Accepted Abstracts

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Antimicrobial activity of *Mesembryanthemun crystallinum* halophyte plant that belong to grand Casablanca region (North Africa)

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Morocco is a country known for its botanical biodiversity that represents infinity of natural resources used by the pharmaceutical industry. Our study focuses on the antimicrobial activity against four bacterial strains and one yeast pathogenic to humans. In the continuity of our subject, we also study the possibility of using these substances as a bio-antifungal against phytophagous fungi that ravage the agriculture of legumes in the Casablanca - Settat axis. Our choice is focused on the *Mesembryanthemum crystallinum* plant belonging to the family of *Azioacea* which populates the Tunisian and Moroccan sides known for its traditional medicinal virtues. Different concentrations of extract were tested. Organic extracts from Mesembryanthemum crystallinum exhibit significant antimicrobial activity confirmed by the two standard micro-dilution and discs methods. This activity is tested on several different Gram bacterial strains, yeasts and phytophagous fungus of Moroccan agriculture.

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Emerging role of pharmacogenomic biomarkers in biological therapy and safety

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Identifying pharmacogenomic biomarkers for therapeutic and safety outcome to biological therapy, echoes advancement towards personalized medicine in the 21st century. Biologics though regarded as "designer" drugs, produce desired therapeutic effect only in a fraction of the treated population, since genetic and non-genetic factors jointly influence variability in response to biological treatment. The demographic diversity and complexity in the prevalence of genomic variants (SNPs and non-SNPs polymorphisms) pose major challenges in development of suitable prognostic pharmacogenomic biomarkers as predictors of response to bio-therapeutic agents. However, a substantial number of pharmacogenomic markers have helped in appropriate patient selection for antineoplastic, anticoagulant, anticonvulsant, cardiovascular and anti-HIV therapies. The pharmacogenetic screening, thus serves as a useful diagnostic tool integrating individual's genetic information with the existing prescribing model to optimally treat the patients. Biologics are large complex molecules with rapidly changing stability profile which intensify the response variation due to genetic polymorphism. Non-clinical challenges, such as hemocompatibility, immunotoxicity, biodistribution, tumorigenicity, contamination etc., faced during biologics development prohibits designing a single testing strategy for all products. Adopting pharmaceutical 'Quality by Design' partly addresses these challenges enhancing safety and performance of biological products. Also, identifying useful predictive biomarkers will have a significant impact on drug development and successful outcome of new biologics. Healthcare authorities have stressed upon developing pharmacogenomic biomarker tests in clinical practice complementing the information available from clinical trials warranting greater success rate of high cost biological therapy.

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Hospital pharmacy leadership turnaround management: Strategies, techniques and change management pearls

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There is a high turnover of hospital pharmacy leadership, typically Director of Pharmacy, due to stress, long hours, constant deadlines, high responsibilities, multiple supervisors, demanding and challenging job to perform well, constant clinical/regulatory/technological changes in the industry to be compliant with, tight budgets/deadlines, and retiring baby boomers. This leads to the need for interim leadership focusing on turnaround change management for poor performing hospitals. In USA, the new and unexplored trend is consultant pharmacist in leadership and turnaround management (interim management). Traditionally, consulting pharmacist roles is in medication therapy management, long term care facilities and clinically oriented. Typically, interim management is stigmatized as incompetent and cannot get a permanent job. Fact is, to be an effective and high impact interim leader, the pharmacist must be very experienced, skilled and talented to turnaround the pharmacy that's failing in a very short time period with limited resources and minimal relationships with staff/other hospital leaders for support. The modern concept of lean and high impact giant healthcare organizations in USA is getting experienced interim leaders in making assessments, formulating an action plan, rapidly developing and implementing the action plan in a brief time frame of usually 3-6 months. They then move the leader around in their organization to facilities/pharmacies that are performing poorly to turn it around. This business strategy is also applicable at the executive CEO level for the whole hospital. This presentation explores the new US business strategy and techniques to improve medium performing and rescue failing healthcare businesses, change management challenges and how to overcome them, clinical/regulatory compliance and best practices, personnel management, work flow to improve productivity, use of technology in healthcare, inventory management, quality assurance and cost reduction in all aspects of the pharmacy operation. The concepts can be extrapolated across other industries and sectors of healthcare. The presenter will conclude with motivational/inspiring key messages and why this is a very rewarding unexplored new field of pharmacy practice as well as resources to help the audience achieve the comparable results in their practices.

