SOUVENIR

OF

2ND NATIONAL CONFERENCE

ON

CLINICAL RESEARCH

(Theme: Drug Discovery & Development)

Organized by

GURU GOBIND SINGH COLLEGE OF PHARMACY,

YAMUNA NAGAR

in collaboration with

CLINIMINDS

(UNIT OF TENET HEALTH EDUTECH PVT. LTD.)

Guru Gobind Singh College Of Pharmacy

Vision & Mission of Institute:

Vision : To develop as centre of excellence in pharmacy education where leaders in pharmacy practice, teaching and public sector are nurtured and developed to serve the mankind.

Mission : To impart profound pharmaceutical knowledge through quality research and training programs to cater the needs of healthcare sector and diverse communities thereby facilitating the development of socially responsible pharmacists.

About the Institute:

Established in 2002, Guru Gobind Singh College of Pharmacy, Yamunanagar is the first college in Haryana to be **accredited by NBA** for the B. Pharma Course under the banner of **Guru Nanak Khalsa Group of Educational Institutions. Courses offered:** B. Pharmacy, LSSSDC Courses (Quality control chemist and Production/Manufacturing Chemist) and Diploma in Clinical research and Pharmacovigilance (certified by Cliniminds).

About Cliniminds...

Established in year 2004, Cliniminds is the global leader in pharmacovigilance training and education. Cliniminds has trained over 4000 pharmacovigilance professionals in India and abroad and provides training solutions to several organizations and institutes. Cliniminds programs are accredited internationally by Accreditation Council for Clinical Research Education, USA. Cliniminds has been awarded as the Best Clinical Research & Health Sciences Business Management Institute by leading agencies including ASSOCHAM.

Facilities at a glance

- Central instrumentation laboratory equipped with sophisticated instruments such as HPLC, UV-VIS spectrophotometer, Viscometer, Flourimeter etc.
- Smart classroom with audio visual facility.
- Qualified and experienced faculty.
- Well equipped 16 state of art laboratories.
- Internet facility round the clock.
- Well stocked digitalized library.
- Herbal garden, museum and seminar hall.
- Training placement cell, college NSS wing.

A BRIEF ABOUT ORGANIZING COMMITTEES

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- S. Bhupinder Singh Jauhar, President, Guru Nanak Khalsa Group of Educational Institutes, Yamuna Nagar, Haryana.
- S. Randeep Singh Jauhar, Vice- President, Guru Nanak Khalsa Group of Educational Institutes, Yamuna Nagar, Haryana.

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- S. Amardep Singh, Off. Finance Secretary, Guru Nanak Khalsa Group of Educational Institutes, Yamuna Nagar, Haryana.

Co-ordinator

- Mr. Amit Sinha, CAO, Guru Nanak Khalsa Institute of Technology & Management, Yamuna Nagar, Haryana.
- S. J. S. Sodhi, Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.

Convener

- Dr. Kumar Guarve, Principal, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.

Organizing Secretary

- Dr. Ashwani K. Dhingra, Associate Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.
- Dr. Sanjeev Kumar, Associate Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.

Joint Organizing Secretaries

- Dr. Geeta Deswal, Associate Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.
- Mrs. Bhawna Chopra, Assistant Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.

- Mrs. Priyanka Kriplani, Assistant Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.
- Mr. Rohit Kamboj, Assistant Professor, Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana.

Registration Committee

- Mrs. Sweta Kamboj
- Ms. Monika Saini
- Ms. Himanshu Kamboj

Hospitality, Transport & Accommodation Committee

- Mr. Rameshwar Dass
- Mr. Abhishek Dabra
- Mr. Deepak Singla
- Ms. Preeti Arya

Advisory Board

- Prof. (Dr.) Gajendra Singh, Dean, Department of Pharmaceutical Sciences, Pt. B. D. Sharma University, Rohtak.
- Dr. B. S. Gaba, MD, Medicine, Gaba Hospital, Yamuna Nagar.
- Prof. (Dr.) Harish Dureja, Department of Pharmaceutical Sciences, MD University, Rohtak.
- Prof. (Dr.) Rohit Dutt, Associate Dean, School of Medical and Allied Sciences, GD Goenka University, Gurugram.
- Mr. Kamal Sahani, Founder & Director, Cliniminds Institute of Health Sciences Training & Management, Noida.

PROGRAM SCHEDULE

S. No.	Event	Time
1	Inaugural session • Speech by Mrs. Priyanka Kriplani • Welcome by token of love • Hyme • Lightening of lamp • Welcome speech by organizing secretary • Speech by Dr.I.K Pandit, Guest of honor of the day • Speech by Dr. R.S Gaba, chief guest of the day • Introduction by Mrs. Priyanka Kriplani • Release of souvenir by dignitaries on the dais	9:30-9:35am 9:35-9:45am 9:45-9:50am 9:50-10:00am 10:00-10:10am 10:10-10:20am 10:20-10:30am 10:30-10:40am 10:40-10:50am
2	First technical session • Dr. Arun Sundriyal • Mr. Abhishek Tyagi	10:50-11:50pm 11:50-1:00pm
3	Lunch break	1:00-2:00pm
4	Second technical session • Mr. Joseph Mathew • Dr. Vandana Garg	2:00-2:30pm 2:30-3:00pm
5	Tea break	3:00-3:30pm
6	Valedictory session • Prize distribution announcement by Dr. Kumar Guarve • Vote of thanks by Amit Sinha	3:30-4:00pm 4:00-4:15pm

Message of the President……

S. Bhupinder Singh Jauhar

I am pleased to learn that Guru Gobind Singh College of Pharmacy, Yamuna Nagar is organizing 2nd National Conference on Clinical Research with theme **"Drug Discovery and Development"** on 24th February 2018 in collaboration with Cliniminds, Noida.

This conference will educate the fundamental of drug discovery and development, including regulatory requirements, clinical research/trial, adverse event reporting and risk management. It is heartening to note that eminent pharmaceuticals professional are joining hands for making there presence felt by contributing to success of conference. Today clinical research and pharmacovigilance based industries are potentially growing and proceeding of the conference would prove helpful in making the people aware about the clinical trial/research. The conference would prove a milestone in that direction.

I wish the conference a grand success

S. Bhupinder Singh Jauhar

President

Guru Nanak Khalsa Group of Educational Institutes

Yamuna Nagar, Haryana.

Message of the Vice President……

S. Randeep Singh Jauhar

It is heartening to know that Guru Gobind Singh College of Pharmacy, Yamuna Nagar is organizing 2nd National Conference on Clinical Research with theme **"Drug Discovery and Development"** on 24th February 2018 in collaboration with Clinimids, Noida.

The theme of conference is of current interest and will serve as a common platform for discussing the clinical research related issues. In modern drug discovery era, successful navigation of clinical research and pharmacovigilance are keys to product longevity. This educational conference will provide a unique platform for scientific deliberation pertaining to pharmacovigilant approaches which can be utilized to mitigate adverse drug reaction and maximize the patient safety.

I welcome all the participants to the conference.

S. Randeep Singh Jauhar

Vice- President

Guru Nanak Khalsa Group of Educational Institutes

Yamuna Nagar, Haryana

From the Desk of Convener……

Prof. (Dr.) Kumar Guarve

It is indeed a matter of great delight to bring out the proceeding of 2nd National Conference on **"Clinical Research"** which is being organized in our college. The theme of the conference was chosen keeping in view the present scenario of globalization and vital role of pharmacists in these fields in the year to come. Many relevant topics pertaining to various aspects of theme were deliberated by eminent scientists, who very kindly accepted to our request and spared time for us out of their heavy work schedule. More than 200 delegates, who attended, were immensely benefited. I fail to find words to express my deep gratitude to these distinguished speakers. I would like to place on record my sincere gratitude to our worthy chairman and chief patron of the conference, **S. Bhupinder Singh Jauhar** for his keen interest, blessing, patronage and encouragement. My deep hearted thanks to **S. Randeep Singh Jauhar**, Vice President of this conference who has always supported and encouraged us to organize activity of this sort. I am also thankful to all members of the college and managing committee for their kind support.

Prof. (Dr.) Kumar Guarve

Convener

Acknowledgment……

Dr. Ashwani Dhingra

It is wonderful feeling of joy, pleasure and privilege to be a part of the organizing committee in one day national level conference held at Guru Gobind Singh College of Pharmacy, Yamuna Nagar on 24th February 2018. The theme of conference **"Drug Discovery and Development"** is first of its kind organized successfully in the area and we are overwhelmed by enthusiastic response obtained from all over the country. I wish to express my sincere gratitude to eminent speakers for giving their expert views on various aspects of Drug Discovery and Development. I am highly indebted to our worthy President of the conference **S. Bhupinder Singh Jauhar** giving valuable support for making this conference a grand success. My deep sense of gratitude extends to **Prof. (Dr.) Gajendr Singh, Prof. (Dr.) Harish Dureja, Dr. B. S. Gaba, Mr. Kamal Sahani, Prof. (Dr.) Rohit Dutt** and **Prof. (Dr.) Sudhir Bhardawaj** for sparing their valuable time and also for their minute to minute guidance during each phase of the conference.

I further take this opportunity to thank all the members of organizing and managing committee for the constant support and also to the students of our institute, who work round the clock for making the conference a grand success.

Dr. Ashwani Dhingra

Organizing Secretary

KEY NOTE LECTURES

Dr. Arun Sundriyal

Sr. Director Clinical Management,

Area Head Central & North Asia at PPD

Clinical Research: Need of Hour

Clinical Research is an indispensable part of drug discovery process to ensure the safety and efficacy of a new drug. Typically it will takes approximately 12-15 years and around 800 million US$ to bring one new drug from conception to market out of which 6-7 years are spent in various phases of clinical trials. India is fast emerging as a preferred destination for the conduct of global clinical trials as there is an inherent advantage of cost, speed and quality. Being a sunrise industry it is offering exciting career avenues as well as an accelerated growth path to Pharmacy students (B. Pharm, M. Pharm) and more number of students are opting it is a preferred career option. However, still a vast majority of B. Pharm students are unaware of this emerging stream and are unable to think beyond the conventional career options of Sales (Medical Representative) and Production (Production Executive). While only a handful can qualify for higher studies (M. Pharm, MBA, PhD) due to limited number of seats, majority of them are left with no option except for joining the sales or production. Now, they can explore clinical research as a new and rewarding career option thereby enhancing the overall employability. In conclusion, I reiterate the relevance of clinical research profession to pharmacy students as a rewarding career option having an unmatched professional growth.

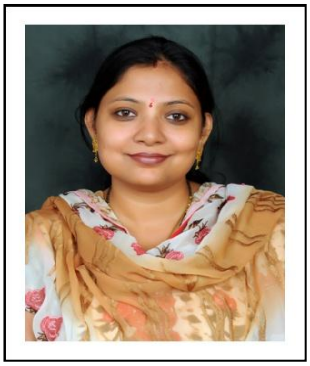
Mr. Abhishek Tyagi

Director Clinical Operations

CNS Syneous Health, Gurugram

Clinical Trial Management System (CTMS)

Clinical trial management system (CTMS) is a software program used by biotechnology, pharmaceutical industries and Hospitals to manage clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones. Often, a clinical trial management system provides data to a business intelligence system, which acts as a digital dashboard for trial managers. In the early phases of clinical trials, when the number of patients and tests are small, in-house or home-grown program are typically used to handle their data. In later phases, data volumes and complexity grow, motivating many organizations to adopt more comprehensive software. CTMSs allow experts easily to access centralized data and thus reducing the number of delayed trials. Clinical trial management systems are cost- and time-effective, as they also can be used for gathering and organizing information that can be shared to different care providers and distributed across different systems. These systems can facilitate site identification and recruitment and they can provide control and tracking over subject enrolment and subject's database. Available software includes budgeting, patient management, compliance with government regulations project management, financials, patient management and recruitment, investigator management, regulatory compliance and compatibility with other systems such as electronic data capture and adverse event reporting systems.



