techniques (PAT). QbD is a patient-centric science and risk-based approach for developing drug products with better understanding of the products and processes by planning quality at first hand in order to avoid quality crisis and using the knowledge obtained during the life-cycle of the product to work on a constant improvement. Implementation of QbD-based strategies in pharmaceutical development would provide excellence and significant time shortening in product development, and enormous flexibility in regulatory compliance. It has been emphasized before if the principles described in the ICH Q8, Q9 and Q10 guidelines are implemented together in a holistic manner, this provides an even greater assurance that the patient will receive product that meets the critical quality attributes.

Biography

Buket Aksu completed her Graduation from Istanbul University and Doctorate degree in Quality by Design (QbD) at Ege University. Currently, she continues her academic career at Istanbul Kemerburgaz University; also works as Consultant in Pharmaceutical Industry. She has given numerous speeches and training programs on QbD, Industrial Pharmacy, Management Skills, Registration and Patent, R&D and Innovative Sales.

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Scientific Tracks & Abstracts

Day 2

Sessions:

Day 2 October 17, 2017

Agriculture Chemistry | Phytomedicine | Natural Products and Heterocyclic Chemistry | Biologically Active Natural Products and Drugs | Herbal Drugs | Advanced Synthesis and Catalysis | Medicinal Chemistry and Drug Synthesis | Bioorganic and Medicinal Chemistry | Marine Drugs

Session Chair
Takashi Takahashi
Yokohama University of Pharmacy, Japan

Session Introduction

Title: **An *in vitro* comparative study on antioxidant, antibacterial and nutraceutical properties of three different coloured scented rice varieties of North- Eastern region**

Manashi Garg, Assam Downtown University, India

Title: **Extraction, isolation and characterization of Tocotrienol from glutinous black rice variety of North East India and its active nanoformulation against chronicity**

Banasmita Devi, Assam Downtown University, India

Title: **Sesquiterpene lactones of *Artemisia L.* endemic species**

Gayane Atazhanova, National Academy of Sciences of the Republic of Kazakhstan, Kazakhstan

Title: **Antineuroinflammatory mechanism of 7-methoxyflavanone in lipopolysaccharide-stimulated BV2 microglia cells**

Zhao Qu, Guangzhou University of Chinese Medicine, China

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An *in vitro* comparative study on antioxidant, antibacterial and nutraceutical properties of three different colored scented rice varieties of North- Eastern region

Rashna Devi, Banasmita Devi, Balagopalan Unni and **Manashi Garg**
Assam Downtown University, India

North-East region of India is rich in production of colored and scented rice, a hulled grain with a distinctive red or purple color in addition to light grey on its bran. Of all the colored rice, especially black rice has long been consumed and is considered as a healthy food in Korea. Although, the colored rice is hard in its cooking texture, they possess beneficial effects of colored pigment, the naturally occurring colored substances like anthocyanin that belongs to flavanoids family which is reported to combat against the damaging effect of toxic free radicals and has great pharmacological property. Equally interesting is this food for the elimination of a series of other problems including obesity, edema, hypertension, diseases of kidneys and diabetes by releasing glucose in a fairly moderate way. The presence of oryzanol in the whole rice also ensures its affectivity in reducing cholesterol level (LDL) in blood. With its potent bio-active compounds such as phenolic compounds, tannins, lignin, oryzanol, tocotrienols, tocopherols, phenyl propanoids, and flavonoids, the colored rice(s) are responsible for counteracting wide range of illnesses.

Biography

Manashi Garg is a professor of Biotechnology & Biochemistry at Assam Downtown University, India. Her research focus *in vitro* antibacterial activity of biosynthesized silver nanoparticles from ethyl acetate extract of Hydrocotyle Sibthorpioides against multidrug resistant microbes.

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Extraction, isolation and characterization of Tocotrienol from glutinous black rice variety of North East India and its active nanoformulation against chronicity

