SOUVENIR

Two Days National Seminar

" CPCO 2k24"

A New Era of Clinical and Pharmacovigilance : A Future Challenges and Opportunities

Sponsored by

CSIR & MPCST

Organized by

CHAMELI DEVI INSTITUTE OF PHARMACY INDORE

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CDIP

CHAMELI DEVI INSTITUTE OF PHARMACY

"CPCO 2k24"

Council of Scientific & Industrial Research

&

Madhya Pradesh Council of Science and Technology

Sponsored

Two Days National Seminar

On

"A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities"

22nd – 23rd March 2024

Organized By
Chameli Devi Institute of Pharmacy
•Affiliated to RGPV * Approved by PCI * Established year 2018
CDGI Campus, Khandwa Road, Indore
www.cdgi.edu.in E mail: seminar_cdip@cdgi.edu.in 6262050008, 9826720320

Content

About Institute

Chameli Devi Institute of Pharmacy is playing a significant role in the holistic development of young professional in addition to bridging the gap between the levels of quality education. The institute has a greater responsibility of making the student fraternity to be competent at national and international levels.

About Seminar

This symposium will provide scientific forum for all stakeholders of pharmaceutical Clinical and Pharmacovigilance to enable the interactive exchange of state of the art knowledge. The Seminar will focus on various challenges and innovations in the field of Clinical & Pharmacovigilance.

In addition novel strains, controversial but scientifically solid ideas approaches and vision will be presented as well. Additionally the event will allow stake holder to build their contact by networking with professionals of renowned industries and institutions

Programme Schedule

Day 01
Online & Offline Poster Presentation

Time	Activity	Venue
11:00 am -4:00 pm	Online Poster Presentation	CDIP Auditorium (Google Meet/ Zoom)
10:30 am- 11:00 am	Registration (for candidates presenting offline e- poster)	CDIP 3rd Floor
11:00 am -4:00 pm	Offline Poster Presentation (e- poster)	CDIP Auditorium

Note:

1. Candidates Presenting Online Research or Review Work will submit JPG or PPT Form for presentation (ppt may contain maximum 5 slides) via Google Meet/ Zoom.
2. Candidates Presenting Offline Research or Review Work will submit JPG or PPT Form for e poster presentation.
3. Only registered candidates will be eligible for presentation.

Day 02

Time	Activity	Venue
9:30 am- 10:30 am	• Registration • Breakfast	CDIPS Auditorium CDGI Canteen
10:30 am- 11:30 pm	Inaugural Function	CDIPS Auditorium
Plenary Lectures		
12:00 pm- 1:00 pm	Scientific Session I	CDIPS Auditorium
1:00-2:00 pm **Lunch (CDGI Canteen)**		
2:00 pm- 3:00 pm	Scientific Session II	CDIPS Auditorium
3:00 pm- 3:50 pm	Scientific Session III	CDIPS Auditorium
4:00 pm- 4:20 pm	Award Ceremony & Valedictory Function	CDIPS Auditorium
04:20-04:40 pm **High Tea/ Certificate Distribution**		

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MESSAGE

It gives me immense pleasure and satisfaction that **Chameli Devi Institute of Pharmacy** is organizing a **CSIR & MPCST sponsored** Two Days National Seminar on **CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd- 23rd March 2024.**

I hope that the event will provide a highly stimulating and interactive platform for all the delegates, to explore and exchange the latest ideas and advancements in health care system. Seminar is composed of lectures by distinguished speakers, plenary talk, keynote addresses and technical papers and presentations to address various challenges and innovations in the field of Clinical & Pharmacovigilance.

I am really delighted to send my best wishes to the organizers and participants of National Seminar and wish all the success for the Seminar.

Shri Vinod Kumar Agarwal
Chairman
Chameli Devi Group of Institutions
Indore (M.P.)

Shri Sanjay Kumar Agarwal

Patron

MESSAGE

I am very glad to know that **Chameli Devi Institute of Pharmacy** is organizing **CSIR & MPCST** sponsored Two Days National Seminar on **CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd- 23rd March 2024** and releasing a souvenir to mark the event.

Chameli Devi Institute of Pharmacy is one of the most vibrant departments and has been actively contributing to the needs and demands of the society at large in fostering academic research and developments.

Seminar is meant essentially for scientific exchange and generation new ideas in the chosen field along with personal interaction. I hope that this Seminar will disseminate innovative ideas in new and emerging technologies in Clinical & Pharmacovigilance field.

I congratulate the organizers for their initiative and attracting a wide range of papers from experts in their fields. I wish all the speakers and delegates a most informative and enjoyable Seminar.

I extend my best wishes for the success of Seminar and release of Souvenir.

Shri Sanjay Kumar Agarwal
Vice-Chairman
Chameli Devi Group of Institutions
Indore (M.P.)

Dr Joy Banerjee

Group Director

Chameli Devi Group of Institutions, Indore

"Patron"

MESSAGE

I have immense pleasure in writing this message on the occasion of the National Seminar on **CSIR & MPCST sponsored** Two Days National Seminar on **CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd- 23rd March 2024**. This Seminar will provide a platform to groom young scientists from all over the country and to bridge the researchers working in academia and other professionals through current technological trends. It is a high time to create research activities among the budding professionals. May this Seminar provide greater opportunities for every member of this specialty to learn more and let this learning be of immense help to the community at huge. I congratulate the organizers for their initiative and wish the Seminar all success.

Dr. Joy Banerjee

Group Director

Chameli Devi Group of Institutions

Indore (M.P.)

Dr. Arun Kumar Gupta
Principal
Chameli Devi Institute of Pharmacy, Indore

"ORGANIZING CHAIRMAN"

MESSAGE

"Learning gives creativity, creativity leads to thinking, thinking leads to knowledge and knowledge makes you competent."

Warm Greeting to All

It gives me an immense pleasure that **Chameli Devi Institute of Pharmacy** is organizing the National Seminar with the theme of **CSIR & MPCST sponsored Two Days National Seminar on CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd- 23rd March 2024.** The Seminar is aimed to provide the platform for industrialists, educationists, researchers and students to debate and discuss on the Clinical & Pharmacovigilance Aspects that will improve nutritional status and health. The unique event will explore the significance of Clinical & Pharmacovigilance and their benefits. The Seminar with your support is putting its best efforts to conduct this mega event in a befitting manner, considering the importance of Clinical & Pharmacovigilance. The theme of the Seminar seeks to not only strengthen our commitment towards the ideals of our specialty. The entire Seminar will be addressed by eminent scientists and professors as key note/invited speaker while it will also attract young researchers, faculties and students across the country, who will take part as poster presentations. I extent my warm welcome to the resource persons young researchers, budding Pharma professionals, eminent scientists, guests, faculties, and industrialists in this splendid Seminar and wish the Seminar a great success. I hope all the delegates will derive maximum benefit from this event and take back fond memories of the Indore experience!

Best wishes…

Jai Hind….

Dr. Arun Kumar Gupta
Principal
Chameli Devi Institute of Pharmacy
Indore (M.P.)

Prof. (Dr.) Saurabh Gupta
Professor & Head Department of Pharmacology
Academic Head
Executive Member IPA, M.P.
Chameli Devi Institute of Pharmacy, Indore

"ORGANIZING SECRETARY"

MESSAGE

"Education is the passport to the future, for tomorrow belongs to those who prepare for his today"

The **CSIR & MPCST sponsored Two Days National Seminar on CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd- 23rd March 2024** is a meeting place for leaders in the field to discuss the issues and challenges scientists and researchers face in all aspects of the Clinical & Pharmacovigilance. National speakers from academia and industry will discuss various aspects and developments in the area of biomarker importance in disease prognosis and the role of proteomics. Through scientific presentations, case studies and panel discussions, these areas will be addressed in an intimate and highly interactive environment with perspectives from industry, academia and the public sector. These international events are authoritative in guiding pharmacy students, scientists, research scholars, medical practitioners, clinical pharmacists, leading pharmaceutical industries to champion professional and social relationship with sister organizations and actively concur within the analysis and safe utilization of the pharmacy drugs with honor and ethics. The scientific sessions will include online and poster presentations and seminars from the professionals working within the field of pharmaceutical sciences.

On the behalf of organizing committee, we welcome all the delegates, dignitaries and participants to CPCO 2K24.

Dr. Saurabh Gupta
Professor & Head Department of Pharmacology
Academic Head
Executive Member IPA, M.P.
Chameli Devi Institute of Pharmacy
Indore (M.P.)

Mr. Saurabh D Jain
Associate Professor
Department of Pharmaceutical Chemistry
Chameli Devi Institute of Pharmacy, Indore

"CONVENER"

MESSAGE

"Education is more than being literate."

With these words, I welcome you all in "CPCO 2k24" **CSIR & MPCST sponsored Two Days National Seminar on CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd - 23rd March 2024**.

This seminar focused on connecting the industry together with the researchers from the Universities and all Research Institutions. This is also planned to have the platform for sharing the research outcome and initiate the industrial collaborations for sustainable development. This forum will be growing up and expected to bring the possibility on technology transfer while providing an excellent platform for exploring the various opportunities in the Clinical & Pharmacovigilance

I am thankful for the enormous and high-quality support of all authors, reviewers and session chairs. I wish that CDIP will keep on growing in coming years with more impact on the research community.

Wish you all a cordial greet and success for life!

Mr. Sourabh D Jain
Associate Professor
Chameli Devi Institute of Pharmacy
Indore (M.P.)

Dr. Gaurav Jain
Professor & Head of Department of Pharmaceutics
Chameli Devi Institute of Pharmacy, Indore

MESSAGE

The **CSIR & MPCST sponsored Two Days National Seminar on CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd- 23rd March 2024** at Chameli Devi Institute of Pharmacy, Indore, is place for leaders in the field to discuss the issues and challenges scientists and researchers face in all aspects of the Clinical & Pharmacovigilance and current trends national speakers from academia and industry will discuss various aspects and developments in the area of Clinical & Pharmacovigilance importance in disease prognosis. Through scientific presentations, case studies and panel discussions, these areas will be addressed in an intimate and highly interactive environment with perspectives from industry, academia and the public sector. These national events are authoritative in guiding pharmacy students, scientists, research scholars, medical practitioners, clinical pharmacists, leading pharmaceutical industries to champion professional and social relationship with sister organizations and actively concur within the analysis and safe utilization of the pharmacy drugs with honor and ethics. The scientific sessions will include e-poster oral and e-poster presentations and seminars from the professionals working within the field of pharmaceutical sciences. On the behalf of committee member, we welcome all the delegates, dignitaries and participants to **"CPCO 2k24".**

Dr. Gaurav Jain
Professor & Head of Department of Pharmaceutics
Chameli Devi Institute of Pharmacy
Indore (M.P.)

Dr. Pankaj Kushwah
Professor & Head of Department (B. Pharm)
Chameli Devi Institute of Pharmacy, Indore

MESSAGE

I am extremely pleased to know that Chameli Devi Institute of Pharmacy is organizing **CSIR & MPCST sponsored Two Days National Seminar on CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd - 23rd March 2024**. Indeed many congratulations on this occasion for putting up such a wonderful seminar. As always CDIP has been a place of innovative teaching. We are extremely happy to be associated with CDIP in terms of training of students in innovative and trained professionals. I am sure this seminar will inspire many a scientists to bring drugs from bench to bedside. It is praise worthy to note that this seminar would give opportunity for young researchers to make presentations of their innovative ideas and research work. This will result in creation of necessary manpower in the areas of drug discovery and development.

We are at the cross roads of personal medicine taking over traditional medicine. In this context there is immense need to focus on Clinical & Pharmacovigilance for various indications. I am sure deliberations from this seminar will result in recommendations for implementations so as to bring new drugs to bedside.

I wish all the best for this conference.

Dr. Pankaj Kushwah
Professor & Head of Department (B. Pharm)
Chameli Devi Institute of Pharmacy
Indore (M.P.)

Mr. Arun Patidar
Head of Department (D. Pharm)
Chameli Devi Institute of Pharmacy, Indore

MESSAGE

The **CSIR & MPCST sponsored Two Days National Seminar on CPCO 2k24 "A New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities", 22nd - 23rd March 2024** at Chameli Devi Institute of Pharmacy, Indore, is a meeting place for leaders in the field to discuss the issues and challenges scientists and researchers face in all aspects of the Clinical & Pharmacovigilance current trends national speakers from academia and industry will discuss various aspects and developments in the area of Clinical & Pharmacovigilance importance in disease prognosis. Through scientific presentations, case studies and panel discussions, these areas will be addressed in an intimate and highly interactive environment with perspectives from industry, academia and the public sector. These national events are authoritative in guiding pharmacy students, scientists, research scholars, medical practitioners, clinical pharmacists, leading pharmaceutical industries to champion professional and social relationship with sister organizations and actively concur within the analysis and safe utilization of the pharmacy drugs with honor and ethics. The scientific sessions will include e-poster oral and e-poster presentations and seminars from the professionals working within the field of pharmaceutical sciences. On the behalf of committee member, we welcome all the delegates, dignitaries and participants to **"CPCO 2k24".**

Mr. Arun Patidar
Head of Department (D. Pharm)
Chameli Devi Institute of Pharmacy
Indore

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3.	CDIP/CPCO/003	Nandini Chahal	Lovely Professional University	Pharmacovigilance- Promising Tool For Optimizing Antibiotic Therapy
4.	CDIP/CPCO/004	Nikita Choudhary	Chameli Devi Institute Of Pharmacy, Indore (M.P.)	Role Of Pharmacovigilance In Radiopharmaceuticals.
5.	CDIP/CPCO/005	Muskan Tanwar	Chandigarh College Of Pharmacy, CGC, Landran, Mohali, Punjab	Pharmacovigilance In Precision Medicine: Tailoring Safety Monitoring To Individualized Therapies.
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59.	CDIP/CPCO/059	Pranjal Karandikar	Sri Aurobindo Institute Of Pharmacy, Indore	Understanding Antibiotic Resistance: A Global Health Challenge
60.	CDIP/CPCO/060	Arpna Indurkhya	Sri Aurobindo Institute Of Pharmacy, Indore	Combined Effect Of Compritol 888ato And Hpmck On Verapamil Hydrochloride Release From Controlled Release Gastroretentive Tablet
61.	CDIP/CPCO/061	Rahul Maurya	National Ayurveda Research Institute For Panchakarma, Central Council For Research In Ayurvedic Sciences, Ministry Of Ayush, Cheruthuruthy, Thrissur, Kerala	Simultaneous Estimation Of Seven Major Bioactive Markers By Developing A Novel Rp-Hplc Analytical Method For The Standardization Of Coded Formulation Jkc
62.	CDIP/CPCO/062	Lakshminarayana Misro	National Ayurveda Research Institute For Panchakarma, Central Council For Research In Ayurvedic Sciences, Ministry Of Ayush, Cheruthuruthy, Thrissur, Kerala	A Comprehensive Comparative Analysis Of Phytochemical, Pharmacognostic, And Chromatographic Profiling Of Commonly Available Sida Species In Kerala
63.	CDIP/CPCO/063	Anubha Jain	Sri Aurobindo Institute Of Pharmacy, Indore	A Pharmaceutical Viewpoint On Organic Volatile Impurities And Their Regulatory Limits
64.	CDIP/CPCO/064	Amreen Qureshi	Faculty Of Pharmacy, Oriental University, Indore	Covid-19 Transmission, Current Treatment, And Future Therapeutic Strategies
65.	CDIP/CPCO/065	Gagan, Amanpreet Kaur	School Of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences And Research University, New Delhi	Development Of The Quality Target Product Profile For Orodispersible Nanofibers Using Electrospinning Method

66.	CDIP/CPCO/066	Ashwin Sharma	Chameli Devi Institute Of Pharmacy, Indore	Design, Formulation And Development Of Nanogel For The Management Of Keratosis Pilaris
67.	CDIP/CPCO/067	Thirupataiah Boini	1national Ayurveda Research Institute For Panchakarma, Cheruthuruthy, Kerala	Precision In Practice: Ich-Guideline-Based Shelf Life Evaluation And Standardization Of Ayush M3 Tablets And Ayush Ss Granules Using Hptlc For Bioactive Marker Quantification
68.	CDIP/CPCO/068	Annu	Sardar Patel College Of Pharmacy, Bakrol, Anand, Gujarat	Revolutionizing Therapy: Probiotics And Engineered Probiotics For Autoimmune CNS Disorders (Multiple Sclerosis)
69.	CDIP/CPCO/069	Rupinder Kaur	Department Of Pharmaceutical Sciences Global Group Of Institutes	Data Mangemnt Of Pharmacovigillance Through Dictionary
70.	CDIP/CPCO/070	S. B Wakodkar	Kamla Nehru College Of Pharmacy, Butibori, Nagpur	A Systematic Review On Pharmacovigilance Study Of Antiasthmatic Agents
71.	CDIP/CPCO/071	Shobhit Shrivastava	Department Of Pharmaceutical Chemistry, Bansal College Of Pharmacy, Bhopal	Synthesis And Antimicrobial Screening Of Schiff Bases Of Isatin Derivatives
72.	CDIP/CPCO/072	Pragya Jamwal	School Of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences And Research University, New Delhi	Impact Of New Drugs And Clinical Trials Rules, 2019
73.	CDIP/CPCO/073	Divya Jain	School Of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences And Research University, New Delhi	Formulation Development And Evaluation Of Multi-Unit Particulate Systems For Bcs Class- Ii Antifungal Drug With Improved Dissolution Profile
74.	CDIP/CPCO/074	Rajani Ruchika	Sri Aurobindo Institute Of Pharmacy, Indore	Soyabean Nanoemuulgels: Novel Herbal Drug Delivery For Management Of Psoriasis
75.	CDIP/CPCO/075	Nidhi Bais	Faculty Of Pharmacy, Oriental University, Indore	Regulatory Intelligence And Its Importance To Pharmacovigilance System
76.	CDIP/CPCO/076	Arpita Srivastava	Madhyanachal Professional University, Bhopal, M.P	Development And Characterization Of Transdermal Patch For Management And Treatment Of Mental Illness
77.	CDIP/CPCO/077	Soumyadip Maity	Department Of Pharmaceutics, Nshm College Of Pharmaceutical Technology, Nshm Knowledge Campus, Kolkata	A Review On Antibiotic Crisis
78.	CDIP/CPCO/078	Rekha Pathak	Faculty Of Pharmacy, B R Nahata College Of Pharmacy, Mandsaur University, Mandsaur, Madhya Pradesh, India	Revolutionizing Safety: Unveiling Artificial Intelligence Applications In Pharmacovigilance For Adverse Event Detection
79.	CDIP/CPCO/079	Yashmita Sharma	Sri Aurobindo Institute Of Pharmacy, Indore	Advancement In The Nanocarriers For Drug Delivery, Biomedical Research And For Diagnostic Purposes
80.	CDIP/CPCO/080	Pandit Perin S	Saraswati Institute Of Pharmaceutical Sciences, Dhanap.Gandhi Nagar, Gujarat	Machine Learning On Adverse Drug Reactions For Pharmacovigilance
81.	CDIP/CPCO/080	Nikita Upadhyay	Chameli Devi Institute Of Pharmacy, Indore	Data Analytics Can Enhance Clinical And Pharmacovigilance
82.	CDIP/CPCO/082	Sonu Prajapati	Chameli Devi Institute Of Pharmacy, Indore	Artificial Intelligence (Ai) Can Enhance Pharmacovigilance Through Advanced Surveillance In Several Ways
83.	CDIP/CPCO/083	Jitendra Singh Chaudhary	Smt. Vidyawati College Of Pharmacy, Jhansi, Up, India	New Era Of Clinical And Pharmacovigilance: A Future Challenges And Opportunities (An Overview)
84.	CDIP/CPCO/084	Princy Vishwakarma	Viveakanand College Of Pharmacy	Applications Of Artificial Intelligence In Pharmacovigilance
85.	CDIP/CPCO/085	Rounak Yadav	Gry Institute Of Pharmacy, Vidhya Vihar Borawan, Khargone	Emergence Of Artificial Intelligence In Healthcare: A Promising Future With Challenges