Dr. Vandana Garg

Assistant Professor

Department of Pharmaceutical Sciences, M.D. University, Rohtak, Haryana

Discovery of Drugs from Plant Sources

Many new drugs and active ingredients of medicine are derived from natural sources. More than 150 molecules/compounds are in preclinical development stage. Plants used in traditional medicine contain a wide range of substances that can be used to treat chronic as well as infectious diseases. Due to adverse effects and microbial resistance of the chemically synthesized drugs, researchers are reverting back to herbal preparations. Plant based new drug discovery include identification of correct plant based upon their traditional uses. The premier steps to utilize the biologically active compound from plant resources are extraction, pharmacological screening, isolation, characterization of bioactive compound and clinical evaluation. Further, extraction is the first and main step in the analysis of medicinal plants, it is necessary to extract the desired chemical components from the plant materials for further separation and characterization that include chromatographic techniques such as HPLC and TLC etc. This certainly leads to isolation of chemical compounds from natural sources. This approach of discovery of drugs from plant sources is safer and having lesser side effects as compared to synthetic drugs.

Mr. Joseph Mathew

Senior Manager Pharmacovigilance,

Cliniminds (Unit of Tenet Health Edutech Pvt. Ltd.), Noida

Pharmacovigilance as Emerging Career Avenue

Pharmacovigilance is a new discipline to the students of India which provides newer and better opportunities to aspirants across the country who wish to build their career in the field of pharmacological science. Pharmacovigilance is a discipline which is concerned with identifying, validating, quantifying, evaluating and minimizing the adverse effects of medicine thereby increasing the safety of drugs in use. It is a study of drug related adverse effect carried out by pharmaceutical industries to suggest warnings and recommendation for product withdrawal. Being a sunrise industry it is offering exciting career avenues as well as an accelerated growth path to medical/paramedical students and more number of students are opting it is a preferred career option. Pharmacovigilance is not only an academic necessity but also a need to ensure security of human beings from the adverse effects of medicines which have been released in the market. The Government also puts forward a supportive hand and takes immediate actions for the implementation of such a course so that people become aware of the adverse effects of drugs which can be reduced by a discipline like pharmacovigilance. Pharmacovigilance at the clinical trial stage, involves drawing up protocols for setting up systems to assess the aim of the research, consider the reasons for recording and notifying adverse events at the trial and which events should be recorded and why. Pharmacovigilance and data management are vast fields of knowledge and information, which may not be addressed with its due importance in a regular course of Clinical Research.

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Clinical Research in the Current Scenario

Shikha Kamboj*, Ashwani Dhingra

Guru Gobind Singh College of Pharmacy, Yamuna Nagar, Haryana (India)

Abstract

Clinical research deals with the safety and potency of medications, medical devices or diagnostic products which are intended to be used for humans for prevention, treatment and diagnosis of the disease. It involves the establishment of treatment that differs from clinical practice which involves the use of established treatment. In fact clinical research involves data collection and analysis of collected data from the inception to target molecule to in the lab to its introduction to the consumer market and beyond. Once the promising test molecule is identified in the laboratory, it is subjected to pre-clinical or animal studies where different aspects of the test molecule (including its safety, toxicity and efficacy) are studied. The data obtained from the pre-clinical studies or other supporting evidences are analyzed and submitted in support of an investigational new drug (IND) application. It will take approximately 800 million USD and 12-15 years to bring a single drug molecule from laboratory to the market. Clinical trials involving new drugs entity is commonly classified into four phases; Phase I - Safety trial, Phase II - Therapeutic exploratory trial, Phase III - Therapeutic confirmatory trial. Each phase of the drug approval process is treated as a separate clinical trial. If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population. Phase IV - Post marketing surveillance belongs to 'post-approval' studies. It is mandatory to conduct the pre clinical and clinical trials for approval of drugs by any regulatory authority. In India, the regulatory authority is **Central Drugs Standard Control Organization** (**CDSCO**) under the ministry of health and family welfare.

Keywords: Clinical research, Clinical trial, Investigational new drug, CDSCO.

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Development of Drug with Different Phases - An Overview

Gaganpreet Kaur

Shaheed Bhagat Singh College of Pharmacy, Patti, Amritsar, Punjab.

Abstract

Drug discovery is the process by which new candidate medications are discovered and bringing a new pharmaceutical drug to the market through identifying the active ingredient from traditional remedies or by serendipitous discovery. It includes pre-clinical research on microorganisms and animals, filing for regulatory status, such as via the United States Food and drug Administration for an investigational new drug to initiate clinical trials on humans, and may include the step of obtaining regulatory approval with a new drug application to market the drug. The information is gathered from pre-clinical testing, as well as information on chemistry, manufacturing, and control and submitted to regulatory authorities (in the US, to the FDA), as an Investigational New drug application. If the IND is approved, development moves to the clinical phase. In Clinical phase, if compound emerges from different tests with an acceptable toxicity and safety profile, and the company can further show it has the desired effect in clinical trials, then the NCE portfolio of evidence can be submitted for marketing approval in the various countries where the manufacturer plans to sell it. In the United States, this process is called a new drug application. The nature of a drug development project is characterized by high attrition rates, large capital expenditures, and long timelines. This makes the valuation of such projects and companies a challenging task. The most commonly used valuation methods are risk-adjusted net present value, decision trees, real options or comparables.

Keywords: Drug, Clinical research, Investigational, Micro-organism.

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Post-Marketing Surveillance (PMS): Reduction of Adverse Effects of Drugs

Surinder Kumar*, D. C. Bhat

Department of Pharmaceutical Sciences, Guru Jambheswar University of Science and Technology, Hisar

Abstract

Post-Marketing surveillance is the practice of monitoring the safety and efficacy of a pharmaceutical drug or device after it has been released on the market. It is an integral part of pharmacovigilance that involves the science of collecting, monitoring, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, medical device and traditional medicines. Since pharmaceutical medications and medical devices has been approved on the basis of clinical trials, which involves relatively small numbers of people who have not been associated with other medical conditions which may exist in the general population. Therefore, post marketing surveillance can further refine or confirm the safety of a drug or device after it is used in the general population by large numbers of people who have a wide variety of medical conditions. Infect, the objective of Post-Marketing surveillance is to reduce the frequency and the severity of adverse effects of drugs while maintaining or, better, improving their efficacy. Post marketing surveillance uses a number of approaches to monitor the safety of licensed drugs, including spontaneous reporting databases, prescription event monitoring, electronic health records, patient registries and record linkage between health databases. These data are reviewed to highlight potential safety concerns in a process known as data mining. Post-Marketing surveillance is mandatory in US, Europe and other developed markets, and most countries globally are changing regulations for the stringent implementation of drug safety reporting.

Keywords: PMS, Clinical research, Pharmacovigilance, Clinical trial.

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Bioenhancers: An Approach to Enhance Bioavailability

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Abstract

Co-administration of natural enhancers with low bioavailable drug augments the bioavailability of the drug. Bioenhancers can be classified based upon their natural origin as well as on different mechanism when they combine with drug. Bioenhancers are mostly plant derivatives, plant extracts and active molecule of plants. Bioenhancers increases bioavailability at cellular level. Various bioenhancers such as piperine, garlic, quercetin, glycyrrhizin, cuminum cymnium, cow's urine are used to increase bioavailability. Some novel properties of bioenhancers are non- toxic to humans or animals and effective at low concentration. The need of recent scenario is to carry out extensive research over bioenhancers to increase the bioavailability.

Keywords: Bioenhancers, Bioavailability, Piperine, *Cuminum cymnium*.

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Turmeric Use as Herbal Medicine

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Abstract

Herbal medicines are gaining increased popularity due to their advantages, such as better patient tolerance, long history of use, fewer side-effects and being relatively less expensive. Furthermore, they have provided good evidence for the treatment of a wide variety of difficult to cure diseases. Curcumin, the active ingredient found in turmeric, has a positive effect on the liver tissue. Even liver tissue that has been damaged by excessive exposure to alcohol or other damaging drugs can be positively affected by turmeric. Internally it can be used in the form of boiled powder or fresh juice. Its use as a condiment in many South Asian cuisines helps in its internal application. Externally it can be used in paste form, as an oil, ointment or lotion. Natural treatments for skin that give lasting results are often better than expensive commercial products and cosmetic procedures. One such natural treatment is turmeric powder for skin. Turmeric is considered safe in amounts found in foods and when taken orally and topically in medicinal quantities. Turmeric's primary biologically active component is curcumin. Research has shown that curcumin has potent antioxidant, wound-healing, and anti-inflammatory properties, which may prove to be therapeutic against acne. This review focuses on the treatment of acne using turmeric as medicinal drug.

Keywords: Curcumin, Turmeric, Herbal medicines, Antioxidant.

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Herbal Drugs: A Therapeutic Utility

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Abstract

Herbal medicines or Phytotherapeutic agents or phytomedicines are standardized herbal preparations consisting of complex mixtures of one or more plants which are used in most countries for the management of various diseases. According to the WHO definition, herbal drug contains active ingredients, plant parts or plant materials in the crude or processed state and certain excipients, i.e., solvents, diluents or preservatives. Usually, the active principles responsible for their pharmacological action are unknown. One basic characteristic of phytotherapeutic agents is the fact that they normally do not possess an immediate or strong pharmacological action. For this reason, phytotherapeutic agents are not used for emergency treatment. All parts of the plant have some use it can be the root, stem, leaf, stamens and pistils. In the neem plant, the root and stem are used for fever and flowers are used for malaria. Other characteristics of herbal medicines are their wide therapeutic use and great acceptance by the population. In contrast to modern medicines, herbal medicines are frequently used to treat chronic diseases.

Keywords: Herbal drugs, Phyto-medicines, Malaria, Herbal medicines.

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Recent Clinical Development in Prevention & Cure of Cancer

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Abstract:

Cancer is an abnormal, continuous multiplying of cells. The cells divide uncontrollably and may grow into adjacent tissue or spread to distant parts of the body. The common causes of cancer are smoking & tobacco, Genetics, Diet & physical activity, sun & other type of radiations, Viruses & other infections. Cancer develops when the body's normal control mechanism stops working. Old cells do not die and cells grow out of control, forming new abnormal cells. These extra cells may form a mass of tissue called a tumor. Some cancers such as Leukemia do not form tumors. The dramatic increases in the rates of occurrence of some cancers, particularly in more developed countries. Although many therapeutic strategies to prevent & cure of this disease have been proposed & evaluated by clinicians & researchers, there remains a need to find more effective approaches. Side effects such as toxicity & drug resistance are two of the most frequent problems faced during ancient time therapies & techniques used for prevention & cure of cancer example-Chemotherapy. The recent techniques to overcome the side effects of ancient time techniques are as- Oncology drug discovery, Monoclonal antibodies, Bone marrow transplantation, Vaccines, Gene therapy, Tissue agnostic therapy etc.

Keywords: Cancer, Monoclonal antibodies, Vaccines, Tissue agnostic therapy.

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Pharmacovigilance: The Present Status and Future Prospects in India

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Abstract

Pharmacovigilance is now accepted to be a continuous process of evaluation accompanied by steps to improve safe use of medicines which involves pharmaceutical companies, regulatory authorities, health professionals and patients. The methodologies have broadened to encompass many different types of study, with spontaneous reporting remaining the cornerstone. In a vast country like India with a population of over 1.2 Billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. The Pharmaceutical industry in India is valued at Rs. 90,000 Crore and is growing at the rate of 12 – 14 % per annum. Exports are growing at 25 % Compound Annual Growth Rate (CAGR) every year. The total export of Pharma products is to the extent of Rs. 40,000 Crore. India is now being recognized as the 'Global pharmacy of Generic Drugs' & has distinction of providing generic quality drugs at affordable cost. India is also emerging rapidly as a hub of Global Clinical trials & a destination for Drug Discovery & Development. Pharmacovigilance is designed to provide crucial data on how drugs work in medical practice, from the short-term to the long-term. Medicines affect the lives of hundreds of millions of people every day. To be eternally vigilant to ensure that medicines, which are developed for treatment of diseases, actually do not do more harm than good, is one of the important pre-requisites for the progress of medicine.

Keyword: Pharmacovigilance, Drug safety, CAGR, Drug Discovery.

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Development and Evaluation of Potential Nanoformulation for Burn Wound Healing.

