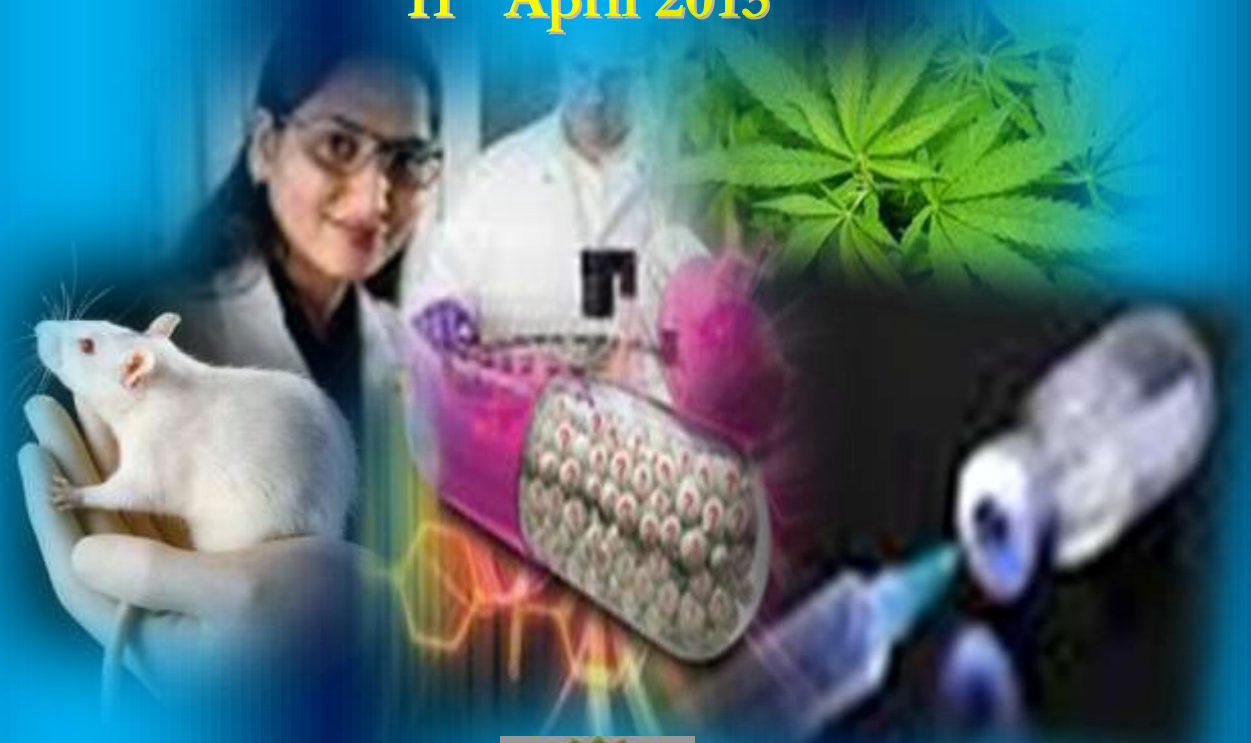
Abstract Book

NATIONAL SEMINAR

On

"Emerging Trends & Innovation in Pharmaceutical Education & Research in India"

11th April 2015



Sponsored by

Society of Pharmaceutical Education & Research (SPER)

Organized at

Bengal College of Pharmaceutical Sciences and Research, Durgapur

National Seminar

on

Emerging Trends & Innovation in Pharmaceutical Education & Research in India

11th April 2015

Sponsored by

SOCIETY OF PHARMACEUTICAL EDUCATION & RESEARCH (SPER)

Organized by

BENGAL COLLEGE OF PHARMACEUTICAL SCIENCES & RESEARCH (BCPSR)

Venue: Seminar Hall, BCPSR, Durgapur, West Bengal

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SPER-BCPSR/15/01

Herbal Lipstick: A Developmental Approach

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Due to various adverse effects of available synthetic preparations, this work was conceived to formulate an herbal lipstick having minimal or no-side effects which will be extensively used by women of our communities with great surety and satisfaction. The formulation consists of cow ghee and honey as natural excipients. Honey helps to promote tissue regeneration and cow ghee is highly effective for all sorts of skin rashes. The natural colour anthocyanin was extracted from the fresh flower petals of *Impatiens balsamina*. The herbal lipstick was prepared by mixing dye colour in cow ghee at 50°C and then added to molten wax phase at 80°C. It was then cooled following addition of honey. The mixture was stirred vigorously till a smooth emulsion was formed and then poured into clean and lubricated moulds. The formulated herbal lipstick were evaluated on parameters such as melting point, softening point, breaking load test, test for force of application, solubility test, skin irritation test, pH and stability studies. After evaluation, the lipsticks exhibited excellent properties such as spreading, luster, smoothness and passed all the evaluation parameters that were carried out. It was concluded that the formulated herbal lipstick having minimal or no side effects was prepared.

SPER-BCPSR/15/02

Assessment of the Impact of a Polyherbal Antidiabetic Formulation on Kidney Function in Diabetic Rats

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The study assesses the impact of a polyherbal antidiabetic medicine, alone and in combination with glibenclamide on kidney function in streptozotocin- induced diabetic wistar rats. A total of 30 adult rats (130-170 g) were employed. IAEC permission was sought and granted for the study. Statistical integrity of baseline data across and within groups was measured prior to the commencement of the study. They were divided into five groups with n=6. Experimental diabetes (type-1) was induced in 24 rats, by a single intraperitoneal injection of streptozotocin (STZ) in buffer solution of pH 4.5 (dose of 55 mg/kg). Blood glucose (FBG, PPG, HbA1c), body weight and biochemical parameters such as SGPT, SGOT, serum creatinine, BUN and albumin levels were measured on days 10, 20 and 30 using semi autoanalyser. Histological investigations, necropsy and tissue collection were carried out on the pancreas, liver and kidney at the end of the study under the supervision of a medical pathologist. Histological observations did not reveal any significant untoward effect on pancreas, liver but showed remarkable changes in the architecture of the kidney that is suggestive of early glomerular nephritis in the disease control group that was arrested by the polyherbal under study group in the experimental animals. These preliminary findings help us to hypothesize that the PHAF under study possesses distinctive efficacy in arrest and potential reversal of STZ induced early glomerular nephritis.

SPER-BCPSR/15/03

Assessment of Nephrotoxic Effects of Gentamicin and Cisplatin Using Chick Embryos, Based on Biochemical Parameters

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The general toxicological experimentation involves termination of a fairly large number of animals. The development of a prescreening technique using chick embryos will lead to reduction of the number of live animals involved, satisfying the criteria of "Reduction" among the 3 R's (Replacement, Reduction, Refinement) given by Russel and Burch as the guiding principles to more ethical use of animals. Here in this study, an effort has been made to develop nephrotoxicity in chick embryos using nephrotoxic agents namely, Gentamicin and Cisplatin and its assessment, based on biochemical parameters.5 day old chick embryos were injected with Gentamicin (0.2mg/ embryo) or Cisplatin (3µg/ embryo). These were sacrificed on day 16 and the amniotic fluid was used for biochemical estimation of Urea, Creatinine and Uric acid. Gentamicin treated group did not show significant changes in biochemical parameters but a significant decrease in the same was observed in the Cisplatin treated group when compared to the Control group (treated with water for injection 0.1 mg/ ml on embryonic day 5). A destruction of the cellular elements of nephrons resulting in the reduction of the kidney's ability to eliminate waste products was believed to cause the above results.

SPER-BCPSR/15/04

Development of Formulation of Ciprofloxacin as an *In-situ* gel for Ocular Delivery

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Ophthalmic drug delivery is one of the most challenging and interesting field of drug delivery because of the anatomy, physiology and biochemistry of the eye, as this is exquisitely impervious to foreign substances. The unique structure of the eye restricts the entry of the drug molecules at the required site of action. Initially attempts were made to overcome the poor bioavailability by instilling in the form of ointments thereby increasing the contact time with eye, minimising the tears and resisting nasolacrimal drainage. *Insitu* gel formation occurs by crosslinking of the polymer chains that can be achieved by covalent bond formation. *Insitu* gel forming systems can be described as low viscosity solutions that undergo phase transition in the conjunctival cul-de-sac to form viscoelastic gels due to conformational changes of polymers in response to the physiological environment. It increases the contact time of drug with the mucus at the site of absorption and has better bioavailability.Environmental conditions like pH, ion activated and temperature stimuli are used for ophthalmic drug delivery.Ciprofloxacin is a second generation fluoroquinolone which is used to treat bacterial infections of the eye including conjunctivitis and corneal ulcers. For the formulation of the *in situ* nasal gel phosphate buffer of pH-5.0 was selected depending on the drug's solubility. Carbopol 940 is selected as the pH sensitive polymer for *insitu* gelling and Methocel K100LV as a release retardant. Mannitol was selected as tonicity modifier. A final optimised formulation was thus prepared.

SPER-BCPSR/15/05

Evaluation of *In-Vitro* Anti-Cataract Activity of *Madhuca longifolia* (Koen.) Macbr. Leaves

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Madhuca longifolia commonly known as the 'Butter nut tree' is a well known medicinal plant used traditionally in the treatment of diabetes mellitus, but its *in-vitro* reports on retinopathic complications of diabetes have not been reported yet. Various concentrations of hydro-ethanolic extract of *Madhuca longifolia* (MLHE) leaves was subjected to *in-vitro* anti-cataract activity against glucose induced cataractogenesis using goat lens. The incubated lens containing 200 μg mL^{-1} and 400 μg mL^{-1} of MLHE extract seemed to retard the progression of opacification in comparison to positive control group. Hence, it can be concluded that MLHE possess significant in-vitro anti-cataract property.