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Regulatory strategies and considerations in monoclonal antibody R&D including biosimilars/biobetters

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Monoclonal antibodies (mAb or moAb) are antibodies that are made by identical immune cells that are all clones of a unique parent cell. Monoclonal antibodies can have monovalent affinity, in that they bind to the same epitope (the part of an antigen that is recognized by the antibody). Given almost any substance, it is possible to produce monoclonal antibodies that specifically bind to that substance; they can then serve to detect or purify that substance. This has become an important tool in biochemistry, molecular biology, and medicine. In particular, mAbs have been used in various diagnostic tests, anti-cancer and anti-viral-therapies, and autoimmune therapies, such as rheumatoid arthritis, Crohn's Disease, Ulcerative Colitis, and to help prevent acute rejection of transplanted organs, such as kidneys transplants, as well as treatments for moderate-to-severe allergic asthma. Biosimilar antibodies are highly similar versions of "innovator" (or "originator") antibodies with the same amino acid sequence but produced from different clones and manufacturing processes. As a consequence, biosimilar mAbs may include possible differences in glycosylation and other microvariations such as charge variants that may affect quality, safety and potency. Biosimilars may also be follow-on biologics and can also refer to second- and third- generation antibodies, which may have enhanced properties, such as greater affinity or longer action, often referred to as "biobetters". In contrast to the low-cost generic versions of small molecules that are off patent, it is currently not possible to produce exact copies of large proteins and glycoproteins, such as antibodies, owing to their structural complexity. Nevertheless, tremendous progress has been made in bioproduction and analytical sciences, and it is now possible to produce proteins and glycoproteins that are highly similar to reference products with little or no clinically-meaningful differences. The European Medicines Agency pioneered the regulatory framework for approval of these products, and now the US and most regulatory authorities have regulatory processes for the approval of biosimilar mAbs. The US Food and Drug Administration is one of the few regulatory authorities that has a regulatory pathway for biosimilars that are interchangeable, meaning that additional studies have been conducted supporting that they may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product. FDA recently published guidance explaining the additional studies that would need to be conducted to support approval of an interchangeable biosimilar. This presentation will look at principally the EMA and US approaches to regulating biosimilar mAbs including interchangeable biosimilar mAbs and biobetter mAbs. The development of legal and regulatory pathways for biosimilars mAbs will continue to raise much debate among lawmakers, regulators, originator and generic industry, patent attorneys, academia and health care professionals.

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Estrogenic isoflavones as modern food compounds can have both beneficial and adverse effects

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Soy isoflavones: genistein, daidzein and glycitein, can exert estrogen-like activities. Their endocrine disrupting activities were first identified in cattle grazing phytoestrogens-rich pastures. If glycitein is an ERβ agonist, genistein, daidzein and its metabolite equol exhibit significant transcriptional activities through both ERα and ERβ. They can also induce gene transcription through GPR-30 and ERRα, β, γ at dietary doses. *In vivo* and in humans, estrogenic effects can be positive or negative depending on the physiological status and the target tissue. These estrogenic activities having been confirmed in toxicological studies by the US National Toxicology Program (NTP), were analyzed in clinical studies. No individual study is definitely convincing, however, putting all data together shows that estrogenic effects on several targets and on reproduction can be recorded for isoflavone daily intakes ranging from 40 to 60mg in adults (about 0.75 mg/kg/day). These active doses lead to free plasma aglycone levels being 500 to 5000 times higher than free-estradiol in human plasma, depending if children, premenopausal women, men or postmenopausal women are considered. In soy, isoflavones are present as glycosides and are soluble in water. This allows them to leak into water during prolonged cooking or simmering. These cooking steps were common in traditional Asian recipes but are no longer found in modern soy industrial processes which were designed to reduce energy and environmental costs. Therefore, the human exposure to estrogenic isoflavones rose recently with the development of industrial soy-based-foods. Estrogenic isoflavones can therefore be considered as modern endocrine disruptors acting in synergy with other environmental compounds. Removing isoflavones from modern food may be a solution. To take advantages of these substances still lowering their deleterious effects for the global population, their use in dietary-supplements or biological preparations should be studied further. Such preparations should allow targeting the right physiological status.