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Abstract

Minimal or no scarring along with complete regeneration and restoration of skin structure is the major goal of wound healing research. This can be only achieved with optimal delivery of active constituents responsible for wound healing at site. Controlled and localized delivery of wound healing drugs to the wounds is more convenient than systemic administration, because higher concentrations of the medications are delivered directly to the desired area in a sustained manner. They also offer optimum environmental conditions to facilitate wound healing while eliminating the need of frequent changes of dressings. Novel drug delivery carriers have potential to deliver wound healing drugs such as antibiotics, antimicrobials, human EGF's etc. Therefore, offering a potential platform to overcome the limitations of conventional wound dressings. This review is emphasised on various techniques such as nanoparticles, liposomes, nano emulsions etc. that that are successfully applied as carriers for wound healing drugs.

Keywords: NDDS, Controlled release, Wound healing, Nanoparticles.

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Taste-masking Assessment of Orally Disintegrating Tablets of Valsartan using Ion Exchange Resin

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Abstract

Oral disintegrating tablets are novel attractive dosage form that disintegrate or dissolve in the buccal cavity within seconds without use of water. The major drawback in designing of this dosage form is unpleasant taste of active entity. Valsartan is an anti-hypertension drug used in treatment of high blood pressure, congestive heart failure (CHF) and post-myocardial infarction (MI). It is characterized by its bitter taste which effects the patient's compliance. The aim of present research work is taste-masking assessment of orally disintegrating tablets of valsartan using ion exchange resin (indion 254). The drug was characterized according to different compendia methods, on the basis of identification by UV spectroscopy, pH, organoleptic properties and other tests. Drug-Resin compatibility and drug polymer compatibility was carried out by FTIR. The values of pre-compression parameters assessed, were within specified limits and showed good free flowing properties. The data obtained of post-compression parameters such as weight variation, hardness, friability, wetting time, water absorption ratio, content uniformity, disintegration time and dissolution was found within the prescribed limits. The F10 batch with disintegration time 20 sec and dissolution 97.46 was selected as optimized formulation. Batch F10 was also subjected to stability studies for three months and was tested for its appearance, average weight, hardness, disintegration time, percent friability and its release rate which in prescribed range and satisfactory.

Keyword: Taste masking, Orally disintegrating tablet, Ion exchange resin, Valsartan.

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Statins in Periodontics

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Abstract

Drug discovery is the process through which potential new medicines are identified, involving a wide range of scientific disciplines, including biology, chemistry and pharmacology. Periodontics, the branch of dentistry concerned with structures surrounding and supporting teeth uses non surgical drug dependent active therapeutic modalities for the treatment of several diseases. Periodontitis, a serious gum infection that damages the soft tissues and destroys bone round the teeth affects approximately 10 million per year in India. Various periodontal therapies aimed at reducing the inflammatory breakdown of periodontal attachment and bone loss have been introduced. One such method involves a class of drugs called statins. Statins also known as HMG CoA reductase inhibitors, area class of lipid lowering medication. They are mainly used in hypercholesterolemia. Recent interest has been focused on non cholesterol dependent plieotropic effect of statins. They have anti-inflammatory and bone stimulating properties that may positively affect chronic periodontitis. Currently available statins, Simvastatin, Atorvastatin, Paravstatin have been reported to promote osteoblastic activity by its inductive effect of BMP2 (bone promoting) and suppress TNF responsible for osteoclastic activity. Statins show promise and further research shall put light on the marvels of this drug.

Keyword: Statins, Periodontics, Periodontics, Anti-inflammatory.

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Role of Clinical Research in Drug Discovery from Plant Sources

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Abstract

Today, natural products have been utilized extensively for the treatment of disease or in the discovery of most active pharmaceutical ingredients as lead. Although, the use of herbal drugs had always been an integral part of the treatment of different ailments ranging from anti-microbial to anti cancer, but the new prospects related to clinical research/trial are being set with latest drug discovery from plants. Clinical research involves the data collection and analysis of collected data from the inception to target molecule to in the lab to its introduction to the consumer market and beyond. In addition, Pharmacovigilance which is an important and integral part of clinical research deals with the study of adverse drug reactions (ADRs) based on the collecting, monitoring, researching, assessing and evaluating the information obtained from healthcare providers and patients. It has been confined, mainly to detect adverse drug events that were previously unknown or poorly understood. Moreover, pharmacovigilence is a key component of effective drug regulation systems, clinical practice and public health programmes. This new drug development brought a new ray of hope for treatment of many indomitable diseases. However, the most recent reports show, more than 100 natural product derived plant sources under clinical trials and at least 100 molecules/compounds are in preclinical development stage. In India, the Central Drugs Standard Control Organization (CDSCO) under the ministry of health and family welfare largely works on developing standards and regulatory measures for drugs, diagnostics and devices; laying down regulatory measures by amending acts and rules; and regulating the market authorization of new drugs.

Keywords: Clinical research, Pharmacovigilance, Adverse drug reactions, CDSCO.

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Potential Biomedical and Pharmaceutical Applications of Versatile Biopolymers: Chitin and Chitosan

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Abstract

Chitin is a unique, ubiquitous versatile and amply documented polysaccharide which is widely distributed in the biosphere. It can be converted into chitosan by deacetylation process. Chitosan is a natural polycationic linear polysaccharide derived from chitin which shows more versatility than chitin due to its solubility and reactive free amino group ($-NH_2$). Chitin and chitosan are recognized as versatile biomaterials because of their interesting biological properties such as non-toxicity, biodegradability, biocompatibility, antimicrobial, anticholesterolemic, antioxidant activity, anti-inflammatory, analgesic, haemostatic action, mucoadhesion, angiogenesis stimulation, macrophage activation and adsorption enhancer. Chitosan and its derivatives can be easily molded into different shapes and forms such as films, fibers, sponges, beads, powder, gel and solutions. Due to these interesting physical and biological properties; they have been used in many applications mainly in the medical and pharmaceutical fields. The medical applications of chitin and chitosan include wound healing/wound dressing, burn treatment, artificial skin, ophthalmology, trauma, dermatitis, artificial tendon, artificial kidney, contact lenses and catheter. The pharmaceutical applications of chitin and chitosan are as antitumor agent, blood anticoagulant, anti-gastritis, haemostatic, hypocholesterolaemic, antithrombogenic agents, drug/gene delivery systems and in dental therapy. Other applications of chitosan include gene silencing in disease vector mosquito larvae, dry mouth syndrome treatment, mucosal immunity enhancer, treatment of age-related and cardiovascular diseases.

Keyword: Chitin, Chitosan, Antimicrobial, Antitumor.

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Synthesis and antimicrobial evaluation of 2-(5-((benzo[*d*]oxazol-2-ylthio)methyl)-1*H*-1,2,3-triazol-1-yl)-N-substituted phenyl acetamide Analogs

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Abstract

Antibiotic resistance is recognized as a major global health security issue that threatens a return to the pre-antibiotic era, with potentially catastrophic economic, social and political ramifications. Hence there is a need to develop more compounds which can overcome the problem of multidrug resistance along with lesser side effects. In the present study, a series of 2-(5-((benzo[*d*]oxazol-2-ylthio)methyl)-1*H*-1,2,3-triazol-1-yl)-N-substituted phenyl acetamide derivatives were synthesized and evaluated for antimicrobial potential. All the synthesized compounds (**1-20**) were investigated for their *in vitro* antimicrobial potential against Gram-positive bacteria (*S. aureus* and *B. subtilis*), Gram-negative bacteria (*E. coli*, *K.pneumoniae*, *S. typhi)* and fungal strains (*C. albicans* and *A. niger*) by tube dilution method using ofloxacin and fluconazole as reference drugs. In case of Gram-positive bacteria, compound **5 (**MIC_{bs} = 1.33 x 10^{-2} µM/ml) was found to be most potent against *B. subtilis* and compound **4** (MIC_{sa} = 2.81 x 10^{-2} µM/ml) was most active against *S.aureus*. In case of Gram-negative bacteria, compound **4** (MIC_{ec} = 1.40 x 10^{-2} µM/ml) was found to be active against *E. coli*, compound **4** and **14** (MIC_{st} = 2.81 x 10^{-2} µM/ml) against *S. typhi*, compound **7** (MIC_{kp} = 2.73 x 10^{-2} µM/ml) against *K. pneumonia* and antifungal activity results indicated that compound **4** displayed most potent antifungal activity against *A. niger* as well as *C.albicans* **(**MIC_{an} = MIC_{ca} = 2.81 x 10^{-2} µM/ml). In this series compound **4** having high antimicrobial potential among the synthesized compounds may be taken as lead compound for the development of novel antimicrobial agents.

Keyword: Antibiotic, Antimicrobial, Phenyl acetamide.

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Mucoadhesive Buccal Films: An Innovative Dosage Form

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Abstract

Over the past few decades, tendency toward innovative drug delivery systems has majorly increased attempts to ensure efficacy, safety and patient acceptability. As discovery and development of new chemical agents is a complex, expensive and time consuming process, so recent trends are shifting toward designing and developing innovative drug delivery systems for existing drugs. Out of those, drug delivery system being very eminent among pediatrics and geriatrics is orally disintegrating films (ODFs). Buccal mucosa has emerged as an attractive site for systemic administration of drug in pediatric patients. This route is simple and non-invasive, even if the saliva wash-out effect and the relative permeability of the mucosa can reduce drug absorption. Mucoadhesive polymers represent a common employed strategy to increase the contact time of the formulation at the application site and to improve drug absorptsion. Various types of polymers along with their excipients used to preparing Orally disintegrating films which allow films to disintegrate quickly releasing incorporated active pharmaceutical ingredient (API) within seconds. Orally disintegrating films have potential for business and market exploitation because of their myriad of benefits over oral disintegrating tablets.

Keywords: Buccal film, Orally disintegrating film, Dosage form.

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Development of potential nanoformulation containing phytochemicals for wound healing and HPLC-FD method for determination of biomarkers involved in wound healing process.

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Abstract

Phyto-chemicals are non-nutritive substances found in plants and can act as a complete wound healing agent due to their wide range of biological activities. Their effect can be optimised by the efficient delivery to the wound site. Controlled and localized delivery of these agents to the wounds is more convenient than systemic administration, because higher concentrations of the medications are delivered directly to the wound site in a sustained manner. Various novel drug delivery systems such as nanoparticles, liposomes, nanoemulsions etc have potential to deliver these phytochemicals to active site. Along with the site specific delivery estimation of healing process is also important especially in chronic wounds as it will suggest which wound will heal or which will not. Various chromatographic along with spectroscopic techniques are available for this purpose. Out of them HPLC-FD is reliable one.

Keywords: Phytochemicals, NDDS, Wound healing, Controlled delivery.

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Let's Check: An Approach for Better and Healthy India

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Abstract

Pharmacovigilance (PhV, PV) came into effect on 1-JAN-2005. The Pharmacovigilance is derived from two words Pharmakon (Greek for Drug) and Vigilore (Latin for keep Watching). PhV heavily focuses on Adverse drug reaction, which is defined as any response to drug which is noxious and unintended, including lack of efficacy after coming in market. They detect, assets monitor, the ADRs. India is one among the leading country in world considering the mobile use and place 2nd Rank in internet use. Keeping the view of this achievement, a user friendly application "LET'S CHECK" is being proposed for the benefit of citizens of the country to make healthy and aware country. The key features of the app is to save medical history, provide knowledge related to medicines, give medical updates and most importantly citizens can give review for medicines which are giving side-effects, this will directly help PhV Sector to monitor the side-effect of various drugs and take further action related to the drug and make a better, healthy India.

Keywords: Pharmacovigilance, Let's Check, ADRs.

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Preparation and Evaluation of Mefenamic Acid Ethosomal Gel Formulation

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Abstract

The present study has been satisfactorily attempted to formulate ethosomes of mefenamic acid and then incorporated into jellified base consisted of gelling agent for topical delivery with a view of enhancing bioavalibility of the drug. Mefenimic acid is a non steroidal anti inflammatory drug. The oral administration of this drug is associated with severe gastro intestinal side effects like ulceration, gastro intestinal bleeding. The solution of this problem lies in the fact that topical application of NSAIDs is safer than the oral administration of NSAIDs. The IR spectra revealed that there was no interaction between phospholipids and drugs. Hence they are compatible. Drug content of optimized ethosomal formulation F1 comes out to be 87.3±0.17 pH of optimized formulation F1 was 6.7±0.058.the release profile of optimized formulation F1 was 99.55±0.05.% entrapment efficiency is higher. Polydispersity index shows the uniformity of all formulation.