SPER-BCPSR/15/06

Evaluation of The Impact of a Polyherbal Antidiabetic Formulation on Liver Parameters in Diabetic Rats

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The study assesses the impact of a polyherbal antidiabetic medicine, alone and in combination with glipizide on liver function in streptozotocin- induced diabetic Wistar rats. A total of 30 adult rats (130-170 g) were employed. IAEC permission was sought and granted for the study. Statistical integrity of baseline data across and within groups was measured prior to the commencement of the study. They were divided into five groups with n=6. Experimental diabetes (type-1) was induced in 24 rats, by a single intraperitoneal injection of streptozotocin (STZ) in buffer solution of pH 4.5 (dose of 55 mg/kg). Blood glucose (FBG, PPG, HbA1c), body weight and biochemical parameters such as SGPT, SGOT, serum creatinine, BUN and albumin levels were measured on days 10, 20 and 30 using auto-analyser. Liver was analysed histologically. The biochemical study parameters performed, especially SGPT, SGOT and BUN revealed that the PHAF has distinct anti hyperglycemic effects on blood glucose in diabetic rats. These preliminary findings help us to hypothesize that the PHAF under study is having putative antihyperglycemic effect without any major adverse effects on the hepatocyte cells of liver in Wistar rats.

SPER-BCPSR/15/07

Role of Pharmacist in Nation's Health Care

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Throughout the third world, wherever there severe shortages of medical services, there are corresponding shortages of pharmaceutical services and pharmacists, and most of the people have no access to basic life saving drugs in some of the more advanced developing countries the ratio of pharmacists to the population is low in rural places than urban places. In general however ratios of less than 1:100000 are common and some countries have too much low ratio. Thus, pharmacist and the profession pharmacy have a unique role in nation's health care system with respect of Community and hospital services. They are the occupational specialist, mainly industrial pharmacist involved in pharmaceutical technology and research. In addition to this Pharmacists are also teachers, managers, administrator of pharmaceutical services and system. With the development of synthetic and potent drug the emphasis of pharmacist's responsibility has moved substantially towards the utilization of scientific knowledge and protection of public against danger and makes their life healthy.

SPER-BCPSR/15/08

Enhancing the Solubility of Poorly Water Soluble Statins by Different Techniques, Formulation and Evaluation

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The objective of the present study is to improve solubility, dissolution profile, absorption efficiency and bioavailability of poorly water soluble statins by using different techniques like co-solvents, solid dispersions, superdisintegrants and sublimation. Lovastatin is a member of statins, used as hypolipidemic agent (lowering cholesterol) in those with hypercholesterolemia and so preventing cardiovascular diseases. Lovastatin is a poorly soluble and highly permeable drug belongs to BCS class II. Rate of its oral absorption is often controlled by the dissolution rate in the gastrointestinal track. Tablets are most widely used solid dosage forms because of their advantages. Lovastatin tablets were prepared by direct compression technique. Solid dispersion of Lovastatin was prepared using PEG 6000 (1:1, 1:2, 1:3 ratios respectively), Crospovidone used as superdisintegrant (2%, 4% and 8%), Urea used as sublimating agent (2%, 4% and 8%). The tablets were subjected to thickness, weight variation test, drug content, hardness, friability, disintegration and *in vitro* release studies. In conclusion, the results suggest that the selected best formulation F_6 was shown improvement in dissolution rate (10% more than other methods) from superdisintegrant method and was preferred due to its low cost, easy method of preparation and industrial benefits.

SPER-BCPSR/15/09

Formulation and Evaluation of Microspheres of Terbutaline Sulphate an Anti-Asthmatic Drug

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Sustained release formulations maintain a constant level plasma concentration of drug so that multiple and night dosing can be avoided. Terbutaline sulphate is a β_2 stimulant drug which is having a very short half-life of less than 4 hours. It is available in sustained release 'once a day' formulation. This study was to formulate and evaluate microspheres of Terbutaline sulphate for sustained release preparation by solvent evaporation technique using ethyl cellulose (EC) and hydroxyl propyl methyl cellulose E 50 LV (HPMC) with different ratio.*FT-IR* study revealed no interaction between the drug and the excipients. The prepared microspheres were characterised for micromeritic properties, drug content, *in-vitro* release, particle size and shape, drug loading, encapsulation efficiency. The drug release characteristics were determined for the prepared microspheres in phosphate buffer pH 6.8 dissolution media. The rate of drug release decreased with increased use of ethyl cellulose. Among the 10 formulations, F_{10} was selected as a best formulation depending on the drug release and encapsulation efficiency which shows 82.91% release after 12 h and 89.62% entrapment.

SPER-BCPSR/15/10

Studies of Ethnomedicinal Plants Used in the Treatment of Scorpion Bite in the Eastern Himalayan Region of Sikkim

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This paper deals with ethnomedicinal use of plants which are used for the treatment of Scorpion bite by the rural & tribal communities in the eastern Himalayan region of Sikkim. These plants have been traditionally used in their curative systems by the village elders as well as 'Kabiraj', 'Ozas'or 'Bezas' for scorpion bite. Effectiveness of the folk medicine for the respective treatment both remedial and curative recipes were studied. The raw materials utilised in the medicaments are procured from in and around the habitats of the communities. The present communication highlighted the use of 20 medicinal plants belonging to 12 families providing details about the plant, local name(s), plants parts used, method of preparations of recipes, dose regime and status of occurrence in the indigenous plant species.

SPER-BCPSR/15/11

Self-Microemulsifying Drug Delivery System (SMEDDS): Enhanced Oral Bioavailability of Quetiapine Fumarate

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Quetiapine fumarate is an atypical antipsychotic drug which is used in the treatment of schizophrenia and bipolar disorders. It undergoes extensive first pass metabolism and shows poor bioavailability. So QF loaded Self-Microemulsifying drug delivery system (QF-SMEDDS) was developed to enhance its bioavailability. The objective of the study was to develop SMEDDS of QF and to characterize the particle size, self microemulsification and *in-vitro* release characteristics. The *in-vitro* self-emulsification properties and droplet size analysis of these formulations upon their addition to water under mild agitation conditions were studied. An efficient Self-Microemulsifying vehicle was selected using Pseudo-Ternary phase diagram constructionsand optimized using solubility testing in various oils and surfactants. Optimized formulations were made using Triethanolamine, Olive oil, PEG 400, Tween 20 and Tween 80 in varied ratios. The SMEDDS readily released the lipid phase to obtain a fine oil-in-water microemulsion. The *in-vitro* release of QF from SMEDDS showed improved results as compared to QF suspension.

SPER-BCPSR/15/12

Formulation and Evaluation of Dicyclomine Hydrochloride Microspheres using Ethyl Cellulose Polymer

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Dicyclomine is an antispasmodic and anti cholinergic (anti-muscarinic) drug was formulated as microspheres by using ethyl cellulose polymer as carrier. The prepared microspheres have been used for the delivery of drugs to affected area and had good spherical geometry and discrete, free flowing properties. The release of Dicyclomine hydrochloride from the microsphere produces the sustained action. Microspheres encapsulated Dicyclomine hydrochloride was prepared by using emulsion-solvent evaporation method employing chloroform as a solvent. Different proportions of core to coat materials namely 9:1, 8:2, 7:3 and 6:4 were used to prepare microspheres.The prepared microspheres were subjected to various evaluation and invitro release studies. The invitro release studies showed that dicyclomine hydrochloride microspheres of 9:1 ratios showed better sustained effect over a period of 24 hours.The increase in concentration of Ethyl cellulose causes the decreasing rate of drug release. The release rate was depended on the core: coat ratio and size of the microspheres. The release rate was increased as the size of microspheres was decreased. The increasing concentration of CMC was slightly retarding the release rate. i.e. the same formulations with 1% CMC were released 88.16. The flow ability of microspheres was found to be excellent according to Carr's index of compressibility. Stability studies were done for all the formulation according to ICH guide line shows no significant change in drug content and release properties. The differential scanning calorimeter thermograms which indicates that no interaction occur between the drug and polymer and they are compatible with each other.

SPER-BCPSR/15/13

Ethno-Medicinal Study of Anti-Psoriasis Plants of Himalayan Region

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Tribal communities of Himalayan region are practicing their traditional ecological knowledge to cure a variety of diseases and ailments. The importance of plants for medicinal use has not reduced in any way because the traditional medicines are still the most important health care source for the vast majority of the population. Now a day, psoriasis is considered as an important public skin health hazard in India. Psoriasis is a common skin condition that changes the life cycle of skin cells. Plaque psoriasis typically appears as raised areas of inflamed skin covered with silvery white scaly skin, commonly found on the elbows, knees, scalp, and back. It is a chronic skin disease characterized by red patches on the skin, often accompanied by silvery-white scales of dead skin cells. In the present paper, we discussed the 10 genera of medicinal plants belonging to 10 families along with their botanical names, local names, parts used in treatment of Psoriasis in Himalayan region by the traditional healers.

SPER-BCPSR/15/14

Dynamic chromatin modification by Benzophenanthridine alkaloid – Chelerythrine

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Chromatin remodelers are essential to various important biological processes such as DNA replication. Deregulation of these remodeling causes loss of transcriptional regulation & thus causes various diseases, including cancer. DNA function can be artificially modulated, inhibited or activated by binding of a small molecule modulator. A number of molecules have been reported that may bind both to DNA & histone (dual binding). Such a small molecule drug is Chelerythrine (which has the structural similarity with sanguinarine). From preliminary pre-clinical studies it has been demonstrated that Sanguinarine causes apoptosis in human cancer cells. This research work is an effort which had dealt with the finding of dynamic chromatin modification by Chelerythrine – specially its interaction with histone core. Results had shown that it had led to inhibition of histone methylation (H3K9) & acetylation (H3K9) both in Hela & HL60 cell lines. Positive results were also shown in HAT assay. Further studies may be undergone with this molecule to observe its apoptosis property.