86.	CDIP/CPCO/086	Anuja Awasthi	Chameli Devi Institute Of Pharmacy, Indore	Pharmacovigilance- Todays Need For Better Tomorrow
87.	CDIP/CPCO/087	Shehnaz Sheikh	Sri Aurobindo Institute Of Pharmacy, Indore	Importance Of Effective Communication In Pharmacovigilance For Early Detection And Assessment Of Adr
88.	CDIP/CPCO/088	Garima Chandak	School Of Pharmaceutical Sciences, Lovely Professional University, Punjab, India	Nucleic Acid & Peptide-Based Therapeutics For Parkinson's Disease
89.	CDIP/CPCO/089	Simran Yadav	Amity University, Noida	Leveraging Industry 4.0 Technology For Enhanced Pharmacovigilance: A Collaborative Approach
90.	CDIP/CPCO/090	Shikhar Rathore	Oriental University, Indore	Development Of Fast-Acting Tablets Of Clozapine By Liquisolid Technique Using A New Carrier Material
91.	CDIP/CPCO/091	Pankaj Kushwah	Chameli Devi Institute Of Pharmacy, Indore	Paripluta Yonivyapad (Pelvic Inflammatory Disease) An Ayurvedic Approach
92.	CDIP/CPCO/092	Simran	Department Of Pharmacy, School Of Health Sciences, Central University Of South Bihar, Gaya	Berberine Chloride Loaded Chitosan/Polyvinylpyrrolidone Hydrogels For Dermal Wound Healing
93.	CDIP/CPCO/093	Saurabh Carpenter	Sri Aurobindo Institute Of Pharmacy, Indore	Exploring Novel Strategies: Piperidine Carboxamide Derivatives Targeting Alk And Ros1 Kinases For Lung Cancer Therapy
94.	CDIP/CPCO/094	Atul Yadav	Department Of Pharmacy, School Of Health Sciences, Central University Of South Bihar, Gaya	Chitosan Decorated Double Layered Paclitaxel Nanoparticles For Colon Targeted Cancer Therapy
95.	CDIP/CPCO/095	Amit Kumar Prusti	Department Of Pharmacy, School Of Health Sciences, Central University Of South Bihar, Gaya	5-Fu Loaded Ch/Ha Conjugated Mwcnts For Colon Targeted Drug Delivery
96.	CDIP/CPCO/096	Kumari Snehlata	Department Of Pharmacy, School Of Health Sciences, Central University Of South Bihar, Gaya	Self-Healing Lignin/Pluronic F127/Epicatechin Based Thermoresponsive Gels For Dermal Wound Healing
97.	CDIP/CPCO/097	Rohit Singh	Department Of Pharmacy, School Of Health Sciences, Central University Of South Bihar, Gaya	Lignin Coated Silver Nanoparticles Based Chitosan/Polyvinylpyrrolidone Nano-Composite Hydrogel For Infected Wounds
98.	CDIP/CPCO/098	Urmila Kotwal	Chameli Devi Institute Of Pharmacy, Indore	A Review On: Probiotics As The Functional Food Components For Human Health
99.	CDIP/CPCO/099	Antim Prajapat	Chameli Devi Institute Of Pharmacy, Indore	Pharmacovigilance- Challenges And Opportunity
100.	CDIP/CPCO/100	Antim Prajapat	Chameli Devi Institute Of Pharmacy, Indore	Pharmacovigilance- An Overview On Indian Scenario
101.	CDIP/CPCO/101	Devansh Shrivastav	Chameli Devi Institute Of Pharmacy, Indore	Safeguarding Health: The Vital Role Of Pharmacovigilance
102.	CDIP/CPCO/102	Sneha Singh	College Of Pharmacy, Dr. A.P.J. Abdul Kalam University, Indore	Optimization Of Process Variables For The Development Of Chitosan Coated Terbinafine Hcl Loaded Ethosomes By Using Qbd Approach
103.	CDIP/CPCO/103	Guneshwari Choudhary	School Of Pharmacy, Devi Ahilya Vishwavidyalaya, Takshila Campus, Indore	Molecular Docking Studies Of Sulpha Drug Analogs As Antimalarial Agents
104.	CDIP/CPCO/104	Gourav Jain	Department Of Pharmacy, Shri G. S. Institute Of Technology And Science, Indore	Gpr119: Therapeutic Target For Antidiabetic Action
105.	CDIP/CPCO/105	Rahul Meena	Kewal Shree Institute Of Pharmacy, Indore	New Era Of Clinical And Pharmacovigilance: Challenges And Opportunities Of Clinical And Pharmacovigilance

CDIP/CPCO/001

Crystallo-Co-Agglomeration- A Method to Enhance Solubility and Tableting Properties by Particle Size Enlargement

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Abstract:

Crystallo-co-agglomeration is a novel particle design technique, to overcome the limitations of spherical crystallization. The process of Crystallo-co-agglomeration involves crystallization followed by simultaneous agglomeration of the drug with the aid of either a good solvent or a bridging liquid and a bad solvent. The agglomeration is performed using bridging liquid. In the field of powder technology various attempts has been made to design primary and secondary particles of pharmaceutical substances for various applications, such as improvement in solubility of drugs, obtaining suitable polymorph, improvement in micromeritics and compression properties, and modification of bioavailability.

Keywords: Crystallo-co-agglomeration, Micromeritics, Bioavailability

CDIP/CPCO/002

Pharmacovigilance: Potential Applications and Difficulties

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Abstract:

Pharmacovigilance plays a vital role in ensuring the safety and efficacy of pharmaceutical products throughout their lifecycle, from preclinical development through post-marketing surveillance. Adverse drug reactions (ADRs) are a major concern for patients, clinicians, and regulatory agencies. The discovery of serious ADRs leading to substantial morbidity and mortality has resulted in mandatory phase IV clinical trials, black box warnings, and withdrawal of drugs from the market. The safety databases such as Vigibase, FAERS, Eudravigilance and Canadavigilance contains a huge data amount of more than 50 million individual case safety reports. Pharmacovigilance encounters various hurdles apart from the challenge of managing a large volume of data. The complexity of pharmaceuticals presents another issue. Also, advancements in technology, such as gene therapies and nanomedicine, introduce new obstacles in assessing and monitoring the safety profiles of different drugs. As pharmaceutical products are used worldwide, pharmacovigilance requires global collaboration and information sharing among regulatory agencies, healthcare professionals, and pharmaceutical companies to ensure comprehensive safety monitoring. Although, pharmacovigilance faces numerous challenges in the future, there are also significant opportunities for innovation and improvement through the adoption of advanced technologies like AI and ML and Blockchain. Pharmacovigilance can benefit from advancements in personalized medicine by tailoring drug safety monitoring strategies to individual patient characteristics, genetic profiles, and enhanced collaboration between regulatory agencies, pharmaceutical companies, and healthcare providers, by Patient-Centered Pharmacovigilance. Overall, pharmacovigilance is essential for maintaining the balance between the benefits and risks of pharmaceutical products, ultimately contributing to improved patient care and public health outcomes.

Keywords: Vigibase, FAERS, Eudravigilance and Canadavigilance, nanomedicine.

CDIP/CPCO/003

Pharmacovigilance- Promising Tool For Optimizing Antibiotic Therapy

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Abstract:

Antibiotic therapy is one of the most widely and insanely used therapies to treat and manage numerous bacterial infections that continue to hamper the health and well- being of humans. Unfortunately, overtime many challenges have come across antibiotic therapy, for instance, several adverse drug reactions (for example, delirium, rhabdomyolysis, kounis syndrome associated with antibiotics), antibiotic resistance, inappropriate use and many more. Pharmacovigilance being the discipline of spotting, assessing and preventing adverse drug effects has noteworthy potential of optimizing the antibiotic therapy. This approach may involve practices such as, sharing of adverse drug reactions across global pharmacovigilance networks, intensive analysis of reports from pharmacovigilance databases, reports on adverse events like resistance and off- lable use etc. Altogether, this review focuses attention on the role and potential abilities of pharmacovigilance in optimising and developing antibiotic therapy, tackling antibiotic resistance and enabling health care professionals to strictly adhere to antibiotic stewardship programs.

Keywords: Antibiotic therapy, antibiotic resistance, pharmacovigilance

CDIP/CPCO/004

Role of pharmacovigilance in Radiopharmaceuticals

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Abstract:

Pharmacovigilance plays a crucial role in monitoring the safety of radiopharmaceuticals, which are medicinal products containing radioactive isotopes used in diagnostic and therapeutic procedures. Here are several key aspects of pharmacovigilance in relation to radiopharmaceuticals: Safety Monitoring: Radiopharmaceuticals involve the use of radioactive materials, which can pose unique safety concerns due to radiation exposure. Pharmacovigilance is essential for continuously monitoring and evaluating the safety profile of these products, including any adverse reactions or radiation-related side effects experienced by patients or healthcare providers. Risk Assessment and Management: By collecting and analyzing data on adverse events and other safety issues, regulatory authorities and healthcare professionals can make informed decisions regarding the safe use of these products and implement risk management strategies as needed. Signal Detection: Pharmacovigilance processes involve the detection of signals, which are potential safety concerns or new information about the risks of a particular drug. For radiopharmaceuticals, signal detection may involve identifying trends or patterns in adverse event reports related to radiation exposure, specific isotopes, or administration procedures. Post-Marketing Surveillance: After a radiopharmaceutical is approved and marketed, pharmacovigilance activities continue to monitor its safety in real-world clinical practice. This post-marketing surveillance helps in detecting rare or unexpected adverse events that may not have been observed during pre-market clinical trials. Regulatory Compliance: Regulatory agencies, such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe, require pharmaceutical companies to have pharmacovigilance systems in place for monitoring the safety of all marketed drugs, including radiopharmaceuticals.

Keywords: European Medicines Agency, Radiopharmaceutical

CDIP/CPCO/005

Pharmacovigilance in Precision Medicine: Tailoring Safety Monitoring to Individualized Therapies

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Abstract:

This review focuses on adapting safety monitoring practices to match the personalized nature of precision medicine. In this approach, vigilant surveillance strategies are crucial to mitigate risks associated with individualized therapies. By integrating patient-specific factors such as genetic makeup, biomarkers, and environmental influences, pharmacovigilance ensures the safety and efficacy of tailored treatments. This paradigm shift from traditional pharmacovigilance methods emphasizes proactive risk assessment and real-time monitoring, enabling early detection and intervention for adverse events. Moreover, collaborative efforts among healthcare providers, researchers, and regulatory agencies facilitate the development of robust pharmacovigilance frameworks tailored to the dynamic landscape of precision medicine. Ultimately, this approach enhances patient safety and optimizes therapeutic outcomes in the era of personalized healthcare.

Keywords: Safety, Precision medicine, Mitigate, Biomarkers.

CDIP/CPCO/006

Neuroprotective effect of Guggulsterone against weight drop induced Traumatic brain injury in Rats

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Abstract:

Traumatic brain injury (TBI) is a form of cerebral injury that leads to alterations in consciousness, cognitive function, and psychosocial dysfunction. The objective of the current study was to examine the therapeutic efficacy of guggulsterone via Nrf-2 pathway in rats with TBI induced by weight drop. A rat under anesthesia was traumatized by a 450-gram mass dropped from 1 meter in an experiment. Two groups received 250 and 500 mg/kg guggulsterone for 28 days. Locomotion, grip strength, motor coordination, and memory impairment were examined at day one, fourteen, and twenty-eight. Animals were euthanized on day 29 of the experiment. Oxidative stress, neuroinflammatory, and neurotransmitter levels were measured in brain homogenate. Trauma greatly affects locomotor activity, grip strength, beam crossing time, foot slips, and memory. Injured rats' brains had decreased GSH and catalase production and increased nitrite and MDA. Brain trauma releases neuroinflammation biomolecules and reduces neurotransmitter levels. Guggulsterone reduced biochemical alterations, increased antioxidant levels, reduced neuroinflammatory response, restored neurotransmitter concentration, and enhanced the Nrf-2 pathway in a dose-dependent manner. Studies have demonstrated that guggulsterone possesses antioxidative, anti-inflammatory, and neuroprotective properties, which may promote the general well-being of individuals with TBI.

Keywords: Traumatic brain injury, weight drop model, guggusterone, neuroinflammation

CDIP/CPCO/007

Zero Shot Learning: The Closest Humanly Artificial Intelligence System in Evolving Pharmacovigilance

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Abstract:

As we approach towards the understanding of the subject matter of Pharmacovigilance, the most profound concept in the field is solving the basic problems that bridge a patient and a drug. The emotional quotient of a patient is quite complex and has to be handled with care and efficacy, in order to reach a profitable solution. With growing influence of AI in this field, the load of understanding complex human emotions becomes easier day by day. Zero Shot Learning is a AI based approach (Natural Language Processing) of understanding patient emotions while reporting adverse events in drug interaction and usage by tools that understand data not fed into them previously, but a similar analytics has been coded in it. This is a revolution as; electronics with AI have gone the human method of approaching solutions by complex analysis of emotions.

Keywords: patient sentiment, analytics, NLP, Artificial Intelligence

CDIP/CPCO/008

Management of oxidative stressed brain of Alzheimer's by potential antioxidant: A Review

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Abstract:

The World Health Organization refers to Alzheimer's disease (AD) as a global health priority. As the average age of the world's population is increasing so too is the rate of AD. There are an estimated forty seven million people globally who have been diagnosed with AD dementia and researchers have yet to figure out the root cause. All misfolded aggregate proteins that are involved in neurodegenerative disorders (amyloid-β,Huntington's, tau, α-synuclein) induce oxidative stress. It is that oxidative stress that leads to inflammation and in conjunction with amyloid protein and tau hyperphosphorylation, progresses to and exacerbates AD. The consumption of antioxidants and nutrients,specifically vitamine E, caffeine and turmeric may slow the progression of AD and can be found in a wide variety of dietary foods. This review explores the role of antioxidants that can potentially combat it, and future directions of how the treatment of the disease can be better understood.

Keywords: Alzheimer's disease, Inflammation, antioxidants, Vitamins, Dementia.

CDIP/CPCO/009

Artificial Intelligence In The Field Of Clinical And Pharmacovigilance

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Abstract:

Artificial Intelligence is continuously evolving to benefit many different Clinical and Pharmacovigilance sector. For patients, AI be a useful for providing guidance on how and when to take a medication, aiding in patient education, and promoting medication adherence and AI used to know how and where to obtain the cost-effective healthcare and how best to communicate with healthcare professionals, optimize the health monitoring using wearables devices, provide everyday lifestyle and health guidance, and integrated diet and exercise. Insertion of structured and unstructured content: insert information through XML, DOCX, Pictures, and PDF for reading the case. ML and NLP are used to extract Report information in a regulatory compliant manner and AI for decision-making: the quality of the Report is usually poor. Therefore, AI may play an important role in making the unlisted or individual random Adverse Effects, drug classifiers, correlation. Artificial intelligence and machine learning may also be useful in pharmacovigilance for the automatic execution of tasks associated with case report entry and processing, the identification of clusters of adverse events representing symptoms of syndromes, the conduction of pharmacoepidemiological studies, data linkage, through the conduction of probabilistic matching within datasets and the prediction and prevention of adverse events through specific models using real-world data. Digital therapeutics (DTx) one of the recent frontiers of medicine and can be defined as "technology that deliver medical interventions directly to patients by using evidence-based, clinically evaluated software to treat, prevent and manage a broad spectrum of disorders and diseases".

Keywords: Artificial Intelligence, Pharmacovigilance, Machine Learning, Clinical.

CDIP/CPCO/010

The Role of Pharma Academics In Fostering Academia-Industry Collaboration: A Descriptive Qualitative & Quantitative Survey

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Abstract:

Academia-industry collaboration has persistently been a matter of debate in academia and industry. The research was done in academia and its translation into marketable products certainly is not new. High-quality academic research can assist the industry to produce economic products for society. The aim of present project is to compile and analysed the database of pharma academicians comprised of academician's details along with their research expertise. With this aim, an attempt has been taken to compiled and analyzed the database of pharma academicians based on personal details, academic details, and professional details including designation, Qualification, Specialization, Expertise, Interested vs. engaged in academia-industry collaborations, Projects handled, Publications, Interest areas of Academic- industry collaborative that can be utilized by Pharma Industries. In total 2401 pharma academicians were participated and responded to the prepared project questionnaire. Based on participation an analysis report has been prepared comprising participation distribution graphical presentation in respect questionnaire. Through this interpretation, one can understand the potential of academicians which helps to shorten the academicians as per their requirements, as well as by seeing the profile of interested academicians they will contact them for their work. The significant database will be useful to foster the academia-industry collaboration, helpful to prove the potential of academicians as innovative researchers to fulfill the requirements of Pharma Industries.

Keywords: Pharma academicians, Academia-industry collaboration, Pharmaceutical research

CDIP/CPCO/011

Intelligent Pharmacovigilance Monitoring and Reporting System: Development of an AI-Driven Medical App for Enhanced Safety Surveillance

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Abstract:

Pharmacovigilance is crucial in monitoring and ensuring the safety of pharmaceutical products post-approval. Traditional methods of adverse event monitoring often face limitations in efficiency and accuracy. In response, this paper presents the development of an innovative AI- driven medical application aimed at enhancing safety surveillance in pharmacovigilance. The proposed system leverages advanced artificial intelligence techniques, including natural language processing and machine learning algorithms, to analyze vast amounts of medical data from various sources such as electronic health records, social media, and regulatory databases. Through real-time analysis and interpretation of diverse data streams, the system can identify potential adverse events associated with pharmaceutical products with higher accuracy and efficiency compared to conventional methods. Furthermore, the application integrates intelligent reporting functionalities, facilitating seamless communication and collaboration among healthcare professionals, regulatory authorities, and pharmaceutical companies. Medical app will be formulated with the collaboration of the engineers. Evaluation of the device will be executed with the help of clinical trial agencies. The development of this intelligent pharmacovigilance monitoring and reporting system represents a significant advancement in enhancing drug safety surveillance, ultimately contributing to improved patient outcomes and public health.

Keywords: Pharmacovigilance, AI-driven, Machine learning, Electronic health records

CDIP/CPCO/012

Carpal Tunnel Syndrome: Clinical magnifications, Diagnosis, and Management

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Abstract:

Carpal tunnel syndrome (CTS) is a prevalent neurological condition characterized by compression of the median nerve as it passes through the carpal tunnel in the wrist. This compression leads to pain, numbness, tingling, and weakness in the hand and wrist. CTS typically develop gradually and can be exacerbated by repetitive hand movements, awkward wrist positions, and certain medical conditions such as diabetes or rheumatoid arthritis. The incidence of CTS in the overall community length is from 1% to 5%. CTS are more common in females than in males, with a ratio of 3:1 (female to male). But the development of CTS is higher in individuals who are overweight/ gross. The pathophysiology of CTS covers a fusion of mechanical trauma, increased pressure and nerve injury and inflammation. The clinical symptoms and physical examination findings in patients with this syndrome are recognized widely and various treatments exist, including non-surgical and surgical options. Despite these advantages, there is a paucity of evidence about the best approaches for assessment of carpal tunnel syndrome and to guide treatment decisions. Methods for assessment, including electrodiagnostic testing and nerve imaging, provide additional information about the extent of axonal involvement and structural change, but their exact benefit to patients is unknown. Although the best means of integrating clinical, functional, and anatomical information for selecting treatment choices has not yet been identified, patients can be diagnosed quickly and respond well to treatment. The high prevalence of CTS, its effects on quality of life, and the cost that disease burden generates to health systems make it important to identify the research priorities that will be resolved in clinical trials.

Keywords: Carpal tunnel syndrome, medial nerve, diagnostic tools. Prevalence

CDIP/CPCO/013

Recent Advances in Understanding and Managing of Guillain–Barré Syndrome

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Abstract:

Guillain-Barré syndrome (GBS) is an acquired disease of the peripheral nerves, clinically characterized by rapidly progressive paralysis, areflexia, and albumin-cytological dissociation. It affects both genders and persons of all ages and is recorded globally. In the post-polio era, it is the most common cause of acute, widespread paralysis. The clinical features are distinct, and a history and an examination generally lead to a high suspicion of the diagnosis, which can then be confirmed by supportive laboratory tests and electrodiagnostic studies. This study discusses the recent advances in understanding of the different variants of GBS, such as acute inflammatory demyelinating polyneuropathy (AIDP), acute motor axonal neuropathy (AMAN), acute motor sensory axonal neuropathy (AMSAN), and the Fisher syndrome. There is discussion of the immunopathogenesis, clinical manifestations, electrodiagnostic standards, and treatment of GBS and its variations. Twenty to thirty percent of individuals have the severe, widespread presentation of Guillain-Barré syndrome involving respiratory failure. Combined with supportive care, treatment with intravenous immunoglobulin or plasma exchange is the best course of action. In the last ten years, there has been significant progress in our understanding of the immunological, pathological, and viral triggers. This understanding is now being used to direct clinical trials searching for new treatments. To help with the creation of outcome predictors and disease biomarkers, researchers conducting extensive, international collaborative studies on the spectrum of Guillain-Barré syndrome are gathering data for clinical and biological databases. The field of acute autoimmune neuropathies is changing both clinically and scientifically as a result of these investigations.

Keyword: Acute Motor Axonal Neuropathy (AMAN), Acute Inflammatory Demyelinating Polyneuropathy (AIDP), Acute Motor Sensory Axonal Neuropathy (AMSAN),

CDIP/CPCO/014

Insilico Study of Triazole Derivatives as Antitubercular Agents

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Abstract:

Tuberculosis (TB) remains a global health concern, necessitating the development of novel antitubercular agents. In this study, an insilico approach was employed to investigate the potential of triazole derivatives as antitubercular agents. Molecular docking simulations were performed to predict the binding affinities and interaction modes of a series of triazole derivatives with target proteins involved in the tuberculosis infection pathway. Pharmacophore modeling was employed to identify common structural features among known antitubercular drugs and aid in the design of triazole derivatives with similar pharmacophoric features. Molecular dynamics simulations provided insights into the dynamic behavior and conformational changes of the triazole derivatives in complex biological environments. Additionally, ADMET prediction tools were utilized to estimate various pharmacokinetic properties, such as solubility, permeability, metabolic stability, and toxicity. Collectively, the insilico study revealed promising candidates among the triazole derivatives with potential antitubercular activity, providing valuable guidance for further experimental testing and the design of more effective and safe antitubercular agents. Future studies involving in vitro and in vivo validation are warranted to confirm the efficacy of the identified compounds and their potential as new antitubercular drugs.

Keyword: Triazole, MDR, MRSA, Tuberculosis.

CDIP/CPCO/015

Development, *In-Vitro* and *In-Vivo* Evaluation of Dexamethasone Sustained Release Matrix Tablets for PCOS

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Abstract:

The purpose of this study was to develop a sustained release matrix tablet that can effectively deliver dexamethasone for the treatment of polycystic ovary syndrome (PCOS). Chitosan and HPMC K4M polymers were used to prepare matrix tablets by the direct compression method. The tablets were evaluated for various parameters such as thickness, friability, hardness, uniformity of weight, drug content, in-vitro dissolution and in-vivo studies. The study showed that the drug release can be modulated by varying the concentrations of polymers. The optimization studies indicated that the F7 formulation exhibited the best release profile of the drug and sustained the drug release for 8 hours with optimum mucoadhesive strength. The mechanism of drug release was investigated by fitting in vitro drug release data to several release kinetic models. The optimized F7 tablet floated continuously in the stomach area of rabbits for over 12 hr, so the gastric retention time could be extended to over 12 hr. The X-ray imaging of the tablet at the 6th hr and 12th hr indicated clearly that the tablet was present in the region of the stomach but had shifted its location in the abdomen. Overall, the study concluded that matrix tablets can be used as a successful carrier for the sustained delivery of dexamethasone with prolonged gastric residence time.