Keywords: Mefenamic acid, Bioavalibility, NSAIDs.

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Pharmacovigilance: An Emerging, Significant and Vital Practice

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Abstract

It is the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reaction. It is also known as drug safety. Pharmacovigilance is arguably the most essential function within a life science company. To develop, manufacture and commercialize a drug a company must adhere to strict regulations. Many of these regulations will focus on the patient's safety and the added benefit to the patient derived from the drug. In other words, analysing which side effects are worth the risk to patients compared with how effective they are at treating a disease. For instance, chemotherapy is known to cause some very serious side effects but when faced with life-threatening cancer, these side effects are considered acceptable given the potential to cure a patient. However, if a drug used to cure a headache caused similar side effects, the risk to the patient would be considered too great and the benefit not substantial enough to justify the potential damage. Indeed, drugs are continuously monitored for other side effects on patients, and any new data is collected and reported to health authorities on a regular basis. While other areas focus on improving patient lives in everything that they do, no other department has such a sharp focus on patient safety as an end-point. Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature**,** plays a critical role in providing the data necessary for pharmacovigilance to take place.

Keywords: Chemotherapy, Adverse drug reaction, Pharmacovigilance, Drug safety.

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Forced Degradation Studies

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Abstract

Forced degradation studies are also known as stress testing, stress studies, stress decomposition studies, forced decomposition studies, *etc*. Forced degradation is a process that involves degradation of drug products and drug substances at conditions more severe than accelerated conditions and thus generates degradation products that can be studied to determine the stability of the molecule. The ICH guideline states that stress testing is intended to identify the likely degradation products which further helps in determination of the intrinsic stability of the molecule and establishing degradation pathways, and to validate the stability indicating procedures used. Forced degradation studies show the chemical behavior of the molecule which in turn helps in the development of formulation and package.

Degradation products generated from forced degradation studies are potential degradation products that may or may not be formed under relevant storage conditions but they assist in the developing stability indicating method As no specific set of conditions is applicable to all drug products and drug substances and the regulatory guidance does not specify about the conditions to be used, this study requires the experimenter to use common sense. The aim of any strategy used for forced degradation is to produce the desired amount of degradation *i.e.*, 5–20%. A properly designed and executed forced degradation study would generate an appropriate sample for development of stability indicating method.

Keywords: Forced degradation, Stress studies, ICH guidelines.

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Spices from Kitchen to Herbal Remedies

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Abstract

Spices were some of the most valuable items of trade in the ancient and Middle Ages. Herbalist and folk practitioners have used plant remedies for centuries, but only recently have scientist begun to study the powers of common herbs and spices. Herbal remedies for healing right from the beginning of human civilization. Spices or their active compounds used as preventive agents for health disorders. Because spices have very low calorie content and are relatively inexpensive, they are reliable sources of antioxidants and other potential bioactive compounds in diet. Herbal remedies are often used to provide first-line and basic health service, both to people living in remote areas where it is the only available health service, and to people living in poor areas where it offers the only affordable remedy. In the current set-up, the anti-oxidative, anti-hypercholesterolemia, anti-diabetic, anti-inflammatory effects of spices have overriding importance, as the key health concern of mankind nowadays is diabetes, cardio-vascular diseases, arthritis and cancer. Treatment with herbal remedies is considered very safe as there is no minimal side effect. These remedies are in sync with nature, which is the biggest advantage. The golden fact is that, use of herbal treatments is independent of any age groups or sex. The role of some spices used in the Indian kitchen for its flavour, taste which is potential to maintain a healthy life.

Keywords: Spice, Anti-diabetic, Anti-inflammatory, Hypercholesterolemia.

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Supercritical Fluid Extraction: An Emerging Extraction Technique

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Abstract

Worldwide, Supercritical Fluid Extraction (SFE) Technology has emerged as a superior alternative to the conventional techniques for extraction of natural products in food, pharmaceutical and chemical industries. It has proved to be effective in the separation of essential oils and its derivatives for use in the food, cosmetics, pharmaceutical and other related industries, in wide range of textile and fiber industries including quality control analysis of fiber finishes. India is rich in botanical resources possessing high potential for the use of SCFE to achieve value added natural products e.g. Decaffeination (coffee & tea), Hop extracts (bitter), Spice extracts (oil & oleoresin), Flavours & fragrances, Food colours, Food preservatives, Herbal medicines, Pesticides (neem), Deoiling of fast foods, Cholesterol free food products, Nicotine / tar free tobacco. SCF extraction depends on the various parameters like solute and modifier polarity, physical and chemical state of the solute, solubility of the solute in the modifier, miscibility of the modifier supercritical fluid mixture under a wide variety of temperature and pressure conditions. SFE is also coupled with GC, MS and also with LC. SFE/GC/MS appears to be a promising method for SOA chemical composition analysis allowing to perform simulation chamber experiments at low precursor concentrations and to collect aerosol with relatively high frequency. Thus, SFE in chemical analysis cover a broad spectrum of samples, including food stuffs, natural products, agrochemicals, environmental samples, fuels and lubricants, synthetic polymers and oligomers, polychlorinated biphenyls (PCBs) and organochlorine pesticides (OCPs) from soils, sediments, fly ash, organometallic compounds, achiral pharmaceutical agents and biologically important chiral compounds.

Keywords: Extraction, Quality control, Herbal medicines, Pesticides.

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Bispecific Antibodies and Their Market

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Abstract

The last two decades have witnessed a revolutionized change in the medicinal sector and the completion of Human Genome Project switched the treatment options from a generalized approach to a patient-based approach. In the patient based approach, the treatment is provided keeping in mind the genetic makeup of the individual whether the drug will be efficacious in the patient or not. For this, monoclonal antibodies are the drug of choice due to their ability to bind to specific receptors with high specificity. Bispecific antibodies (BsAbs) are composed of two different antigens and therefore recognize two different epitopes/targets on two different cell types. The two target functionality provides them edge over other monoclonal antibodies (mAbs) which target only a single epitope and have clinical application. Currently, more than 55 different BsAb formats exist, some of them making their way into the clinical pipeline. This presentation summarizes types of BsAbs, their market status and BsAbs in pipeline.

Keywords: Bispecific antibodies, Monoclonal antibodies, Patient-based approach.

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Current Scenario of Pharmacovigilance in India

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Abstract

Pharmacovigilance is a discipline which is related to the detection, assessment, understanding and prevention of adverse drug reactions, particularly long-term and short-term adverse effects of medicines. India is the fourth largest producer of pharmaceuticals in the world and emerging as an important Clinical trial hub in the world. With more and more clinical trials and other clinical research activities being conducted in India, there is an immense increase in need to understand the importance of pharmacovigilance and how it impacts the life cycle of the product. Recently, the concerns of pharmacovigilance have been widened to include herbal, traditional and complementary medicines, blood products, biological, medical devices and vaccines. Ultimate goals of pharmacovigilance are to promote the rational and safe use of medical drugs, to assess the risks and benefits of drugs on the market and to educate and informing the patients. It also follows the ICH regulatory guidelines, good clinical practices (GCP) which is considered as an important pre-aspects in the way of transformation from practicing clinical trials to the objective of pharmacovigilance. Director General of Health Services in collaboration with CDSCO launched the National Pharmacovigilance Program. But due to lack of organization, funding and awareness among healthcare professionals pull India backward in the ground. Good Pharmacovigilance Practice into the processes and procedures to help ensure regulatory compliance and enhance clinical trial safety and post marketing surveillance. So that other countries rely on India for drug safety.

Keywords: Pharmacovigilance, Adverse drug reactions, Drug safety, CDSCO.

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Chronotherapeutic Drug Delivery System (ChrDD): A Review

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Abstract

Chronotherapeutic drug delivery system (ChrDD) involves treatment through targeting circadian rhythms (CR) of the body. A lot of ailments like cardiovascular disorders, diabetes, arthritis, asthma etc. follow circadian rhythms such that there exist a mutual relationship between peak-to-trough rhythmic activity in disease symptoms and pharmacokinetic profile of drug. The treatment success in such scenarios is significantly influenced by the dose and frequency of medication taken by the patient. In ChrDD, circadian rhythms are used to optimize in vivo drug availability thereby maximizing therapeutic outcomes and minimize side effects. The greatest advantages ChrDD offers are reduction in dosage frequency, patient compliance, toxicity and delivery of drug at times when symptoms are worse. Pulsatile drug delivery is one of the foundation stones of chronopharmaceutics, involves designing formulations that allow programmable release of active pharmaceutical ingredients (APIs) in accordance with the disease's time profile. Other technologies such as triggered, programmed and time-controlled drug delivery methods have been developed and are under extensive research. Few examples include Diffucaps, Timerx, Pulsincaps and Chronotopic.

Keywords: Chronotherapeutic, Circadian rhythms, Diabetes, Chronotopic.

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TNF- α as a Key Cytokine in the Inflammatory Processes of Rheumatic Arthritis

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Abstract

Tumor necrosis factor alpha (TNF-α) is a cytokine produced primarily by monocytes and macrophages. Tumor Necrosis Factor-α is a single, non-glycosylated, polypeptide chain containing 158 amino acids and having a molecular mass of 17.5kDa. Dysregulation of TNFα production has been implicated in a variety of human diseases, including major depression, Alzheimer's disease, inflammatory diseases and cancer. The Tumor necrosis factor (TNF) superfamily (TNFSF) and the TNF receptor (TNFR) superfamily (TNFRSF) form the corresponding ligand and receptor systems that are widely distributed in different tissues and cell types. Two distinct membrane receptors that have been identified and cloned are Tumour necrosis factor-receptor1 (TNF-R1) and tumour necrosis factor-receptor 2 (TNF-R2). Both these receptors are typical transmembrane proteins with extracellular and intracellular domains of about equal size and a single transmembrane domain. Both receptors bind the membrane-associated and soluble forms of TNF-α, although most cellular responses to soluble TNF-α are mediated by TNF-R1 and the stimulation of cells with the transmembrane form of TNF-α after cell-to-cell contact acts via both TNF receptors. The TNF-R2 receptor is believed to have a primary role in stimulating the proliferation of T-cells and in suppressing TNF-α mediated inflammatory responses, whereas the TNF-R1 receptor appears to be critical in triggering host defense and inflammatory responses. TNF-α play a dominant role in Rheumatoid synovitis. In cultures of synovial cells from patients with RA, blocking TNF-α with antibodies significantly reduced the production of IL-1, IL-6, IL-8, and GM-CSF. In recent clinical trials have shown promising results when therapy involved blocking TNF-α in human arthritis.

Keywords: TNF-α, Rheumatic Arthritis, Cytokine, Inflammation.

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Ethics in Clinical Research: The Indian Perspective

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Abstract

History of unethical clinical research practice date back to a very long time, though the most remarkable unethical clinical research was those by the Nazis during second world war, which eventually shaken the scientific community and gives birth to the first guideline of ethics in clinical research, the Nuremberg Code. With increasing research all over, World Health Organization formulated guidelines in the form of Declaration of Helsinki in 1964. The US laid down its guidelines for ethical principles in the Belmont Report after discovery of the Tuskegee's Syphilis study. These guidelines are internationally accepted and without following these guidelines, no clinical research is acceptable in the world. The Indian Council of Medical Research has laid down the 'Ethical Guidelines for Biomedical Research on Human Subjects' in the year 2000 which were revised in 2006. It gives twelve general principles to be followed by all biomedical researchers working in the country. The Ethics Committee stands as the bridge between the researcher and the ethical guidelines of the country. The basic responsibility of the Ethics Committee is to ensure an independent, competent and timely review of all ethical aspects of the project proposals received in order to safeguard the dignity, rights, safety and well-being of all actual or potential research participants. A well-documented informed consent process is the hallmark of any ethical research work. Informed consent respects individual's autonomy, to participate or not to participate in research. Concepts of vulnerable populations, therapeutic misconception and post trial access hold special importance in ethical conduct of research, especially in developing countries like India, where most of the research participants are uneducated and economically backward.