SPER-BCPSR/15/15

"Electronic Nicotine Delivery System (ENDS)" A Tobacco Free World: The future Prospects of the Pulmonary Drug Delivery Systems

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Pulmonary drug delivery (PDD) is primarily used to treat conditions of the airways, delivering locally acting drugs directly to their site of action. These routes of drug delivery may give the advantages like small amount of drug, less adverse reaction and rapid onset of action.Nowadays PDD is useful to treat Diabetes, angina pectoris, cancer, bone disorders, tuberculosis and others. The recent advancement of this delivery system is "Electronic nicotine delivery systems (ENDS)", which include e-cigarettes; are devices capable of delivering nicotine in aerosolized form. ENDS are designed to deliver nicotine with fewer toxicants and carcinogens than traditional cigarettes, by vaporizing a nicotine solution instead of combusting tobacco. When a user inhales from the device, air flow is detected by a sensor, which activates a heating element that aerosolizes a solution typically containing nicotine from the mouthpiece cartridge.ENDS may be beneficial as they may reduce smoking rates or reduce the known adverse health effects of smoking.*AACR and *ASCO recommend additional research on these devices, including assessing the health impacts of ENDS, understanding patterns of ENDS use, and determining what role ENDS have in cessation. In this review we study the mechanism, usefulness and future prospect of ENDS.

SPER-BCPSR/15/16

Fabrication and Evaluation of Ciprofloxacin Loaded Gastroretentive Capsules

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The aim of the present investigation was to develop and evaluate the sustained release hydrodynamicbalanced systems for Ciprofloxacin HCl using polymers such as Starch and Ethyl Cellulose (EC). Gastro retention was achieved due to effervescenceobtained by addition of sodiumbicarbonate.The caps and base of the capsule shells were cross-linked with 5 % formaldehyde solution in ethanol. The capsules were filled with 250mg of the powder mixture each containing 50mg of Ciprofloxacin HCl. The capsule walls were perforated with a hypodermic needle. One set of formulations got three pores and the other two formulations got 6 pores on their walls.Formulations were evaluated for *in-vitro* buoyancy and *in-vitro* release studies.The *in vitro* drug release followed zero order kinetics and the drug release mechanism was found to be anomalous type. It was found that both starch and Ethyl Cellulose and their interaction had significant impact on the releaseand floating properties of the delivery system.Further, capsules were evaluated for in-vitro release characteristic for 12 hrs. It's found that the hardness of the capsule shells obtained due to cross-linking and pores synergistically affects the buoyancy characteristic of thedosage form. All formulations possessed good floating properties.

SPER-BCPSR/15/17

Study on Cerebroprotective Action of *Fumaria officinalis* against Acute Transient Bilateral Common Carotid Artery Occlusion in Rats

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Flavonoid and phenolic compounds exhibit a broad spectrum of biological activity, including antioxidant. *Fumaria officinalis* is a medicinal plant widely used in folk medicine for various purposes. So that, the goal of this research was to study *in vivo* cerebroprotective action of ethanolic extract of *Fumaria officinalis* in comparison with cerebprotective -antioxidant – quercitine. Experiment was carried out on Wistar rats of either sex of 200-250 g of body weight. For assessment of cerebroprotective action of extract by cerebral ischemia and that was reproduced by bilateral common carotid arteries occlusion (BCCAO). Acute cerebral ischemic condition was achieved by BCCAO method for 30 min ischemia, followed by 4 h reperfusion. At the end of ischemic reperfusion period animal was sacrificed, brain was isolated, homogenized, centrifuged and estimated for following parameters like SOD, CAT, MDA and MPO. Infarct size and histopathological changes were observed in entire groups. In cerebral ischemia reperfusion model revealed that ischemic changes were preceded by increase in concentration of MDA, MOP and followed by decreased SOD CAT, GST, GR, GPx and GSH activity in ischemic group. Treatment with *Fumaria officinalis* significantly attenuated ischemia–induced oxidative stress. Ethanolic extract of *Fumaria officinalis* (200 and 500 mg/kg), pre-treated markedly reversed and restored to near normal levels in the groups. Similarly, *Fumaria officinalis* reduced brain infarct size in the ischemia reperfusion animals compared to vehicle or control groups. The neurodegenaration was also confirmed by the histological changes in the cerebral-ischemic rats. The findings from the present investigation reveal that *Fumaria officinalis* (500 mg/kg, p.o.) cerebroprotective more significant than 200 mg/kg, p.o. of ethanolic extract of *Fumaria officinalis* by transient ischemia in experimental rats by attenuating oxidative stress.

SPER-BCPSR/15/18

Evaluation of Neuropharmacological Activity of *Fumaria officinalis Linn.* by Study of Analgesics Activity on Experimental Animals

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Pain is a common and distressing feature of many diseases such as tumour, surgical procedures, physical trauma, noxious chemical stimulation etc. It is mostly a warning signal and primarily protective but excessive pain can lead to other side effects such as sweating, apprehension, nausea and palpitation. Preliminary phytochemical investigations of different extracts of leaves of *Fumaria officinalis Linn.* were studied. The petroleum ether extract contains phytosterols, saponins and fixed oils. The chloroform extract contains proteins. The ethanolic extract contains carbohydrates, saponins, flavonoids, phytosterols, tannins and phenolic compounds. Acute toxicity studies were carried out and 100, 200 and 500mg/kg b.w.dose were selected to evaluate analgesic activity of ethanolic extract of *Fumaria Officinalis* (EEFO). PRT (Pain Reaction Time) time was significantly increased with higher dose of extract (500mg/kg, b.w.) in both hot plate and tail flick method, pain was induced using analgesiometer.The percentage inhibition of writhing was also dose dependently increased from zero in the control group (normal saline) to 33% in the group that received 500mg/ kg of the extract. In all models we have found that standard drug Diclofenac sodium and high dose of extract shown significant analgesic activity compared to lower dose of extract.

SPER-BCPSR/15/19

Nanoparticles targeting Blood Brain Barrier (BBB): A Source of Potential Thrombolytics

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The human Blood Brain Barrier (BBB) affords selectively and protection in cerebral tissues. This hypothetical barrier regulates biochemical reactions within the brain and renders protection against invading pathogens and various chemical substances including drug molecules. Such a innate protection facilities strict monitoring of the influx of drug molecules often required for the management of several diseases and disorders including cerebral vascular and neurological disorders. However, in recent times the ischemic cerebrovascular disease and clinical manifestation of acute arterial thrombosis are one of the most common causes of mortality and morbidity worldwide. The pharmacological management of cerebral ischemia requires immediate infusion of external thrombolytic into systemic circulation and must cross the Blood Brain Barrier (BBB). The major limitation with available thrombolytic is their poor affinity toward blood brain barrier (BBB) and cerebral tissue subsequently. In clinical practice, a high dose of thrombolytics are often administered to deliver drugs across the Blood Brain Barrier(BBB) which results in drug dependent toxicity leading to damage to the neurons at the tissue level. In recent times, more emphasis has been given to utilize Blood Brain Barrier (BBB) transport mechanism to deliver drugs in neuronal tissue. The Blood Brain Barrier represents series receptors at the membrane level that has become an obvious target for selective drug delivery. In this review, the more emphasis is given on the use of solid lipid nanoparticles and their innate potential as a carrier for drug molecules to target cerebral tissues of the body. Further, the use of nanoscsle design and real time monitoring for developed therapeutic to encounter drug dependent toxicity emanating has been reviewed in this work.

SPER-BCPSR/15/20

Dry Liposomal Inhalation Powder of Salbutamol Sulphate

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Salbutamol sulphate is an anti-asthmatic drug which undergoes extensive first pass metabolism. This study aimed at developing and optimizing liposomal formulation of Salbutamol sulphate in order to sustain the release of the drug. Moreover liposomal delivery by dry powders will be more stable. In evaluation study the effect of the varying composition of lipids on the properties such as encapsulation efficiency, particle size and drug release were studied. Phase transition study was carried out to confirm the complete interaction of Salbutamol sulphate with bilayer structure of liposomes. F4 emerged as the most satisfactory formulation in so far as its properties were concerned. Further, release of the drug from the most satisfactory formulation (F4) was subjected to graphical treatment to assess the kinetics of drug release. Higuchi's plot confirms the release as diffusion mediated. The optimized formulations were subjected to lyophillization to form dry powder.

SPER-BCPSR/15/21

Recent Trends in use of Biosimilar Drug and Pharmacovigilance perspective at par Indian Scenario: An Overview

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Biosimilars are "similar but not the same" or in other words Biosimilars are "the twin but not the clone" to the original biologic innovator product. These products are approved through an abbreviated route which relies on limited safety and efficacy data enabling the generic companies to keep the production cost low and pass on the price-benefit to the patient and make the product affordable to the masses, as well as to maintain benefit-risk ratio of the product according to Pharmacovigilance point of view. Due to limited clinical database at the time of approval of a biosimilar, vigorous pharmacovigilance is required. Immunogenicity is a unique safety issue with biosimilars. However, lack of validation and standardization of methods for detection of immunogenicity further implies the necessity for robust Pharmacovigilance, as well as monitoring of adverse drugs reactions, including the type of adverse event is also required. Indian Biopharmaceutical and Biotechnological Industries have been growing in conjunction with economic evolution. But, at par Indian scenario scientific use and affordability must be considered with respect to cost-to-benefit and benefit-risk ratio from patient point of view.