Keywords: Dexamethasone, Matrix tablets, sustained release, Chitosan and HPMC K4M

CDIP/CPCO/016

Blockchain Technology for Secure Pharmacovigilance Data Management

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Abstract:

Blockchain pharmacovigilance deals with the detection, medical assessments, evaluations, monitoring & prevention of (ADRs) Adverse Drug Reactions. Blockchain can help address the challenges in pharmacovigilance (PV). Blockchain provides an evenly distributed and decentralized database in terms of nodes, safeguarding security. With the rapid increase of information across the globe, Pharmacovigilance (PV) practices/departments need to face enormous and endless challenges in keeping up with the public expectations of drug safety, management of various systems to report (ADRs), clinical trials dealing with a complex & large landscape of legacy systems, data security & privacy, and evolving regulations. Blockchain allows various entities to process data via various nodes with no central authority. All pharma & drug companies are exploring blockchain-based (PV) solutions to ensure drug monitoring and safety. Blockchains ensure the security and integrity of healthcare data. Each transaction or entry is recorded as a block and linked in a chain, forming a record. This ensures that healthcare data remains unchanged and secure, reducing the risk of data breaches and unauthorized access. Blockchain is a technology that has the potential to transform research and clinical trials by enabling secure and auditable data sharing among researchers, healthcare providers, and patients. It facilitates improved research collaborations, enhances the traceability of clinical trial data, and consents to data sharing, thereby ensuring data integrity. Blockchain offers significant opportunities to reinvent the way drug companies access, collect, distribute, share, and monitor clinical trial data or medical /patient records.

Keywords: Blockchains, Adverse drug reactions, databases, Healthcare systems, Data safety, Drug Monitoring, and Clinical Trial Data.

CDIP/CPCO/017

Formulation Development and Evaluation of Fast Release Solid Dispersion of Ibuprofen

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Abstract:

Solid dispersion is a promising technique to enhance the dissolution rate and bioavailability of poorly water-soluble drugs like ibuprofen. In this study, we aimed to formulate and evaluate a fast-release solid dispersion of ibuprofen using a novel approach. Various polymers such as PVP K30, PEG 6000, and HPMC were employed to prepare solid dispersions by the solvent evaporation method. The formulations were characterized for drug-polymer interactions using FTIR spectroscopy and DSC analysis. The physical properties of solid dispersions were evaluated through SEM and XRD studies. Dissolution studies were conducted to assess the dissolution rate enhancement of ibuprofen from solid dispersions compared to pure drug powder. Moreover, stability studies were performed to evaluate the shelf-life of optimized formulations. Our results indicate successful formulation of fast-release solid dispersions of ibuprofen, exhibiting improved dissolution rates and enhanced drug release kinetics. This approach holds promise for improving the therapeutic efficacy of ibuprofen formulations, particularly in enhancing its oral bioavailability and onset of action.

Keywords: Ibuprofen, Solid Dispersion, Fast Release, Dissolution Rate Enhancement, Bioavailability.

CDIP/CPCO/018

Crosstalk between mitochondrial dysfunction and endoplasmic reticulum stress in Alzheimer's disease: current challenges, treatment strategies and future prospective

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Abstract:

Alzheimer's Disease (AD) is a progressive Neurogenerative Disease (NDs). Globally, more than 44 million people are affected with AD. Various factors are responsible for the progressing AD such as increased Amyloid-beta protein, oxidative stress, Neuro-inflammation, mitochondrial dysfunction, endoplasmic reticulum stress(EPRS) , NFT(Tau protein)and decreased production of acetylcholine(neurotransmitter). In past one decade, various studies have been conducted where mitochondrial dysfunction and EPRS were noticed for enhancing neuronal cell apopstosis in AD. Increased oxidative stress and amyloid-beta are the main factors for the mitochondrial dysfunction and EPRS. In present world, we have discussed the cross talk between mitochondrial dysfunction and EPRS. We have also covered various treatment strategies and the future prospective of AD.

Keywords: Alzheimer's Disease, Endoplasmic reticulum dysfunction, mitochondrial dysfunction, oxidative stress.

CDIP/CPCO/019

Plant Based Antioxidants – A Gift of Nature Against Diseases

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Abstract:

All life forms, including plants, must undergo certain physiological processes to survive and grow. These processes produce highly reactive oxygen species like O2 and hydroxyl radicals, which have the potential to cause harm to the system. To combat this damage, both plants and animals have developed the capacity to produce antioxidant molecules. Though plants containing antioxidant molecules are found throughout the world, certain geographical regions have a high prevalence of antioxidant-rich plants. Examples include Mediterranean regions (olives, grapes, tomatoes, and citrus fruits), tropical rainforests of the Amazon basin (acai berries, cacao, and goji berries), south-east Asia (ginger, cinnamon, and turmeric), North America (blueberries and cranberries), and Sub-Saharan Africa (baobab fruits, African mango, etc.). Both genetic and environmental factors play a major role in the production of antioxidants. Some plants produce high levels of antioxidants as a part of their natural defence against environmental stresses. Plants grown in extremely high sunlight exposure produce more antioxidants to protect themselves from the harmful effects of sunrays. Plants infected with fungal pathogens produce higher levels of ascorbic acid and phenolic compounds to protect themselves against oxidative stress. Antioxidants interrupt these sequences of events and prevent additional oxidation reactions by removing free radical intermediates. Reactive oxygen species (ROS) are produced because of the many physiological processes that the body engages to balance oxidative stress. The biological benefits of these naturally occurring antioxidants, particularly polyphenols and carotenoids, are diverse and include anti-inflammatory, anti-aging, anti-allergenic, and anti-atherosclerosis properties. Among the sources of natural antioxidants, the most important are those coming from routinely consuming vegetables and fruits. However, antioxidant from other plant and agriculture waste should not be ignored.

Keywords: Antioxidants, Geographical origin, Oxidative Stress, Reactive oxygen species

CDIP/CPCO/020

Importance of Pharmacogenomic for Personalized Cancer Therapy

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Abstract:

First used in 1959, the term pharmacogenomic refers to the study of genetic variables that impact reaction to medications and chemicals. Pharmacogenetics, which studied the complete range of genes in the human genome, has recently changed to pharmacogenomics due to breakthroughs in massive genome sequencing and advances in bioinformatic methods for processing vast volumes of data. The objective of the nascent fields of pharmacogenomics and pharmacogenetics, collectively referred to as PGx, is to customize treatment plans according to a patient's genotype. As of right now, PGx success has extended to every area of medicine. The BRCA1 mutation test, for example, is used to assess the risk of breast cancer. Genetic data has also been utilized to identify illness risk and select medicine HLA-B*1502 for carbamazepine; treatment for breast cancer). By customizing medication regimens to each patient's unique genetic profile, the area of pharmacogenomics has arisen as a potentially effective means of improving cancer treatment. This research study aims to enhance therapeutic efficacy and reduce side effects by examining the intricate interactions between pharmacogenomics and anti-cancer medications. Understanding genetic factors influencing medication response is crucial in cancer treatment. Pharmacogenomics helps customize medication regimens based on a patient's genetic makeup, predicting potential drug responses and reducing side effects. Genetic variant identification can improve overall cancer treatment. This review summarizes existing knowledge on pharmacogenomics and highlights areas for further advancements in personalized therapy.

Keywords: Cancer, drug efficacy, drug safety, oncology, pharmacogenomics, personalized medicine, drug therapy.

CDIP/CPCO/021

Patient-Centric Approaches In Pharmacovigilance

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Abstract:

The study aims to ensure the safety and efficacy of medicines that are reaching the patients for treatment of diseases. The patient's safety is the foremost important and this approach can be achieved by using pharmacovigilance. By understanding patient perspectives and experiences, pharmacovigilance can become more effective in identifying and mitigating drug safety issues. Incorporating patient feedback into safety monitoring can help to ensure that medications are safe and effective for the people who use them. Pharmacovigilance is ensuring related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Patient-centric approaches in pharmacovigilance focus on involving patients in the monitoring, assessment, and reporting of adverse drug reactions (ADRs) to ensure medication safety for the patient. Pharmacovigilance has been primarily driven by healthcare professionals and regulatory authorities. However, recognizing the importance of patient perspectives and experiences can contribute significantly to a more comprehensive understanding of drug safety. It's an important role of a patient to know his or her treatment and care. Patient reporting of Adverse Drug Reactions (ADRs) it provides real-world insights into the safety profile of medications. In conclusion, it is very important to assess the Adverse drug reactions and ensure that all the patients are freely able to report the ADRs for a better patient-centric approach towards pharmacovigilance. Here are some key aspects of patient-centric approaches in pharmacovigilance first one is to allow patients to directly report ADRs, the second one is aware of the importance of reporting ADR feedback mechanisms provided to patients, potential side effects on a patient's quality of life, involving patients in decision-making processes.

Keywords: Pharmacovigilance, adverse drug reactions, monitoring, patient-centric approach, drug safety.

CDIP/CPCO/022

Pharmacovigilance for ATMP'S (Advanced Therapy Medicinal Products)

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Abstract:

The main objective of the study is to ensure the safer use of advanced therapy medicinal products. This can be achieved by using pharmacovigilance for ATMPs. Pharmacovigilance for Advanced Therapy Medicinal Products (ATMPs) is a critical aspect of ensuring the safety and efficacy of these innovative therapies nowadays. ATMPs, including gene therapies, cell therapies, and tissue-engineered products, offer promising treatments for various diseases but pose unique challenges in terms of safety monitoring due to their complex mechanisms of action and potential for long-term effects. Pharmacovigilance is the study of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems. It involves monitoring the safety of medicines post-market approval to ensure their benefits outweigh the risks. One of the key challenges in pharmacovigilance for ATMPs is the long-term monitoring of patients for potential adverse effects. Unlike traditional pharmaceuticals, which often have well-defined safety profiles based on extensive preclinical and clinical studies, ATMPs may have unpredictable long-term effects due to their novel mechanisms of action and the potential for unintended biological interactions. Another challenge is the need for specialized expertise in assessing the safety of ATMPs. This is achieved through the systematic collection, analysis, and dissemination of data on their safety profile throughout their lifecycle. ATMPs often have unique safety concerns, such as the risk of immune reactions, tumorigenicity, and off-target effects, which require specialized approaches in pharmacovigilance. In conclusion, pharmacovigilance for ATMPs plays a crucial role in ensuring patient safety and maintaining public trust in these innovative therapies.

Keywords: Advanced therapy medicinal products), clinical studies, pharmacovigilance.

CDIP/CPCO/023

Moxifloxacin as an Antitubercular Agent: Current Status and Future Perspectives

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Abstract:

Tuberculosis (TB) continues to pose a significant global health challenge, exacerbated by the emergence of drug-resistant strains. Moxifloxacin, a fourth-generation fluoroquinolone antibiotic, has demonstrated promising activity against *Mycobacterium tuberculosis* and is being explored as a potential component of TB treatment regimens. This review provides an overview of the current status and future prospects of moxifloxacin as an antitubercular agent. It discusses the mechanisms of action underlying moxifloxacin's efficacy against TB, including its ability to inhibit DNA gyrase and topoisomerase IV. The review also examines the results of clinical trials assessing the safety, tolerability, and efficacy of moxifloxacin-containing regimens in TB treatment. Additionally, it explores ongoing research efforts aimed at optimizing moxifloxacin-based therapy, such as dose optimization, combination therapy, and pharmacokinetic/pharmacodynamic considerations. Through a comprehensive analysis of available evidence and research findings, this review aims to provide insights into the potential role of moxifloxacin in addressing the challenges of TB treatment and advancing efforts to combat this global epidemic.

Keywords: Moxifloxacin, Antitubercular Agent, Tuberculosis, Drug Resistance, Mechanisms of Action, Clinical Trials, Treatment Optimization, Future Perspectives.

CDIP/CPCO/024

To Introduce Adverse Drug Reactions (ADRs) and ADR Monitoring

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Abstract:

Pharmacovigilance plays a consequential role in the surveillance of adverse drug reactions, which are provoked by the drug used to cure diseases. Adverse drug reactions produce detrimental or undesirable effects on the body after the administration of drugs. A serious adverse drug reaction that results in death, is life-threatening, has significant disability or incapacity, or is a birth defect. Many types of Adverse drug reactions were studied in the past and classified based on severity and reactions. Hospital-based ADR monitoring and reporting programs aim to identify and quantify the risks associated with the use of drugs. This information may be useful for identifying and minimizing preventable adverse drug reactions and may enhance the ability of drug effects. A serious adverse drug reaction should be primarily explained to the person consuming the drug as well as the physician prescribing them by manufacturers. ADRs are monitored by different methods like spontaneous reporting, stimulated reporting, case-control, and active surveillance. The spontaneous reporting system is to regulate and control the safety of drugs. This system makes it easier for physicians, patients, and pharmacists to report suspected. All known and unknown, serious, non-serious, frequent, or rare reactions to be reported Adverse Drugs Reaction Monitoring Center (AMC) then AMC is reported to the NCC (National Coordination Center). Stimulated reporting systems encourage and facilitate health professionals to report ADRs in specific situations.

Keywords: Pharmacovigilance, Adverse drug reaction monitoring (ADRs monitoring), surveillance, National Coordination Center.

CDIP/CPCO/025

A Comparative Study of Dysmenorrhea Severity and Non-Steroidal Anti-Inflammatory Drug Assessment in Women

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Abstract:

Dysmenorrhea, characterized by painful menstrual cramps, significantly impacts the quality of life for many women worldwide. This comparative study aimed to evaluate the severity of dysmenorrhea pain and assess the efficacy of non-steroidal anti-inflammatory drugs (NSAIDs) among women. The sample size comprised 130 women, which includes 100 unmarried and 30 married women, selected by divided into groups based on the severity of pain. On the first day of menstruation, there was a significant difference in the level of severity of pain among unmarried and married women, as the majority (78.57%) of unmarried women experienced the worst pain, whereas the majority (80%) of married women reported mild pain during menstruation. There was no significant difference in the level of severity of pain among unmarried and married women on the second and third days of menstruation. Pain severity was assessed using validated scales, and NSAID effectiveness was measured through pain reduction and symptom relief. Additionally, factors such as age, menstrual history, and medication usage were considered. The findings revealed varying degrees of pain severity among participants, with NSAIDs demonstrating varying levels of efficacy in pain management. Moreover, demographic, and medical factors were found to influence both pain severity and NSAID response. This study underscores the importance of tailored approaches to dysmenorrhea management and highlights the need for further research to optimize treatment strategies for women experiencing menstrual pain.

Keywords: dysmenorrhea, severity of pain, numerical pain, and utilization of non-steroid anti-inflammatory drugs.

CDIP/CPCO/026

Pharmacovigilance Services for Vaccine Safety: An Overview of Aefi and Gacvs

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Abstract:

India runs one of the largest programs Universal Immunization Programme (UIP) in the world for the prevention of various vaccine-preventable diseases targeting around 27 million newborns and 30 million pregnant women every year and hence one of the largest manufacturers and exporters of vaccines in the world. The primary intention behind initiating a vaccine pharmacovigilance program is to ensure the safety of people receiving immunizations. Vaccines and vaccination are one of the best medical interventions in medical science for promoting public health. According to the CIOMS/WHO working for the group on vaccine pharmacovigilance, Vaccine pharmacovigilance is defined as "the science and activities relating to the Detection, Assessment, Understanding, and Communication of adverse events following immunization and other vaccine or immunization-related issues, and to the prevention of unwanted effect of the vaccine or immunization. Monitoring of Adverse Events Following Immunization (AEFI) is an essential strategy for ensuring vaccine safety. The WHO defines an AEFI as "any untoward medical occurrence following immunization which does not necessarily have a casual relationship to a vaccine." The government of India initiated the AEFI surveillance program in 1948 and in 2008 national and state AEFI were set up by Government. Based on the advice from GACVS (Global Advisory Committee on Vaccine Safety) to review the causality assessment system, WHO commissioned a group of experts to develop a methodology and tools to assist healthcare personnel in the assessment of the causality of an adverse event and use of a vaccine. The Global Advisory Committee on Vaccine Safety (GACVS) monitors novel vaccines, from the time they become available for large-scale use.

Keywords: Vaccine pharmacovigilance, global advisory committee on vaccine safety, Immunization, Adverse Events Following Immunization.

CDIP/CPCO/027

Comprehensive study on Pharmacophore Modelling

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Abstract:

Computer-aided drug discovery techniques reduce the amount of time and money needed to develop novel pharmaceuticals. As individualized therapy becomes more common and health-related issues arise, their significance increases. The most advanced method for determining and extracting a potential interaction between ligand-receptor complexes are pharmacophore modeling. The detected interaction consists of common steric and electronic characteristics (HBAs, HBDs, aromatic groups, positively and negatively ionisable groups) that are necessary to cause a biological reaction. This interaction can be generated to improve knowledge of ligand protein interactions found in docking, NMR structures, and X-ray crystal structures. A pharmacophore model can be created using either a structure-based approach, which involves exploring potential points of interaction between the macromolecule target and ligands, or a ligand-based approach, which involves superimposing a set of active molecules and extracting common chemical features that are crucial to their bioactivity. The pharmacophore approach makes the process of finding new drugs quicker, less expensive, and more effective. Because of its versatile yet basic application, it can be used at different phases of the drug discovery process. Virtual screening, ADME-tox, prediction, side effect modeling, off target prediction, target identification, and de novo lead design are just a few of the many uses for it. This article explains the process of modeling pharmacophores followed by virtual screening, the software that is most commonly used, and some exciting potential uses that are noted in the literature for the future.

Keywords: HBA, HBD, NMR, X-ray.

CDIP/CPCO/028

Comprehensive study on antifungal and antibacterial activity of Rose petals & Rose hips

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Abstract:

Pityriasis capitis a common disorder from which almost 50% of the population of any ethnicity are affected in both male and female, but majorly prevalent in males between the age of 20-60 years all over the world. Pityriasis capitis (dandruff) is characterized as a hyper proliferation of the scalp epidermis layer accompanied with irritation of scalp including scalp itching & redness. The disorder known as Seborrheic dermatitis which affect the sebaceous gland rich area of skin, it targets the scalp, followed by face. The main cause of Pityriasis is yeast like fungus Malassezia globose, Malassezia furfur, and Candida Albicans which live on the scalp and feeding on skin oils. Dandruff is a scalp disease which can be treated including application of topical, antifungal, or other products. Since there are chances of recurrence, commonly prophylaxis using products to maintain good healthy skin of scalp as well as hair. One of the natural products which are likely to use as a antidandruff is Rosa damascene (Rose) also known as Damask rose, the king of flowers belonging to the family Rosaceae. From ancient times is it there in our culture as ethno medicine. Petals and seed pots (hips) of rose plant is a rich source of Vitamin C, phenolic, and flavonoid compound, the major medicinal property of plant is attributed to the phenolic compound. Rose hips contain Vitamin C which has an antifungal property and used to treat flaky scalp. The petals and hips of damask rose have many pharmacological effects including antioxidant & antimicrobial. The extract of petals and hips shows activity against gram positive and gram-negative bacteria *Staphylococcus Aureus*, Bacillus Subtilis and Escherichia Coli and dandruff causing fungi such as Candida Albicans and Malassezia furfur.

Keywords: Candida Albicans, Malassezia furfur, *Staphylococcus Aureus*, Pityriasis.

CDIP/CPCO/029

Beyond Traditional Topicals: An in-Depth Analysis of Nanoparticulate Gel Formulations

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Abstract:

The stratum corneum layer of the skin acts as a primary barrier, regulating the transport of substances into the skin. Topical administration aims to deliver drugs through this barrier, either into specific skin layers or systemically. In recent years, nano-sized drug carriers have shown promise as formulations for topical therapy. This review focuses on nanoparticulate gel formulations as a novel approach in drug delivery. Nanoparticle systems such as nanogels, nanospheres, solid lipid nanoparticles, polymeric nanoparticles, and nanoemulsions have been investigated. Specifically, the use of polymeric nanoparticles in gel-based delivery systems, employing natural and synthetic polymers, is highlighted. Nanoparticulate gels represent a versatile class of three-dimensional polymeric networks characterized by hydrophilic groups cross-linked via strong interactions. This unique structure enables the incorporation of both hydrophilic and lipophilic drugs, providing precise therapeutic delivery, stability, and flexibility. The exceptional biocompatibility, biodegradability, and controlled drug release capabilities of gels make them attractive for drug delivery and biomedical engineering. They can retain large volumes of aqueous fluid without dissolution and offer control over physicochemical properties and particle size through the polymeric network. However, the crucial role of the polymeric network in determining the properties of gel systems, particularly their hydrophilicity and their ability to accommodate small molecules through intricate pore structures. The potential clinical applications of nanoparticulate gels in skin diseases, such as psoriasis and skin cancers, are explored. By enhancing skin penetration, these innovative formulations have the potential to improve the efficacy of topical therapies and enable targeted drug delivery. In conclusion, nanoparticulate gels represent a promising frontier in topical drug delivery.

Keywords: Topical therapies, Nanoparticulate gel, Polymeric network, Clinical application.