Key words: Clinical research, Ethics, Nuremberg Code.

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Human Papillomavirus Vaccination: An Immediate need in Regular Immunization Schedule in India

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Abstract

Cervical cancer is the fourth leading cancer in women globally, but its major burden in the low- and middle-income countries (LMICs). In most Asian countries including India, cervical cancer is the second most common cancer in women. India accounts for an estimated 122,800 new cases and 67,500 deaths annually due to cervical cancer. The human papilloma virus (HPV) is the most common sexually transmitted infection cause of cervical cancer and genital warts. HPV type 16 and 18 are responsible for 70% cervical cancer. Globally, three types of HPV vaccines are currently available for their treatment i.e. bivalent vaccine, quadrivalent vaccine and 9-valent vaccine. The first two are available in India. The WHO recommended a two-dose schedule for girls (at an interval of 6 months, which may be extended to 12 months to facilitate vaccination) if vaccination is initiated prior to 15 year of age and a three-dose schedule (at 0, 1-2 and 6 months) if vaccination is initiated after 15th birthday. It can reduce a significant number of infections when given to women with some prior HPV exposure. Cost of vaccine is much lesser than treatment of cancer. Indian association of Paediatric (IAP) and policy makers of public health administrators in India need to be aware about including HPV vaccine in regular immunization schedule.

Key words: Vaccination, Cervical cancer, IAP, Human papilloma virus.

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Comparison of the Efficacy of Chlorohexidine Chip with and without Scaling and Root Planing in Chronic Periodontitis Patients

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Abstract

Periodontal disease is characterized by chronic inflammatory process caused by specific microorganisms, thereby causing progressive destruction of alveolar bone and apical migration of connective and epithelial attachment. The objective of present study was to evaluate and compare the efficacy and effects of Chlorhexidine chip, with and without scaling and root planing by assessing clinical and microbial parameters (motile rods and spirochetes). The study sample consists of 30 patients with chronic periodontitis. Patients were divided into control group (SRP) and test group (SRP+CHX) and clinical and microbiological parameters were recorded at baseline, 3 months and 6 months. There was a significant reduction in plaque index, gingival index, probing depth and gain in clinical attachment level at both the sites at 6 months postoperatively but there was significantly more improvement and reduction in periodontopahogenic microflora in test group as compared to control group. The adjunctive use of chlorohexidine chip with SRP resulted in significantly more PD reduction and gain in CAL as compared to SRP alone.

Key words: Chlorohexidine Chip, Chronic Periodontitis, Microbial parameters.

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A Prospective Study on Drug Utilization in Obstetric Procedures with Emphasis on Antibiotic Usage at a Tertiary Care Hospital

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Abstract

Drug utilization studies help to identify and overcome the drug prescribing pattern problem. The aim of this prospective study was to evaluate the drug utilization in obstetric procedures with emphasis on antibiotic usage at a tertiary care hospital. The data of one hundred twenty (n=120, pre-operative & post-operative) gynaecological patient was collected in a specially designed format over a period of six month. The most prescribed drugs were antibiotics, next commonly prescribed were analgesics and antacids. In pre- operative prescription orders, the percentage of single antibiotic therapy (Inj. Ceftriaxone) was 53.33%, dual antibiotic therapy (Inj. Ceftriaxone with Inj. Metronidazole) was 12.50% and triple antibiotic combination therapy (Inj. Ceftriaxone, Inj. Metronidazole with Inj. Gentamycin) was 5.83%. In post- operative prescription orders, the dual therapy (Inj. Ceftriaxone with Inj. Metronidazole) was most commonly (19.16%) prescribed, in triple antibiotic combination therapy (Inj. Ceftriaxone, Inj. Metronidazole with Inj. Gentamycin) was 62.50% and in quadruple antibiotic combination therapy (Inj. Ceftriaxone, Inj. Metronidazole, Inj. Gentamycin, and Inj. Amoxicillin with Clavulanic acid) was 0.83%. Out of 2216 drugs, branded drugs were 1893 (85.42%) and generic drugs were 323 (14.58%). In this study, the maximum prescribed monotherapy antibiotic (Inj.Ceftriaxone) was given to the female patient for prophylaxis and after caesarean section triple antibiotic therapy (Inj. Ceftriaxone, Inj. Metronidazole with Inj. Gentamycin) by the gynaecologists.

Key words: Antibiotic, Ceftriaxone, Metronidazole, Gentamycin.

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In vitro evaluation of anti-arthritic potential of fractions of *Eclipta prostrata*

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Abstract

Eclipta prostrata is the traditional herb commonly called as false daisy and Bhringraj, mostly seem to find habitat on roadsides and wastelands of India. *Eclipta prostrata* belongs to the family Asteraecea, and contains chemical constituents such as phytosterol, β-amyrin, triterpenes, flavones such as luteolin and coumarins like wedelolactone. The plant has been found to be traditionally used in rheumatoid arthritis. The present study is done to evaluate the *in-vitro* anti-arthritic activity of *Eclipta prostrata* leaf extract. *In-vitro* anti-inflammatory activity of *Eclipta prostrata* is evaluated by employing three methods involves induction of protein denaturation by injecting 1ml of Bovine serum albumin (Inhibition of protein denaturation) and injection of 0.06 mg trypsin, 1ml 20 mM Tris HCl (Proteinase inhibitory activity) and stabilization of red blood cell (HRBC) membrane by hypotonicity induced membrane lysis(Membrane stabilization test/Inhibition of membranelysis) followed by giving various concentrations (50, 100, 250, 500, 1000, 2000 µg/ml) n-hexane, chloroform, ethyl acetate and n-butanol fraction of leaves of *Eclipta prostrata* (test solution) and diclofenac sodium (standard) respectively. Parameters such as the absorbance were measured using UV-visible spectrophotometer at 660 nm. The percentage inhibition and stabilization of the membrane activity was calculated. Both EPCF and EPEAF was found to posses very good membrane stabilizing property which is one of the preliminary steps involved in the screening of anti-arthritic property.

Key words: *Eclipta prostrata*, Bhringraj, Coumarins, Anti-arthritic property.

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Pharmacovigilance in Layman Language

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Abstract

Pharmacovigilance plays a key role in the healthcare system. It's main function is practice of monitoring the effects of medical drugs and discovery of interactions amongst the drugs after they have been licensed for use , especially in order to identify and evaluate previously unreported adverse reactions or it is defined as the process of identifying and responding to drug safety issue. The Indian pharmaceutical industry is growing at a rate of 15% over the last five years and is still growing. It has thrown up challenges of monitoring Adverse Drug Reactions (ADR's) over the global population. In India the program was inaugurated on 23rd November 2004 and became operational on 1st January 2005. Since clinical trials involve only smaller numbers and selected groups of patients, less common adverse events are often unknown at the time when a drug enters the market. Also, use of drugs in organ-impaired patients and use in special populations like pregnant women and children are not studied extensively in clinical trials because of ethical limitations but in pharmacovigilance we use tool such as data mining and investigation of case report to identify the relationship between drugs and ADR's.

Key words: Pharmacovigilance, Adverse Drug Reactions, Drug safety, Clinical trials.

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An Effective Anti-HIV Drug: Need of Hour

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Abstract

AIDS (acquired immunodeficiency Syndrome) is spreading rapidly in virtually every country. The human immunodeficiency virus (HIV) has been established as the causative agent of the AIDS. Over 20 million people are now believed to be infected with HIV throughout the world. During the last 20 years, an unprecedented success has been achieved in discovering anti-HIV drugs. The currently Food and Drug Administration (FDA) approved anti-HIV drugs can be divided into seven groups: nucleoside reverse transcriptase inhibitors (NRTIs), nucleotide reverse transcriptase inhibitors (NtRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors (FIs), co-receptor inhibitors (CRIs), and integrase inhibitors (INIs). Inspite of considerable advancement in the research of Anti HIV drugs development, there is no satisfactory or curative treatment for this disease. Current antiretroviral therapies (ART) available for symptomatic treatment of AIDS are quite expensive or unaffordable by common men and are associated with rapid emergence of drug resistance. The present paper attempts to review the currently available anti HIV drugs and emphasizes on urgent need for new effective anti-HIV/AIDS drug.

Keywords: AIDS, HIV, FDA, ART.

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Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring

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Abstract

Pharmacovigilance is like a sunshade to describe the processes for monitoring and evaluating Adverse Drug Reactions and it is a key component of effective drug regulation systems, clinical practice and public health programmes. The number of Adverse Drug Reactions reported resulted in an increase in the volume of data handled, and to understand the pharmacovigilance, a high level of expertise is required to rapidly detect drug risks as well as to defend the product against an inappropriate removal. Effective pharmacovigilance requires a set of rules, operating procedures, and practices that must be followed to ensure the quality and integrity of marketed product. Good Pharmacovigilance Practice is a quality standard for monitoring the safety of medicines and if necessary, taking action to reduce the risks and increase the benefits of medicines. It ensures the detection, collection, assessment, understanding, and prevention of adverse effects with medicinal products. Recently, pharmacovigilance has been confined, mainly to detect adverse drug events that were previously either unknown or poorly understood. Pharmacovigilance is an important and integral part of clinical research and these days it is growing in many countries. Today many pharmacovigilance centers are working for drug safety monitoring in this global pitch, however, at the turn of the millennium pharmacovigilance faces major challenges in aspect of better safety and monitoring of drugs.

Keywords: Adverse Drug Reactions, Drug safety, Pharmacovigilance.

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Antimicrobial Activity of Unsaturated Fatty Acid Maltose Ester

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Abstract

In this work we investigated antimicrobial property of maltose mono-esterified and octa-esterified with different unsaturated fatty acid through in-vitro studies .for this fatty acid were converted to corresponding acid chlorides using thionyl chloride. Acid chloride was reacting with maltose taking chloroform as solvent and "pyridine as catalyst". A broth dilution method was used to determine the minimal inhibitory concentration of a series of fatty acid esters**.** In the broth dilution method prepare two-fold dilutions of the antimicrobial agent in a liquid growth medium dispensed in tubes containing a minimum volume of 2 mL (macro dilution) or with smaller volumes using 96-well micro titration plate (micro dilution). Then, each tube or well is inoculated with a microbial inoculum prepared in the same medium after dilution of standardized microbial suspension adjusted to 0.5 McFarland scale. After well-mixing, the inoculated tubes or the 96-well micro titration plate are incubated under suitable conditions depending upon the test microorganism. The MIC is the lowest concentration of antimicrobial agent that completely inhibits growth of the organism in tubes.

Keywords: Antimicrobial activity, Fatty acid ester, Microorganism.

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Recent Advancement in Treatment of Gout

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Abstract

Hyperuricemia is a condition in which blood uric acid levels increases then its normal range. The normal range of uric acid is 2.18-7.7mg/dl. From several years, treatment of hyperuricemia or gout is done by urate lowering regimens like xanthine oxidase inhibitors and uricosuric drugs. Sometimes treatment with these drugs remains ineffective and also cause many complications. Uricase administration is proved to be effective in treatment of gout but due to its derivation from animals and microbes, it is higly antigenic and can lead to various hypersensitive reactions. External administration of uricase have very short half life as it is inactivated by proteolysis. To overcomes these problems PEG-uricase was introduced. PEG-uricase was a recombinant form of drug uricase as it is conjugation of uricase with polyethyleneglycol. This drug is effective in treatment of gout as it breaks uric acid deposits. PEG-uricase is given at a dose below 4µg/kg of body weight in treatment of refractory gout. PEG-uricase is more suitable in treating gout as it is more effective than its former drug. The biological half life of PEG-uricase is more as compared to uricase and also less risk of immunological reactions. The conjugate have high molecular weight as compared to uricase and also more stable at pH 6 which is quiet close to physiological pH.

Keywords: Hyperuricemia, Uric acid, Gout, Xanthine oxidase.