SPER-BCPSR/15/22

Formulation and Evaluation of Pioglitazone Transdermal Patch by Using Different Polymers

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The purpose of this research work was to develop and evaluate matrix-type transdermal patches containing Pioglitazone with Ethyl cellulose, Poly vinyl pyrrolidone in different ratios like 1:1, 1:2, 1:4, 1:6, 1:8, 8:1, 6:1, 4:1 and 2:1 prepared by the solvent evaporation technique. Dibutyl phthalate was used as plasticizer and DMSO penetration enhancer in this formulation. The physicochemical compatibility of the drug and the polymers were studied by FTIR. The results suggested no physicochemical incompatibility between the drug and the polymers. The prepared transdermal patches were evaluated for weight variation, thickness, folding endurance, moisture loss, moisture absorption, *in vitro* drug release, drug release kinetics and *ex vivo* permeation studies. Phosphate buffer pH 5.8 was used for the *in vitro* skin permeation study. It was found that though the matrix type patches following the first order kinetics but predominantly they follow the Higuchi square root model. From the 'n' value obtained from Korsemeyer-Peppas model it can say that the release pattern of the drug form the patches was though diffusion mechanism. The diffusion studies were performed by using modified Franz diffusion cells. The best formulation, TEP 3 was selected.

SPER-BCPSR/15/23

Hepatoprotective Ethnomedicinal Plant of Assam Hilly Region

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There are various types of medicinal plants of Assam Hilly Region used by the ethnic people of this region. Hepatic disorder is one of the major problems in India. Liver region is an amazingly complex organ which virtually affects every physiological process of the body. Our body is protected from various injurious substances and toxic metabolic by-products by the liver, which has been absorbed from intestinal tract. Xenobiotics are often reported to cause potential hepatic damage. In this review paper we discuss about 10 different genera of 10 different family plants with local names which are used by the Healers of Assam Hilly Region.

SPER-BCPSR/15/24

Effects of Anxiolytic Drug as Pretreatment Therapy for Anxiety of Zebra Fishes Induced by the Exposure of Unfamiliar Environment

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The research investigation was designed to find the behavior of zebra fish when it was exposed into unfamiliar atmosphere. The animals were divided into three different groups containing 6 zebra fishes. After pretreatment with high and low dose of Midazolam, two groups were undergone an exposure of unknown environment by immersing into novel dive tank. The last group of fishes as control group was immersed into the dive tank for 5 minutes without any pretreatment group. Induction of the anxiety was observed in the form of different parameters like number of cross to middle, number to cross upper 2/3rd , time spent in middle half (s), time spent in upper 2/3rd of the tank, total number of turns and latency time to enter middle half. The results illustrated that the improvement of anxiety disorder was clearly evident when the pretreatment of the animals with lower and high doses was done. It was also evident that higher dose a pretreatment significantly improved the anxiety as compare to lower doses. Overall the model can be described as a distinct behavioral method tool that is highly sensitive to find the proper drug and dose for the treatment with anxiolytic compounds.

SPER-BCPSR/15/25

Simultaneous Spectrophotometric Estimation of Moxifloxacin Hydrochloride and Doxorubicin Hydrochloride

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To develop a simple, accurate, and precise spectrophotometric method for the simultaneous estimation of moxifloxacin hydrochloride (MOX) and doxorubicin hydrochloride (DXR). MOX and DXR solution were simultaneously determined in 0.1M HCl at their respective λ_{max}. The absorbance λ_{max} of MOX and DXR were 295nm and 480nm, respectively. The developed method was validated according to ICH guidelines for parameters like linearity, accuracy, precision, ruggedness and robustness. Molar absorptivities of MOX and DXR were found to be more in 0.1M HCl with compared to water, methanol and 0.1M NaOH. Linearity was obtained over the range 0.5 – 30.0 µg/ml and 1.5-40 µg/ml with a lower limit of quantitation of 0.25 µg/ml and 1.5 µg/ml for MOX and DXR, respectively. For each level of samples, inter- and intra-day precision (% RSD) was <1.3% and <1.4%for MOX and < 2.5 and 2.4 % for DXR, respectively. The mean recovery of MOX and DXR were in the range 96.21%-98.77% and 97.13%-99.64%, respectively. The method so developed was validated as per ICH guidelines for analytical method validation tool which includes the analytical method validation parameters like linearity, accuracy, method precision, robustness and ruggedness. The results obtained were well within the acceptable criteria. The method can be used for routine analysis of MOX and DXR.

SPER-BCPSR/15/26

CAFFEINE-CAPSAICIN COMBINATIONAL THERAPY TO TREAT DIABETES

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Now-a-days Diabetes is one of the most prevalent diseases all over the world. India holds the second position followed by China as far as the diabetes is concerned. There are many synthetic anti-diabetic drugs in the market that are not free from side effects. Aim of eradicating these side effects by introducing alternative herbal formulation with a minimum side effect is the search engine for many researchers. Recently Caffeine-Capsaicin combinational therapy is found to be effective to treat obesity induced Insulin resistance in obese mice model. This Caffeine-Capsaicin combination shows effect by simply acting on the Transient Receptor Potential Vanilloid Type-1(TRPV-1) receptor. This TRPV-1 receptor is present on the β-cells of pancreas and gets activated by capsaicin which increases insulin secretion and cause reduction in blood glucose level in hyperglycaemic patients. It is a novel finding to manage diabetes in very cost effective manner.

SPER-BCPSR/15/27

Preparation of Some Life Saving Medicine According to Green Chemistry

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Green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Discovery and application of new chemistry/technology leading to prevention/reduction of environmental, health and safety impacts at source. Lots of medicine are prepared with a large number of chemicals and different steps producing lots of by products that may be harmful, toxic, may not require and are totally waste of time, chemical, producing pollution and health hazards. Our objective is to develop medicine without excess solvents and excess steps. In the preparation of ibuprofen by conventional method it follows 6 steps and many by products. But scientist Hoechst has produced a route which is of 3 steps and only one by product will be there. Like this way formation of a cyclic adduct of trans-1,2-bis(4-pyridyl)ethylene is directed by dihydroxybenzene in the solid state in the presence of UV light.Atul Kumar has developed an efficient and green method for the synthesis of tryptanthrin - employing β-cyclodextrin as a catalyst in aqueous media at room temperature . Like this way there are many methods which applies the green chemistry process and minimizes the waste and toxic chemical.

SPER-BCPSR/15/28

Synthesis of Adipic acid According to Green Chemistry

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Green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Discovery and application of new chemistry/technology leading to prevention/reduction of environmental, health and safety impacts at source. Lots of medicine are prepared with a large number of chemicals and different steps producing lots of by products that may be harmful, toxic, may not require and are totally waste of time, chemical, producing pollution and health hazards. Our objective is to develop medicine without excess solvents and excess steps. Currently, the industrial production of adipic acid uses nitric acid oxidation of cyclohexanol or a cyclohexanol/cyclohexanone mixture. The nitrous oxide emission from this process measurably contributes to global warming and ozone depletion. Therefore, the development of an adipic acid production process that is less damaging to the environment is an important subject in chemical research. Cyclohexene can now be oxidized directly to colorless crystalline adipic acid with aqueous 30 percent hydrogen peroxide under organic solvent- and halide-free conditions, which could provide an ideal solution to this serious problem.

SPER-BCPSR/15/29

'A Review on Red Meat as Carcinogenic Material''

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Most of us known about the harms of red meat. A new study has thrown some interesting facts on how consumption of red meat may increase the risk of cancer. Researchers from University of California in San Diego found that red meat contain certain kind of chemical that can play a crucial role in causing tumor formation.The cancer causing chemical is called Neu5Gc(N-Glycolylneuraminic acid) .It can be found in mammals but in trace amount in humans. A group of scientists conducted several experiments on mice modules that were injected with Neu5Gc doses. The researchers found that Neu5Gc doses promoted the growth of spontaneous cancer in a remarkable manner in those mice. Red meats like- pork, beef & lamb contain a rich amount of Neu5Gc that can't be naturally accepted by our body & the sugar can be distributed to tissue all over the body via blood. The consumption of red meat could cause inflammation in the immune system of the body constantly generates antibodies against Neu5Gc, said researchers.Chronic inflammation accelerates the process of tumor formation.

SPER-BCPSR/15/30

Antivenom Activity of *Datura Metel* Against *Vipera Russelli* Induced Venom in Mice

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Snakebite affects around 2.5 million humans annually, with greater than 100,000 deaths. Coagulopathy is a significant cause of both morbidity and mortality in these patients, either directly, or indirectly. This paper reviews clinical aspects of snakebite coagulopathy, including types of coagulopathy (procoagulant, fibrinogen clotting, fibrinolytic, platelet-active, anticoagulant, thrombotic, haemorrhagic). The present study was carried out to understand the *in vitro* effect of datura metel extract, and Russell's viper venom (RVV) on clot formation. Although, RVV has shown to exhibit fibrinogenolytic activity, but only at a concentration greatly in excess, we therefore assessed the procoagulant effect only at a low dose. Moreover, reports show that RVV do not directly activate the fibrinolytic system *in vitro*, even at very high concentrations (10,000 micrograms/ml). Our studies indicate that root extract of *Datura metel* at different concentration (125, 145, 200, 400 or 600 mg) failed to form clot. The rate of clot formation and clot time was significantly inhibited, when compared to the blank as well as venom. This indicates that root extract of *Datura metel* exhibit anticoagulant property. To the best of our knowledge, this is the first report of its kind and needs further investigations. Therefore, the present study possibly indicates the antidote property of *Datura metel* against the Russell viper venom.