CDIP/CPCO/030

Diacerein: A Potential Anti-Necroptotic Agent

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Abstract:

Necroptosis is believed to play a role in the pathogenesis of acute kidney injury caused by rhabdomyolysis. Necroptosis is a form of regulated cell death that shares physical characteristics with necrosis, but is controlled at the molecular level. The process relies on the interaction between receptor interacting protein kinase 3 (RIPK3) and MLKL (mixed lineage kinase domain-like pseudo kinase). Diacerein (DIA) is a pharmacological agent that reduces inflammation and relieves pain. It is specifically prescribed for the treatment of osteoarthritis. In addition, studies have demonstrated that Rhein, the active metabolite of the substance, possesses a range of pharmacological properties, such as anti-inflammatory, antioxidant, and anticancer activities. Diacerein has demonstrated renoprotective effects against doxorubicin and cisplatin-induced acute kidney damage (AKI) as a result of its antioxidant and anti-inflammatory characteristics. Several studies have shown that Diacerein treatment leads to a significant decrease in RIPK3 and MLKL expression, as well as a decreased proportion of necrotic cells by inhibiting TNF-induced necroptosis. This demonstrates the protective effect of Diacerein in preventing kidney damage in acute kidney injury (AKI).

Keywords: Necroptosis, Diacerein, Acute kidney injury, Reno protective mechanism

CDIP/CPCO/031

Herbal Therapeutic Agents for Baldness: A Review

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Abstract:

Baldness is also known as" alopecia". The issue of baldness is an increasing problem in cosmetic as well healthcare domains. It is a condition where hair is lost from the various areas from the scalps. It includes various factors such as genetic, ambient conditions, hormonal imbalance, medication, ageing, poor hair care practices, nutritional deficiencies etc. In India about 50% of men affect by hair loss. For women, the prevalence of female pattern baldness is lower, affecting around 20-30% of women. Male pattern baldness and female pattern baldness are the most common types, but there are also other forms such as alopecia areata, which involves patchy hair loss, and telogen effluvium, which is temporary hair shedding. Herbal therapeutic agents mention natural substances which are obtained from the plants that are used for medicinal purpose as well as widely used for hair growth promotion. In recent years, there has been a popularity of herbal systems of medicine. Approximately about 80% of residents recommended that the Herbal drugs have beneficial effect, it proven safe and have fewer side effects as compared to the synthetic drugs. Herbal therapeutic agents can be used in various forms, including hair oils, Shampoo, hair serum, hair gels and topical treatments and even many people accomplish effective results with herbal remedies for hair growth. Herbal drugs are used internally as well as externally for hair growth to prevent to hair loss. The commonly used herbs and natural ingredients include use to prevent hair loss and regrowth of hairs involves Amla (Indian Gooseberry), Bhringraj (Eclipta alba), Rosemary (Rosemarinus officinalis), Lavender (Lavandula angustifolia) ginseng, aloe vera, Brahmi etc. There are ample of benefits of using herbal therapeutic agents. Herbal remidies are often preferred for their natural ingredients which are gentler to the scalp and hair follicles in comparison of synthetic chemicals.

Keywords: Baldness, Alopecia, Telogen effluvium, Herbs, Hair Follicles, Ingredients.

CDIP/CPCO/032

View of Oral Films in the treatment of Schizophrenia

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Abstract:

Schizophrenia is a severe brain disorder causing disturbances in thinking, perception, and behaviour. Antipsychotic drugs, given in mouth dissolving matrix films, are beneficial for patients with these syndromes due to better patient compliance and better management of idiosynchronies in behaviour. The drug can be disguised with aesthetic appearance, sweet taste, and likely flavours, resembling a mouth freshener. Mouth dissolving films offer a promising method for systemic drug delivery due to improved bioavailability, better permeability, and ease of ingestion and swallowing. They also provide pain avoidance, making the oral mucosa a feasible site for drug delivery. Globally, multidisciplinary research groups are collaborating on strategies and products to prevent mental disorders, leveraging knowledge from psychology, neuroscience, medicine, and biotechnology, to address the increasing prevalence of these disorders.

Keywords: Schizophrenia, Oral Films, Mental Disorder, Antipsychotic Drug

CDIP/CPCO/033

Depofoam Technology in Cancer Disease Treatment

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Abstract:

Encapsulation of drugs into multivesicular liposomes (DepoFoam) is nanotechnologies that allow delivery of the active constituent at a sufficient concentration during the entire treatment period. This guarantees the reduction of drug administration frequency, a very important factor in a prolonged treatment. Currently, diverse DepoFoam drugs are approved for clinical use against neurological diseases and for post-surgical pain management while other are under development for reducing surgical bleeding and for post-surgical analgesia. Also, on pre-clinical trials on cancer DepoFoam can improve bioavailability and stability of the drug molecules minimizing side effects by site-specific targeted delivery. The genetic and phenotypic complexity of the cancer cells leads to the clinical diversity and therapeutic resistance, a major hurdle in the therapy of cancer. Chemotherapy, despite being one of the most common approach for cancer treatment, possesses critical limitations, such as poor bioavailability and severe side effects. Multivesicular particles (Depofoam) technology have revolutionized the concept of cancer therapy by overcoming these limitations via improving bioavailability and stability of the drug molecules and minimizing side effects by site-specific targeted delivery of the drugs. There are various liposomal formulations approved for cancer therapy such as Doxil® (PEGylated liposome), DaunoXome® (daunorubicin citrate liposomal formulation), Depocyt® (multivesicular liposome), Myocet® (nonpegylated liposomal formulation), Mepact® (multilamellar liposomes), Marqibo® (vincristine sulfate liposomal injection), and Onivyde™ (irinotecan liposome injection). Depocyt, a multivesicular liposome based formulation using DepoFoam technology, is approved by the FDA for clinical use in cancer therapy.

Keywords: Multivesicular liposomes, Cancer, DepoFoam drugs, DepoFoam technology

CDIP/CPCO/034

Effect of Dried Moringa Oleifera Leaves on the Nutritional and Organoleptic Characteristics of Cookies

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Abstract:

In this study, dried Moringa oleifera leaves powder (DMLP) was utilized to enhance the nutritional quality of cookies. Various levels of DMLP (5%, 10%, and 15%) were incorporated into the cookie formulations, and their sensory and nutritional attributes were assessed. Results indicated that the inclusion of DMLP led to increased levels of protein, dietary fibre, and minerals in the cookies, with a dose-dependent relationship observed. Sensory evaluation revealed that cookies containing up to 10% DMLP exhibited acceptable quality and retained the characteristic flavour of Moringa leaves. Therefore, incorporation of DMLP presents a viable means to enhance the nutritional profile of cookies while maintaining sensory appeal.

Keywords: Moringa, Organoleptic, Cookies

CDIP/CPCO/035

Synthesis, Characterization, Docking and Evaluation of *in vitro* Anti-cancer Activity of Novel oxazole derivatives

Pradeep Golani*, Devendra Singh Lodhi, and Sanjay Nagdev
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Abstract:

Breast cancer is one of the most common types of cancer in females. Aromatase is one of the important targets for drugs that interfere with production of estrogen in the treatment of estrogen receptor positive breast cancer. Novel aromatase inhibitors that can kill the growth of cancer cells selectively with minimal toxic effects on normal healthy cells are desirable. Novel 5-(4-bromophenyl)-1,3-oxazole derivatives were synthesised, characterized and screened for biological effects in this study. The Auto Dock technique was used to dock a series of new 5-(4-bromophenyl)-1, 3-oxazole derivatives, OXL-1 to 6, to assess their aromatase inhibition. All of the derivatives were made using a flexible and convenient technique. The synthesised compounds were analysed using spectroscopic methods in order to establish their structures. A total of six compounds were produced and analysed in vitro for aromatase inhibitory action, with all derivatives investigated for cytotoxicity against breast cancer cell lines (MCF-7). Docking parameters showed that polar (M303, P429) and non-polar (A306, M311, F430, A443 and A307) residues were essential for interaction with the aromatase inhibitors. Aromatase inhibitory activity of produced compounds was assessed with reference to the vehicle-treated control Letrozole (IC50 15.83µM). With an IC50 value of 16.8µM at 50% maximal inhibitory concentration, OXL-2 showed good inhibition. The in vitro cytotoxicity of oxazole derivatives was tested against MCF7 cell lines using Cisplatin (IC50 12.46µM) as a control. The compounds OXL-2, OXL-6, and OXL-3 showed significant cytotoxic action, with IC50 values of 15.6, 18.43, and 21.4µM, respectively.

Keywords*:* Aromatase; drug design; Auto Dock; Breast cancer; molecular docking; Cytotoxic activity; aromatase inhibitors.

CDIP/CPCO/036

CAR-T Cell Therapy: Pioneering the New Era of Cancer Treatment

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Sri Aurobindo Institute of Pharmacy, Indore

Abstract:

The main stray of cancer treatment has three basic treatments radiation, chemotherapy, and surgery but in to redefine the future of cancer treatments, CAR-T cell therapy was introduced in early 2000s after which it really started getting clinical acceptance in 2010. CAR-T cell therapy and acronym for Chimeric Antigen Receptor T-cell Therapy, represents a groundbreaking approach in cancer treatment. This innovative therapy involves genetically modifying a patient's T-cell to equip the patient's immune system with enhanced targeting capabilities again specific type of cancer. The remarkable successful trials and ongoing research highlights its potential to revolutionise cancer care and provide renewed hope for patient facing challenging diagnosis, particularly in the case of Acute Lymphoblastic Leukaemia (ALL), diffuse large B-cell Lymphoma (DLBCL), Mantle Cell Lymphoma (MCL), Follicular Lymphoma (FL), Chronic Lymphocytic Leukaemia (CLL), Multiple Myeloma. Six CAR T-cell therapies have been approved by the Food and Drug Administration (FDA). All are approved for the treatment of blood cancers, including lymphomas, some forms of leukaemia, and most recently, multiple myeloma. In 2017, with FDA's approval of tisagenlecleucel (Kymriah), the first CAR T-cell therapy based on clinical trials demonstrated it could eradicate cancer in children with relapsed all. Into the future this therapy is expected to become an important cancer treatment and may provide new ideas and strategies for individualised immunotherapy.

Keywords: Cancer Therapy, CAR-T Cell Therapy, Acute Lymphoblastic Leukaemia, Myeloma, FDA.

CDIP/CPCO/037

Chitosan and Its Derivatives: Exploring the Potential Anti-Diabetic Activity

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Compfeeders Aisect College of Professional Studies, Pharmacy College, Indore

Abstract:

Diabetes mellitus, the most common endocrine disorder, is defined by sustained hyperglycemia resulting from impaired insulin synthesis or resistance to insulin. Despite notable progress in treatment approaches, diabetes remains a prominent contributor to global morbidity and mortality. As of now, there is no definitive preventive measure or cure for diabetes. Owing to the enduring adverse consequences, conventional methods such as pharmacological therapy are not suitable for long-term treatment. Chitosan and its derivatives possess significant potential for various medicinal applications, showcasing diverse biological functions. They demonstrate favorable anti-diabetic effects, including the inhibition of α-amylase and α-glycosidase activities, improved glucose metabolism, and mitigation of β-cell dysfunction. These compounds contribute to the maintenance of pancreatic cells, elevated insulin production, reduced insulin resistance, and improved gut flora, effectively suppressing diabetes mellitus and hyperglycemia. Chitosan and its monomers, such as COS and glucosamine's, exhibit robust actions in reducing fat accumulation, cholesterol levels, and inhibiting the development of pancreatic beta cells. Research indicates that chemical modifications to these molecules can enhance their effectiveness, providing insights into the mechanisms underlying their anti-diabetic benefits. Collectively, the evidence underscores the potential of chitosan-based compounds as highly effective neutraceuticals for both the treatment and prevention of diabetes and its associated complications.

Keywords: Hyperglycemia, Chitosan, α-amylase, Glucosamine, α-glycosidase.

CDIP/CPCO/038

The Role of Pharmacovigilance in Relation to Herbal Products

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Abstract:

As per the World Health Organization, Pharmacovigilance studies are outlined as encompassing the scientific endeavors and actions focused on identifying, evaluating, comprehending, and averting adverse drug reactions and associated interactions. This involves the active participation of healthcare professionals, patients, pharmaceutical manufacturers, and regulatory authorities. Herbal medicine and its formulations are pivotal in treating a wide array of diseases worldwide, including diabetes, arthritis, memory disorders, and liver disorders. Despite a prevalent misconception that these medicines are entirely safe and can be used without a prescription, literature reports highlight potential adverse drug reactions. To ensure the safety of herbal medicines, pharmacovigilance is crucial. While current systems are effective for synthetic medicines, adjustments are needed to accommodate the unique characteristics of medicinal herbs. A clinical trial cannot comprehensively unveil the complete spectrum of a drug's effects across all situations, as dictated by legislation and contemporary judgments on the acceptable balance of benefit and harm. This limitation stems from various noted shortcomings: Animal experiments have limited efficacy in predicting human safety, Clinical trials are constrained by both time and the number of participants involved, and patient selection is influenced by diverse factors and conditions, such as adults without concurrent drug usage or other illnesses, Results may not accurately reflect real-life usage scenarios, Rare or delayed serious reactions are prone to go unnoticed.

Keywords: Herbal products, efficacy, adverse drug reactions, clinical trials, pharmacovigilance, medicinal herbs.

CDIP/CPCO/039

The Connection between Pharmacovigilance and Studies in Pharmaceutical Chemistry

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Abstract:

The role of pharmacovigilance becomes important when the works go through dealing with drugs-related pharmaceutical chemistry studies. The processes involved in drug discovery and development are structured to ensure that drugs meet standards of efficacy, safety, and quality suitable for human consumption. However, upon approval, only a fraction of the intended target population gains access to these drugs. A comprehensive understanding of medication safety often emerges post-marketing authorization or feedback that goes through pharmacovigilance or post-marketing surveillance. The post-marketing studies will help the industry to understand the required changes that are necessary to make the marketed product more potent and reliable for use. When the studies are based on the pharmaceutical chemistry aspects the content may include computational studies which are further important in the structural modification or better understanding of structural activity relationships. Pharmacovigilance defined by the World Health Organization as the science and activities addressing the detection, assessment, understanding, and prevention of adverse drug reactions and related interactions, engages health professionals, patients, drug manufacturers, and regulatory authorities. Effectively managing the knowledge, attitudes, and practices of pharmacovigilance will contribute to the enhancement of the country's pharmacovigilance systems. And also the knowledge of the patient about the drugs that they are consuming for treatment. If these studies remain in practice, then the ratio of negative results and drug loss will decline.

Keywords: Drug discovery, post-marketing surveillance, pharmacovigilance studies, drug safety, efficacy

CDIP/CPCO/040

Quality by Design Approach Method Development Validation of Bulk and Pharmaceutical Dosage Form by Using RP- HPLC

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Abstract:

Pharmaceutical analysis is crucial for ensuring the quality of pharmaceutical products, where the degradation rate and stability of drugs under various conditions are essential considerations. Forced degradation (FD) studies accelerate deterioration to understand product stability and detect impurities that may compromise efficacy and safety. Impurity profiling has become integral in pharmaceutical research due to the potential risks posed by contaminants in active pharmaceutical ingredients (APIs).Multi-component formulations, popular for their therapeutic advantages, pose challenges in accurate estimation of individual components. Instrumental techniques like spectrophotometry, gas chromatography (GLC), high-performance thin-layer chromatography (HPTLC), and high-performance liquid chromatography (HPLC) are commonly employed for their analysis. Recent advancements in HPLC technology have enhanced separation efficiency and analytical capabilities. HPLC, known for its speed, specificity, sensitivity, and accuracy, operates in two modes: normal phase and reversed phase. Reversed phase mode, widely used in pharmaceutical analysis, separates compounds based on their hydrophobicity. Various stationary phases like octadecyl silane (C18) are employed to achieve optimal separation. The development and validation of stability-indicating RP-HPLC methods for pharmaceutical compounds, including telmisartan, rosuvastatin calcium, capecitabine, gemcitabine hydrochloride, metformin hydrochloride, saxagliptin, lamivudine, tenofovir disoproxil fumarate, efavirenz, and esomeprazole magnesium trihydrate, are described. These methods ensure reliable, accurate, and cost-effective analysis of drugs in bulk and pharmaceutical dosage forms.

Keywords: HPLC, octadecyl silane (C18), hydrophobicity, Forced degradation.

CDIP/CPCO/041

Fabrication and Evaluation of Corticosteroid-Loaded Oral Mucoadhesive Nanofibers by Electrospinning for Oral Lichen Planus

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Abstract:

Oral lichen planus (OLP) is a chronic inflammatory immune-mediated muco-cutaneous disease that affects the oral mucosal lining. Currently available treatment options for these conditions often involve the use of steroids in the form of mouthwashes, creams, or ointments. However, the effectiveness of these treatments is limited due to inadequate drug contact times with the lesions. Therefore, there is an urgent need for alternative drug delivery systems that can increase the residence time of the drug to the affected areas. One potential solution is the development of mucoadhesive nanofibers that can adhere to the oral mucosa, penetrate effectively and release corticosteroids over an extended period of time. These mucoadhesive nanofibers were fabricated using mucoadhesive polymers via the technique of electrospinning, which allows for the production of uniform polymeric nanofibers with high surface area and controlled drug release properties. In this study, corticosteroid-loaded oral mucoadhesive nanofibers were successfully fabricated and evaluated for the effective treatment of oral lichen planus.

Keywords: OLP, mucoadhesive, nanofibers, electrospinning.

CDIP/CPCO/042

Pharmacovigilance and Clinical Trials: Enhancing Drug Safety and Efficacy through Collaborative Monitoring

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Abstract:

Pharmacovigilance and clinical trials are integral components of the drug development and monitoring process, each playing a crucial role in ensuring the safety and efficacy of pharmaceutical products. This review article explores the intersection of pharmacovigilance and clinical trials, focusing on their collaborative efforts to enhance drug safety and efficacy through comprehensive monitoring strategies. It examines the synergistic relationship between post-market surveillance and pre-market clinical research, highlighting the importance of continuous monitoring throughout the drug lifecycle. The review discusses key methodologies and tools used in pharmacovigilance and clinical trials, including adverse event reporting, signal detection, risk assessment, and regulatory oversight. Additionally, it explores emerging trends and technologies, such as real-world evidence and digital health solutions that are reshaping drug safety monitoring practices. Through an in-depth analysis of case studies, regulatory frameworks, and best practices, this review elucidates the critical role of collaborative monitoring in optimizing patient outcomes and promoting public health.

Keywords: Pharmacovigilance, Clinical Trials, Drug Safety, Digital Health Solutions, Patient Outcomes, Public Health

CDIP/CPCO/043

Pharmacovigilance in Focus: Understanding and Confronting Key Challenges

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Abstract:

Pharmacovigilance, the science and practice of monitoring and assessing the safety of pharmaceutical products, faces numerous challenges in its mission to safeguard public health. This abstract presents an overview of the key challenges encountered in pharmacovigilance, drawing attention to factors such as underreporting of adverse drug reactions, data quality and completeness issues, complexities in signal detection and causality assessment, diverse regulatory requirements, emerging therapies and technologies, resource constraints, and the imperative for robust post-marketing surveillance. Addressing these challenges requires collaborative efforts among healthcare stakeholders, regulatory agencies, and technology innovators to enhance data collection and analysis methodologies, improve communication and education initiatives, and harmonize pharmacovigilance standards globally. By overcoming these challenges, pharmacovigilance can fulfil its vital role in ensuring the safety and efficacy of pharmaceutical products and maintaining public trust in healthcare systems.

Keywords: ADR, stakeholders, PV.

CDIP/CPCO/044

Emergence of Artificial Intelligence in Healthcare: A Promising Future with Challenges.

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Abstract:

Artificial intelligence (AI) is a powerful and disruptive area of computer science, with the potential to fundamentally transform the practice of medicine and the delivery of healthcare. Artificial intelligence is very known buzz word and double edged sword, where some people see it as useless or harmful, while others find it very helpful. The complexity and rise of data in healthcare means that artificial intelligence (AI) will increasingly be applied within the field. Several types of AI are already being employed by pairs and providers of care and life science companies. These transformative technology promises to revolutionize healthcare, starting with early disease detection and accurate diagnosis. The key categories of applications involve diagnosis and treatment recommendation, patient engagement and adherence, and administrative activities. AI tools include cancer, neurology and cardiology. This maximizes treatment efficacy, minimizes adverse reactions, and improves patient's wellbeing. Although there are many instances in which AI can perform healthcare tasks as well or better than humans, implementation factors well prevent large scale automation of healthcare professional jobs for a considerable period. AI can be applied to various types of healthcare data (structured and unstructured). In this review article, we outline recent breakthroughs in the application of AI in healthcare.

Keywords: Artificial Intelligence, Healthcare, Diagnosis, AI tools.

CDIP/CPCO/045

Cost of illness studies in clinical depression using discounting methods: A comprehensive analysis

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Abstract:

Cost of Illness (COI) studies, particularly on depressive disorders, using a bottom-up approach. It examines depression's economic implications, emphasizing direct and indirect costs. The analysis explores discounting methods like Net Present Value (NPV) and Discounted Cash Flow (DCF), with a specific focus on the Indian context to understand unique socio-economic factors. Methodologically, the study systematically reviews scientific literature from the past decade, prioritizing patient-based studies on the cost of illness associated with depression. It employs a comprehensive approach, considering various methodologies and discounting techniques to enhance understanding of economic implications. The comparative analysis of the total cost of illness across diverse countries unravels significant variations. Specific breakdowns for each country consider factors such as currency exchange rates, inflation, and Purchasing Power Parity (PPP) adjustments, shedding light on the complexities involved. The study across five countries reveals significant variations in depression-related costs. Direct medical costs average $42,668 (SD=16,940) with a high t-statistic of 27.83 (p-value 0.001), indicating substantial differences. Direct non-medical costs average $27,171 (SD=13,220) with a t-statistic of 14.07 (p-value 0.001), highlighting an economic burden beyond medical expenses. Indirect costs related to depression average $63,816 (SD=25,230), with a t-statistic of 35.30 (p-value 0.001), indicating significant impacts on productivity and societal costs. The total cost of illness, encompassing both direct and indirect costs, averages $113,590 (SD=43,990), with a t-statistic of 49.49 (p-value 0.001), reflecting the extensive economic implications of depression across diverse nations. In conclusion, this analysis deepens our understanding of the economic impact of depressive disorders, offering insights for policymakers, healthcare providers, and researchers.