Banasmita Devi, Manashi Garg, Rashna Devi and **Balagopalan Unni**
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The reported nutraceutical content in Chakhao, the Manipuri aromatic black glutinous rice of North East India has been reported with great value for human health benefit. Besides these, the dietary supplement of anthocyanin rich berries has shown effective in reducing oxidative stress, the risk of cardio vascular disease and cancer with anti-inflammatory, and also inhibits tumor cell proliferation. The present study conducted to evaluate the antioxidant, antibacterial and nutraceutical properties of three colored scented rice varieties grown in North Eastern region showed a significant correlation of all the rice varieties. Antioxidant activity was measured using hydrogen peroxide and 2,2-diphenyl-1-picrylhydrazyl (DPPH) free radical scavenging assays. The antioxidant activities of the studied samples were expressed as percentage (%) of DPPH and H2O2 radicals' inhibition and IC50 value. Among different extracts of crude rice, methanolic extract of the black rice showed highest antioxidant activity compared to the aqueous extract of the other two varieties, each for DPPH (89.29±0.139) as well H2O2 (80.97±0.091) with an IC50 value of 40 µg/ml and 42.6 µg/ml respectively. Also the result of MIC against the tested *Staphylococcus* strain was notably found to be effective with a significant value of 119 µg/ml for black rice taken DMSO as the positive control. In further continuation of our research, one of the potent nutraceuticals of black rice, Tocotrienol has been extracted, isolated and characterized for its activity by formulating it in various forms including nanocapsules. As a preliminary work of study, the active compound was evaluated against various few prevalent pathogenic microorganisms in dermatophytic infections. The active compound was re-introduced against various infections aided by a novel nanocapsular drug delivery system. Tocotrienol along with curcumin was encapsulated in a biodegradable polymer (Chitosan) pluronic composite nanocapsule (TOC-Cur-CHI-P NCs) which functions exceptionally well as topical therapeutics and helped to achieve better hydrophilicity, bioavailability and controlled drug delivery with enhanced therapeutic index. The TOC-Cur-CHI- P NCs could encapsulate 98.68% of the active compounds and were found to be stable for around three months duration. The *in vitro* anti-bacterial activity was performed and exhibited significantly enhanced anti-chronicity activity against few isolates. With sustain release kinetics, this novel delivery system for the active compounds could bring into new point of its application. Various studies have been extended for its further application in cancer research.

Biography

Banasmita Devi is a professor of Biotechnology & Biochemistry at Assam Downtown University, India. Her research focus *in vitro* antibacterial activity of biosynthesized silver nanoparticles from ethyl acetate extract of Hydrocotyle Sibthorpioides against multidrug resistant microbes.

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Sesquiterpene lactones from *Artemisia* L. endemic species

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Plants from *Artemisia* L. genus belonging to Asteraceae Dumort. family are one of the main sources of sesquiterpene lactones. Ninety species of wormwood grow in the territory of Kazakhstan, 20 of which are endemic and considered as potential sources of novel, previously unexplored natural compounds, especially sesquiterpene lactones. We have carried out the chemical analysis of 11 endemic plant species from *Artemisia* L. genus for the first time, they are as follows: *Artemisia aralensis* Krasch., *Artemisia* cina Berg., *Artemisia* filatovii A. Kuprijanov sp. nova, *Artemisia* glabella Kar. et Kir., *Artemisia halophila* Krasch., *Artemisia hippolyti* Butkov, *Artemisia karatavica* Krasch. et Abol., *Artemisia radicans* A. Kuprijanov sp. nova, *Artemisia saissanica* (Krasch.) Filat., *Artemisia* semiarida (Krasch. et Lavr.) Filat., *Artemisia succulenta* Ldb. Fl. Alt. From 11 endemic species of *Artemisia* L. 25 sesquiterpene lactones were determined. In doing so, 7 new sesquiterpene lactones were isolated, and the structures of their molecules elucidated by means of modern physical, chemical and spectral methods (IR-, PMR-, 13C NMR, mass-), including X-ray analysis.

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Anti-neuroinflammatory mechanism of 7-methoxyflavanone in lipopolysaccharide-stimulated BV2 microglia cells

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Microglia plays an important role in the neurodegenerative diseases in the central nervous system. Over activated microglia also leads to the production of excessive inflammatory molecules and deleterious consequences, including neuronal death. 7-methoxyflavanone (MF), one of the nature flavone extracted in Ixeridium gracile, has been shown to inhibit the cytochrome P450 aromatase and the MAO-B. However, its function and the underlying mechanisms in neuroinflammation responses in microglia remain poorly understood. In this study, we investigated MF inhibited expression of COX-2 and inflammation mediators ICAM-1 and MCP-1 in Lipopolysaccharide (LPS)-stimulated BV-2 microglia. MF also reduced the production of pro-inflammatory cytokines (TNF-α and IL-6) induced by LPS. Furthermore, investigation of the molecular mechanism indicated that MF inhibited the phosphorylation of ERK and JNK at a lower concentration than that for p38 MAPK. Further experiments revealed that MF treatment considerably increased the activation of Nrf2 and the expression of its target genes, including HO-1 and NQO1. MF also induced phosphorylation of AMPK/LKB in microglia. Interestingly, we found that MF inhibits TLR4/MyD88 signaling by interfering with LPS and TLR4 interactions. Therefore, MF might be useful as a therapeutic agent for the treatment of neuroinflammation-associated disorders such as Alzheimer's disease and Parkinson's disease.

Biography

Zhao Qu is a post-doctoral fellow at Guangzhou University of Chinese Medicine, China. She is expertise in natural products and medicinal chemistry.