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Formulation and *in-vitro* Evaluation of Eudragit coated Alginate based Microspheres of Pravastatin Sodium

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Abstract

The present study has reported the methodology of development of Pravastatin sodium coated microspheres using polymers Sodium alginate by Ionic gelation method. Microspheres indicated different micromeritics properties, floating behavior, drug entrapment efficiency and drug release by varying the polymer concentration. The formulated microspheres were found to be spherical and free flowing. Total 36 formulations were prepared out of that six formulations were coated with Eudragit RL 100, and they were found to remain buoyant for more than 12 hrs. *In-vitro* Pravastatin sodium release data showed that all the prepared formulations released drug in a controlled manner for over 12 hrs. Based on the results obtained, it can be concluded that **F5C** batch was found to be the ideal formulation considering its micromeritics properties, drug entrapment efficiency, particle size and release profile. The mechanism of drug released was found to be diffusion controlled. They are thus may be reduce frequency of dosing, thereby minimizing the occurrence of side effects, increase residence time in stomach and increase the effectiveness of the drug. It may be concluded that the fabrication of Pravastatin sodium microspheres by Ionic Gelation method were promising in the treatment of Hyperlipidaemia.

Keywords: Pravastatin Sodium, microspheres, Hyperlipidaemia, Sodium Alginate.

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Safety Pharmcovigilance of Biological Products

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Abstract

Biologics products are biological medicine that contain an active substance made by a biological process such as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood derived product, blood component or derivative, or an allergenic product used for the prevention, treatment or cure of diseases. The absorption, distribution, metabolism, and elimination (ADME) of biological products is different than small molecules or chemical entities, which lead to significant differences in their drug development process. A review of development safety and pharmacovigilance of biologics is presented here with their differences from small molecules. As the biologics are active proteins, they have the concern of developing immunogenicity, with possible loss of therapeutic efficacy to severe life threatening adverse events. The monoclonal antibodies (mAbs), which are considered to be the most important subset of biologics, bind to their targets by specific or non-specific binding. The most common adverse events in biologics are acute infusion reactions or cytokine release syndrome. The safety adverse events can be due to a generalized and intensified immune response or due to cross-reactivity of neutralizing anti-drug antibodies (ADA) with endogenous substances. The safety of all biological products is monitored closely during post-approval phase.

Keywords: Pharmcovigilance, Biologics, Vaccine, ADME, Drug safety.

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Emblica officinalis: A Review on Traditional Uses and Pharmacological Aspects

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Abstract

Emblica officinalis (Indian gooseberry) commonly known as Amla belonging to family *Euphorbiaceae*, is small to medium size tree that can reaches upto a height of 1–8 m. The tree is commonly found in Sri Lanka, Myanmar and also found in all deciduous forests of India. It is the most important medicinal plant in the Indian traditional system of medicine, the Ayurveda. Several parts of the plant are used to treat a variety of diseases, but the most important is the fruit. Many ailments are treated by the fruit which is used either alone or in combination with other plants. Traditionally, it is used in the treatment of common cold, fever, diarrhoea, dysentery, dyspepsia, anemia, peptic ulcer, as a diuretic, , blood purifier, laxative, liver tonic, refrigerant, stomachic, restorative, as hair tonic and to enhance digestion. The *E. officinalis* is a rich source of vitamin C (ascorbic acid), phosphorus, iron, calcium and also contains fat, phyllemblin, tannin and pectin which is responsible for various pharmacological activities like hepatoprotective, anti-oxidant, nephroprotective, hypolipidemic, metabolic syndrome, cardioprotective, immunostimulant, anti-anemic, anti-microbial, anticancer, analgesic, antipyretic anti-inflammatory, osteoporosis, gastroprotective, eye disorder, dermoprotective, and anti-ageing properties. Various formulaions of *E. officinalis* are available in market for various diseases. Hence the present study includes the detailed exploration of traditional uses and pharmacological aspects of *Emblica officinalis*.

Keywords: *Emblica officinalis*, Ayurveda, Ascorbic acid, Anti-oxidant.

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Formulation and Evaluation of Release Retardant of Aceclofenac Tablet with Comparative Evaluation of Some Marketed Brands

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Abstract

The aim of this study was to assess the pharmaceutical quality of new formulation and four commercial brands (B1 to B4) of SR aceclofenac tablets. Cumulative release greater than 89% was obtained from all formulations tested with in12 h. Model fitting was done on release data using zero order, first order and Higuchi model. Some model independent parameter such as t50%, t90%, dissolution efficiency (D.E%) and mean dissolution time (MDT) were computed. Now here is a need for development of a sustained release matrix tablet of aceclofenac for 12 h by direct compression technique using different polymers like hydroxyl propyl methyl cellulose, guar gum, talc, magnesium stearate and microcrystalline cellulose. The tablets were evaluated for thickness, diameter, hardness, weight variation, drug content and in- vitro drug release studies. The tablets formulations showed acceptable pharmacotechnical properties and complied with Pharmacopoeial specifications for tested parameters. Some model independent parameter such as t50%, t90%, D.E% and MDT were also calculated. F4 and F3 emerged as successful tablet formulation formulated with different approaches and were subjected to comparison with one popular marketed brand. Marketed brand and formulation F4 extended the drug release 83.62% and 90.10% in 8-12 h. whereas F3 formulation extend the drug release up to 12 h followed by zero kinetic order (r2 = 0.9630). The similarity in dissolution profile (f2) was assessed using the FDA recommended approach. The (f2) factor increase in pH 6.8 is optimum for co-relation for marketed brands (B1, B2, B3 and B4). The F3 formulation had a dissolution profile similar to the marketed brands and had the highest f2 similarity factor at pH 6.8.

Key words: Aceclofenac, Dissolution, zero order, tablets, dissolution efficiency.

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Microspheres a Novel Drug Delivery System: An Overview

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Abstract

Microspheres are typically free flowing particles made up of natural or synthetic polymers that may be biodegradables or non biodegradables in nature. They are having particle size about 200microns. A numbers of techniques like single emulsion, double emulsion, polymerization, phase separation coacervation and solvent diffusion are used for preparation of microparticles that provides variety of opportunities to control aspects of drug administration and enhance the therapeutic efficacy of a given drug. A variety of approaches are used in delivering the therapeutic substances to target site in a sustained drug release pattern. Microspheres are also as carriers for active pharmaceutical substances are known as microparticles. Microparticles received much attention not only for prolong release, but also for targeting of anticancer, diagnostic and genetic materials. Microsphere carriers improve bioavailability, stability and target the drug to specific site. Microparticles are vital carriers for safe and effective drug delivery.

Keywords: Microspheres, Therapeutic, Biodegradable, Bioavailability, specific site.

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Natural Polymers: Today's Need

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Abstract

Polymers are the backbone for drug delivery system as they control the release of the drug from the device. Biodegradable polymers have been extensively explored in drug delivery as they can be degraded to non-toxic monomers and most important, a constant rate of drug release can be achieved from a biodegradable polymer based controlled release device. Mainly two types of polymers are used i.e. natural and synthetic. Natural polymers are linear or branched long chain, non-toxic, biocompatible and biodegradable which is essential in drug delivery. These have high efficiency to encapsulate a variety of drugs. These polymers may be used to formulate various controlled and targeted drug delivery systems. Natural polymers are classified into proteins and polysaccharides. Proteins include gelatin, albumin, lecitin, legumin and vicillin whereas polysaccharides include alginate/dextran, chitosan and pollulan. These polymers have vast application in formulation development for drug delivery viz. the manufacture of solid monolithic matrix systems, implants, films, beads, microparticles, nanoparticles, inhalable and injectable systems as well as viscous liquid formulations.

Keywords: Biodegradable polymers, Proteins, Polysaccharides, Natural Polymers.

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Challenges in Pharmacovigilance Program in India

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Abstract

Pharmacovigilance plays a significant role in clinical research and practice. In India, Pharmacovigilance program initiated in the late 80's. Now India is a hub for clinical trials flooded with thousands of licensed drug manufacturers and branded formulations. The major objective of the program is to safeguard the health of people of India but the advancements in this discipline have taken place in Western countries, its implementation and compliance still a challenge in India. In India the adverse events are not properly reported due to lack of time, low motivation and ignorance. Lack of medical education on pharmacovigilance and lack of drug information and updates particularly at the level of primary health centers and private practitioners lead to underreporting of ADR. Self-medication and use of traditional medicines are also a major cause of underreporting of ADR. In addition to it, communication gap among healthcare professionals and a shortage of trained personnel and inadequate training on pharmacovigilance. These challenges can be reduced by initiating such steps like making pharmacovigilance reporting mandatory at all levels and introducing pharmacovigilance inspections. Proper training should be given in all aspects of pharmacovigilance to the patients as well as an efficient system of communication should be formed also a clinical trial database for reporting ADRs should be there. Thus it will help in proper execution and compliance of the programme.

Keywords: Pharmacovigilance, Clinical trials, ADRs, Self-medication.

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SALIVA: A New Way of Testing

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Abstract

Salivanomics is the study of saliva which has developed over time and proved as an important pool of biological markers. Saliva biomarker ranges from changes in the biochemical indices of DNA, RNA and proteins to the diversification of microbiota structures. Saliva is non-invasive and safe source and could be used as a substitute for blood. It helps in the early diagnosis of many diseases such as caries, periodontal diseases, oral cancer, Sjogren's syndrome, diabetes mellitus, cardiovascular diseases, viral infections, pancreatic cancer, lung cancer, prostate cancer and other diseases. Saliva test can be used to predict 25 hereditary cancer and also mutations in 98 genes. BRCA1 and BRCA2 are two widely recognized genes known to increase the risk of breast and ovarian cancer. Salivary proteins and DNA of tumour related viruses, also tumour specific bio markers increase in tumour antigen such as CA15-3 and antibodies for tumour protein markers c-erbB2, CA-125 can serve as an basis for the detection of cancer of many sites. Change in levels of several other indicators can help in diagnosis of several other disorders and disease. Testing of saliva is an easy, rapid, inexpensive and doesn't involve any painful or prolong procedure. Salivanomics is now a rapidly evolving field of testing and in near future it may completely replace serum and urine testing which are painful and embarrassing respectively.

Keywords: Biomarker, Diabetes mellitus, Cancer, Salivanomics.

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Recent Advancement in Treatment of Tuberculosis.

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Abstract

Tuberculosis, a contagious disease caused by Mycobacterium tuberculosis. Suitable drug therapy of TB is still an important challenge. According to STG, treatment of TB is done using DOTS therapy including regimens like Isoniazid, rifampin, pyrazinamide, ethambutol or streptomycin. There is a great risk of development of resistance for anti TB regimens by mycobacterium. Multi drug resistant TB, when Mycobacterium gets resistant to at least two powerful regimens like isoniazid and rifampin. Bedaquiline and Delamanid are the drugs recently approved for the treatment of multi/extensively drug resistant TB (MDR/XDR-TB). Bedaquiline is used with other anti-TB drugs in case of drug resistant pulmonary tuberculosis. Bedaquiline acts by blocking ATP synthase enzyme in mycobacterium. ATP synthase is responsible for generating energy in Mycobacterium. Nix-TB trials were performed recently (first trial for combination of TB therapy). Bedaquiline is used in combination with pretomanid and linezolid (Nix-TB drug combination). Delamanid, dihydro-nitroimidazooxazole derivative is another active drug used in TB. It was recently approved for treatment of MDR-TB by European medicines agency. Delamanid acts by inhibiting mycolic acid and ketomycolic acid (Cell wall components of mycobacteria.) Pretomanid (another nitroimidazole), used in treatment of XDR-TB. Pretomanid have a complex mechanism of action as it plays role in inhibiting cell wall components and ATP synthase as well.

Keywords: Tuberculosis, Isoniazid, Mycobacterium, Pyrazinamide.