Keywords: Cost of Illness, Purchasing Power Parity, Discounted Cash Flow

CDIP/CPCO/046

Characterization of Encapsulated essential oil for different delivery systems

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Abstract:

Nanoencapsulation is a method that involves enclosing substances within tiny capsules at the nanometer scale, which finds applications in various industries including pharmaceuticals, food, and cosmetics. Through this process, the effectiveness of active ingredients is heightened, food textures and qualities can be modified, and a more consistent quality in products is achieved. The characterization of these nanoencapsulated particles is a critical step, involving several analytical techniques to understand their physical and chemical properties. Morphological characteristics such as shape and size are often determined using Atomic Force Microscopy (AFM) and Transmission Electron Microscopy (TEM), while the size distribution of the particles is usually assessed by Dynamic Light Scattering (DLS) and laser diffraction methods, which reveal the particles' hydrodynamic diameters. Additionally, the chemical composition and structure of the nanoparticles are analyzed through X-ray diffraction and various spectroscopic techniques, providing deeper insights into their behavior and interaction with other substances. In drug delivery, nanoencapsulation has been applied using various types of nanoparticles, such as Solid Lipid Nanoparticles (SLNs), nanoemulsions, and polymeric nanoparticles, each having unique benefits. SLNs are particularly noted for increasing the stability and bioavailability of drugs, and they can cater to both hydrophilic and hydrophobic drugs while providing a sustained release mechanism. Nanoemulsions aim to enhance drug solubility and stability in a manner similar to SLNs. Polymeric nanoparticles, which are made from materials like polylactic acid (PLA) and polyethylene glycol (PEG), are capable of transporting both soluble and insoluble drugs, ensuring a stable, controlled release and are known for their biocompatibility.

Keywords: Essential oil, Encapsulation, Characterization, Drug delivery, Morphology

CDIP/CPCO/047

Fabrication of Nanofibrous Oro-Dispersible Film Loaded with Antibiotic for Treatment of Local Throat Pathologies

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Abstract:

Throat pathologies, such as infections and inflammation, pose a challenge for effective treatment due to the difficulty in achieving targeted drug delivery and sustained release. The use of nanofibrous Oro-dispersible films loaded with antibiotic offers a promising solution to this problem. These films, fabricated using electrospinning technique, provide a high surface area to volume ratio and customizable surface charge. Additionally, the large drug payload capacity and tunable release properties of these films allow for controlled and prolonged drug release, increasing the therapeutic efficacy. This innovative approach addresses the limitations of traditional drug delivery systems by utilizing polymeric nanofibers, which exhibit a large loading capacity and are easily manipulated and functionalized. Furthermore, the use of natural-based polymeric nanofibers and synthetic polymeric nanofibers in combination allows for the development of efficient drug delivery systems. Their antibacterial properties can be utilized to prevent the growth of harmful microorganisms. Fabrication of nanofibrous Oro-dispersible films loaded with antibiotics for the treatment of local throat pathologies (Strep throat, Pharyngitis, tonsillitis etc) presents a promising solution to the challenges in treating these conditions.

Keywords: Nanofibers, Pharyngitis, electrospinning, Local Throat Pathologies.

CDIP/CPCO/048

Meta - analysis of evidence based practices and personalized therapy in minimizing anticipated drug toxicity

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Abstract:

Traditionally, patient safety research has focused on data analyses to identify patient safety issues and to demonstrate that a new practice will lead to improve quality and patient safety. But, much less research attention has been paid to how to implement practices however, the development of evidence based medicine and pharmacogenetics allows a personalized treatment to improve clinical practice and patient care. The research methodology involves observational, retrospective, quantitative and epidemiological findings which derived from the systematic collection of retrospective data through observation and experiment, as well as formulation of questions and testing of hypothesis comprise the evidence supporting practice. The evidence based practices (EBP) and personalized therapy is based on the integration of the best research evidence with clinical expertise felicitate clinical decision making. Yet, only by putting into practice what is learned from research will care be made safer. The results and conclusion of the study were analyzed and found barriers to implement EBP are insufficient time to read scientific research articles and the cost to its access. Those patients who receive evidence based therapies have better outcomes than those who do not. However challenges exist regarding how to make EBP a reality, particularly in hospitals and as a routine sustained aspect of professional practice. Therefore, for enhanced treatment effectiveness and avoidance of predictable side effects: by tailoring treatment plans to an individual's genetic and clinical profile, the personalized and evidence based medicine has been introduced which not only improves treatment effectiveness but also minimizes adverse effects.

Keywords: Evidence based medicine; Evidence based Practice, Personalized therapy, Pharmacogenomic, Adverse effects.

CDIP/CPCO/049

Depofoam Technology: An Updated Review

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Abstract:

A major challenge in the development of sustained-release formulations for protein and peptide drugs is to achieve high drug loading sufficient for prolonged therapeutic effect coupled with a high recovery of the protein/peptide. This challenge has been successfully met in the formulation of several peptide and protein drugs using the DepoFoam™, multivesicular lipid-based drug delivery system. DepoFoam technology consists of novel multivesicular liposomes characterized by their unique structure of multiple non-concentric aqueous chambers surrounded by a network of lipid membranes. Encapsulation of drugs into multivesicular liposomes (DepoFoam) is a nanotechnology that allows delivery of the active constituent at a sufficient concentration during the entire treatment period. This guarantees the reduction of drug administration frequency, a very important factor in a prolonged treatment. Currently, diverse DepoFoam drugs are approved for clinical use against neurological diseases and for post-surgical pain management while other are under development for reducing surgical bleeding and for post-surgical analgesia. Also, on pre-clinical trials on cancer DepoFoam can improve bioavailability and stability of the drug molecules minimizing side effects by site-specific targeted delivery.

Keywords: Multivesicular liposomes,DepoFoam drugs, DepoFoam technology, Encapsulation, site-specific targeted delivery

CDIP/CPCO/050

Self-Medication: A Serious Concern in Developing Nations

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Abstract:

Often mistaken as self-care, self-medication is a prevalent practicein developing nations of South East Asia and Africa is scaringly leading to antibiotic resistance in human. In addition, drug interactions with food or other ongoing drugs, if any, can initiate adverse effects or other unfavourable conditions, when, done by common men, without sufficient knowledge. Widespread, irrational use of antibiotics without consulting a doctor increases the risk of pathogen resistance, missing diagnoses, improper, wrong medication, or excessive treatments, and increased morbidity are other apprehensions. Studies have illustrated that patients undergoing self-medication without consulting medical practitioners are several times more likely to have acquire medicine-related problem. It would be safe if users are well informed about the medication dosage, timing of administration, and adverse consequences from regular or overdosing. Insufficient understanding can result in major side effects like allergy, hypersensitivity, and antibiotic resistance. To encourage prudent and secure behaviour, laws must be put in place and awareness raised. As an alternative to this practice of self-medication with synthetic drugs, educating the common people to switch to better practice of herbal drug intake, though it takes a longer duration to have a pronounced effect, can be one of the ways to handle self-treatment, be it for infection or many other ailments.

Keywords*:* Self-care, self-medication, antibiotic-resistance, adverse effects, drug-interactions

CDIP/CPCO/051

Artificial Intelligence in Clinical Trials

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Abstract:

Clinical trials are essential for delivering novel medications, technology, and procedures to the market and clinical practice. Only 10% of these studies complete the entire procedure from the drug design to the four phases of development, because clinical trials are becoming more expensive and difficult to perform. Artificial intelligence is one of the tools that could streamline some of the processes which are the most tedious operations, like patient selection matching and enrollment better patient selection could also minimize harmful treatment and its side effects. The investigation showed that the literature in this field is emerging focuses on health services,management, predictivemedicine, patient data and diagnostics, and clinical decision -making. Interest and advances in medical AIapplication have surged in recent year due to the substantially enhance computing power of modern computers and the vast amount of digital data available for collection and utilization. AI is gradually changing medical practice. These technologies can also identify new drugs for health services management and patient care treatment.

Keywords: Artificial intelligence, Clinical trials, Patients care.

CDIP/CPCO/052

Pharmacovigilance in Oncology: Challenges and Opportunities with Targeted Therapies

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Abstract:

Pharmacovigilance is termed as the study of the effects of drugs after completion of their licensing especially to identify and evaluate the adverse effects of drugs after the intake which was previously unreported. Pharmacovigilance in oncology, particularly concerning targeted therapies, represents a critical frontier in personalized medicine, offering both unique challenges and significant opportunities for enhancing patient outcomes by exploiting specific molecular targets associated with cancer progression. While the advancements in the pharmacovigilance industry have significantly enhanced the precision of effectiveness of cancer treatments, they also introduce a complex array of challenges and opportunities within the realm of pharmacovigilance. The primary challenges identified include the identification and management of unique adverse events (AEs) associated with targeted agents, the variability in individual patient responses due to genetic polymorphisms, and the intricate interactions between targeted therapies and other medications or treatments. There has been a rapid pace in the development of new oncologic drugs that are approved and introduced to the market demands a robust, agile pharmacovigilance system capable of quickly identifying and addressing unforeseen safety concerns. Individual patient monitoring improves their compliance because patients receive more information and are directly involved in treatment. In recent years, anticancer treatments have seen an enormous evolution. Targeted therapies are a new generation of anticancer drugs that interfere with specific molecules that are involved in the growth, progression, and spread of cancer, and are expressed by specific cancer types. Pro-active pharmacovigilance is important to improve spontaneous reporting that can generate new signals on adverse drug reactions (ADRs).

Keywords: Adverse drug reactions (ADRs), patient Monitoring

CDIP/CPCO/053

Molecular Docking Techniques: A Review

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Abstract:

Molecular docking is technique in which computer modeling of structural complexes are produced by two or more interacting molecules .Docking is a technique for determining the affinity between ligand and protein interaction, thus it is a crucial step in the drug development process. It is a part of structure-based computer-aided drug design. Ligand and Protein docking is new concept, Small molecules are inserted into the enzyme's active region using docking techniques. There are two primary steps in the docking process: first is- sampling the ligand and other is- applying a scoring functions. Taking into account the ligand's binding mode, sampling algorithms assist in determining the most energetically beneficial conformations of the ligand within the protein's active site. Then a scoring function is used to rank this confirmation. Molecule docking allows one to predict the kind and strength of signals that the molecules will produce. Since molecular docking can predict the coupling compliance of small particle ligands to the appropriate target restriction site, it is a commonly used technique in structure-based drug design. Some commonly used molecular docking techniques include- Flexible Docking, Rigid-body Docking, and Induced-fit Docking. When docking is done well, it finds high-dimensional spaces and ranks function use, producing an appropriate candidate docking grade. The molecular docking method is capable of efficiently screening extensive databases of compounds, resulting in a reduced cost compared to experimental techniques such as high throughput screening. Molecular docking is an economical, user-friendly, and secure method that facilitates the exploration, comprehension, elucidation, and identification of molecular characteristics by employing three-dimensional structures.

Keywords: Induced-fit Docking, three-dimensional structures

CDIP/CPCO/054

Parkinson's disease and brain delivery of therapeutics: Bridging the gap using nanostructured lipid carriers

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Abstract:

Parkinson's disease (PD) persistently imposes a significant burden on individuals and society, impacting the quality of life and economic stability. Current treatments only alleviate symptoms. Moreover, the undesirable side effects of levodopa, such as cardiac arrhythmias, motor fluctuations, hallucinations, psychosis, constipation, blurred vision, nausea, vomiting, exacerbation of angina, anomalous developments (dyskinesias), behavioral impacts, andm variance in motor performance are the major side effects of levodopa but nanocarriers such as nanostructured lipid carriers offer promising non-invasive approaches. Nanostructured lipid carriers are nanometer-sized carriers that increase solubility, improve permeability, target specific sites, remain stable, and entrap drugs efficiently. They can transport medication across the blood-brain barrier with minimal toxicity and perform neuroprotective functions such as mitigating oxidative stress and neuroinflammation, inhibiting specific biochemical parameters, and modifying protein misfolding and aggregation. Drug-loaded nanostructured lipid carriers demonstrate the capability to halt the death of dopaminergic neurons and interfere with protein aggregation, making them a novel treatment strategy for neurodegenerative diseases (NDs) such as Parkinson's disease.

Keywords: Parkinson's disease; neurodegeneration; nano-structured lipid carriers; neuro-regeneration; dopamine.

CDIP/CPCO/055

Preparation and Characterization of Ganciclovir Loaded Nanogel for Topicalapplication

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Abstract:

This study focuses on the development and characterization of a novel nanogel formulation intended for topical application of ganciclovir, an antiviral medication. The nanogel was synthesized using a method based on [insert specific method, such as emulsion polymerization or crosslinking]. The physicochemical properties of the nanogel, including size distribution, surface charge, and morphology, were thoroughly characterized using techniques such as dynamic light scattering, zeta potential measurement, and scanning electron microscopy. Furthermore, the encapsulation efficiency and drug loading capacity of the nanogel were determined using validated analytical methods. The release kinetics of ganciclovir from the nanogel matrix were studied under simulated physiological conditions to assess its sustained release profile. Stability studies were conducted to evaluate the physical and chemical stability of the nanogel formulation over time. In vitro experiments were performed to assess the cytotoxicity of the ganciclovir-loaded nanogel using relevant cell lines. Additionally, the efficacy of the nanogel in inhibiting viral replication was evaluated through in vitro antiviral assays. Moreover, in vivo studies using appropriate animal models were conducted to investigate the pharmacokinetics, tissue distribution, and therapeutic efficacy of the topical nanogel formulation. Overall, the results demonstrate the successful preparation and comprehensive characterization of a ganciclovir-loaded nanogel formulation suitable for topical administration. The formulation exhibits sustained drug release, excellent stability, low cytotoxicity, and potent antiviral activity, highlighting its potential as a promising therapeutic option for the treatment of [relevant viral infections or conditions].

Keywords: Nanogel, Ganciclovir, Antivira, Antiviral activity, Crosslinking

CDIP/CPCO/056

Emerging Potential of Chitosan based film forming Gel in Wound Healing and Drug Delivery

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Abstract:

The topical film-forming gel represents an innovative strategy for addressing skin diseases by offering both topical and transdermal treatments. Chitosan, a naturally-occurring polysaccharide obtained from chitin, has drawn much attention in the pharmaceutical field because chitosan possess numerous valuable properties. Chitosan-based film forming gels are considered as ideal materials for enhancing wound healing owing to their biodegradable, biocompatible, non-toxic, antimicrobial, bioadhesive, biological activity and hemostatic effects. For various kinds of wounds, Chitosan-based hydrogels are able to promote the effectiveness of wound healing by modifying or combining with other polymers, and carrying different types of active substances. The additional qualities of chitosan such as controlling the release rate of drug, scope for modification, cross-linking ability with other polymers, antimicrobial properties, gel forming ability, bioadhesion, and gas permeability, make chitosan one of the most versatile co-polymer for drug delivery. The unique biological properties of a chitosan-based FFG enable it to serve as both a wound dressing and as a drug delivery system (DDS). In this review, we will take a close look at the Mechanism, composition and application of chitosan-based Film forming gel in wound dressings and DDS to enhance wound healing.

Keywords: FFG, Biodegradable, Bioadhesive, Chitosan, Wound Dressing.

CDIP/CPCO/057

Introduction to Wearable Health Devices

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Abstract:

Wearable medical devices are portable devices designed to monitor, diagnose, or treat various health conditions. They can range from fitness trackers and smart watches to more advanced devices like continuous glucose monitors, ECG monitors, and smart clothing with built-in sensors. Wearable Health Devices is a rising innovation that empowers steady ambulatory monitoring of human vital signs during day-to-day life or in a clinical setting, with the satisfaction of minimizing discomfort and hindrance with normal human activities. Maximum of the public, use wearable devices primarily for fitness tracking but recently evolved devices are designed to track a mass of physiological data similar as heart rate, skin temperature, and blood oxygen levels. Such data is of limited use to a common consumer and even to a general physician but could be critical to clinical investigation professionals. The crucial benefit of wearable devices is that the subjects can be monitored remotely giving away high-quality data with meaningful cost savings. The integration of wearable devices into pharmacovigilance strategies extends a promising result to enhance patient safety and optimize drug therapy management. Wearable devices offers benefit similar as real-time data collection, remote patient monitoring, drug adherence, and health status outside of conventional clinical settings, contributing to the early discovery of adverse drug reactions, optimization of drug therapy management, and enhancement of patient issues. The future of wearable medical devices entails smaller, AI-integrated devices with expanded applications, including mental health monitoring. Nevertheless, some challenges like data privacy, regulatory considerations, and device confirmation need to be addressed for their widespread acceptance in healthcare practice.

Keywords: Wearable health devices, clinical trials, pharmacovigilance

CDIP/CPCO/058

Most Usable Techniques for Human Cancer Detection

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Abstract:

Despite technical advances in many areas of diagnostic radiology, the detection and imaging of human cancer remains poor. A meaningful impact on cancer screening , staging and treatment is unlikely to occur until the tumor-to-background ratio improves by three to four orders of magnitude (i e , 103 to 104-fold) , which in turn will require proportional improvements in sensitivity and contrast agent targeting . The use of various contrast agents and radiotracers for cancer imaging is reviewed, as are the current limitations of Ultrasound, X-ray imaging, Magnetic Resonance Imaging (MRI), Single-Photon Emission Computed Tomography, Positron Emission Tomography (PET), and Optical Imaging. There are only six imaging modalities available to clinicians, who diagnose, stage, and treat human cancer : X-ray (plain film and computed tomography [CT]), ultrasound (US), magnetic resonance imaging (MRI), single-photon emission computed tomography (SPECT), positron emission tomography (PET), and optical imaging. Of these, only four (CT, MRI, SPECT, and PET) are capable of three-dimensional (3-D) detection of cancer anywhere in the human body. The root of the problem is one of scale. A typical cell in the human body is 10 μm in diameter, with a volume of only 1 pL. Hence every 1 cm3 (1 g) of solid tissue contains approximately 109 or one billion cells; the entire human body is estimated to contain approximately 1014 cells. Because a malignant clone evolves from a single cell, initially one would need a detectability of 10−14, an inconceivably small number, to detect the genesis of a tumor. However, solid tumors typically display Gompertzian kinetics, with a first lag phase starting from the single cell stage, a log phase heralded by angiogenesis and an escape from diffusion-limited nutrition at approximately the 105 cell stage, and a second lag phase culminating in death of the patient at approximately 1012 cell.

Keywords: Cancer Detection, Gompertzian kinetics, MRI, CT, SPECT, PT.

CDIP/CPCO/059

Understanding Antibiotic Resistance: A Global Health Challenge

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Abstract:

Antibiotic resistance has emerged as a significant threat to public health worldwide, rendering many once-effective antibiotics ineffective against bacterial infections. Bacteria that cause disease can develop resistance on their own or be purposefully added to a biological weapon. Drugs that could save lives are rendered useless in both scenarios. A multimodal strategy is needed to combat antibiotic resistance, including wise antibiotic use, the creation of novel antibiotics, improved infection prevention and control practices, and international cooperation. Antibiotic-resistant bacteria are becoming more prevalent, which compromises the effectiveness of treatments for common diseases and raises morbidity, death, and healthcare costs. Furthermore, as bacterial strains grow more resistant to current therapies, the issue is made worse by the absence of new antibiotic development. A multifaceted strategy is needed to combat antibiotic resistance, including improved antibiotic management, strain surveillance, and the creation of new antimicrobial medicines. This abstract provides an overview of antibiotic resistance, its causes, consequences, and strategies for combating this pressing global health challenge.

Keywords: Antimicrobial, Antibiotic-resistant bacteria, Strain surveillance.

CDIP/CPCO/060

Combined Effect of Compritol 888ato and Hpmck on Verapamil Hydrochloride Release from Controlled Release Gastroretentive Tablet

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Abstract:

The aim of this study to understand the combined the effect of hydrophobic Compritol 888ATO and hydrophilic HPMC on Verapamil HCl release from the controlled release gastroretentive tablet. The response surface 3 factors 3 levels (3^3) Box-Behnken Design using Design Expert Software (Version 11) was selected for efficient investigation of the independent variables effects on the dependent variables, 15 runs were obtained with 3 centre points. *In-vitro* drug dissolution study were conducted using USP Dissolution Apparatus II. The dissolution profile data of 15 formulations were generated. Experimentally developed formulation dissolution profile data was fitted into Zero order, First order, Higuchi and Korsmeyer Peppas models to identify the kinetic modeling or release mechanism of drug form CRGR, the ideal model is the one with the greatest correlation coefficient. Drug release data was the best fitted in Higuchi with r^2 = 0.999 and Krosmayer Peppas with r^2 = 0.998, the critical value of n= 0.54 as compared to Zero order r^2 = 0.918 and first order r^2 =0.989, suggesting diffusion and non-fickian anomalous transport i.e. drug release by diffusion from hydrated matrix simultaneously and by rearrangement of polymeric chains occurring slowly cause time-dependent anomalous effects. In general the faster VH release rate with the HPMC increased content with compritol 888 ATO could be due to more rapid penetration of water into the matrix and/or more matrix erosion. However, a gradual disintegration of the swollen HPMC-based tablets was observed during the release studies.