SPER-BCPSR/15/31

Preliminary Findings from the Hydro-Alcoholic Extract of the Leaves of *Eryngium foetidum Linn.*

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Eryngium foetidum L. is a tropical perennial and annual herb in the family Apiaceae found in Assam and North Eastern states of India. The present study is aimed at assessment of the pharmacognostic properties and the innate pharmacological potential of leaves of *Eryngium foetidum*. The study objective also included the evaluation of the different hydro-alcoholic concentrations of Eryngium foetidum extracted and to find correlates with its yield value and the biological effect in animal models of hepatoprotectivity. The plant was collected from a rural garden of Tangla, Udalguri B.T.A.D, Assam. The plant was subsequently authenticated at the Botanical Survey of India, Shibpur, Howrah and a specimen number was accorded the number NN/BCPSR/02 and retained for future reference. The extraction process was carried out by maceration and the hydro-alcoholic (ethanol) extract was prepared in the ratio of 30:70,50:50 and 70: 30 respectively. The yield of the three different extracts was compared and the acute toxicity study was performed as per OECD guidelines after obtaining prior permission from IAEC of the institute. No mortality or untoward physiological or psychological morbidities was reported in the experimental animals post the oral acute toxicity study. Subsequently the efficacy study of the drug was performed using 18 swiss albino mice (n=3) as a pilot prospective, interventional efficacy study to evaluate the beneficial effect of the drug in hepatotoxicity caused by Carbon tetrachloride (CCl_4) in murine models. The experimental groups were: negative control, disease control, standard (silymarin treated) and hydro-alcoholic extract groups. The findings from the efficacy study shows promise in putative role of this indigenous plant in the amelioration of hepatotoxicity and poses no signs of morbidity or mortality upto a dose of 2000 mg/kg body weight with the drug. Follow up studies with larger sample size are however, warranted to corroborate findings to definitely arrive at a meaningful conclusion regarding the standing and the hepatoprotective potential of this indigenous drug of the north-east and its possible greater role in the future phyto-therapeutics of liver disorders.

SPER-BCPSR/15/32

Antivenom Activity of *Calotropis gigantean* Against *Vipera russelli* Induced Venom in Mice

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Snakebite affects around 2.5 million humans annually, with greater than 100,000 deaths. Coagulopathy is a significant cause of both morbidity and mortality in these patients, either directly, or indirectly. This paper reviews clinical aspects of snakebite coagulopathy, including types of coagulopathy (procoagulant, fibrinogen clotting, fibrinolytic, platelet-active, anticoagulant, thrombotic, haemorrhagic). The present study was carried out to understand the *in vitro* effect of datura metel extract, and Russell's viper venom (RVV) on clot formation. Although, RVV has shown to exhibit fibrinogenolytic activity, but only at a concentration greatly in excess, we therefore assessed the procoagulant effect only at a low dose. Moreover, reports show that RVV do not directly activate the fibrinolytic system *in vitro*, even at very high concentrations (10,000 micrograms/ml). Our studies indicate that extract of *Calotropis gigantean* at different concentration (125, 145, 200, 400 or 600 mg) failed to form clot. The rate of clot formation and clot time was significantly inhibited, when compared to the blank as well as venom. This indicates that extract of *Calotropis gigantean* exhibit anticoagulant property. To the best of our knowledge, this is the first report of its kind and needs further investigations. Therefore, the present study possibly indicates the antidote property of *Calotropis gigantean* against the Russell viper venom.

SPER-BCPSR/15/33

Alternatives to Animal Testing

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Animal testing is a phrase that most people have heard but are perhaps still unsure of exactly what is involved. Whether it is called animal testing, animal experimentation or animal research, it refers to the experimentation carried out on animals. It is used to assess the safety and effectiveness of everything from medication to cosmetics, as well as understanding how the human body works. Animal testing may take place at Universities, Medical Schools, Pharmacy Companies etc. If atrocious acts like poisoning, shocking, burning, and killing animals were committed outside laboratories, they would be like felonies. Here are the top five reasons to stop this:

1. It's unethical to sentence 100 million animals to pain, loneliness, and fear.
2. It's bad science. The FDA reports that 92 out of every 100 drugs that pass animal tests fail in humans.
3. It's wasteful. Animal experiments prolong the suffering of people waiting for effective cures by misleading experimenters and squandering precious money, time, and resources that could have been spent on human-relevant research.
4. It's archaic.
5. The world doesn't need another eyeliner, hand soap, food ingredient, drug for erectile, or pesticide so badly that it should come at the expense of animals' lives.

This article suggests certain alternative procedures (3R concept, cell line studies etc.) and some CPCSEA guidelines to prevent frequent animal testing in society. Animals are the gifts of god and we should preserve them.

SPER-BCPSR/15/34

Ultrasonic Assisted Extraction [UAE]

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Ultrasound is composed of sound waves with frequency beyond the limit of human hearing. This technique is relatively cheap, simple and energy saving and thus became an emerging technology for probing and modifying food products extraction etc.Ultrasonic assisted extraction increases yield of extracted components, increased rate of extraction, achieving reduction in extraction time and higher processing. This technique can enhance existing extraction processes and enable new commercial extraction opportunities and processes.

New UAE (Ultrasound Assisted Extraction) processing approaches have been proposed, including:-

a) The potential for modification of plant cell material to provide improved bio – availability of micro – nutrients while retaining the natural like quality,
b) Simultaneously extraction and encapsulation
c) Quenching of the radical sono chemistry especially in aqueous systems to avoid degradation of bio actives
d) Potential use of the radical sono chemistry to achieve targeted hydroxylation of poly phenolics and carotenoids to increase bio activity.

Ultrasonic assisted extraction is one of the finest techniques to reduce the wastage of the various resources during extraction process and increasing the yield value, making it quite efficient and selective. And it also reduces the time and labour.

SPER-BCPSR/15/35

Shilajit Attenuates Compulsive and Depressive-Like Effects in Mice

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Indian ancient traditional medicine has used shilajit as a rejuvenating agent. It has been validated for a number of pharmacological activities, including aphrodisiac, chronic fatigue syndrome and memory. Recent studies demonstrate that shilajit modulates the HPA axis and decreases the plasma cortisol levels. Since HPA axis plays a vital role in the pathogenesis of neuropsychiatric diseases like compulsion behavior, we in the present study investigated the effect of shilajit on compulsive-like behavior using marble burying behavior (MBB) test. Swiss male mice weighing 20-25 g were treated with shilajit (25, 50 and 100mg/kg, p.o) and were subjected to MBB test either in presence of saline or pCPA (para chlorophenyl alanine). It was interesting to find that shilajit dose-dependently decreased MBB as compared to the standard drug fluoxetine. Moreover, pre-treatment of pCPA blocked the effects of shilajit on MBB. This indicates that shilajit exhibits anticompulsive-like effect by modulating the serotonergic pathways. Based on our findings we believe that shiliajit has the potential to be used as anticompulsive drug in the treatment of obsessive-compulsive behavior.

SPER-BCPSR/15/36

Toxicity of Immunosupressive Drugs

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Immunosuppression involves an act that reduces the activation or efficacy of the immune system. This can be the result of diseases such as AIDS and cancer, or therapies including immunosuppressivedrugs,radiation,plasmapharesis orsplenectomy.Clinically immunosuppressive drugs (ISDs) are used to prevent the rejection of transplanted organs and tissues (e.g. bone marrow,heart,kidney, liver) ,treatment of autoimmune diseases or diseases that are most likely of autoimmune origin (e.g. rheumatoid arthritis, myasthenia gravis, systemic lupus erythematosus, Crohn's diseaseTreatment of some other non-autoimmune inflammatory diseases (eg. long term Allergic Asthma control).However, immunosuppressive drugs need to be given long term, lack specificity,and are accompanied by adverse metabolic derangements, toxicities, the risk of infection, and a myriad of other side effects. Immunosuppressants make transplantation possible by warding off the body's rejection of the foreign organ, but they inevitably contribute to the development of cancer. Reining in the immune system protects the transplanted organ, but at the same time immunosuppressants cripple immune responses that can attack incipient tumor.Epidemiological studies and cancer registries have consistently shown an increased risk of malignancies in transplant patients although the calculated risk (4-500-fold increase) differs markedly between studies essentially because of differences in methodologies and selection of patients. Skin and lip cancers, lymphomas and Kaposi's sarcomas are the main types of cancer in these patients. A number of risk factors have been identified, such as latent viral infections, the treatment regimen and the level of immunosuppression. The increasing use of immunosuppressive drugs in nontransplant patients is useful to delineate more accurately the consequences of mild-to-moderate immunosuppression.

SPER-BCPSR/15/37

Radioisotopes and its use in Diagnostic Treatment

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Many chemical elements have various numbers of isotopes. The isotopes possess same number of protons in their atoms (atomic number) but different masses due to different numbers of neutrons. These electrons determine the chemistry of the atom. There are 82 stable elements and about 275 stable isotopes of these elements. When a combination of neutron and protons, which does not already exist in nature, is produced artificially, the atom will be unstable and is called a radioactive isotope or radioisotope. Overall there are 1800 radioisotopes. At present there are 200 radioisotopes used in a regular basis and most must be produced artificially. The diagnostic treatments in nuclear medicines are Radionuclide Therapy (RNT), Targeted Alpha Therapy (TAT), Biochemical Analysis, Diagnostic Radiopharmaceuticals, Therapeutic Radiopharmaceuticals, Radio isotopes Poisons. The future of medicines lies in radioisotopes even though it's costly, yet it's the only way out in the distant future.