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Fast dissolving drug delivery systems

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Fast-dissolving formulations represent excellent opportunities for life cycle management to the pharmaceutical companies. Fast dissolving technologies have many advantages like ease of swallowing, administration without water, quick onset of action for improving both patient convenience and compliance as benefits for the patient; extended life cycle, product differentiation, patent protection as benefits for pharmaceutical companies. But, there are some challenges for formulation development studies like taste-masking, disintegration time, moisture sensitivity, friability, packaging and intellectual property issues, especially for the generic companies. The technologies are under patent protection like Zydis®, Flashtab®, OraSolv® and DuraSolv™, WOWTAB®. One of the major issues is a taste-masking problem may be overcome with using cyclodextrins, polymer coating, flavoring and sweetening agent, microencapsulation techniques. There are some modified excipients for providing both taste-masking and productability properties in the formulation like Ludiflash®, Pharmaburst® etc. From the analytical development point of view, there are a number of different methods from conventional dosage forms which are determined in the Pharmacopoeias. And for comparison and assessment of taste masking, electronic tongue may be a good opportunity which was developed by Alpha MOS. In the sense of generic companies, developing a fast dissolving tablets version of an existing immediate-release product means that the two formulations must be bioequivalent, and this can be challenging for *in vivo* studies especially if the method of taste masking retards the dissolution rate of the active ingredient after disintegration. What about the future of fast dissolving technologies? Orally disintegrating extended release (ODT-ER) dosage forms are providing all of the benefits of these two drug delivery technologies in a single pharmaceutical product. And oral rapid films also may be a good alternative, especially for the OTC market.

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Synthesis of borono-fluoro-deoxy-D-glucose as boron carrier for Boron Neutron Capture Therapy (BNCT)

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Objective: The 18F-labeled Deoxy-D-Glucose exhibits high affinity to cancer tissue as a PET (Positron Emition Tomography) imaging agent for metastatic cancers. Complexation of 10B to 18F-DG complex may create a useful BNCT (Boron Neutron Capture Therapy) agent for cancer therapy. In previous studies, complexation and characterization of 10B with DG was evaluated and bio distribution analysis was completed successfully. Radio labelled 10B-DG will be useful approach for uses for BNCT applications.

Methods: The 18F-DG synthesized by ion exchange and complexed with 10B(OH)3 via pH reactions. 18F-DG-10B complexation was assayed with Agilent 1260 Infinity HPLC-DAD and Agilent 6420 Triple Quad LC/MS. Complexed molecule defragmented and fragmentation products assayed with Agilent 6420 Triple Quad LC/MS for confirmation.

Results: 10B-18F-DG complex was obtained with ion-exchange pH reaction successfully. Complexation of two 10B(OH)3 to 18F-DG was determined with Triple Quad LC/MS. Purification of 10B-18F-DG is currently in progress.