Keyewords: Verapamil hydrochloride, Compritol 888ATO, HPMC, Box-Behnken Design

CDIP/CPCO/061

Simultaneous estimation of seven major bioactive markers by developing a novel RP-HPLC analytical method for the standardization of coded formulation JKC

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Abstract:

JKC is a coded formulation that is employed and widely used for fever (especially chronic type), cold, and malaria, improves digestion and appetite, boosts immunity, and protects against common bacterial infections. Practitioners and people claim it is also effective in treating COVID-19. With this objective, CCRAS, an RP-HPLC method, has been developed to estimate seven bioactive marker compounds simultaneously to ensure the quality, safety, and efficacy of the JKC formulation. Simultaneous estimation of major bioactive markers: Andrographolide (AG), Piperine (PP), Picroside-I (P-I), Picroside-II (P-II), α-Cyprone (AC), 6-Shogaol (6S), and 6-Gingerol (6G) in JKC formulations by HPLC method. The mobile phase (methanol: water, 80:20 v/v), low-pressure gradient. Major bioactive compounds in JKC formulations were observed in different retention times are detected and estimated (mg/g) in plants and formulation are: AG (41.282±0.48; 9.50±0.68), PP (53.81±0.25, 13.82±0.37 in PN, PL; 4.13±0.25), P-I (15.97±0.01; 0.48±0.01), P-II (63.24±0.35; 2.46±0.01), AC (0.42±0.01; 0.37±0.01), 6S (0.71±0.03; 0.17±0.01), and 6G (2.63±0.09; 0.19±0.01) respectively. The proposed method was validated with acceptable linearity (r^2 0.9995-0.9999), precision, robustness & ruggedness, and accuracy (RSD < 2%) under optimum conditions. The present study concluded that this HPLC technique is fast, precise, and accurate for simultaneously quantifying seven major bioactive markers: AG, PP, P-I, P-II, AC, 6S and 6G in a plant sample and the formulations.

Keywords: Zingiber officinale, Andrographis paniculata, Cyperus rotenduslinn, Piper longum, Piper nigrum, and Picrorhiza kurroa.

CDIP/CPCO/062

A Comprehensive Comparative Analysis of Phytochemical, Pharmacognostic, and Chromatographic Profiling of Commonly Available Sida Species in Kerala

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Abstract:

Background: Bala, a prevalent Ayurvedic ailment for rheumatic arthritis, conventionally derives its roots from Sida cordifolia, as documented in the Ayurvedic Pharmacopeia of India. However, within the Kerala region, locally abundant Sida species like Sida acuta, Sida cordifolia, and Sida alnifolia are utilized for medicinal applications. This study seeks to thoroughly compare the pharmacognostical, phytochemical, and chromatographic features of these commonly accessible Sida species in Kerala with the established Sida cordifolia. **Method:** The research conducted a comprehensive analysis of the HPTLC fingerprint profiles and HPLC chromatograms of both plant specimens. Additionally, a chemoprofile investigation was simultaneously conducted, comparing the Total Phenolic Content (TPC) and Total Flavonoid Content (TFC) profiles of the selected Sida species.

Result and discussion: The Total Phenolic Content (TPC) and Total Flavonoid Content (TFC) profiles of both plant species were assessed, revealing comparable levels of flavonoids and phenols across all species. The HPTLC fingerprint profiles of both plants exhibited identical band numbers with similar Retention Factors (Rf). Similarly, the HPLC chromatograms displayed analogous patterns and Retention Times (Rt). These results suggest a similar chemical profile for both species, indicating their potential interchangeability as substitutes for each other.

Conclusion: This study reveals notable similarities in the chemical profiles of commonly available Sida species in Kerala. Such findings establish a groundwork for future investigations, underscoring the promising potential of these Sida species for application in Ayurvedic practices.

Keywords: *Sida*, Bala, Kerala, Phytochemistry, HPLC, HPTLC finger print profiling.

CDIP/CPCO/063

A Pharmaceutical Viewpoint on Organic Volatile Impurities and Their Regulatory Limits

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Abstract:

The Office of Generic Drugs has identified impurities in drug substances and drug products as major regulatory concerns because they have a substantial effect on the approval of abbreviated new drug applications (ANDAs). OVIs, also known as residual solvents in the pharmaceutical industry, are traces of organic volatile compounds that are generated or utilized during the production of excipients, active ingredients, or pharmaceutical products.

In the pharmaceutical sector, organic solvents are frequently utilized as reaction media, for equipment cleaning, to separate and purify synthesis products, and for other purposes. Since leftover solvents are undesirable ingredients in a finished product, several techniques for getting rid of them are acceptable as long as they meet safety standards. The choice of solvent is typically a crucial factor in the synthetic process; nevertheless, since most of these solvents can't be eliminated entirely in actual production processes, their content needs to be assessed and justified. Generally, Headspace GC/FID is used for OVI identification and quantification. The International Conference on Harmonization (ICH) method Q3C1, US Pharmacopoeia (USP) method 467 2, and European Pharmacopoeia (EP) method 2.4.24 3 serve as the guidelines for this process.The purpose of this review was to offer information about OVI and/or residual solvent.

Keywords: Gas Chromatography, Organic volatile impurities, Regulatory guidelines.

CDIP/CPCO/064

COVID-19 Transmission, Current Treatment, and Future Therapeutic Strategies

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Abstract:

In Wuhan, China, at the start of 2020, a zoonotic illness known as COVID-19—which would go on to become a worldwide pandemic—was discovered. Similar to other zoonotic diseases like MERS and SARS-CoV, COVID-19 also causes severe flu-like symptoms and acute respiratory distress, although being distinct in its severity and mode of transmission. Numerous similarities between SARS and COVID-19 have been found, even at the molecular level; in fact, the COVID-19 virus is now known as SARS-CoV-2. These commonalities have made it possible to treat COVID-19 patients with clinical strategies that have been shown to be successful in treating SARS on several occasions. Crucially, opportunities have been identified by comparing the ways in which SARS-CoV and SARS-Cov-2 multiply, enter the host, and cause life-threatening pathological diseases.we began this essay by giving a general review of the aetiology of COVID-19 in comparison to other zoonotic illnesses, specifically SARS and MERS. The features of the groplets and aerosols released by COVID-19 patients were then outlined, along with how they contribute to the virus's spread among humans. Additionally, we talked about the molecular pathways that allow SARS-CoV-2 to infect the host and spread more widely than other betacoronaviruses like SARS-Cov. We also described the many methods that are being used in the clinic right now to identify and treat COVID-19 symptoms.Lastly, we discussed the many strategies and technology used to create COVID-19 vaccines and provided an overview of the efforts made to repurpose different medication classes and innovative therapeutic techniques.

Keywords: -Transmission, COVID-19, Vaccines, SARS, Beta-corona-viruses.

CDIP/CPCO/065

Development of the Quality Target Product Profile for Orodispersible Nanofibers Using Electrospinning Method

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Abstract:

Orodispersible films are slender, small-sized, swiftly disintegrating, and appealing oral drug delivery forms ideally designed for pediatric and geriatric patient groups facing challenges in swallowing. The electrospinning technique shows significant potential in the creation of orodispersible films containing various drugs, enabling rapid onset of their effects. In recent times, the pharmaceutical industry has increasingly adopted the "quality by design" (QbD) approach. A crucial initial step in utilizing this effective method involves outlining the quality target product profile (QTPP), which entails identifying the critical quality attributes (CQAs) necessary for the final product. These QAs are influenced by both the ingredients used and the parameters of the manufacturing process. Therefore, it is imperative to define critical material attributes (CMAs) and critical process parameters (CPPs). This study comprehensively outlines and specifies the QTPP, CQAs, CMAs and CPPs essential for the development of an orodispersible film using the QbD approach.

Keywords: QTPP, CQAs, CMAs and CPPs.

CDIP/CPCO/066

Design, Formulation and Development of Nanogel for the Management of Keratosis Pilaris

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Abstract:

Keratosis Pilaris (KP) is a common dermatological condition characterized by the formation of small, rough bumps on the skin, often resembling goosebumps or chicken skin. In this study, we present the design, formulation, and development of a novel nanogel specifically tailored for the management of KP. The developed nanogel was characterized for physical parameters such as compatibility, TEM, and stability studies. Further, it was also evaluated for pH, viscosity, spread ability, and extrudability, as well as through texture analyses, *in vitro* studies, and skin irritation tests. The formulation was successfully developed with all the necessary attributes. The nanogel was formulated using biocompatible and biodegradable polymers, ensuring safety and minimal risk of adverse effects. Furthermore, the nanogel was loaded with therapeutic agents known for their keratolytic, anti-inflammatory, and moisturizing properties, targeting the underlying causes of KP and providing comprehensive management of the condition. Nanogel exhibited a spherical morphology with a uniform particle size distribution of approximately 100 nm. Drug loading efficiency was determined to be >90%, ensuring optimal therapeutic payload. The development of a targeted nanogel formulation holds great promise for improving the treatment outcomes and quality of life of KP patients, paving the way for future clinical trials and eventual commercialization of this innovative therapeutic approach.

Keywords: Keratosis Pilaris, Nanogel, TEM, Anti-inflammatory.

CDIP/CPCO/067

Precision in Practice: ICH-Guideline-based Shelf Life Evaluation and Standardization of AYUSH M3 Tablets and AYUSH SS Granules Using HPTLC for Bioactive Marker Quantification

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Abstract:

Background: CCRAS has developed AYUSH M3 Tablets and AYUSH SS Granules to cater to unique healthcare needs. AYUSH M3 has ingredients such as *Elaeocarpusgranitrus*, *Rauwolfiaserpentina*, and *Boerhaviadiffusa*, which are said to improve the treatment of migraine and hypertension. The AYUSH SS Granules include *Asparagus racemosus*, *Cuminumcyminum*, *Anethumsowa*, and *Elettariacardamomum*, which are specifically designed to meet the nutritional needs of nursing moms.

Objective: The primary aim of this investigation is to conduct a shelf life evaluation and standardization of AYUSH M3 tablets and AYUSH SS granules.

Method: Utilizing High-Performance Thin-Layer Chromatography (HPTLC) as the analytical method, this study entails a systematic evaluation of shelf life. Adhering rigorously to ICH guidelines, the process incorporates stringent controls and measures to ensure the stability of formulations. Bioactive markers are quantified, and physicochemical parameters are monitored throughout the duration of the study.

Result & Discussion: In AYUSH M3 tablets, four significant bioactive compounds are identified and quantified, leading to a determined shelf life of 17 months. AYUSH SS granules, on the other hand, contain two major bioactive compounds and demonstrate a shelf life of 18 months. Throughout the duration of their shelf lives, all physicochemical parameters remain consistent, indicating the physical stability of the formulations. **Conclusion:** The findings affirm the efficacy and durability of both AYUSH M3 tablets and AYUSH SS granules in regulated environments, highlighting their promising prospects for clinical utilization.

Keywords: ICH -guidelines, Stability Testing, HPTLC, AYUSH M3 Tablet and AYUSH SS granules.

CDIP/CPCO/068

Revolutionizing Therapy: Probiotics and Engineered Probiotics for Autoimmune CNS Disorders (Multiple Sclerosis)

Annu*

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Abstract:

Autoimmune disorderstargeting the nervous system can impact different components, encompassing the brain and spinal cord (central nervous system, CNS), peripheral nerves, neuromuscular junction, and skeletal muscle (peripheral nervous system, PNS). Probiotics have shown tremendous potential in the treatment of autoimmune CNS disorders. Probiotics consist of live microorganisms that, when appropriately administered, offer health advantages to the host, and have gained attention for their potential role in autoimmune central CNS disorders.The gut microbiota plays a crucial role in regulating the immune system and influencing CNS function through the gut-brain axis. Probiotics could modulate this axis, affecting inflammation and immune responses implicated in autoimmune CNS disorders. Probiotics have shown promise in regulating immune responses, potentially reducing inflammation, and modulating immune cell activity associated with autoimmune conditions like multiple sclerosis (MS) or neuromyelitis optica (NMO). The investigation into nanonization strategies for probiotics and the application of nanoprobiotics in delivering encapsulated bacteria is underway**.**The primary method for probiotic encapsulation involves using nanoparticles, specifically selenium and gold particles. The current review provides insights into precision probiotics and nanoformulationsrepresenting a groundbreaking frontier in the quest for innovative therapies for autoimmune CNS disorders.

Keywords: Multiple Sclerosis; Probiotics, Precision Probiotics, Nanoparticles.

CDIP/CPCO/069

Data Mangemnt of Pharmacovigillance through Dictionary

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Abstract:

They are meant to enforce some order among them. They aim to bring some discipline to the large array of descriptive terminology that patients and health professionals use to describe medical disorders, as well as to the vast array of drugs that the former impose on the latter. The characteristics of the dictionary exert a profound effect on the data. If there are too few terms in the dictionary, then compromises have to be made when coding the data. Details that have been reported may be lost, e.g. staphylococcal bronchopneumonia and acute exacerbation of chronic bronchitis might both just become 'respiratory infection'. If the relationships within the dictionary are not completely valid, then a case reported as 'psychological problems' might be transformed into 'psychotic' in the database – which is enough to drive anyone mad. At the other end of the scale, it could be that the dictionary accurately reflects the facts, but does not group conditions appropriately. If grouping is not effective, then it might be difficult to find items in the database. Paradoxically, being overly particular in one's dictionary selection can also have an impact on one's worldview. Answering the straightforward question of whether there were more reports of headache with the beta-blocker ololol in patients receiving active drug or placebo in a comparative trial with 100 patients in each treatment arm could be challenging if a dictionary included 25 different types of headaches. The answer may be that Stephens' new side effects were: two reports of tension headache, two reports of throbbing headache, four unspecified headache and three sinus headache with ololol; and one tension-type headache, two unspecified headaches, one vascular headache, and one headache with flashes in placebo-treated patients. Without the group name "headache", the true differences between treatments may be missed. Such "sharing" may similarly reduce the ability to detect evidence of new adverse reactions in the post-marketing safety database.

Keywords: Dictionary, Coding, Health Professionals, Pharmacovigillance.

CDIP/CPCO/070

A Systematic Review on Pharmacovigilance Study of Antiasthmatic Agents

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Abstract:

Bronchial asthma is one of the most common chronic inflammatory diseases in the world affecting the lung airways of around 334 million people. Management of bronchial asthma includes multidrug therapy for long duration, which leads its association with adverse drug reactions (ADRs). Pharmacovigilance study reports on monitoring adverse drug reactions (ADRs) of antiasthmatic agents are scarce in India.The present review stated the various methods that were implemented to monitor and evaluate adverse drug reactions associated with antiasthmatic agents. Inhaled medication, chronic use of oral glucocorticoids in patients with severe asthma is associated with several adverse events (AEs). Biological drugs have been successfully tested in asthma, being especially effective in the most severe forms of the disease, have been developed as alternative therapies for the treatment of asthma. As asthma medications are frequently prescribed for children, knowledge of the safety of these drugs in the pediatric population is important. Adverse drug reactions (ADR) are the known dangers of any medicinal therapynot only responsible for increasing the mortality and morbidity, but also for multiplying the health care expenditure. Retrospective analysis, risk of anaphylactic reactions associated with biologics. The Naranjo's probability scale was used for causality &Hartwig and Seigel scale for severity assessment. Spontaneous reports (SRs) of suspected ADRs obtained from EudraVigilance, the European Medicine Agency's database. World Health Organisation-Upasala Monitoring Centre (WHO-UMC) causality categories were used for assessment of causality.

Keywords: Antiasthmatics, Hartwig and Seigel scale, Naranjo's scale, pharmacovigilance.

CDIP/CPCO/071

Synthesis and Antimicrobial Screening of Schiff Bases of Isatin Derivatives

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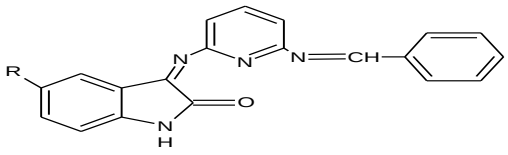
Abstract:

Objective: Synthesis and study of *in-vitro* antimicrobial activity of Schiff bases of 5-substituted isatin. **Method:** Isatin and its 5-substituted derivatives were prepared by Sandmeyer method and N^2-benzylidenepyridine-2,6-diamine was obtained by the reacting 2,6-diaminopyridine with benzaldehyde. Schiff bases (MS1-5) were prepared by reacting isatin derivatives with N^2-benzylidenepyridine-2,6-diamine. Structures of resultant compound were confirmed by some analytical techniques data. All synthesized compound were screened for *in vitro* antimicrobial activity by well diffusion methods against *Staphylococcus aureus* (MTCC-3160), *Bacillus subtilis* (MTCC-441), *Escherichia coli* (MTCC-452), *Klebsiella pneumoniae* (MTCC-432), *Candida albicans* (MTCC-183), *Aspergillus niger* (MTCC-282) using ciprofloxacin and fluconazole as standard drugs.

Result: All compounds exhibited significant antibacterial activity as compared to standard. It was discovered that MS2 and MS4 were the most efficient chemicals against all bacterial strains. Against both fungal strains, only MS3 and MS5 exhibited antifungal action. **Conclusion:** All compounds showed antibacterial activity, in which electron withdrawing group substituted Schiff bases of isatin showed significant antibacterial activity against the tested strain of bacteria, while only few compounds were found effective against fungal strain.



R= H,F,Cl,NO $_2$,CH$_3$

[MS 1-5]

Keywords: *Klebsiella pneumonia*, *Aspergillus niger*, Sandmeyer, Isatin.

CDIP/CPCO/072

Impact of new Drugs and Clinical Trials Rules, 2019

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Abstract:

Clinical trials play a vital role in the process of developing new drugs by ensuring their effectiveness and safety. On March 19th 2019, the Indian government rolled out the new Drugs and Clinical Trials Rules, to supersede the provisions outlined in part XA and schedule Y of the drugs and cosmetics rules of 1945. The document is structured into 13 sections comprising 107 regulations and eight schedules. It covers a wide array of aspects including definitions, guidelines for ethics committees, trial procedures, and regulatory requirements. The rules mandate diverse ethics committee membership and streamline processes for registration, renewal, and record-keeping. They also specify timelines for trial approval, conditions for conducting trials, and reporting obligations. Furthermore, the rules introduce provisions for compensation in case of trial-related injuries and outline procedures for conducting bioavailability and bioequivalence studies. Moreover, there are revisions in the fees for various applications required for clinical trials under the new rules. This study aims to shed light on the pivotal changes introduced by these rules, emphasizing their impact on ethical oversight, streamlined processes, and the resulting opportunities for advancing clinical research in the country.

Keywords: Clinical Trials Rules, bioavailability, bioequivalence.

CDIP/CPCO/073

Formulation Development and Evaluation of Multi-Unit Particulate Systems for BCS Class- II Antifungal Drug with Improved Dissolution Profile

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Abstract:

The study aims to investigate innovative formulation strategies to enhance the therapeutic effectiveness of Itraconazole (ITZ), a widely used antifungal medication with poor aqueous solubility and limited bioavailability. The main objective of the study to formulate ITZ-Multiple Unit Particles (MUPs) incorporating weak organic acids (citric acid, succinic acid and tartaric acid) and super disintegrants, and assess their dissolution profiles under simulated physiological conditions. The methods employed include pH-solubility studies to determine the influence of organic acids on ITZ solubility, dissolution studies to evaluate the drug release profiles of formulated MUPs, and physicochemical characterization techniques to ensure the quality and consistency of the ITZ samples. Results indicate that tartaric acid exhibits the most promising effects on enhancing ITZ solubility, particularly in acidic environments, leading to rapid and sustained drug release rates in the formulated MUPs. Conclusion, this study highlights the potential of innovative formulation approaches, such as leveraging organic acids and MUPs, to address the challenges associated with ITZ's poor solubility and variable bioavailability. By enhancing the dissolution profile of ITZ, these formulations offer a promising avenue for improving patient outcomes and optimizing the management of fungal infections.

Keywords: Itraconazole, citric acid, succinic acid and tartaric acid.

CDIP/CPCO/074

Soyabean Nanoemuulgels: Novel Herbal Drug Delivery for Management of Psoriasis

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Abstract:

Ethanolic extract of defatted soya bean seeds (EE-S) with comparable antioxidant activity was considered for the formulation of nanoemulgel. Preliminary screening of excipients for solubility of EE-S in oils, surfactants and co-surfactants and for emulsifyingability of surfactants and co-surfactants and construction of pseudo-ternary phase diagram by water titration method was performed. Nanoemulsions ofEE-S were prepared using oleic acid, Tween 20 and PEG400 as oil, surfactant and co-surfactant and evaluated by physical appearance, PDI, determination of globule size, solubility per gm nanoemulsion and Zeta potential, pH and drug content. Nanoemulgel was prepared by mixing of nanoemulsion to gel base and was characterized for physicochemical properties, *in-vitro* studies, *ex vivo* studies, *in- vivo* studies as per protocol approved by IAEC and stability studies. Stable and effective nanoemulsion and nanoemulgel of EE-S were formulated with improved release and permeation.

Keywords: Nanoemulsion, nanoemulgel, Ethanolic extract, Tween 20.

CDIP/CPCO/075

Regulatory Intelligence and its Importance to Pharmacovigilance System

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Abstract:

The process of obtaining, compiling, and analyzing regulatory data that is readily accessible about pharmacovigilance regulations are known as pharmacovigilance (PV) regulatory intelligence. Its primary objective is to stay current and comply with the most recent Pharmacovigilance regulations put in place by governments and other relevant bodies. Any clinical trial sponsor or holder of a marketing authorization for medicinal products must engage in PV regulatory intelligence. When creating or releasing pharmaceuticals or medical equipment for sale, it assists in guaranteeing adherence to patient and product safety regulations. Owing to constantly evolving laws and regulations, all changes pertaining to safety need to be closely watched and their possible effects on the PV system and safety procedures assessed. The European Medicines Agency (EMA) is the primary regulatory body responsible for overseeing PV throughout the European Union (EU) and issuing local laws and guidelines. The EU member states also have national local legislation requirements in addition to the central requirements from EMA. This holds true for every nation on the planet as well as other regional organizations like the Eurasian Economic Union (EAEU). The installation diagram of a regulatory intelligence tailored to the pharmaceutical business is proposed in this article. It provides details at different phases leading up to the process of global economic intelligence rationing.