SPER-BCPSR/15/38

Emerging Role of Selective Neurotransmitters and Anti-Oxidant in Brain Disorders

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Majority of the brain disorders are result of an imbalance in the excitatory or inhibitory neurotransmission process, or impaired energy metabolism, or compromised antioxidant defence mechanism. Glutamate being the major excitatory neurotransmitter is present in about 90% of cortical neurons of the adult mammalian brain. Interestingly, it is the precursor for its conjugate inhibitory neurotransmitter gama-amino butyric acid (GABA) and glutathione (GSH)—the primary antioxidant component of the neurons. In addition, it has shown to modulate the levels of lactate in hypoxia state. Convergent evidence from physiological and magnetic resonance imaging studies indicates interplay between these neurometabolites. Changes in the concentration of one neurochemical adversely affect the other. The alterations may be either of genetic or nongenetic origin, which consequently affect their synthesis, receptor expression or degradation, and are implicated in various disorders. Understanding the mechanisms underlying the change is the concentration of these metabolites might be crucial in meaningful interpretation of their biological functions as well as their interplay in the eitology of a disease. This review brings an insight into the interaction of these neurotransmitters with relevance to various brain disorders.

SPER-BCPSR/15/39

Current Status of Antiretroviral Drugs in the Prevention of Mother-to-Child Transmission of HIV: An Appraisal

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The Human Immunodeficiency Virus (HIV) pandemic is already recognized as one of the chief medical threats faced by modern world but the matter of much concern now is a high prevalence of perinatal HIV infection due to transmission of the deadly virus from mother to child through various routes. Approximately 5-0% of all the cases infected by HIV are children. Majority of these children acquire infection through mother-to-child transmission (MTCT) either during pregnancy, delivery or by breast feeding. Our research has identified several maternal and non-maternal factors associated with the development of HIV in infants. In this paper we have also thrown light on the various pharmacological and non-pharmacological approaches adopted currently for combating MTCT of HIV. Both prospective and retrospective clinical studies have shown that MTCT can be reduced to less than 2% by use of antiretroviral drugs in women during pregnancy and labour. The regimen is also effective in infants in the first 6 weeks of life if combined with obstetrical interventions including elective caesarean delivery and avoidance of breastfeeding. Thus this review not only summarizes the current opinion on the issue available in the literature but also presents a holistic viewpoint from a clinical perspective which may help the future researcher to frame a rationalized approach to prevent vertical transfer of virus from HIV- infected pregnant woman to her children.

SPER-BCPSR/15/40

Green Chemistry in Daily Life

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Green Chemistry is the new and rapid emerging branch of Chemistry. The beginning of green Chemistry is considered as a response to the need to reduce the damage of the environment by manmade materials & the processes used to produce them. Chemistry brought about medical revolution till about the middle of 20^{th} century in which drugs & antibiotics were discovered. The world's food supply increased enormously due to the discovery of hybrid varieties, improved method of farming, better seeds, use of insecticides & fertilizers. The quality of life on earth becomes much better due to discovery of dyes, plastics, cosmetics & other materials. Pollution of land, water & atmosphere also been decreased. The industrial by-products affect the air, rivers, oceans & land as they are being discharged into atmosphere. Now a day's Govt. attempts have been made laws to minimize it. Some attempts have been made in such a way that the waste products are minimum. They have no effect on environment & their disposals convenient. For this, the Starting Material, Solvents, Catalysts should be chosen carefully. Such as, Benzene (C_6H_6) as a Solvent must be avoided since it is carcinogenic in nature. It is best to carry out the reactions in aqueous phase. The reactions should not generate any toxic by-products.

SPER-BCPSR/15/41

Synthesis of Acetenalide and Maleic Acid According to Green Chemistry

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Green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Discovery and application of new chemistry/technology leading to prevention/reduction of environmental, health and safety impacts at source.Lots of chemicalsare prepared with a large number of chemicals and different steps producing lots of by products that may be harmful, toxic, may not require and are totally waste of time, chemical, producing pollution and health hazards. Our objective is to develop chemical without excess solvents and excess steps. Acetanilide and maleic acid are two very important chemical required for preparation of different reagent, dyes, intermediate and many medicines. Conventionally they were prepared with such solvent and chemicals that were very much harmful and toxic. So according to green chemistry process they are prepared in such a way minimization of solvents, production of toxic chemicals and minimization of energy consumption are done with the same yield comparing with conventional procedure.

SPER-BCPSR/15/42

Swine Flu Virus: A New Challenge to Humankind

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Influenza viruses have not only affected the human race but also the birds and pigs worldwide. During the past few months, the Swine Flu virus has been in limelight especially with respect to India. The swine flu H1N1 reassorted subtype caused the first global pandemic in last 40 years, resulting in substantial illness, hospitalizations of millions of peoples and thousands of deaths throughout the world. Moreover, the role of pig as 'mixing bowl' for the virus to get reassorted has added to the complicated epidemiological scenario. Since with the continuous evolution and emergence of new strains, the flu viruses pose a challenge to researchers to discover effective vaccines and therapeutics. The scientific community has to win the race to save the mankind from this emerging flu viruses. In this review we highlight the characteristics of the causative virus, the disease and its public health consequences, advances made in its diagnosis, vaccine and control, precautionary measures to be adapted in the wake of an outbreak.

SPER-BCPSR/15/43

Application of Foam Fractionation Technology in the Field of Pharmacy

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Foam Fractionation is the foaming branch of Adsorptive Bubble Separation Technology. The generic name of the technology was first proposed by Robert Lemlich (1966) and sent to IUPAC committee on that year.The methodology of the technology is classified into Foam Separation Technique and Non Foam Separation Technique.Foam Fractionation is the foam separation technique. Foam Fractionation Technology is based on the surface chemistry known as adsorption. Chemical or physical adsorption is the principle of separation of soluble solute in waste water on the gas-liquid interface of air bubbles rising through the liquid feedof waste water. Soluble waste solid particles in the waste water is extracted or separated at the top of the foam fractionation column carried by air bubbles in the form of foam by adsorption. Adsorption of surface active species from bulk solution of waste water at the gas liquid interface can be quantitatively expressed *Give's Equation of Adsorption Isotherm*. Foam Fractionation is one of thebranch of Foam Separation Technique. This technique can be compared with Fractional Distilation and the separation can be quantitavely expressed by McCabeThile diagram. Some applications of this technology are separation of enzyme, protein, microorganisms from cultivation medium, enrichment of plant protein, separation of pharmaceutically costly protein from dairy waste water. Separation of alkaloid from plant source, separation of enzyme from pineapple peel. Separation of lysosome from Mousambi peel and Separation of pectin from apple.

SPER-BCPSR/15/44

Cubic Phase Nanoparticles for Sustained Release of Ibuprofen

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Ibuprofen is a non-steroidal anti-inflammatory drug inhibiting prostaglandin synthesis but having no effect on the adrenal pituitary axis. In addition, ibuprofen has an analgesic property that is related to its anti-inflammatory effect. Moreover, ibuprofen has been proven effective in the treatment of rheumatoid osteoarthritis, spondylitis, gout, and Bartter's syndrome. Current trends in ibuprofen research have concentrated on the development of potential delivery systems to increase its aqueous solubility and bioavailability, as well as to achieve controlled delivery of ibuprofen. In order to improve the oral bioavailability of ibuprofen, ibuprofen-loaded cubic nanoparticles were prepared as a delivery system for aqueous formulations. The cubic inner structure was verified by cryogenic transmission electron microscopy. With an encapsulation efficiency greater than 85%, the ibuprofen-loaded cubic nanoparticles had a narrow size distribution around a mean size of 238 nm. Differential scanning calorimetry and X-ray diffraction determined that ibuprofen was in an amorphous and molecular form within the lipid matrix. The in vitro release of ibuprofen from cubic nanoparticles was greater than 80% at 24 hours, showing sustained characteristics. The ibuprofen-loaded cubic nanoparticles provided an efficient drug delivery for therapeutic treatment.

SPER-BCPSR/15/45

In Silico and *In Vitro* Models to Study the Effect of Drug-Drug Interactions

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A modification of the effect of a drug is generally observed when the drug is concomitantly administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug. The particular interaction may be the result of a chemical-physical incompatibility of the two drugs or a change in the rate of absorption or the quantity absorbed in the body, the binding ability of either drug, or an alteration in the ability of receptor sites and cell membranes to bind either drug. Most adverse drug-drug interactions are either pharmacodynamic or pharmacokinetic in nature. Gene expression of transport protein of human tissues can be used for the identification of transport protein inhibitor and this model could be used to develop predictive in silico models. The model helps to detect previously known drug-drug interactions and enable new ones to be identified at the transport protein level.

SPER-BCPSR/15/46

Pharmacy Profession in India: A Present Scenario

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The profession of pharmacy is an integral part of the healthcare system worldwide. With the undergoing rapid transformation in the global pharmaceutical market, it has been proposed that Indian pharmaceutical market will grow to USD55 billion by 2020 driven by steady increase in affordability and a step jump in market access. Further, the huge potential of the Indian pharmaceutical industry is impossible for global pharma companies to ignore, given that India will be one of the top 10 sales markets in the world by 2020. In view of such massive growth in the Indian pharma sector, the pharmacy education in India has not been both industry and product oriented, nor has the status of a pharmacy professional received much attention in comparison to other profession in terms of salary and recognition. This review discusses the present status of the pharmacy professional and the changing face of the profession with the need of the hour to meet the demands of the Indian healthcare sector.