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Notes:

Sessions:

Pharmaceutical Sciences | Pharmaceutical Analysis | Drug Discovery and Research | Drug Therapy Pharmaceutical Analysis | Innovations in Drug Development | Regulatory Affairs

Session Chair
Minjun Chen
US Food and Drug Administration, USA

Session Co-Chair
Peyman Salehi
Shahid Beheshti University, Iran

Session Introduction

Title: **Modern tool of pathogenetic therapy as exemplified in application of antibodies to S100 protein in the released-active form**

Gulnara Kahakimova, "NPF" Materia Medica Holding, Russia

Title: **Adverse drug reaction reporting in primary care in Kuwait: A comparative study between physicians and pharmacists**

Jacinthe Lemay, Kuwait University, Kuwait

Title: **Importance of data integrity in pharmaceuticals**

Raghunandan H V, JSS University, India

Title: **Hot-Melt Extrusion: A cost effective approach leading to enhancement of bioavailability and acceleration of drug product development process via turning poorly water soluble drugs into viable therapeutics**

Devendra Ridhurkar, Egis Pharmaceuticals PLC, Hungary

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Modern tool of pathogenetic therapy as exemplified in application of antibodies to S100 protein in the released-active form

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Statement of the Problem: Pathogenetic therapy is considered to be one of the most effective approaches in any disease treatment. For mental disorders most commonly applied drugs are benzodiazepines and selective serotonin reuptake inhibitors. However, these drugs have a number of side effects which limit their use in ambulatory practice, especially for people whose profession requires quick mental and motor responses. Furthermore, long-term use of such drugs creates a high risk of mental and physical dependence.

Methodology & Theoretical Orientation: The alternative is to correct violations of brain integrative activity. That could be done by modulating the functions of endogenous regulatory molecules, for example, those of S100 protein. It is involved in the pathogenesis of different psychiatric disorders. S100 function can be influenced by the use of antibodies. Modulation of S100 proteins' functions is a key mechanism of action of Tenoten® and Divaza® – drugs presented on Russian and CIS pharmaceutical markets. As the active pharmaceutical ingredient they contain antibodies to S100 in released-active form (RA anti-S100) produced by ultra-high dilution technology. It was found that these types of drugs can modify conformation of their targets and thereby change the strength of ligand-receptor interaction. Spectrum of RA anti-S100 pharmacological activity has been shown in the numerous experimental and clinical studies.

Findings: It has been proved that RA anti-S100 have anxiolytic, antidepressant, anti-stress, anti-aggressive, nootropic (anti-amnestic, neuroprotective) and neurotrophic activities without sedative and muscle relaxant effects and any type of dependence.

Conclusion & Significance: Treatment with drugs containing released-active forms of antibodies to S100 protein is modern tool of pathogenetic therapy.

Biography

Gulnara Khakimova completed her Graduation from Kazan State University (Kazan, Russia) with a Master degree in Physiology. Then, she received her PhD in Neurobiology from the Koltzov Institute of Developmental Biology of Russian Academy of Sciences (Moscow, Russia). Presently, she is a Senior Researcher in Research & Analytical Department of Russian Pharmaceutical Company Materia Medica Holding.

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Adverse drug reaction reporting in primary care in Kuwait: A comparative study between physicians and pharmacists

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Adverse Drug Reactions (ADRs) are a significant cause of morbidity and mortality. However, little is known about ADR reporting practices among Healthcare Professionals (HCPs) in Kuwait, especially in the primary healthcare setting. The objective of this study is to investigate and compare knowledge, attitude and practices regarding Pharmacovigilance (PV) and ADR reporting among physicians and pharmacists in primary care. A descriptive, cross sectional study was carried out. A validated self-administered questionnaire was distributed to a total of 583 physicians and pharmacists in 38 primary care clinics in Kuwait. Statistical analysis was done using the Statistical Package for Social Science version 23. Categorical variables were described using numbers and percentages. The Pearson chi-square or Fisher's exact tests were used wherever appropriate. Out of 583 distributed questionnaires, 485 were completed giving a response rate of 83.2%. The study sample consisted of 318 physicians and 167 pharmacists. A total of 52.8% and 70.5% of study participants were knowledgeable about PV and ADR definitions, respectively, with pharmacists demonstrating significantly better knowledge ($p<0.001$). However, the majority (89.4%) was not aware of an ADR reporting system in Kuwait. Almost every participant (97.7%) thought it is necessary to report ADRs. However, significantly fewer physicians compared to pharmacists believed that ADR reporting is a professional obligation (78.0% vs. 88.0%; $p=0.007$). Only 27.8% had reported them, with pharmacists having reported significantly less compared to physicians (21.7% vs. 30.8%; $p=0.036$). The major barrier to reporting ADRs, cited by significantly more physicians was not knowing how to report (75.2% vs. 64.7%; $p=0.015$). Despite the positive attitudes, results indicate suboptimal knowledge and poor practices among primary care HCPs with regards to PV and ADR reporting. Targeted and practical training on ADR reporting while ensuring a robust regulatory framework may encourage a better ADR reporting culture in the primary healthcare setting in Kuwait.