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Preparation and Evaluation of a Novel Buccal Adhesive System

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Abstract

The aim of the present study was to prepare and evaluate a novel buccal adhesive system (NBAS) containing propranolol hydrochloride (PH). A special punch was fabricated and used while preparing an NBAS. Solubility of PH in phosphate buffer solution (pH 6.6), partition coefficient between phosphate buffer (pH 6.6) and 1-octanol, and permeability coefficient through the porcine buccal mucosa were performed and found to be 74.66 mg/mL, 5.17, and 5.6, respectively. Stability of NBAS was determined in natural human saliva, and it was found that both PH and device are stable in human saliva. NBAS was evaluated by weight uniformity, thickness, hardness, friability, swelling, mucoadhesive strength, in vitro drug release, and in vivo human acceptability studies. Swelling index was higher (4.4) for formulations containing hydroxyl propyl methyl cellulose (HPMC) K4M alone, and it decreases with its decreasing concentration in the NBAS. Mucoadhesive strength (MS) was measured by using a modified apparatus. All NBASs showed higher MS with porcine buccal mucosa when compared with that of rabbit buccal mucosa. NBASs containing carbopol (CP) 934P and HPMC K4M at the ratio of 1:1 showed higher MS (44.76 g) with porcine buccal mucosa when compared with 1:2 (39.76 g), 0:1 (23.29 g), and 1:0 (22.22 g) ratios, respectively. The mechanism of PH release was found to be by non-Fickian diffusion (value of "n" between 0.5 and 1.0) and followed first order kinetics. In vivo human acceptability study showed that the newly prepared NBAS was comfortable in the human buccal cavity. It can be concluded that NBAS is a superior, novel system that overcomes the drawback associated with the conventional buccal adhesive tablet.

Keywords: Buccal delivery, Carbopol 934P, HPMC K4M, Propranolol hydrochloride.

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Detrimental Effect of Synthetic Drugs on the Environment

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Abstract

Synthetic drugs are widely used all over the globe due to their fast action effects and easy handling. But synthetic drugs are proving to have detrimental effects on the environment. The human and veterinary therapeutics which are released to the environment by various routes have become a major issue of human and environmental health concern. Residues are released during the manufacturing process and after administration; human medicines are excreted to the sewer system. Veterinary medicines are excreted to soils or surface waters. Other minor routes of entry include emissions to air and through the disposal of unused medicines and containers. Many pharmaceuticals are not fully degraded in wastewater treatment plants (wwtps). For example diclofenac is a widely used non-steroidal anti-inflammatory drug (NSAID) is known to inhibit the cyclooxygenase activity, an enzyme present in many species of the animal kingdom responsible for the synthesis of prostanoids which can cause a shift in the arachidonic cascade and increase the synthesis of other eicosanoids and chronic exposure to environmental diclofenac may result in side effects such as kidney failure and intestinal pathology which may be detrimental to the health and survival of aquatic vertebrates. . Therefore herbal renaissance is happening all over the globe with the incorporation of Novel drug delivery system in herbal drug formulations to overcome the problems associated with herbal drugs.

Keywords: Synthetic drugs, NSAID, Cyclooxygenase, Arachidonic acid.

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High Dose of Black Tea Extract Induced Prenatal & Postnatal Changes in Experimental Animals

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Abstract

Tea (*Camellia sinensis*) is the most popular beverages in the world and is rank second after the pure water. Tea has been considered as a health promoting beverage since ancient times due to its immune-modulatory, anti-arthritic, anti-oxidant, anti-cancer and cardio-protective activity. Beside the beneficial effect few studies on animal models suggests that the maternal intake of black tea has an adverse effect during pregnancy. The aim of the present study is to evaluate the role of Black Tea Extract (BTE) in experimental pregnant albino rat and to study the different physiological parameters of mother and pups during prenatal and postnatal developmental period. BTE was orally administered in LD (50 mg BTE/kg/day) and HD (100 mg BTE/kg/day) except control group of rats (n=6/group) throughout the prenatal and postnatal periods. During prenatal period (0, 7th, 14th, 20th days) body weight, urinary calcium, magnesium, urea and creatinine was measured. In postnatal period (0, 7th, 14th, 20th days) physical parameters of pups like body weight, weight of liver, kidneys, heart and lungs, cranial length, cranial diameter, neck width, tail length, cranio-sacral length of pups were analyzed. There was a significant ($p=0.05$) change in the weight of kidney, liver, lungs, heart and physical parameters in pups of treated groups as compared to control. The body weight of LD and HD mothers were also significantly ($p=0.05$) less than control mothers at 20th day of pregnancy. This study clearly indicates that BTE has some effect on pregnant mother in experimental animal model.

Keywords: *Camellia sinensis*, Anti-arthritic, Anti-oxidant, Anti-cancer.

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Entresto (Sacubitril/Valsartan): First-in-Class Angiotensin Receptor Neprilysin Inhibitor Better than Existing Treatment in Heart Failure

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Abstract

Entresto, the combination of sacubitril plus valsartan inhibits neprilysin (neuro endopeptidase) and valsartan blocks angiotensin- II type-1 (AT1) receptor indication. On July 7, 2015, the US Food and Drug Administration (FDA) approved sacubitril plus valsartan (Entresto; Novartis) to reduce the risk for cardiovascular (CV) death and hospitalization in patients with chronic heart failure (NYHA Class II-IV) associated with reduced ejection fraction. Pharmacologic treatments for heart failure typically comprise a combination of drugs depending on the symptoms. Until recently, these drugs included renin-angiotensin system inhibitors, such as angiotensin- converting enzyme (ACE) inhibitors and angiotensin II receptor blockers, in addition to beta-blockers, diuretics, aldosterone antagonists, inotropes, and digoxin. In a study this combination showed, the primary composite end point was (21.8%) CV deaths as first event and (12.8%) HF hospitalizations as first event with entresto (sacubitril plus valsartan) and (26.5%) with enalapril. A total of (17.0%) patients receiving entresto and (19.8%) patients receiving enalapril died (P<0.001). With entresto (13.3%) and with enalapril. (16.5%), respectively, died who had known CV events before death (P<0.001) and rehospitalisation of patients with known events of CV was reduced to 12.8% from 15.6% with the use of entresto (sacubitril plus valsartan). Entresto (sacubitril plus valsartan) improved overall survival, a finding driven entirely by a lower incidence of CV mortality with sacubitril plus valsartan treatment. This robust finding provides strong evidence that combined inhibition of the angiotensin receptor and neprilysin is superior to inhibition of the renin-angiotensin system alone in patients with chronic heart failure.

Keywords: Entresto, Sacubitril, Valsartan, ACE inhibitors.

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A Newer Indication: An Antihypertensive Drug for Diabetes

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Abstract

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. According to WHO In 2015, an estimated 1.6 million deaths were directly caused by diabetes. Another 2.2 million deaths were attributable to high blood glucose in 2012. WHO projects that diabetes will be the seventh leading cause of death in 2030. Among various type of diabetes, only 5% of population is affected by type1 diabetes. The recent studies shows that Type 1 diabetes has been presented with DQ8 molecule, a significant disease risk that also involved in pathogenesis. .The mechanism of action of drug involves the blockage of DQ8 antigen presentation that would provide therapeutic benefit by preventing recognition of self peptides by pathogenic T-cells. The study was conducted on computerized systems, in which crystal structure of DQ8 is used to select drug –like small molecules predicted to bind structural pockets in the MHC antigen-binding cleft. In vitro studies shows a limited number of predicted compounds inhibited DQ8 antigen presentation in vitro with one compound preventing insulin autoantibody production and delaying diabetes onset in an animal model of spontaneous autoimmune diabetes. An existing drug of similar structure, methyldopa, specifically blocked DQ8 in recent-onset patients with type 1 diabetes along with reducing inflammatory T-cell responses toward insulin, highlighting the relevance of blocking disease-specific MHC class II antigen presentation to treat autoimmunity.

Keywords: Diabetes, Insulin, Autoimmune disorder, Methyldopa.

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Nanoparticles: The Modern Formulation Approach for Drug Delivery

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Abstract

Nanoparticles are defined as particulate dispersions or solid particles having size in the range of 10-1000nm.Nanoparticles are nano-sized stable, colloidal or solid particles, generally made of polymers or lipids. Nanoparticles, nanospheres or nanocapsules can be obtained on the basic method of preparation. Nanocapsules are systems in which the drug is confined to a cavity surrounded by a unique polymer membrane, while nanospheres are matrix systems in which the drug is physically and uniformly dispersed. The polymeric nanoparticle consists of a biodegradable and biocompatible polymer. The major objective behind designing nanoparticles as a delivery system are to control particle size, surface properties and control release of drug in order to achieve the site-specific action of the drug at the therapeutically optimal rate and dose regimen. Nanoparticles offer many advantages over conventional oral dosage forms. Nanoparticle formulations can also offer advantages like limiting fluctuation within therapeutic range, reducing side effects, decreasing dosing frequency with improving patient compliance. The application of Nanotechnology in medicine and drug delivery is spreading very rapidly. From Last few decades pharmaceutical sciences have been using nanoparticles to minimize toxicity and adverse effects of drugs. The nanoparticulate systems have great potentials, being able to convert poorly soluble, poorly absorbed and labile biologically active substance into promising deliverable drugs. It is expected that nanotechnology will bring a fundamental change in manufacturing in the next few years. Furthermore advances are required in order to turn the concept of nanoparticle technology as the next generation of drug delivery system.

Keywords: Nanoparticles, Drug delivery system, Nanospheres, Nanocapsules.

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New approaches in the treatment of Parkinson`s disease

Chahat

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Abstract

Parkinson`s disease is a progressive neurological disorder caused by a degeneration of dopaminergic neurons. It is characterized clinically by four main features including Resting tremor, Rigidity, Bradykinesia and Postural instability. Annual incidence rates are estimated at approx. from 7 to 328 per 1,00,000 in India. With treatment, life expectancy and death rates for Parkinson`s disease and non-Parkinson`s disease individuals are essentially equal. It is infectious, drug and chemical indused, reversible and non-reversible. Parkinson`s disease is characterized by the destruction of the presynaptic neurons of substantia nigra. Dopamine is secreated from the neurons in the mid brain *i.e.* substantia nigra and ventral tegmental ares. It is released by hypothalamus when approx. 60-80% of dopamine producing neurons of the substantia nigra are lost, the symptoms of Parkinson`s disease appear. A relative excess of dopaminergic activity would result in abnormal involuntary movements or dyskinesia. Many type of clinical disorders are Rigity, Bradykinesia, Hypophonia, Micrographia, Many drugs and antagonist are used in the treatment of Parkinson`s disease are MAO-inhibitors, COMT-inhibitors (catechol-o-methyl transferase) is given in less amount due to hypertoxicity risks ,Talcaphone (COMT-inhibitor) are reserved for patients with fluctuations that are responding toother therapies. Additiomally, delayed onset of Diarrhea (weeks to months later) can occur in upto 5% of patients. Brownish-orange urinary discoloration may occur, dopamine agonists, Levodopa and carbidopa/levodopa. Non-fludrocortisone. Phase I assessed the compliance, safety and efficiency of non-pharmacological measures. Phase II was a doble-blind randomized controlled cross-over trials of the two medications. Primary outcome measures are clinical global impression of change (CGI) and postural blood pressure testing via bedside sphygnomanometry and COMPASS-OD (Composite Autonomic Symptom Scale).

Keywords: Parkinson`s disease, Dopaminergic, COMT-inhibitor.

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Enzalutamide - A new Hormonal Therapy for Treatment of Prostate Cancer

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Abstract

Antiandrogen drug called Enzalutamide is the hormonal therapy that can delay the spread of prostate cancer which is the mostly common cancer in worldwide. It improves metastasis castration resistant prostate cancer while receiving androgen deprivation therapy in men. Enzalutamide is inhibiting androgen binding to androgen receptor and restrains androgen receptor nuclear translocation and interacting with DNA of cell. This event effects the prostate gland by decreasing the tumour volume, decreasing the proliferation and leads to tumour cell death. The drug is administered in 40mg capsule four times a day, with total dose of 160 mg a day. The drug delays metastasis about 33.6 months. From the patients receiving enzalutamide show the adverse reaction of rashes, constipation, back pain, fatigue, falls, upper respiratory tract infection and hypertension. When using enzalutamide avoid the use of warfarin and CYP2C8 inhibitors (clopidogrel, ritonavir) as they increase plasma concentration of it. Do not take the drug if you have history of seizuire, brain injury, stroke or brain cancer and hypertension. From analysis of prostate cancer patients shows a statistically significant decrease in the risk of death for men administering enzalutamide. The ability of enzalutamide in decreasing the production of testosterone hormone along with binding and entering cancer cells which result to the meaningful clinical advancement of prostate cancer patients prior to the start of chemotherapy. The drug as approved with FDA appears to be safe with almost nearly few side effects.