SPER-BCPSR/15/47

Used of *Plantago Ovata* (Isabghol) as a Pharmaceutical Excipient

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In recent years there have been wide developments in different dosage forms for existing and newly designed drugs and natural products, and semi-synthetic as well as synthetic excipients. Different parts of different plants are widely used natural materials for conventional and novel dosage forms. These natural materials have advantages over synthetic because they are chemically inert, nontoxic, less expensive, biodegradable and widely available in different varieties. So the main objective of this study was to Exploitation of whole seeds powder obtained from the *Plantago ovate* as a pharmaceutical "Excipient. Some research articles shows that only husk shows very good swelling property in water due to the presence of mucilage and due to these mechanisms some tablets are disintegrated very quickly. But when we used whole seeds powder then we observed opposite characteristic where it showed sustained release effect. Beside this phenomenon the powder obtained from the *plantago ovata* was characterized for micromeritical properties, swelling index, p^H, solubility, ash value etc.

SPER-BCPSR/15/48

Antiproliferative Activity of Leaves of *Lawsonia alba* Lam. Against Hepatocellular Carcinoma

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Hepatocellular carcinoma (HCC) most commonly appears in a patient with chronic viral hepatitis (hepatitis B or hepatitis C, 20%) or/and with cirrhosis (about 80%). In recent years, focus has shifted to inducing multiple modes of cell death coupled with systemic toxicity. Identification of bioactive molecules that induces apoptosis has been the mainstay of anticancer therapeutics for several decades. The plant *Lawsonia alba* Lam has been traditionally used in ayurvedic medicine in India for treatment of broad spectrum of diseases. We evaluated the cytotoxic and apoptotic activity of methanolic extract of *Lawsonia alba* Lam and its fraction on hepatocellular carcinoma (HepG-2) cell lines. HepG-2 is a perpetual cell line derived from the liver tissue of a 15-year-old Caucasian American male with a well-differentiated hepatocellular carcinoma. Cell viability by MTT [(4,5-dimethylthiazol-2-yl)-2,5-diphenyl-tetrazolium bromide] assay, Morphological study by light and florescence microscopy.DNA laddering assay by gel electrophoresis study. MLA and its fraction were found to be responsible for cytotoxic and apoptotic activity on hepatocellular carcinoma. Similarly both the morphological images and DNA laddering assay were also found to be responsible for the apoptosis potentiality of hepatocellular carcinoma cells. Thus, it merits consideration and further investigation as a therapeutic option for the treatment of cancer.

SPER-BCPSR/15/49

Superdisintegrants: An Overview

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Disintegrants helps in dissolution of the tablet and thereby help in attainment of bioavailibility. Recent advances in novel drug delivery system aim to enhance safety and to achieve better patient compliances. One such approach is orally disintegrating tablets and these are useful paedriatric and generic drug and also dysphagic patients leading to improved patient compliance. Superdisintegrants are used to improve the efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhances drug dissolution rate. Superdisintegrants are generally effective in a low concentration, and generally at higher concentrations they hinder disintegration. Examples of Superdisintegrants are crosscarmelose, crosspovidone, sodium starch glycolate which represents crosslinked cellulose, crosslinked polymer and a crosslinked starch. Superdisintegrants oppose the efficiency of the tablet binder and the physical forces that act under compression to form the tablet. With the improvement innovation of superdisintegrating agent it has become possible to develop ODTs with reduced content of superdisintegrants. The present review highlights various kinds of Superdisintegrants like natural and synthetic, along with their role in tablet disintegration and drug release, which are being used in the formulation to provide the safer, effective drug delivery with patient's compliance.

National Seminar on Emerging Trends & Innovation in Pharmaceutical Education & Research in India-2015

SPER-BCPSR/15/50

Superbugs, the Antimicrobial Resistant Bacteria: A Review

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Antibiotics have revolutionized medicine in many respects and countless lives have been saved; their discovery was a turning point in human history. The overuse of antibiotics especially taking antibiotics even when they're not the appropriate treatment and also failure to take an antibiotic as prescribed can contribute to antibiotic resistance. As resistance to antibiotics becomes more common, a greater need for alternative treatments arises. In the fight against "superbugs," scientists have discovered a class of agents that can make some of the most notorious strains vulnerable to the same antibiotics that they once handily shrugged off. And the report on the promising agents is called metallopolymers. These discoveries could pave a new platform to design antibiotics and antimicrobial agents to battle multidrug-resistant bacteria and superbugs.Common types of drug-resistant bacteria include MRSA (methicillin-resistant *Staphylococcus aureus*), VRSA (vancomycin-resistant *S. aureus*), ESBL (extended spectrum beta-lactamase), VRE (vancomycin-resistant *Enterococcus*) and MRAB (multidrug-resistant *A. baumannii*). Resistance may take the form of a spontaneous or induced genetic mutation, or the acquisition of resistance genes from other bacterial species by horizontal gene transfer via conjugation, transduction, or transformation. The present review included somecommon types of drug resistant bacteria and the discovery of metallopolymers that fight against them and also how to get rid from antibiotic resistance.

SPER-BCPSR/15/51

Antidiabetic and Antihyperlipidemic Effect of Hydroalcoholic Extract of *Gmelina arborea* Leaf on Dexamethazone Induced Diabetic Rats

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The research was conducted to evaluate the possible hypoglycemic and hypolipidemic effect of *Gmelina arborea* in Dexamethazone-induced diabetic Rats. Hypoglycemic and hypo-lipidemic effect of hydroalcoholic extract of leaf of *Gmelina arborea* was tested at two different doses of 200 & 400 mg/kg p.o. on rat. Every 4^{th}, 8^{th} and 12^{th} day of treatment, blood was collected from retro-orbital plexus of rat for estimation of serum glucose and lipid parameters. Leaf extract was compared with standard Glibenclamide at a dose of 400 mcg/kg p.o. Hydroalcoholic extract of leaf and Glibenclamide significantly decreased (P<0.05) dexamethazone induced elevation of serum glucose when compared to disease control group. Leaf extract at a dose of 400 mg/kg showed better activity than standard. The present study indicates that hydro alcoholic extract of leaf of *Gmelina arborea* shows significant glucose and lipid lowering activity and also exert beneficial effects on the clinical course of NIDDM, hypertension and coronary artery disease conditions.

SPER-BCPSR/15/52

Effect of Antioxidant on Herbal Formulation

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Natural compounds are of great interest in the present day life. Natural substances from plants and other life forms including bacteria, fungi, marine organism etc represent a major source of molecules having enormous medicinal properties. Among them, antioxidant substances are of particular interest. Oxygen free radicals induce damage due to per oxidation in biomembranes and also to DNA, which leads to tissue damage thus cause occurrence of a number of diseases. Antioxidants can be categorized into natural and synthetics with the synthetics having numerous side effects. Some of medicinal plants, traditionally used for thousands of years, are present in a group of herbal preparations of the Indian traditional health care system (Ayurveda) named Rasayana proposed for their interesting antioxidant activities. The present review indicates that herbal antioxidant plays a vital role for the prevention and cure of various symptomatic diseases.

SPER-BCPSR/15/53

Assessment of Microbial Load of Unripe Banana Fruit Powder

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Plants are nature's remedies and have been used by human beings on earth since ancient times for food and medicine. In both developing and developed countries, use of natural agents is increasingly popular nowadays. Herbal medicines have been used all over the world and have been recognized by the physicians and patients for their better therapeutic value as they have fewer adverse effects as compared with modern medicines. The herbal excipients are preferred due to lack of toxicity, easy availability and economic consideration as compared to synthetic one. With this increased usage, the safety, efficacy and quality of these medicines have been an important concern for health authorities and health professionals but they are not free from adverse effects which may be due to factors such as adulteration, substitution, contamination, misidentification, lack of standardization, incorrect preparation, inappropriate labeling as well as advertisement. Consumption of natural agents contaminated with harmful microorganisms may result in food poisoning. So microbiological control is very important in food industry as well as pharmaceutical industry to prevent food born diseases.

SPER-BCPSR/15/54

A Review on Sabudana Used as Pharmaceutical Excipient

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The sagudana is a cheap, easily available, biodegradable and a versatile natural agent which has always been an important excipient in the pharmaceutical industry. It is conventionally used as a binder, disintegrant, diluent, granulating agent. It is generally extracted from Manihot esculenta belonging to Euphorblaceace family. It contains about 5-13% starch content, 60-70% moisture content, 7-12% protein (32-35% total carbohydrates) and fat present in trace amount. It is also a starting material for many other chemicals like ethanol, glucose and cyclodextrin. Several modifications were attempted on native starch to improve and modulate its physiochemical properties.

SPER-BCPSR/15/55

Soyabean Powder: A New Prospective Approach In Pharmacy World

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Soy flour refers to soybeans ground finely enough to pass through a 100-mesh or smaller screen where special care was taken during desolventizing (not toasted) to minimize denaturation of the protein to retain a high protein dispersibility index, Different types of soyaflour are available like Defatted soy flour,Natural or full-fat soy flour I,high fat soya flour,low fat soyaflour. Soy flour has 50% protein and 5% fiber. It has higher levels of protein, thiamine, riboflavin, phosphorus, calcium, and iron than wheat flour. It does not contain gluten.health benefits of soyaflour are cancer, cholesterol and cardiovascular disease and inflammation. It has high health risk like gout,allergy,carcinogenic. Soybean in comparison to other legumes is far superior in terms of health benefits. A large number of clinical trials have been conducted for conditions (eg, menopause, osteoporosis, breast cancer, cardiovascular diseases) using daily doses of isoflavones from 40 to 120 mg. Minor GI disturbances have been reported. The National Toxicology Program (US Department of Health and Human Services) has concluded that there is minimal concern for developmental effects in infants fed soy infant formula.