Keywords: Pharmacovigilance, Intelligence, regulations, regulatory.

CDIP/CPCO/076

Development and Characterization of Transdermal Patch for Management and Treatment of Mental Illness

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Abstract:

Psychosis is a psychiatric condition that has significant overlap with neurologic disease. This article is intended to educate the neurologist on the psychiatric manifestations of psychosis and its evaluation, diagnosis, and treatment**.** To diagnose patients with psychosis, it is important for clinicians to be able to evaluate and assess the five domains of psychotic illness: delusions, hallucinations, disorganized thinking (speech), grossly disorganized or abnormal motor behavior (including catatonia), and negative symptoms. Oral route is the most preferred route fastens in patient fulfilment; though, oral administration is more prone to hepatic first pass metabolism required higher dose of drug. Hence the non-invasive, non-paining, non-irritating topical delivery of formulation is an alternate technique associated with several advantages such as delivery of drug to specific site of action with reduced systemic toxicity, avoidance of first pass metabolism and gastric irritation, increasing release rate of drug from formulation to get better percutaneous absorption and for a moment topical application related to increase bioavailability with sustained release profile. The primary mode of administering macromolecules is therefore via injection, which is not without limitations, such as the invasive nature of injections eliciting pain and lower acceptance/compliance by patients, in addition to the requirement for administration by a trained administrator, Logically, the conventional routes of medication delivery have many inherent limitations which could potentially be overcome by advanced drug delivery methodologies such as transdermal drug delivery (TDD). We may be improving the therapeutic effect of drugs via approaches as transdermal patch hold on to part of skin. The power of adhesion of patch creates good penetration ability of TDDs by using arrangement of different penetration enhancers.

Keywords: Transdermal, percutaneous, TDD, Catatonia.

CDIP/CPCO/077

A Review on Antibiotic Crisis

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Abstract:

The rapid emergence of resistant bacteria is occurring worldwide, endangering the efficacy of antibiotics, which have transformed medicine and saved millions of lives. Many decades after the first patients were treated with antibiotics, bacterial infections have again become a threat. The antibiotic resistance crisis has been attributed to the overuse and misuse of these medications, as well as a lack of new drug development by the pharmaceutical industry due to reduced economic incentives and challenging regulatory requirements. The Centers for Disease Control and Prevention (CDC) has classified a number of bacteria as presenting urgent, serious, and concerning threats, many of which are already responsible for placing a substantial clinical and financial burden on the U.S. health care system, patients, and their families. Coordinated efforts to implement new policies, renew research efforts, and pursue steps to manage the crisis are greatly needed.

Keywords: Resistant bacteria, antibiotics, pharmaceutical industry, CDC, research efforts.

CDIP/CPCO/078

Revolutionizing Safety: Unveiling Artificial Intelligence Applications in Pharmacovigilance for Adverse Event Detection

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Abstract:

Pharmacovigilance, a pivotal discipline in ensuring drug safety, has witnessed a transformative impact with the integration of artificial intelligence (AI) applications. This comprehensive review explores the multifaceted role of AI in the detection and monitoring of adverse events associated with pharmaceutical interventions. Leveraging machine learning, natural language processing, and data mining, AI facilitates advanced analytics on diverse datasets, including electronic health records, social media, and scientific literature. The automated processing of adverse event reports, real-time social media monitoring, predictive analytics, and causality assessment contribute to a more proactive and efficient pharmacovigilance framework. This review discusses the challenges, considerations, and ethical dimensions of implementing AI in pharmacovigilance, emphasizing the need for continued collaboration between stakeholders to harness the full potential of these technological advancements.

Keywords: Pharmacovigilance, Adverse Event Detection, Artificial Intelligence, Machine Learning, Data Mining

CDIP/CPCO/079

Advancement in the Nanocarriers for Drug Delivery, Biomedical Research and for Diagnostic Purposes.

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Abstract:

Nanotechnology is science and engineering behind the development, synthesis, characterization, and use of materials and devices with the lowest possible functional organization.In the area of pharmaceutical and related sciences, Nano drug delivery systems, also known as nanocarriers (NCs), are Nano engineered biocompatible materials or devices that, when combined with desired bioactive substances, serve an important functional role. The various types of carriers are used most widely nowadays for the diagnostic and treatment purpose of various diseases. With the use of nanotechnology, metal's essential characteristics can be developed and modified to produce new nanoparticles (NPs) with promising applications in the fields of treatments and diagnostics (Nano medicine). Nano particulate system are developed on the basis of their origin, morphology and their beneficial such as liposomes, dendrimers, micelles, polymer based, silica based and carbon based.Currently, a number of diseases and disorders, including cancer, neurodegenerative disorders, chronic lung infections, hypertension, pulmonary tuberculosis, malaria, HIV-AIDS, metabolic disorders, and many more, are treated with targeted drug delivery systems and modified control release tactics with the help of nanotechnology. In the present review, the study was done for the nanocarriers used in the nanotechnology along with recent advancement.

Keywords: Nanocarriers, Diagnosis, Nanotechnology, Targeted drug delivery**.**

CDIP/CPCO/080

Machine learning on adverse drug reactions for pharmacovigilance

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Abstract:

Machine learning, especially deep learning, has the predictive power to predict adverse drug reactions, repurpose drugs and perform precision medicine. We provide a background of machine learning and propose a potential high-performance deep learning framework for its successful applications in these practices. ADR's are an unresolved issue that can result in mortality morbidity and substantial health care cost. Motivated by the drug discovery research studies that have shown that deep learning outperformed machine learning matter over prediction tasks. Monitoring adverse drug events or pharmacovigilance has been promoted by the World Health Organization to assure the safety of medicines through a timely and reliable information exchange regarding drug safety issues. We aim to discuss the application of machine learning methods as well as causal inference paradigms in pharmacovigilance. We first reviewed data sources for pharmacovigilance. Then, we examined traditional causal inference paradigms, their applications in pharmacovigilance, and how machine learning methods and causal inference paradigms were integrated to enhance the performance of traditional causal inference paradigms. Finally, we summarized issues with currently mainstream correlation-based machine learning models and how the machine learning community has tried to address these issues by incorporating causal inference paradigms. Our literature search revealed that most existing data sources and tasks for pharmacovigilance were not designed for causal inference. Additionally, pharmacovigilance was lagging in adopting machine learning-causal inference integrated models. We highlight several currently trending directions or gaps to integrate causal inference with machine learning in pharmacovigilance research. Finally, our literature search revealed that the adoption of causal paradigms can mitigate known issues with machine learning models.

Keywords: Machine learning,Adverse Drug Reactions (ADR), Mortality, Morbidit

CDIP/CPCO/081

Data Analytics Can Enhance Clinical and Pharmacovigilance

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Abstract:

Exploring advancements in technology, data analytics, can enhance clinical and pharmacovigilance efforts. Streamlining data collection, improving signal detection for adverse events, and ensuring timely reporting are key areas where new opportunities can arise. Integrating real-world evidence and harnessing big data can contribute to more efficient and comprehensive pharmacovigilance practices.Data analytics plays a crucial role in vigilance by analyzing patterns, anomalies, and trends in large datasets. It helps identify irregularities, potential risks, and suspicious activities, enhancing the ability to detect and prevent fraudulent or unethical behavior.In clinical settings, data analytics is vital for extracting meaningful insights from healthcare data. It helps in improving patient outcomes, optimizing resource allocation, and enhancing decision-making for medical professionals. Applications include predictive modeling, personalized medicine, and population health management.

Keywords: Clinical, Pharmacovigilance, Data.

CDIP/CPCO/082

Artificial Intelligence (AI) Can Enhance Pharmacovigilance through Advanced Surveillance in Several Ways

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Abstract:

AI systems can analyze diverse data sources, such as electronic health records and social media, for early signs of potential adverse reactions, enabling quicker responses. AI algorithms can sift through extensive datasets to uncover hidden relationships between drugs and adverse events, facilitating more comprehensive Pharmacovigilance.AI can enhance signal detection by automatically recognizing patterns that may indicate potential safety concerns, contributing to proactive risk management.AI can automate repetitive tasks like data entry and report generation, allowing Pharmacovigilance professionals to focus on more complex analyses and decision-making.NLP enables the analysis of unstructured data, such as medical literature and patient narratives, improving the accuracy of adverse event detection.AI models can predict potential safety issues based on historical data, enabling preventive measures and optimizing resource allocation for monitoring high-risk drugs.Developing machine learning models can improve the accuracy of risk assessment and provide more personalized insights into patient safety.By leveraging these capabilities, AI enhances Pharmacovigilance by providing a more efficient and proactive approach to monitoring drug safety, ultimately improving patient outcomes.

Keyword: Artificial intelligence (AI), Pharmacovigilance, Data.

CDIP/CPCO/083

New Era of Clinical and Pharmacovigilance: A Future Challenges and Opportunities (An overview)

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Abstract:

Twenty years ago, there were almost no Pharmacovigilance (PV) activities in low-and middle-income countries (LMIC). Today, 144 countries are participating in the WHO Programme for International Drug Monitoring, and 102 of them belong to the LMIC category according to the World Bank classification. Many factors have contributed to the positive development. Among them are: - Creation of evidence of the general burden of drug-related harm in all populations. Concerns of the high prevalence of substandard and fake medicines in LMIC - Capacity building and competence development in PV, mainly driven by the WHO Programme. Public health programs realizing that drug-related harm may jeopardize program success. Global health initiatives and donor organizations prepared to protect public health programs also by supporting Pharmacovigilance. Most of the national Pharmacovigilance systems in LMIC still have inadequate capacity to adequately protect their populations from the risk of medicine and medicine use–related harm. There are many challenges that need to be addressed; for example: - The capacity of National Regulatory Authorities and collaboration and integration with vertical disease programs. Training of health workers, local industry, and the public about the need to record and report medicine-related harm. Keeping of systematic patient records. Documentation of the burden of medicine-related harm in the local setting in most LMICs, the first requisite for PV activities, the political will, is in place. Further support for the young PV systems is needed to make them fully functional. The WHO Programme builds regional and global networks to support PV in LMIC particularly

Keywords: LMIC, National Regulatory Authorities, Pharmacovigilance.

CDIP/CPCO/084

Applications of Artificial Intelligence in Pharmacovigilance

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Abstract:

Pharmacovigilance (PV) is seeing an increasing amount of the extremely interdisciplinary science of artificial intelligence (AI). Gaining a deeper comprehension of the artificial intelligence in pharmacovigilance (AIPV) field could prove beneficial in precisely identifying terms, procedures, assignments, and datasets that fall under the purview of AIPV use. Artificial intelligence (AI) solutions hold great promise for improving pharmacovigilance efforts. Although they don't have to be AI experts, pharmacovigilance specialists should be knowledgeable enough to consider working with people who are. Alan Turing's work from the late 1940s and early 1950s, particularly his paper on "the imitation game," is credited with helping to shape modern conceptions of AI. It is possible to design machines to learn by employing neural networks that imitate human cognitive processes. Human brain, leading to deep structural learning. Limitations of AI include difficulties with language, arising from the need to understand context and interpret ambiguities, which particularly affect translation, and inadequacies of databases, requiring careful preparation and curation. New techniques may cause unforeseen difficulties via unexpected malfunctioning. Relevant terms and concepts include different types of machine learning, neural networks, natural language programming, ontology's, and expert systems. Adoption of the tools of AI in pharmacovigilance has been slow. Machine learning, in conjunction with natural language processing and data mining, to study adverse drug reactions in databases such as those found in electronic health records, claims databases, and social media, has the potential to enhance the characterization of known adverse effects and reactions and detect new signals. As a result, this article provides a possible working description of the scope of AIPV and examines pertinent issues to take into account when defining it.

Key words: Pharmacovigilance, conception, artificial intelligence, ontology.

CDIP/CPCO/085

Emergence of Artificial Intelligence In Healthcare: A Promising Future with Challenges

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Abstract:

Artificial intelligence (AI) is a powerful and disruptive area of computer science, with the potential to fundamentally transform the practice of medicine and delivery of healthcare. The complexity and rise of data in healthcare means that artificial intelligence (AI) will increasingly be applied within the field. Several types of AI are already being employed by pairs and providers of care and life science companies. These transformative technology promises to revolutionize healthcare, starting with early disease detection and accurate diagnosis. The key categories of applications involve diagnosis & treatment recommendation, patient engagement and adherence, and administrative activities. AI tools include cancer, neurology & cardiology. This maximizes treatment efficacy, minimizes adverse reactions, and improves patient's well being. Although there are many instances in which AI can perform healthcare tasks as well or better than humans, implementation factors well prevent large scale automation of healthcare professional jobs for a considerable period. In this review article, we outline recent breakthroughs in the application of AI in healthcare.

Keywords: Artificial Intelligence, Healthcare, Diagnosis, AI tools.

CDIP/CPCO/086

Pharmacovigilance- Today's Need for Better Tomorrow

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Abstract:

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is indeed crucial for ensuring the safety and efficacy of medications. Today, as advancements in medicine continue to accelerate and new drugs are developed at a rapid pace, the need for robust pharmacovigilance practices has become more pronounced than ever before. Here's why pharmacovigilance is essential for a better tomorrow: Safety Monitoring: Pharmacovigilance ensures continuous monitoring of the safety profile of medications throughout their lifecycle. With new drugs constantly entering the market, it's vital to promptly identify and address any adverse effects or safety concerns that may arise. Early Detection of Risks: By systematically collecting and analyzing data on adverse drug reactions, pharmacovigilance helps in the early detection of potential risks associated with medications. This enables regulatory agencies, healthcare professionals, and pharmaceutical companies to take timely action to mitigate these risks and prevent harm to patients. Improving Drug Labeling and Guidelines: Pharmacovigilance data often contribute to updates in drug labeling, warnings, and guidelines, providing healthcare professionals and patients with the latest information on the safe and appropriate use of medications. Enhancing Public Health: By promoting the safe and effective use of medications, pharmacovigilance plays a critical role in protecting public health. It helps prevent adverse events, reduces the burden on healthcare systems, and fosters public confidence in the healthcare system. Facilitating Drug Development: Pharmacovigilance data contribute to our understanding of drug safety and efficacy, guiding the development of new medications and therapeutic strategies. By identifying common adverse effects and risk factors, pharmacovigilance helps researchers design safer and more effective drugs.

Keywords: Safety, PvPi, Risk, Assessment, Clinical Research.

CDIP/CPCO/087

Importance of Effective Communication in Pharmacovigilance for Early Detection and Assessment of ADR

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Abstract:

Under reporting (UR) of adverse drug reactions (ADRs) is widespread and a daunting challenge in pharmacovigilance (PV). This is because primarily most countries, including India follow the spontaneous or voluntary system of ADR reporting. There are patient-related reasons for UR like failure to recognize ADR or inability to link the ADR with a drug. According to reports, the annual number of patients dying from pharmacological side effects climbed by up to 2.6 times. Furthermore, a growing number of individuals are being admitted to hospitals as a result of medication side effects. As a result, doctors, healthcare organizations, the World Health Organization, and the pharmaceutical industry find it difficult to address the related issue of ADRs. The main concern of pharmacovigilance is evaluating the risk vs. benefit drug profile for increased potency and increased safety while using different medications in individuals with different conditions. In the healthcare industry, pharmacovigilance—the practice of compiling data and sharing reports on a range of adverse medication reactions among different users—is essential to the responsible use of pharmaceuticals in society. This review's objective is to highlight the need of effective communication for early detection of adverse reactions and to prevent them from occurring in future which will protect patients from experiencing serious long term consequences of ADR.

Keywords: Pharmacovigilance, Adverse Drug Reaction.

CDIP/CPCO/088

Nucleic acid & peptide-based therapeutics for Parkinson's disease

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Abstract:

Parkinson's disease (PD) is a neurodegenerative disorder characterized by the progressive loss of dopaminergic neurons in the substantia nigra, leading to motor impairments and cognitive dysfunction. Ongoing treatments for PD primarily aim at alleviating symptoms rather than targeting the underlying causes of neurodegeneration. However, emerging therapeutic strategies utilizing nucleic acids and peptides offer promising avenues for disease modification and neuroprotection. Nucleic acid-based therapeutics, including antisense oligonucleotides (ASOs), small interfering RNAs (siRNAs), and gene editing tools like CRISPR-Cas9,can silence the alpha-synuclein,LRRK2, Parkin, and other genes, that are key culprit in Parkinson's.n Additionally, nucleic acids can also be used to deliver genes encoding dopamine biosynthetic enzymes, enhancing dopamine production in the brain. Peptides, short chains of amino acids, can directly target alpha-synuclein aggregates, preventing their formation and toxicity. They can also act as carriers for delivering nucleic acids across the blood-brain barrier, ensuring the therapeutic effect reaches the target neurons. Both these approaches hold immense promise due to their high target specificity and potential for disease modification. However, challenges like efficient delivery to the brain and potential off-target effects need to be addressed. Nevertheless, ongoing research in nucleic acid and peptide-based therapies offers a glimmer of hope for Parkinson's patients.

Keywords: Parkinson's disease, Nucleic acid, Peptides

CDIP/CPCO/089

Leveraging Industry 4.0 Technology For Enhanced Pharmacovigilance: A Collaborative Approach

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Abstract:

The pharmaceutical industry is undergoing a transformation driven by Industry 4.0 technologies, offering unprecedented opportunities to enhance pharmacovigilance practices. This paper explores the potential of leveraging Industry 4.0 technologies to improve pharmacovigilance through a collaborative approach. Industry 4.0 technologies such as artificial intelligence, big data analytics, Internet of Things (IoT), and blockchain have the capability to revolutionize pharmacovigilance by enabling real-time monitoring, early detection of adverse drug reactions, and enhanced risk management. This collaborative approach involves partnerships between pharmaceutical companies, regulatory agencies, healthcare providers, and technology vendors to harness the full potential of Industry 4.0 technologies in pharmacovigilance. Key considerations for successful implementation, including data privacy, interoperability, and regulatory compliance, are discussed. By embracing a collaborative approach and leveraging Industry 4.0 technologies, stakeholders can enhance pharmacovigilance practices, ultimately leading to improved patient safety and healthcare outcomes.

Keywords: Industry 4.0, Pharmacovigilance, IoT, Big data Analytics, Real-time monitoring.

CDIP/CPCO/090

Development of Fast-Acting Tablets of Clozapine by Liquisolid Technique Using a New Carrier Material

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Abstract:

The atypical antipsychotic medication clozapine is well-known for its effectiveness in treating schizophrenia; yet, because of its poor solubility in water, it acts slowly at first. The purpose of this work was to create Clozapine fast-acting tablets by employing a new carrier material and the cutting-edge liquisolid technology. In order to find viable carrier materials with advantageous qualities for improving medication solubility and bioavailability, a thorough literature research was carried out. Excellent flowability, compressibility, and compatibility with the medication and the liquid vehicle were displayed by the chosen carrier material. Clozapine was dissolved in an appropriate liquid medium to create a liquid medicine. Subsequently, the liquid medication was mixed with the selected powder blend of carrier material and suitable excipients, including coating material, powder flow enhancer, and disintegrant. The resulting liquisolid powder blend's compressibility, flow ability, and other important characteristics were assessed. The liquid-solid powder mixture was then crushed into tablets with the appropriate tableting apparatus. The tablets underwent a thorough examination that included an assessment of the amount of clozapine, as well as measurements of hardness, friability, and stability under both short-term and long-term settings. The suggested fast-acting Clozapine tablets demonstrated positive results in terms of improved dissolving rate and greater bioavailability when compared to existing formulations. The liquisolid technique can be inventively utilized with the new carrier material to maximize the therapeutic effects of clozapine therapy, particularly with regard to a faster onset of action and improved patient compliance. Further formulation process optimization and scale-up are required in order to eventually put the created product into clinical practice and market it.

Keyword: Clozapine, liquisolid technique, solubility, fast-acting

CDIP/CPCO/091

Paripluta Yonivyapad (Pelvic Inflammatory Disease) An Ayurvedic Approach

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Abstract:

Yonivyapad comprises around 70% of gynaecological problems and commonly encountered in the practice of Gynaecology. Among them some are causing painful coitus, dysmenorrhoea etc., and Paripluta is one among them. Pelvic Inflammatory Disease (PID) is a condition that primarily affects the female reproductive organs, including the uterus, ovaries, fallopian tubes, and cervix. It is often caused by bacterial infections, most commonly sexually transmitted infections (STIs) such as chlamydia and gonorrhea. While modern medical treatments for PID typically involve antibiotics to clear the infection, Ayurveda, the traditional system of medicine from India, offers holistic approaches to support overall health and address the underlying imbalances contributing to PID. Here is an Ayurvedic approach to managing PID.

Keyword: Paripluta, Yoni Vyapads, Pelvic.

CDIP/CPCO/092

Berberine Chloride Loaded Chitosan/ Polyvinylpyrrolidone Hydrogels for Dermal Wound Healing

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Abstract:

Aim: Treatment of skin ulcers has become a vital need of today as it becomes extremely painful and life threatening. The aim of current research is to synthesize and fabricate vanillin crosslinked CH/PVP hydrogels loaded with berberine chloride for wound healing applications.