Conclusions: Radio-labelled 10B will supply new insight to research for BNCT studies. Cancer detection and therapy will be applicable in same schedule with 10B-18F-DG complex

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Micro needles: A novel and minimally-invasive drug delivery approach to overcome limitations of hypodermic needles for bio pharmaceutics

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Transdermal drug delivery including topical application is regarded as a potential route of delivering therapeutics that is capable of overcoming limitations of oral delivery and hypodermic injections. Among transdermal drug delivery systems, microneedles have gained a high interest due to their ability in delivering drugs with a high efficacy compared with topical application. Microneedles are referred to microscopic needles that are capable of delivering therapeutics into the skin in a minimally invasive manner. There are three main categories of microneedles; hollow type, solid type and dissolving type. Dissolving microneedles are polymeric structures fabricated over a patch that encapsulate drug and deliver it into skin upon application. However, due to stiffness of skin, only small portion of therapeutics are delivered into the skin. Therefore, we developed a patch-less dissolving microneedle delivery system which delivers microneedles into skin through micro-pillar structures without causing pain in less than a second. We have also developed novel microneedle fabrication techniques by which activity of encapsulated biotherapeutics can be maintained at high activity levels during the fabrication process.

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Synthesis of new sorafenib/ruthenium complexes and development of polymeric carrier systems to investigate drug potentials

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Cancer is the second leading cause of death globally and was responsible for 8.8 million deaths in 2015. The development of novel molecules and targeted therapies has gained attention because of currently available chemotherapeutic methods of limitations such as side effects/toxicity of existing drugs, high metastatic rates, and drug resistance. The improvement of the design of metal-based therapeutic agents which have a very important role in cancer treatment, have been accelerated by the development of platinum complexes. In the treatment of anticancer properties of metal complexes, many studies have been carried out on the development of new compounds with less toxic effect. Ruthenium is thought to have a lower side-effect profile, especially in platinum-resistant cancers and all other cancers, due to the greater accumulation of ruthenium, especially in cancer cells and hypoxic environments as well. Studies of anticancer and antimetastatic properties of ruthenium complexes have been published. Ruthenium complexes have been shown to be effective compounds in many cancers such as melanoma, lymphoma, breast and gastrointestinal cancers. It has been emphasized in many research articles that ruthenium complexes of phenanthroline-like compounds' toxicity are lower and show higher cytotoxic and apoptotic activity as compared with cisplatin. In cancer, activation of tyrosine kinases and intracellular pathway increases proliferation and angiogenesis and prevents apoptosis. Sorafenib is a multikinase inhibitor that has been approved for renal cell carcinoma, hepatocellular carcinoma, thyroid cancer, and the study of Sorafenib continues in other types of cancers. Sorafenib, which inhibits tumor proliferation and angiogenesis, in addition to Raf kinase also inhibits receptor tyrosine kinases such as VEGFR, PDGFRβ, c-KIT, RET. Receptor tyrosine kinases play a role in many cellular events such as proliferation and differentiation, cell survival and metabolism, cell cycle control. The fact studies that obtaining new metal complexes of the known drug active substances and investigation of their activities enable to reach the new drug substance in a shorter time and a lower cost has led to a remarkable increase in the researches in this field. Based on this data, in this study, firstly Sorafenib and ruthenium complexes of Sorafenib bearing hetrocyclic structures prepared as regards to valuable literature data. The structures of the obtained compounds were elucidated by elemental analysis, NMR, UV-Vis, FT-IR and APCI-LC/MS methods. Biological activity studies of the obtained products are performed. In this part of the study, MTT assay, cell cycle assay, apoptosis/cell death assay, *in vitro* tyrosine kinase assay, Western blot assay will be conducted. In addition, copolymers of poly (ethylene glycol) methyl ether-block-poly (D, L-lactate) (PEG-b-PLA) obtained to prepare polymeric micelles with active Sorafenib/metal complexes and drug release profiles examined. Finally, molecular modeling studies conducted by utilizing project outputs

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Curcumin derivatives: Anti-inflammatory, analgesic, ulcerogenic, cyclooxygenase-2 inhibition and molecular docking studies