SPER-BCPSR/15/56

Bioequivalent Modulation by Adding Starch-5-Phosphate and Solid Dispersion of Rosuvastatin Calcium in Sublingual Tablet

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During the last two decades, pharmaceutical researchers have tried different methods as well as different adjuvants to improve therapeutic performance of drug delivery systems. The dissolution profile and bio-availability of a drug from solid dosage form depend on its formulation additives and method of manufacture. Improving oral bioavailability of solid dosage forms of drugs byincrease in dissolution of poorly soluble drugs by solid dispersion technique presents a challenge to the formulation scientists. Considering that only in-vitro bioequivalence studies can predict in-vivo bioequivalence of all therapeutically equivalent branded and generic versions of the same API formulations; the present study had been performed to explore and justify interchangeability of marketed drug products by comparing the multipoint in-vitro dissolution profile of different marketed formulations of Rosuvastatin Calcium 5mg tablets along withthe application of starch-5-phosphate as solid dispersion to improve solubility and bioavailability.Solid dispersion is one of the methods, most widely and successfully applied to improve the solubility, dissolution rates and consequently the bioavailability of poorly water soluble drugs.Starch-5-phosphate was prepared by reacting starch IP with di-sodium hydrogen orthophosphate anhydrous at elevated temperatures was found to be white, crystalline, non-hygroscopic powder, insoluble in water and aqueous fluids of acidic and alkaline pH.Rosuvastatin calcium, a widely prescribed anti-hyperlipidemic, HMG-CoA reductase inhibitor, belonging to BCS class II reduces low density lipoprotein (LDL) cholesterol and triglycerides (TG) and increases high density lipoprotein (HDL) in patients with hypercholesterolemia and dyslipidemia. The dissolution efficiency (DE_5) thus obtained for formulations F4 & F5 are found as 101.1 & 100.5 in comparison to 29.4 & 25.2 for crestor&rosuvas confirming Rosuvastatin solid dispersion technique as significantly better than Rosuvastatin Calcium with improved bioavailability.

SPER-BCPSR/15/57

Controlled Release of a Topical Antifungal Drug from Multiparticulate Drug Delivery System

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Multiparticulate controlled release drug delivery systems such as liposomes, niosomes, transferosomes, microspheres and microsponges have been developed recently for topical use providing advantages including reduced local irritation, availability of higher concentration of active molecule at the site of infection, sustained drug release, increased bioavailability and improved therapeutic efficacy. The present study involves fabrication and *in-vitro* characterization of multiparticulate controlled release drug delivery systems of an anti-fungal agent, ketoconazole from ethyl cellulose using quasi emulsion solvent diffusion technique. For the purpose of the study, three formulation batches (KEC-1, KEC-2 and KEC- 3) were developed with drug:polymer ratios as 1:5, 1:7 and 1:11 respectively. Yield of the particulates was highly influenced by the viscosity of the aqueous phase. Addition of higher percentage of ethyl cellulose hindered the phase separation into individual, discrete and spherical particles. Drug release studies in phosphate buffer (pH 5.5) found KEC-2 to release drug in a sustained fashion till 11hrs following Korsmeyer-Peppas kinetics. However, after 11 hrs, drug release from KEC 1 became slower releasing 71% ketoconazole in 13hrs. Periodic kinetic analysis of drug release data showed KEC 1 to follow zero-order kinetics from 0-7hrs as also from 8-13hrs. Higher polymer percentage in KEC-3 revealed zero-order drug release with 91% drug being released within 11hrs. The Dissolution Efficiency values of the three batches were found to be comparable at 44%. Therefore, it can be concluded that multiparticulate drug delivery system formulated with least drug: ethycellulose ratio of 1:5 was most effective in releasing drug in a controlled manner till 13hrs following zero-order kinetics and can be regarded as an ideal sustained release drug delivery system.

SPER-BCPSR/15/58

Phytochemical Analysis of Unripe *Musa paradisiaca* Powder Occurring in Local Area of West Bengal

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Different parts of medicinal plants have bioactive compounds which are used for curing of various human diseases and also play an important role in healing. Phytochemicals have two categories i.e., primary and secondary constituents. Primary constituents have chlorophyll, proteins sugar and amino acids. Secondary constituents contain carbohydreds, alkaloids , Flavonoids and terpenoids . The phytochemical analysis of the plants is very important commercially and has great interest in pharmaceutical companies for the production of the new drugs for curing of various diseases. The main objective of the research work was to check the presence or absence of the phytochemical constituents in the selected unripe musa paradisiacal powder.

SPER-BCPSR/15/59

Review on Pharmacoeconomic Trends in Indian Healthcare system

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Pharmacoeconomics is defined as the description and analysis of the cost of drug therapy to healthcare systems and society. Especially pharmacoeconomic research aims at identifying, measuring and comparing the costs, risks and benefits of programs, services, or therapies and determining alternative way which produces the best health outcome for the resource invested taking pharmaceutical care at efficient low cost . Pharmacoeconomics is a division of outcomes research that can be used to quantify the value of pharmaceutical care products and services. Pharmaceutical care is defined as the responsible provision of drug therapy for the purposes of achieving definite positive outcomes in healthcare. Consideration of both costs and consequences distinguishes most pharmacoeconomic evaluation methods from traditional cost-containment strategies and drug-use evaluations. Pharmacoeconomics is a set of methods to evaluate and compare the Economic, Clinical and Humanistic Outcomes (ECHO) of pharmaceutical products and services (or any health care service). Five types of pharmacoeconomic analysis (COI, CMA, CBA, CEA and CUA) differ by how we measure the consequences or outcome. Before conducting a Pharmacoeconomic evaluation, clinicians should be familiar with the similarities, differences, and appropriate application of Pharmacoeconomic methods. In conclusion, ISPOR-India providing an environment for knowledge sharing among researchers, healthcare practitioners, and decision-makers interested in Pharmacoeconomics and outcomes research at low cost with better efficacy of drug therapy with lesser adverse effects.

SPER-BCPSR/15/60

Antiangiogenic Gene Therapy for Cancer Treatment: Recent Developments

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Angiogenesis, the development of new blood vessels from the existing vasculature, is important for normal developmental process & progression of solid. The tumors formation of a 'tumor – associated vasculature', a process referred to as Tumor angiogenesis. Antiangiogenic agents have recently received much widespread attention but strategies for their optimal use are still being developed. Gene therapy represents an attractive alternative to recombinant protein administration. Advantages of gene transfer for antiangiogenic cancer therapy with endogenous angiogenesis inhibitors demonstrating the feasibility of effectively suppressing and even eradicating tumors. Candidate genes for antiangiogenic gene therapy-Thrombospondin(thbs1), Endostatin,Tumstatin,Arresten,Canstatin(2000),Plateletfactor-*4*,Vastatin,Restin,Angiostatin16kd, Prolactin fragment. The Vectors used for gene transfer- Non viral vectors including Naked DNA, Antisense RNA, Small interfering (si) RNA, cationic liposomes and Viral vectors including adenoviruses, adeno-associated viruses, Retroviruses, Lentiviruses, and Bacteriophage vectors have been used. In case of combination therapy combining agents that target a number of different and synergistic pathways may yield improved antitumor effects and long term suppression of metastatic progression. Combination of (Su5416, vegfr2 tyrosine kinase inhibitor and low-dose endostatin) reduced tumor growth more efficiently than monotherapy alone . In conclusion, gene therapy holds great promise in advancing antiangiogenesis as an effective cancer therapy and will undoubtedly be evaluated in human clinical trials in the near future.

SPER-BCPSR/15/61

Micropropagation of Medicinal Plants using Low Cost Medium

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The last three decades have seen a very rapid rise in the number of plant scientists using the techniques of organs, tissues and cell cultures for plant improvement. Plant Tissue Culture broadly refers to the culturing of any part (cell ,tissue or organ) of the plant in a specially designed growth media under aseptic laboratory condition . This project aims to conceptualise large scale micropropagation systems with low cost technology by designing low cost plant tissue culture medium alternative to Murashige and Skoog (MS) Medium for high quality medicinal plant production especially *Ocimum sanctum* (tulsi) *Ocimum sanctum* (*Tulasi)* has been considered to be an adaptogen, balancing different processes in the body, and helpful for adapting to stress. Marked by its strong aroma and astringent taste, it is regarded in Ayurveda as a kind of "elixir of life" and believed to promote longevity. Main chemical constituents of *tulsi* are: oleanolic acid, ursolic acid, rosmarinic acid,eugenol, carvacrol, linalool, β-caryophyllene, (about 8%), β-elemene (c.11.0%), and germacrene D (about 2%).Potential use in future pharmaceutical applications in the field of cancer treatment, and mitigating the effects of radiation exposure. In this culture carrot callus grown in MS medium has been used as an explant to standardise a low cost medium. The low cost medium was prepared by replacing the conventional sources of MS medium by natural substitutes containing both macro and micro nutrients, A total cost reduction of 82.3%has been obtained. The current status of the project is that in vitro growth of young plantlets have been obtained on the media. Once the media is standardised using carrot callus we can use it for micropropagation of various medicinal plants thus reducing the cost and propagating it for commercial purposes on regular basis. It will also become possible for us to produce somatic embryos with further works under this project. We would like to exploit the low cost medium for the rigorous propagation of important medicinal plants.