Methods: Berberine loaded CH/PVP hydrogels were synthesized via vanillin (5%,10%, 15%) as crosslinking agent. The hydrogels were evaluated via *in-vitro* antimicrobial, antioxidants, and in-inflammatory properties. Hydrogels were further characterized by FTIR, SEM, TGA, XRD, ESR, degradation, and hemocompatibility study. It was further characterized for its *in vitro* drug release, cell viability, and *in vivo* wound healing activity. **Results:** CH/PVP hydrogel films were successfully synthesized *via* formation of hydrogen bond from the hydroxyl and amino group of CH, and the carbonyl group of PVP. The IR spectral peaks of CH (3446.2 cm^{-1}; stretching vibrations of the –O-H, –N-H groups, 2890.7 cm^{-1}; C-H symmetric stretch), PVP (1650 cm^{-1}; stretching vibration of C=O group, 1268 cm^{-1} and 1168 cm^{1}; stretching vibration of C-N) and BER (1601cm^{-1}, 2170cm^{-1}) maintain their place in CH/PVP and CH/PVP@BER hydrogels. The morphological images of hydrogels exhibited inter-connecting porous structure. Further, on increasing vanillin by 5-10 folds, swelling and degradation rate of the hydrogel decreases. Percentage haemolysis was found to be less than 2% that demonstrate its non-toxic nature. *In vitro* drug release studies demonstrate the extended release up to 24 hours on increasing vanillin concentration. **Conclusion:** The overall results suggest that the synthesized CH/PVP@BER hydrogel is an ideal dressing for wound healing and tissue engineering applications.

Keywords: Berberine, hemocompatibility, haemolysis.

CDIP/CPCO/093

Exploring Novel Strategies: Piperidine Carboxamide Derivatives Targeting ALK and ROS1 Kinases for Lung Cancer Therapy

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Abstract:

The emergence of crizotinib as a potent therapy for non-small-cell lung cancer has underscored the significance of ALK and ROS1 kinases as viable therapeutic targets. This review article explores the recent advancements in small molecule development targeting these kinases, particularly focusing on the utilization of piperidine carboxamide derivatives as novel inhibitors. Through comprehensive high-throughput screening, piperidine carboxamide 1 was identified as a promising inhibitor demonstrating potency against ALK and ROS1 with notable selectivity over IGF1R. Further structural analysis and molecular modeling led to the synthesis of 2-amino-4-(1-piperidine) pyridine derivatives, notably compound 2e, which exhibited enhanced inhibitory activity against both wild-type and mutant forms of ALK and ROS1. While piperidine carboxamide displayed selectivity towards ALK, compound 2e emerged as a versatile therapeutic candidate with potent inhibitory effects against both ALK and ROS1. The structural modifications in compound 2e highlight its potential for further development as a therapeutic agent for cancers associated with ALK and ROS1 dysregulation. Overall, this review illuminates the promising pathway for the development of dual-inhibitor compounds targeting ALK and ROS1, with compound 2e demonstrating notable potential for clinical translation.

Keywords: ALK, IGF1R, ROS1, Piperidine Carboxamide.

CDIP/CPCO/094

Chitosan Decorated Double Layered Paclitaxel Nanoparticles for Colon Targeted Cancer Therapy

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Abstract:

Aim: Herein, to achieve an effective delivery system specifically targeting the colon, we have designed paclitaxel (PTX)-loaded colon targeted double layered nanoparticles via chitosan decorated hyaluronic acid-inulin (HA-IN) nanoparticles.

Methods: The nanoparticles were synthesized via copolymer synthesis of HA/IN in the first step followed by coating of chitosan on the above synthesized nanoparticles. The synthesized nanoparticles were characterized via particle size, zeta potential, ^{1}HNMR, FTIR, TEM, pXRD, TGA/DSC, stability studies at different pH conditions followed by drug release (pH 1.2, 6.8 and 7.4) and release kinetics studies in the presence and absence of rat faecal. **Results:** The particle size and zeta potential of prepared nanoparticles was found to be in the range of 200-250 nm and ± 20 mV with a narrow PDI of 0.148 ± 0.004, respectively. The FTIR spectra of chitosan show absorption peak 1174cm^{-1} (NH_2), HA stretching vibration at 1739.1 cm^{-1} (COOH). HA-IN copolymer absorption peaks 1738.1cm^{-1}. Stability studies at different pH medium indicate no change in particle size and zeta potential even after storage for a period. Surface morphology via TEM indicated presence of spherical nanoparticles with a size range of 100-200 nm. TGA/DSC data indicates thermal stability as we increase the temperature from 25 to 700 ^{o}C. Hemocompatibility was found to be less than 5% confirms its non-toxic potential in comparison to positive control. The drug release study confirms the controlled release of PTX for a period of 24 h (~95%).

Conclusion: The results provide evidence of possible therapeutic effect of CH/HA-IN@PTX for colon cancer treatment.

Keywords: Hemocompatibility, ^{1}HNMR, FTIR, TEM, pXRD, TGA/DSC.

CDIP/CPCO/095

5-FU Loaded CH/HA Conjugated MWCNTS for Colon Targeted Drug Delivery

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Abstract:

Aim: The aim of current research is to load 5-FU in a CH/HA surface functionalized multiwalled carbon nanotubes for colon targeted cancer.

Methods: The multiwalled carbon nanotubes were functionalised via Piranha treatment to introduce carboxylic acid group. Further, CH was introduced in the functionalised MWCNTs bonding between amine and carboxyl group of CH and MWCNTs, respectively. Finally, the HA is linked to CH. The prepared MWCNTs were characterised via $_1$HNMR, Raman spectroscopy, particle size, zeta potential, morphology using TEM, TGA/DSC, SEM, pXRD and *in vitro* drug release and kinetics studies.

Results: The initial confirmation of carboxylic acid functionalization was confirmed via Raman spectra followed by COOH peaks in FTIR spectroscopy. Further FTIR spectra show the presence of 5-FU peaks in 5-FU loaded CH/HA/MWCNTs@5-FU. TGA/DSC studies confirms the thermal stability of synthesized nanotube in the range of 25 to 700 °C. TEM images confirms the cylindrical shape of nanotubes with a size range of 100-200 nm. pXRD reveals the presence of different crystal lattice structure in the obtained spectra. The hemocompatibility of synthesized MWCNTs was found to be less than 5% indicating its nontoxic behavior. The colonic pH (7.4) favours the drug release in the presence and absence of rat faecal for more than 24 hours.

Conclusion: The prepared Chitosan/Hyaluronic acid decorated functionalised MWCNTs loaded with 5-FU to enhance anti-cancer activity against colorectal cancer. The cellular toxicity, in-vitro and hemocompatibility outcomes were evident that the prepared CH/HA/MWCNTs-5FU have spectacular anticancer activity against CD44 cells.

Keywords: TEM, TGA/DSC, SEM, pXRD, hemocompatibility.

CDIP/CPCO/096

Self-Healing Lignin/Pluronic F127/Epicatechin Based Thermoresponsive Gels For Dermal Wound Healing

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Abstract:

Aim: The aim of current study is to synthesize self-healing thermoresponsive nanogels of lignin/Pluronic F127 loaded with epicatechin for wound healing applications.

Methods: In this study Self-healing thermoresponsive Lig/PF127 nanogels loaded with EpC (epicatechin) were developed by cold process method to treat chronic wounds. The synthesized hydrogels were evaluated via TGA, FTIR, FESEM, pXRD, rheological studies followed by in vitro swelling, degradation, drug release, release kinetic and hemocompatibility studies.

Results: Lig/PF127@EpC base self-healing hydrogels have been successfully synthesized via cold process. Major infra-red spectral peaks of sulphonate lignin at (1514 and 1726 cm-1 aromatic structural vibrations,1730 cm-1 stretching vibration of C=C in alkenes groups, 1098cm-1 sulfonate group) and PF127 (2878 cm-1 C–H stretching vibrations, 1472 cm-1 O–H bend, and 1090 cm-1C–O stretching vibrations) maintain their place in Lig/PF127 and Lig/PF127@EpC nanogels. At (1:1) content of both Lig and PF127, the ESR increases by 155.73% (pH 6.5). On the other hand, *in vitro* degradation shows ~97 % of degradation as we increase the concentration of lignin up to 100%. The nanogel was assessed by *in vitro* EpC release, antibacterial activity, cytotoxicity, and wound-healing activity. The Lig/PF127 @EpC nanogel demonstrated thermal responsiveness and biocompatibility, and it showed sustained EpC release (93%) in 72 h. The hemocompatibility study revealed that Lig/PF127 @EpC gel and Lig/PF127 gel value were 0.77 % and 0.75 %, that was <5% that show both are hemocompatible.

Conclusion: Thus, the newly developed self-healing nanogels were found to be promising approach to tackles with the issue related to chronic wound healing.

Keywords: Hemocompatibility, Thermoresponsive, Hemocompatible, pXRD.

CDIP/CPCO/097

Lignin coated silver nanoparticles based chitosan/polyvinylpyrrolidone nano-composite hydrogel for infected wounds

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Abstract

Aim: The current research investigates the development of ultra-thin, quickly dissolving films loaded with AgNPs for infected wounds.

Methods: CH/PVP@Ln-AgNps hydrogel films were synthesized via amino-propyl-tri-ethoxy silane crosslinking, casting, and drying technique. The formation of AgNPs and CH/PVP hydrogels was confirmed by UV spectroscopy, morphology, particle size, stability, equilibrium swelling ratio, and in-vitro drug release kinetics.

Results: The particle size of AgNPs was found to be in the range of 18-41 nm (at 25°C) with an intense peak at 423 nm. The zeta potential of AgNPs was found to be in the range from -27.5 to 6.99 mV with a polydispersity index (PDI) of 0.464. The degradation profile of CH/PVP@Ln-AgNps (0.3, 0.6 and 0.9 % v/v) silane is based on the increasing concentration of silane (93, 86 and 80 %), respectively. The results of hemocompatibility study of blank hydrogel and silver loaded hydrogels are found to be 0.89% and 0.74%, respectively. The SEM studies confirms the presence of interconnecting 3D network of polymeric materials. On the other hand, drug release studies shows %CR for up to 95% in 24 hours.

Conclusion: Therefore, the new technology hydrogels may prove to be an appropriate dressing material for applications including wound healing.

Keywords: AgNPs, Hemocompatibility, Wound healing.

CDIP/CPCO/098

A Review on: Probiotics as the Functional Food Components for Human Health

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Abstract:

Nowadays, food is no longer just for nutrition. Consumers are more demanding and expect to get health benefits from their daily meals. Various areas of the food industry are in great demand of functional chemicals to enhance the taste and nutritional value of their products. Probiotic bacteria have already been part of the human's routine for good gut microbiota maintenance in terms of pharmaceutical products. Probiotics are live microorganisms that, when consumed in adequate amounts, offer health benefits to the host. They are often referred to as "good" or "friendly" bacteria because of their positive effects on the digestive system and overall well-being. Combination of milk and cereal can provide better nutrition to mankind with higher growth of the probiotic organism. Composite probiotic products may lead to product diversification with improved nutrition at a lower cost. However, the sensory acceptability of these types of food products remains to be a major problem. Further, Probiotic composite dairy products are not systematically evaluated for their health beneficial properties in animal and human model. Systematic and in-depth study is required in this field.

Keywords: Probiotic, functional foods, gut microbiota.

CDIP/CPCO/099

Pharmacovigilance- Challenges and Opportunity

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Abstract:

According to WHO, Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, faces several challenges and opportunities in the modern healthcare landscape. Globalization of Drug Development: With drug development becoming increasingly globalized, pharmacovigilance systems must adapt to varying regulatory standards, data collection methodologies, and cultural factors across different regions. Despite efforts to encourage reporting, underreporting of adverse drug reactions (ADRs) by healthcare professionals and patients remains a significant challenge, leading to incomplete safety profiles of drugs. Data Quality and Standardization: Variability in data quality, terminology, and standards across different databases and healthcare systems hampers the interoperability and effectiveness of pharmacovigilance efforts. Regulatory Compliance: Meeting evolving regulatory requirements and ensuring compliance with regulations such as GDPR (General Data Protection Regulation) and HIPAA (Health Insurance Portability and Accountability Act) adds complexity to pharmacovigilance activities.

Opportunities: Advanced Analytical Techniques: Integration of artificial intelligence, machine learning, and natural language processing enables more efficient signal detection, data mining, and predictive analytics in pharmacovigilance. Real-World Evidence (RWE): Leveraging real-world data from electronic health records, claims databases, and observational studies provides valuable insights into drug safety profiles and supports regulatory decision-making. Collaborative Networks: Building collaborative networks among stakeholders including regulators, pharmaceutical companies, healthcare providers, and academic institutions fosters knowledge sharing, harmonization of standards, and best practices in pharmacovigilance.

Keywords: Pv, Safety, Risk, Assessment, Challenges, Opportunity.

CDIP/CPCO/100

Pharmacovigilance- An overview on Indian Scenario

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Abstract:

In India, pharmacovigilance has gained increasing attention and importance in recent years due to the growing pharmaceutical industry, expanding healthcare infrastructure, and regulatory advancements. An overview of the Indian scenario of pharmacovigilance: Activities and Initiatives: PvPI is responsible for the collection, monitoring, and analysis of adverse drug reactions (ADRs) across India. It comprises various Adverse Drug Reaction Monitoring Centers (AMCs) located in medical colleges, hospitals, and other healthcare institutions across the country. PvPI encourages healthcare professionals and consumers to report ADRs through the use of standardized reporting forms, online reporting portals, and mobile applications. The program conducts training sessions, workshops, and awareness campaigns to educate healthcare professionals, patients, and the public about the importance of pharmacovigilance. Limited resources and infrastructure in some regions hinder the effective implementation of pharmacovigilance activities. Regulatory capacity building and coordination among stakeholders are essential for strengthening pharmacovigilance systems and ensuring timely regulatory action. Opportunities in India- The increasing adoption of digital technologies and mobile health solutions presents opportunities for enhancing ADR reporting and pharmacovigilance surveillance. Collaborative efforts between the government, pharmaceutical industry, healthcare professionals, and academic institutions can strengthen pharmacovigilance infrastructure and promote knowledge sharing. Integration of pharmacovigilance into medical and pharmacy curricula can improve healthcare professionals' understanding of ADR reporting and surveillance. Continuous evaluation and refinement of pharmacovigilance processes and systems are essential for addressing emerging challenges and optimizing patient safety.

Keywords: PvPi, CDSCO, IPC, Data, AMCs.

CDIP/CPCO/101

Safeguarding Health: The Vital Role of Pharmacovigilance

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Abstract:

Pharmacovigilance, a cornerstone of modern healthcare, is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a critical role in ensuring patient safety and enhancing public health outcomes by monitoring the safety profile of medicinal products throughout their lifecycle. Pharmacovigilance is indispensable for maintaining the safety and efficacy of medicinal products in clinical practice. By fostering a culture of transparency, collaboration, and continuous improvement, we can maximize the benefits of pharmacotherapy while minimizing the risks, ultimately advancing patient care and public health worldwide. Pharmacovigilance stands as an indispensable pillar in contemporary healthcare systems, tasked with the crucial responsibility of monitoring, detecting, and mitigating adverse effects associated with medicinal products. This review delves into the fundamental importance of pharmacovigilance in safeguarding patient health and promoting drug safety. Through a comprehensive exploration of its key components and significance, the review highlights the essential role pharmacovigilance plays in ensuring patient safety and enhancing public health outcomes. By analyzing challenges and proposing future directions, it underscores the ongoing efforts to strengthen pharmacovigilance practices globally. This article serves as a concise yet comprehensive overview of the vital role pharmacovigilance plays in maintaining the safety and efficacy of medicinal products, thereby contributing to improved patient care and public health.

Keywords: Pharmacovigilance, Safety and Efficacy, Public Health, Challenge and Future Directions.

CDIP/CPCO/102

Optimization of Process Variables for the Development of Chitosan Coated Terbinafine HCL Loaded Ethosomes By Using QBD Approach

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Abstract:

There is wide attention to using nanotechnology-based carriers to effectively deliver drugs through the skin. Chitosan and ethosomes nanocarriers have recently gained increased attention due to their valuable biopharmaceutical properties. Chitosan, a cationic polysaccharide, is biodegradable, biocompatible, and bioadhesive, while ethosomes are novel lipid carriers composed of ethanol, phospholipids, and water. Formulations were optimized by varying concentrations of phospholipid, tween80, and ethanol by using the Design of Experiment version 13 (DoE). It is a systematic, efficient method that studies the relationship between multiple input variables (factors) and critical output variables (responses). It is a structured approach for collecting data and making discoveries. The Terbinafine HCl-loaded ethosomes were prepared and optimized based on three factors, i.e., the ratio of Soya lecithin, Ethanol, and Tween 80. The software predicted that the proposed formulation would achieve a particle size of 166.4 nm with desirability of 0.801. The optimized ethosomes showed increased topical delivery for a drug (Terbinafine HCl) with poor aqueous solubility. Ethosome preparation employing the Box-Behnken Design was a suitable and sound method for obtaining stable ethosomes formulation. In conclusion, ethosomes could be an effective formulation with improved topical delivery for anti-fungal activity against *C. Albicans*. Ethosomes are made up of ingredients generally recognized as safe (GRAS) status. Ethosomes contain phospholipids, water, and a high percentage of ethanol. The evaluation of skin tolerability and safety of topical ethosomes to intact and wounded, infected, and damaged skin is very important. In the *In-vitro* and *In-vivo* studies, the safety of topical application of ethosomes was investigated.

Keywords: Terbinafine HCl, Ethosomes, Design of Experiment, Box-Behnken Design, Antifungal activity, Optimization of Ethosomes.

CDIP/CPCO/103

Molecular Docking Studies of Sulpha Drug Analogs As Antimalarial Agents

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Abstract:

Objective: The aim of this work is to carry out docking studies of sulpha drug analogs as antimalarial agents. Method: In-silico studies using docking methodology were performed. The compounds were sketched and energy minimized using Chem draw ultra 8.0 and Chem 3D ultra 8.0 respectively. Further, the compounds were docked into Plasmodium falciparum Cysteine protease falcipain-2 using Molegro Virtual Docker 6.0. Thirty seven compounds along with standard drug chloroquine were docked into the active site of Pf-cysteine protease falcipain-2 and all of them found to have similar binding interactions of a co-crystalized ligand. Result: The compounds were showed good docking score like moldock score and re-rank score. The finding of docking studies shows a typical molecular interaction pattern with cysteine protease falcipain-2. The binding interaction information derived from these molecules will be useful in future antimalarial agent design. Conclusion: From the docking study, it was observed that ligands bind to the electrostatic, hydrophobic clamp formed by different amino acid residues which play an important role for Plasmodium falciparum inhibition. The binding affinity, grid calculation and RMSD percentage lower and upper parameters were calculated. Hence, the observable data indicated that, docked compounds can serve as good leads for further modification and optimization in the of treatment malaria.

Keywords: Molegro Virtual Docker, Moldock, Falcipain-2, Chloroquine.

CDIP/CPCO/104

GPR119: Therapeutic Target for Antidiabetic Action

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Abstract:

Type 2 diabetes mellitus (T2DM) represents a significant global health burden, necessitating the development of innovative therapeutic strategies. GPR119, a G protein-coupled receptor expressed in pancreatic β-cells and intestinal enteroendocrine cells, has emerged as a promising target for T2DM management due to its role in regulating glucose metabolism and insulin secretion. In this study, we report the design, synthesis, and biological evaluation of a novel series of GPR119 agonists aimed at modulating GPR119 activity for potential therapeutic interventions in T2DM. Using a rational drug design approach, a diverse library of compounds was synthesized, guided by structural insights into the GPR119 receptor. These compounds will bescientifically evaluated for their agonistic activity towards GPR119 using *in vitro* assays, together with binding affinity assays and functional assays measuring intracellular cAMP accumulation and insulin secretion. Structure-activity relationship (SAR) studies were conducted to explain key molecular determinants influencing GPR119 agonist activity. Our findings revealed several lead compounds with potent and selective agonistic activity towards GPR119, demonstrating promising therapeutic potential for T2DM management. Overall, the identification of this novel series of GPR119 agonists represents a significant step forward in the quest for innovative therapies for T2DM and highlights the therapeutic promise of targeting GPR119 in diabetes management. Further preclinical and clinical studies are necessary to validate the efficacy and safety of these compounds and to elucidate their potential as valuable additions to the battery of T2DM therapeutics.

Keywords: GPR119, T2DM, cAMP, Enteroendocrine.

CDIP/CPCO/105

New Era of Clinical and Pharmacovigilance: Challenges and Opportunities of Clinical and Pharmacovigilance

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Abstract:

The new era of clinical and pharmacovigilance involves advancements in technology, data analytics, and regulatory frameworks to enhance drug safety and effectiveness. It includes the use of real-world evidence, artificial intelligence, and machine learning for drug surveillance, adverse event monitoring, and risk assessment. Additionally, there's a focus on patient-centered approaches, personalized medicine, and proactive risk management strategies. Challenges in clinical and pharmacovigilance includes: Data Quality: Ensuring the accuracy and completeness of data collected from various sources can be challenging. Regulatory Compliance: Keeping up with evolving regulatory requirements across different regions and jurisdictions. Signal Detection: Identifying potential safety signals amidst large volumes of data can be complex. Patient Engagement: Encouraging patients to report adverse events and actively participate in pharmacovigilance efforts. Resource Constraints: Limited resources and funding for pharmacovigilance activities can hinder effectiveness. Opportunities in clinical and pharmacovigilance include: Advanced Technologies: Leveraging artificial intelligence, machine learning, and data analytics to improve signal detection and risk assessment. Real-World Evidence: Utilizing real-world data to supplement clinical trial findings and provide insights into drug safety and effectiveness in diverse patient populations. Collaboration: Partnering with stakeholders across the healthcare ecosystem to enhance pharmacovigilance efforts and share best practices. Patient-Centric Approaches: Empowering patients to actively participate in pharmacovigilance activities and incorporating patient perspectives into drug safety assessments. Personalized Medicine: Tailoring pharmacovigilance strategies to account for individual patient characteristics and genetic factors, leading to more precise risk management.

Keywords: Clinical, Pharmacovigilance, data analytics, artificial intelligence, machine learning.

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