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Curcumin has shown pharmacological properties against different phenotypes of various disease models. Different synthetic routes have been employed to develop its numerous derivatives for diverse and improved therapeutic roles. In present study, we have synthesized curcumin derivatives containing isoxazole, pyrazoles and pyrimidines then the synthesized molecules were evaluated for their anti-inflammatory and antinociceptive activities in experimental animal models. Acute toxicity of synthesized molecules was evaluated in albino mice by oral administration. Any behavioral and neurological changes were observed at dose of 10mg/kg body weight. Additionally, cyclooxygenase-2 (COX-2) enzyme inhibition studies were performed through *in vitro* assays. *In vivo* anti-inflammatory studies showed that curcumin with pyrimidines were most potent anti-inflammatory agents which inhibited induced edema from 74.7-75.9%. Compound 7, 9 and 12 exhibited relatively higher prevention of writhing episodes than any other compound with antinociceptive activity of 73.2, 74.9 and 71.8% respectively. This was better than diclofenac sodium (reference drug, 67.1% inhibition). Similarly, COX-2 *in vitro* inhibition assays results revealed that compound 12 (75.3% inhibition) was the most potent compound. Molecular docking studies of 10, 11 and 12 compounds in human COX-2 binding site revealed the similar binding mode as that of other COX-2 selective inhibitors.

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Traditional siddha breast cancer medicines of Kulasekharam, Kanyakumari district, India

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Breast cancer is the leading cause of death in women worldwide among other types of cancers. The present investigation was mainly focused on the scientific analysis to assess the qualitative and quantitative phytochemical constituents, antioxidant potential, cytotoxic, antiproliferative and apoptotic effect of traditional siddha breast cancer medicine (Herbal Formulation); To create an awareness regarding the value of Siddha Medicine and to utilize the cheapest source of traditional Siddha Breast Cancer medicine to relapse the patient from breast cancer without side effects. The plant materials required for the formulation of medicines were collected from the hills and hill locks of Molliadi and other ingredients were procured from Siddha raw drug stores. The herbal formulation is prepared as prescribed in the Palm leaf parchments by my Ancestors, and Grandpa's Siddha Practitioners, India. The scientific analysis of Siddha Breast Cancer medicines and case reports highlight the effect of medicine to relapse the patient from breast cancer. This research work makes the society to believe that treatment is also possible without any side effects.

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In-vivo in-vitro correlation (IVIVC) studies of the BCS class II drug

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During the last few years, especially after the introduction of Biopharmaceutics Classification System (BCS) and its acknowledgment by various health regulatory agencies, the concept of Biowaivers and IVIVC are the main focus of attention in academia, regulatory agencies, pharmaceutical industrial sectors and R&Ds. The aim of this study was to develop and optimize Nimesulide oral controlled release tablet formulations using various excipients for IVIVC studies. In present work, HPMC K4M was used in the development of three types of dosage form immediate, intermediate and controlled release tablets. Design expert® version 7. Using central composite rotatable design (CCRD) was used for the optimization of all formulations. Weight variation, friability, hardness, disintegration, dissolution and assay were found to be in acceptable limits. The assay was performed using an isocratic HPLC method. RP-18 column (Supelcosil LC-18-DB 250x4.6 mm, 5 µm (Supelco, Bellefonte, PA, USA) having mobile phase consisting of Acetonitrile, Phosphate buffer (pH 5.5) and methanol in the ratio of 35:45:20 was used respectively. All validation parameters were found within the acceptance limits. Single centered cross over, four cycle healthy human volunteer study was performed on 12 healthy male volunteers after taking informed consent. The time versus plasma drug concentration was then used for evaluating pharmacokinetic parameters including in-vivo bioequivalence using Kinetica 4.4.1. a PK/PD software while Phoenix WinNonlin IVIVC toolkit 1.0 was used for IVIVC studies. All values of average and individual internal percentage prediction error of Cmax and AUClast were less than 10 and 15 respectively, in all medium. Internal percentage prediction error (%PE) of Cmax was 1.840 and 3.05% while AUClast were found to be 9.98 and 7.17% at pH6.8 and 7.4 with USP dissolution apparatus II at 100rpm.