Keywords: Enzalutamide, Hormonal therapy, Metastasis, Cancer.

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Rivaroxaban with or without Aspirin in Stable Cardiovascular Disease.

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Abstract

Rivaroxaban, is an anticoagulant and the first orally active direct factor Xa inhibitor. It inhibits both free Factor Xa and Factor Xa bound in the prothrombinase complex. It is a highly selective direct Factor Xa inhibitor with oral bioavailability and rapid onset of action. Only the 10 mg tablet can be taken without regard to food. The 15 mg and 20 mg tablet should be taken with food. Aspirin (in low dose) irreversibly blocks the formation of thromboxane A_2 in platelets, producing an inhibitory effect on platelets aggregation during the life time of the affected platelet (8-9 days). Rivaroxaban in combination with aspirin has more effective than aspirin alone for secondary cardiovascular prevention. In a study, the outcome stating the effectiveness of the combination was more than aspirin alone, but the major bleeding effects had occurred in the patients taking combination than from aspirin alone but for the proportion of death the percentage was reduced to 3.4% from 4.1% with combination therapy and aspirin alone, respectively. Alone rivaroxaban (5mg twice a day) is nowhere better than aspirin rather it has more bleeding events recorded in proportion of CV effectiveness. Combination of rivaroxaban (2.5mg twice a day) plus aspirin results in better PT-INR regular monitoring which could prevent major bleeding events.

Keywords: Rivaroxaban, Anticoagulant, Thromboxane, Aspirin.

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Unidentified Cause of Metabolic Syndrome in Primary Aldosteronism: "Connshing Syndrome"

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Abstract

In Primary Aldosteronism, adrenal glands overproduce aldosterone that results in loss of potassium along with sodium retention, leading to secondary hypertension. Hypertension in Cushing's syndrome results from increased plasma volume, greater peripheral vascular resistance and higher cardiac output. Connshing Syndrome is a combination of both Primary Aldosteronism & Cushing's Syndrome, together leading to complications such as Type 2 DM, Osteoporosis. Extensive background literature survey was conducted for a period of 6 months, to find a significant role of Connshing Syndrome in secondary hypertension and associated perivascular complications. In Primary Aldosteronism, glucocorticoid co-secretion is common and associated with risks for metabolic disorders. Patients with Conn Syndrome had significantly increased cortisol & total glucocorticoid metabolite excretion. In patients with Conn Syndrome, the adrenal glands not only overproduce aldosterone, but also cortisol. Aldosterone excess has been found to be associated with disorders in glucose metabolism, and may also contribute to cardiovascular damage. Adrenalectomy in patients with Primary Aldosteronism significantly reduces the risks of New-Onset Diabetes Mellitus, compared to that of mineralocorticoid receptor antagonist therapy. Connshing Syndrome, a recently identified condition, is characterized by combined overproduction of aldosterone and cortisol, which is highly associated with metabolic syndromes like Type 2 DM, osteoporosis and fractures. Treating Connshing Syndrome, rather than that of aldosterone excess alone, will result in clinically significant reduction risk of secondary hypertension and associated perivascular complications.

Keywords: Connshing Syndrome, Hypertension, Osteoporosis, Glucocorticoid.

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Role of Gender in Stroke Risk: A New Study

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Abstract

It is a clinical syndrome consisting of rapidly developing clinical signs of focal disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than a vascular origin. There are many risk factors associated with stroke. One of the risk factor for stroke is gender. Women are more prone to stroke than men. A recent study shows that the following risk factors were more significantly responsible for stroke in female, these includes Mensuration cycle before the age of 10, having low dehydroepiandrosterone levels, starting menopause before the age of 45 years, taking combined oral contraceptives and oral estrogen, who had a history of complications related to pregnancy such as hypertension during or just after pregnancy and gestational diabetes, had an increased risk of diabetes. The women who had these risk factors should be monitored carefully, they should be aware about that and should be motivated to follow the healthiest lifestyle to decrease the risk of stroke.

Keywords: Stroke, Cerebral function, Contraceptives, Estrogen.

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Gestational Diabetes is - A Condition in Pregnant Woman

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Abstract

Gestational diabetes is a condition in which a pregnant woman without diabetes grows high glucose levels in pregnancy and which mostly disappear after giving birth. Gestational diabetes mellitus (GDM) influences in the vicinity of 2% - 10% of pregnant women. Risk factor for the gestational diabetes mellitus is overweight or body mass index more then 29, glucose intolerance, some medication like glucocorticoids, antipsychotic drugs, depression and beta-blockers. Regular exercise, eating balanced meals, taking diabetes medications like metformin and insulin shots can decrease the risk factor of gestational diabetes. As per diabetes in pregnancy study group India (DIPSI) guideline in India, a pregnant woman strolls around the antenatal concentration in the fasting state, she ought to be given a 75g oral glucose stack and at 2 hours a venous blood test is collecting for evaluating plasma glucose. This procedure is simple and economical for diagnosing GDM in pregnant women. Screening is recommended between 24 and 28 weeks of gestation and the diagnostic criteria of American Diabetes Association (ADA) are applicable. For GDM management physical activity, diet plan, intensive monitoring and insulin are necessary. A transitory concentrated care gives an entire arrangement pay off in the fundamental desire of weight, Impaired Glucose Tolerance (IGT), and diabetes in the posterity, as the preventive course of action begins before birth.

Keywords: Diabetes, Insulin, Glucocorticoids, Antipsychotic drugs.

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Botulinum Toxin A – A new Injectable for Treatment of Lower Urinary Tract Symptoms/ Benign Prostratic Hyperplasia

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Abstract

Botulinum Toxin-A (BOTOX) is a neurotoxic protein produced by the Gram-negative bacterium Clostridium botulium and related species. In skeletal muscle, it prevents the release of the neurotransmitter acetylcholine from axon endings at the neuromuscular junction. In smooth muscle, the drug has been shown to decrease the amount of acetylcholine release. For lower urinary symptoms and benign prostractic hyperplasia, the efficacy of intraprostratic Botox may result from glandular apoptosis and/or targeting afferent sensory pathways. The efficacy and safety of Botox given at different doses and via different approaches like: transrectal, transperineal and transurethral. Botox injected transperineally at 100U or 200U depending on postrate size. At 1month, there was a reduction by 15%, 48% and 46% in prostrate volume for men who were treated with 100U of Botox. In men who were treated in with 200U of Botox, there was a reduction by 15%, 51% and 51% in prostrate volume. These effects were maintained within 3 and 6month follow-ups. 12 out of 41 patients interestingly, presented no change in prostrate size yet had symptomatic improvement. Patient on Botox may experience effects like muscle weakness, pain, redness, swelling in injected area, headache, muscle stiffness, neck or back pain, fever, cough, sore throat, runny nose, flu, dizziness, drowsiness, tiredness . Botox also serves as a non-invasive treatment option in poor surgical male candidates. Don't use Botox if you have preexisting motor neuron disease. Botox may not only work by prostrate shrinkage but also by inhibiting smooth muscle tones and sensory innervation as well.

Keywords: Botulinum Toxin, Acetylcholine, Headache, Apoptosis.

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Lutathera – A Radiolabeled Somatostatin, Analog for the Treatment of Gastroenteropancreatic Neuroendrocine Tumors.

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Abstract

Lutathera is a radiolabeled somatostatin analog, specifically indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) including foregut, midgut and hindgut neuroendocrine tumors in adults. It binds to somatostatin receptors with highest affinity for subtype 2 receptors (SSRT2). Upon binding to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors, the compound is internalized. The beta emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighboring cells. The recommended dose is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. Administer long-acting octreotide 30 mg intramuscularly 4 to 24 hours after each lutathera dose and short-acting octreotide for symptomatic management. Lutathera is supplied as an injection for intravenous administration (Injection: 370 MBq/mL (10 mCi/mL) in single-dose vial). Administer antiemetics 30 minutes before the recommended amino acid solution. Initiate an intravenous amino acid solution containing L-lysine and L-arginine 30 minutes before administering lutathera. Most common grade 3-4 adverse reactions are lymphopenia, increased GGT, vomiting, nausea, increased AST, increased ALT, hyperglycemia and hypokalemia. Patients with baseline renal impairment may be at greater risk of toxicity; perform more frequent assessments of renal function in patients with mild or moderate impairment. Monitor patients for flushing, diarrhea, or other signs and symptoms of tumor-related hormonal release.

Keywords: Lutathera, Somatostatin, Tumors, Hyperglycemia, Hypokalemia.

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Pharmacognostic and Phytochemicals Analysis of *Fumaria parviflora* Lam.

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Abstract

The pharmacognostic and phytochemicals evaluation were carried out in terms of organoleptic, macroscopic, microscopic, fluorescence analysis and physiochemical parameters. The organoleptic and morphological study of *Fumaria parviflora* leaves are green in colour, compound, apex acute or sub acute, petiole is very thin, long and bitter in taste. Root was branched, about 3mm thick, cylindrical cream coloured, and bitter in taste. Pentagonal stem was pale green, smooth, hollow bitter and slightly acrid taste. Fruits Capsule, are single seeded, and taste bitter. The main microscopic characters of collenchyma, brown spotted parenchyma, phloem fibre and epidermis of pinnules with stomata. Further, physiochemical analysis of different part of plant powder were determined total ash, acid insoluble ash, water soluble ash, water soluble and alcohol soluble extractive value. The pharmacognostic and physiochemical data was observed in this study is helpful in the botanical identification and standardization of this crude drug.

Keywords: *Fumaria parviflora*, Herbal drug, Standardization.

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Synthesis and Antimicrobial Evaluation of Pyrimidine Derivative of 5-Bromoisatin

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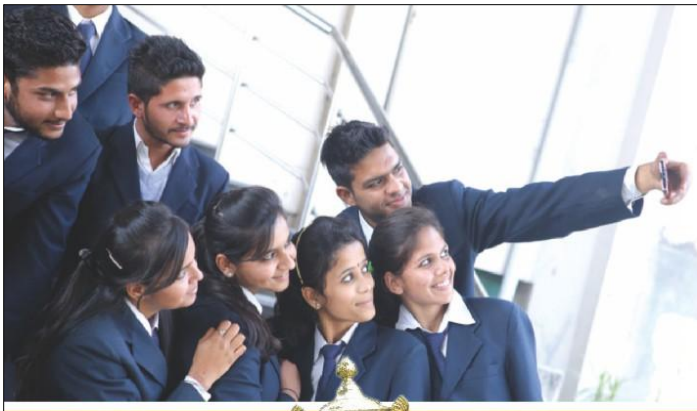
Abstract

In the present study novel pyrimidine derivatives of 5-bromoisatin were synthesized and screened for their in vitro antimicrobial activity. 5-Bromoisatin was reacted with 4-aminoacetophenone to give 3-(4-acetylphenylimino)-5-bromo-1, 3-dihydroindol-2-one, which was further reacted with different aromatic aldehyde in alkaline ethanolic medium to give chalcone (a-o). Final pyrimidine derivative were synthesized by reaction of chalcone with guanidine. All synthesized compounds were characterized by IR and H^1NMR spectroscopy. Compounds were evaluated for their in vitro antimicrobial activity by tube dilution method. Among the synthesized compounds, compound 7, 8, 9 showed both antibacterial and antifungal activity while compound 6 showed only antibacterial activity.

Keywords: Antimicrobial Activity, Pyrimidine, Chalcone, Antifungal activity.



Life @ GGSCOP

The various co-curricular and extra-curricular events are organized at our institute, where students are actively participates in various inter-collegiate and intra-collegiate competitions. This regular exposure enhances the competence, communication and interpersonal skills of the budding pharmacists

Three Days Workshop

Fresher Party

Rock On

Health Check-up Camp

Rangoli Competition

Rally on Health Awareness

Women's Day Celebration

National Conference 2015

Dental Check-up Camp

Pharmacy Week Celebration

Diwali Celebration

Annual Sports Meet