Biography

Jacinthe Lemay joined the pharmaceutical industry in 2002 where she held different positions in the fields of clinical research, medical affairs and regulatory affairs in a wide-range of therapeutic areas. In her current position as an Assistant Professor at Kuwait University, her main research interests include optimization of healthcare delivery by working on the development and implementation of clinical pharmacy in Kuwait and developing strategies to improve medication safety and adherence to treatment.

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Importance of data integrity in pharmaceuticals

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As per USFDA, data integrity refers to the completeness, consistency and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA).World Health Organization (WHO) defines data integrity as the degree to which a collection of data is complete, consistent and accurate throughout the data lifecycle. The collected data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices. USFDA expects data to be reliable and accurate, necessary to have flexible and risk-based strategies to prevent and detect data integrity issues, implement meaningful and effective strategies to manage their data integrity risks. The expectation of MHRA with respect to data integrity is the governance system should be integral to the pharmaceutical quality system. Data integrity is related to many stakeholders like patients, regulators and organization. Data integrity is applied at all stages of product life cycle from discovery to distribution and applied on GXP systems, facilities, quality system, data functions and regulatory submissions. Data integrity does matter because it is necessary to establish confidence that the quality related activities are being performed effectively and regulatory decisions depends on accurate data across product lifecycle. Data integrity lapses lead to prosecution, injunction, penalty, warning letters and import alerts affecting the overall business of the organization.

Biography

Raghunandan H V is currently working as Professor of Pharmaceutics JSSCP and worked as Pharmacist with over 23+ years of progressive experience in pharmaceutical quality assurance, quality control, regulatory affairs, manufacturing of formulations/API's/biologicals, contract manufacturing and pharmaceutical technical consultation (reg. affairs, product development and quality). He has good understanding of the audits and risk management in pharmaceuticals/bio pharmaceuticals, consumer health care products like OTC/OHC/nutritional health care. He is an experienced Quality Auditor and has good experience in auditing and site quality management.

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Hot-Melt Extrusion: A cost effective approach leading to enhancement of bioavailability and acceleration of drug product development process via turning poorly water soluble drugs into viable therapeutics

Devendra Ridhurkar
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For orally administered drugs, water solubility and permeability are the rate-limiting factors to achieve their desired concentration in systemic circulation for the pharma¬cological response. Poor water solubility of new chemical entities belonging to Biopharmaceutical Classification System (BCS) class II and IV accounts for 40 to 70% incidence of delay or failure during the drug product development process. Therefore, turning poorly water soluble drugs into viable therapeutics is the recurring and most challenging aspect of drug product developmental process facing by formulation scientist. Hence, the poor bioavailability of the drugs has intensified demand for technologies and methods in the pharmaceutical industries to overcome their traits and meet the aforesaid challenges. Development of the formulations of BCS class II and IV drugs by converting the poorly water-soluble crystalline form into a more soluble amorphous form within the polymeric blends will enhance the solubility which in turn leads to the improved bioavailability. These formulations can be developed by adopting various solid dispersion technological approaches like Hot-Melt Extrusion (HME), kneading technique, co-precipitation, co-grinding, spray-drying, lyophilization, melt agglomeration process and supercritical fluid process. Among all these approaches, solid dispersion prepared by HME has gained popularity in the pharmaceutical industry as a means of improv¬ing the bioavailability of drugs due to its wide applications, simple pro¬cess and low cost. HME is an efficient technology for producing solid molecular dispersions with considerable advantages including the absence of solvents, few processing steps, and con¬tinuous operation over solvent-based processes such as spray drying and co-precipitation. Also, HME is one of the recommended processes by FDA to encourage move from batch-to-continuous manufacturing. Moreover, it is a value addition to intangible property of organization and can be used as non-infringing strategies for product developments.

Biography

Devendra Ridhurkar works as a Senior Scientist at Egis Pharmaceu¬ticals PLC, Budapest, Hungary with a focus towards development of platform and other emerging technologies in innovative and complex generic formulations. Before Egis, he worked at Dr. Reddy's Laboratories, India. He has served as a Scientist at IPCA laboratories, Macleods Pharmaceuticals and Alkem laboratories, India. He has 11 years of experience in drug products development, using different approaches and various technologies which include hot melt extrusion (HME), gastro-retentive drug delivery systems, and nanotechnology and cyclodextrin complexation. He is an expert in materializing the design of experiments (DOE) and quality by design (QBD). He obtained his MPharm and PhD in Pharmaceutics from Indian Institute of Technology, Banaras Hindu University, India. He has five patents and published eight peer-reviewed papers in reputed national and international journals. He has attended and presented his research work at various national and international conferences.

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