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Challenges and bioequivalence requirements of Orally Inhaled Drug Products (OIPs) - Salmeterol xinafoate/fluticasone propionate HFA pMDI pharmacokinetic studies

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Orally inhaled drug products (OIPs), such as corticosteroids and bronchodilators are most widely used for the treatment of respiratory diseases, such as asthma and chronic obstructive pulmonary disease (COPD). Salmeterol/fluticasone propionate is a fixed-dose combination inhalation agent containing a long-acting b2-adrenoceptor agonist (LABA) plus a corticosteroid and is known to be effective and well accepted in the treatment of asthma and COPD. Introducing generics of these products is essential as the pricing of these medications remains a barrier to adequate patient care. Establishing bioequivalence of OIPs is very challenging. Study procedures and bioequivalence requirements of OIPs in US, Canada and Europe will be discussed in this presentation. Four pharmacokinetic studies were conducted in healthy volunteers to determine bioequivalence of test and the reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI, two with the higher strength (25/250mcg per actuation) and two with the lower strength (25/125mcg per actuation). All the studies were single dose, randomized, crossover studies with a minimum washout period of 14 days. Two of the four studies (for each strength) also compared the pulmonary deposition by blocking gastrointestinal absorption (GI) using charcoal blockade. Since the 90% CI for Cmax and AUC0-t for both salmeterol and fluticasone were within the 80–125% interval in all the studies, it was concluded that test and the reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI were bioequivalent with and without charcoal blockade for both the strengths as per EMA guidelines.

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Wonders and worries of nanotechnologies in health care

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From science fiction to reality: nanotechnologies bring fresh hope to the medical world. Nano medicine can offer impressive resolutions for various life-threatening diseases including effective drug delivery systems, drug discovery and development, medical diagnosis and devices. The advent of nanomedicine and techniques for the early diagnosis of diseases could usher in a new era of superior prophylactic or preventive medicine. Nanobots could be sent into a patient's arteries to clear away blockages. Surgeries could become much faster and more accurate. Injuries could be repaired cell-by-cell. It may even become possible to heal genetic conditions by fixing the damaged genes. Nanotechnology could be used in cancer treatment, drug delivery, drug development, medical tools, diagnostic tests, imaging novel drug delivery systems of herbal drugs. Technology faces biggest challenges of scalability. There is an urgent need for standardized manufacturing techniques and quality control concerns of nanotubes through inhalation, ingestion, or absorption through the skin are increasing. Challenges: Are nanotechnology inventions required by the society? What about nanotoxicity? Are products commercially viable? Physicians use the most potent tools to conquer human disease

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Novelties of magnesium dietary supplement in emergency care setting

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In this paper the author will talk about magnesium dietary supplement and its use in the management of certain disease states in an emergency setting. A literature search of PubMed, Google search and Scopus using key words such as magnesium, supplement, magnesium citrate, chloride, lactate or aspartate migraine, and torsades de pointes were conducted in January 2017. There was no exception made to limit inclusion of relevant clinical trials and the trials referenced were not published yet. Magnesium is an essential electrolyte regulating a myriad of metabolic processes. Besides replenishing hypomagnesaemia levels, Mg is also used in the management of Torsades de pointes (Tdp), eclampsia and severe asthma exacerbations in the emergency setting. However, clinical justification for the use of Mg supplement in treatment of migraines and alcohol withdrawal syndrome remains inconclusive. Consideration for Mg supplementation use including pharmacology, dose, and adverse effects are discussed in this article. However, the use is based on practitioner's choice and requires validated randomized controlled studies to establish dose regimens. Given the versatility and reasonable-cost Mg diet treatment offers in acute emergency settings, pharmacists should be well informed regarding the potential therapeutic role and considerations of Mg dietary sources, recommended intake, and supplementation.

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Thioredoxin reverses age-related hypertension by chronically improving vascular redox and restoring eNOS function

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Hypertension is a major risk factor for cardiovascular diseases, and especially poses health problems for aging people. However, the pathogenesis of hypertension and the basic mechanism of blood pressure responses to aging are incompletely understood. Cytosolic thioredoxin (Trx-1) is a small (12kDa) antioxidant protein that protects against oxidative stress. As a reducing agent, it regenerates proteins and enzymes inactivated by oxidation. Considering that inactivated oxidized vessel protein accumulation is a major factor in age-related hypertension, we hypothesized a potential role of Trx-1 in amelioration of age-related hypertension by regenerating oxidized vessel proteins. To investigate this possibility, we recently developed a transgenic mouse line that is deficient in functional Trx-1 (dnTrx-Tg), and a complementary line that overexpresses functional Trx-1 (Trx-Tg). We observed that young dnTrx-Tg mice had significantly higher blood pressures than Trx-Tg mice. However, aged (>2 years) dnTrx-Tg and wild-type (WT) mice showed markedly decreased arterial relaxation, while aged Trx-Tg mice continued to function normally. Functional NO release, phosphorylation of eNOS, and decreased levels of superoxide generation were observed in aged Trx-Tg mice in contrast to aged WT or dnTrx-Tg mice. Further, injection of recombinant human Trx-1 for three consecutive days reversed hypertension in aged WT mice, and this effect lasted for at least 20 days. Our study established that the preservation of vessel redox state in aged mice is critical in protection against endothelial dysfunction and maintenance of normal blood pressure. Further, our study shows that reversal of hypertension in aging could be achieved by pharmacological intervention with redox-active drugs, which is a novel conceptual advance over the current treatment strategies in hypertension.

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Biopharmaceutical companies and market analysis

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Biopharmaceutical medicines represent a growing share of the global pharmaceutical market, and with many of these biopharmaceutical products facing loss of exclusivity rights, also biosimilars may now enter the biopharmaceutical market. Totaling US$ 228 billion in global sales in 2016 (Troein, 2017), biopharmaceutical medicines represent a growing share of the global pharmaceutical market. With many of these biopharmaceutical products facing loss of patent protection and other exclusivity rights, also non-innovator versions of these molecules, biosimilars, may now enter the market, resulting in a shift of market shares (IMS Health, 2016), revision of strategies of companies and attraction of new players to the biopharmaceutical market. Due to lower research and development costs and increase in competition, biosimilars offer a lower cost alternative to expensive biopharmaceutical therapies. By adopting biosimilars, health care systems can expand patient access, offer more treatment options to physicians and have a new tool to control increasing health care expenses (IMS Institute for Healthcare Informatics, 2016). Overall, large investments have been made by companies to compete on the biopharmaceutical market.

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Impact of novel N-aryl piperamide on NF- B translocation in neuro-inflammation: Rational drug designing, synthesis, and biological evaluation

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The discovery of the role nitric oxide (NO) in the various pathophysiological and physiological processes leaded to develop new drugs for modulation of the nitric oxide (NO) production directly and/or indirectly, for therapeutic purposes such as NO-releasing drugs, NO-inhibiting drugs, and phosphodiesterase V inhibitors. There are numbers of NO donor drugs showed an important therapeutic effect in the treatment of many diseases such as arteriopathies, various acute and chronic inflammatory conditions, and several degenerative diseases (Alzheimer's disease and cancer). The NO donor anti-inflammatory drugs are a novel class of compounds in which NO combined to an anti-inflammatory agent to improve the efficacies and reduce the side effects. They are combining the pharmacological activities of anti-inflammatory and antinociceptive of drugs with those of NO (vasodilator, anti-aggregant, anti-microbial and immune modulator agent). In our pervious study, the anti-inflammatory activity of different alkyl nitrate derivatives of the various types of N-Aryl Piperamides (NAP) have been screened and verified. In this study, we are investigating the biological activity by targeting NF- B subunits and Cyclooxygenase-2 *in silico and in vitro*, and pharmacological profiling along with toxicity predictions of various NAPs linked via an ester bond to a spacer that is bound to a NO -releasing moiety (-ONO2). The result in *silico* investigation indicated that among 51 designed molecules, 3-((2E,4E) -5-(benzo [d] [1,3] dioxol-5-yl) -N-(4-(hydroxymethyl) phenyl) Penta-2,4-dienamido) propyl nitrate with code number PA-3'K showed the best anti-inflammatory potential. These findings have been tested and supported by the *in vitro* investigation and will presenting along with.

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