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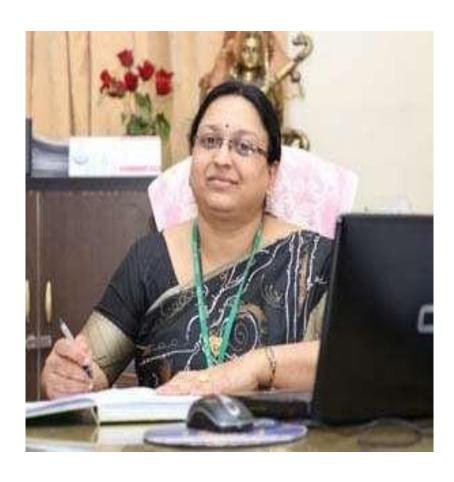


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(B. Pharm, Third Year)
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#### Messages from the desk of the Editor



It gives us immense joy and satisfaction to introduce the second issue of 2024 of the magazine 'Pharma Innovations'. I hope you will enjoy reading the magazine which will be beneficial to enrich your knowledge in Pharmacy, medicines, and health. As always this issue is also an attempt to bring out the knowledge concealed within the students and faculty. Before looking ahead, however, I would like to offer a word of thanks to our readers, our contributors, and our editorial board for their support of the journal and its mission I hope you enjoy reading this issue as much

DR. R. MAZUMDER
PROFESSOR AND DEAN

NOIDA INSTITUTE OF ENGINEERING & TECHNOLOGY (PHARMACY INSTITUTE )
GREATER NOIDA

#### Messages from the desk of the Associate Editor



DR. SWARUPANJALI PADHI
ASSOCIATE PROFESSOR scientific pavement.

DEPARTMENT OF PHARMACEUTICS
NOIDA INSTITUTE OF ENGINEERING & TECHNOLOGY (PHARMACY INSTITUTE )
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On behalf of the editorial board members, announced that the second issue of 2024 "Pharma Innovations". has been published. "Pharma Innovations" is a magazine that sturdily focuses on inspiring the faculty and students to gain knowledge and actively driving the mind toward research in health, medicines, and pharmacy. This unprejudiced attitude toward the scope of the magazine allows the reader to have a divergent and convergent aspect on different topics. Enables budding researchers to think in a rational way to make the scientific pavement.

### **FACULTY FORUM**

#### EXPLORING THE APPLICATION ROBOTICS IN HEALTHCARE: AN IN-DEPTH REVIEW

Ms. Sonia Chauhan
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Noida Institute of Engineering and Technology (Pharmacy Institute)



Robotics is a transformative technology that has profoundly impacted healthcare worldwide. Currently, this innovation plays a pivotal role in various critical functions, including performing surgeries across diverse specialties and overseeing the entire surgical environment. Globally, surgical robots are utilized for procedures like knee replacements, hernia corrections, and colon resections. Long before their broader medical applications, surgical robots made their debut in operating rooms, now aiding in improved outcomes across various healthcare solutions. Amidst the COVID-19 crisis, several robots were deployed in hospitals for tasks like medicine delivery, patient screening, general errands, and ensuring cleanliness. This article offers insight into robotics and its multifaceted utility in the healthcare sector. We also delve into the remarkable improvements, service quality, and innovations brought about by this technology in medical services.

#### EXPLORING THE APPLICATION ROBOTICS IN HEALTHCARE: AN IN-DEPTH REVIEW

We highlight how robotics has emerged as a game-changing force in healthcare. AI-powered robots, with their capacity to emulate creative processes through algorithms and programming, play a significant part. By eliminating manual tasks, hospitals are now more efficient, saving both time and financial resources. Robotics proves beneficial in areas like surgical training, exoskeletons, smart prosthetics and bionics, robotic nursing, treatment administration, logistics, telepresence, and sanitation tasks. Advanced features of robotics, such as gesture control, visual processing, voice recognition, and tactile sensors, are also discussed. With decreasing setup and upkeep costs, the horizon looks promising for further advancements in robotics.

### STUDENTS' FORUM

#### PHARMACY PRACTICE IN THE ERA OF ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING

**Fareed Ahmed** 

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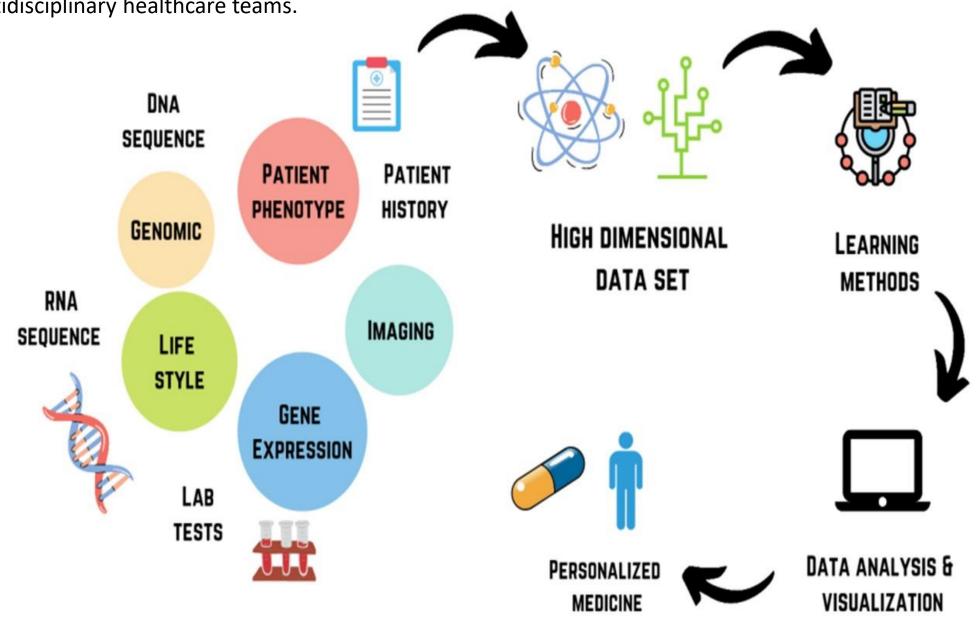


The integration of artificial intelligence (AI) and machine learning (ML) in pharmacy practice is revolutionizing healthcare delivery. These technologies enhance medication management by enabling pharmacists to analyze large datasets, leading to more informed decision-making and personalized patient care. AI tools can predict adverse drug reactions and improve patient adherence, which is vital for optimal health outcomes. Additionally, ML algorithms streamline drug discovery, reducing the time and costs associated with developing new medications.

As pharmacy practice evolves, pharmacists must embrace these advancements while ensuring patient-centered care remains a priority. The adoption of AI and ML improves operational efficiency and positions pharmacists as essential members of multidisciplinary healthcare teams. However, challenges such as data privacy concerns, potential algorithmic errors, and the need for ongoing education must be addressed. Successfully navigating these challenges will enhance the quality of care provided to patients in an increasingly complex healthcare landscape.

#### PHARMACY PRACTICE IN THE ERA OF ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING

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However, challenges such as data privacy concerns, potential algorithmic errors, and the need for ongoing education must be addressed. Successfully navigating these challenges will enhance the quality of care provided to patients in an increasingly complex healthcare landscape.

#### Advantages:

- 1. Improved medication management and personalized treatment plans.
- 2. Enhanced decision-making through data analysis.
- 3. Predictive analytics for identifying adverse drug reactions.
- 4. Streamlined drug discovery processes.
- 5. Increased operational efficiency in pharmacy workflows.

#### Disadvantages:

- 1. Potential for errors in AI algorithms leading to incorrect treatment recommendations.
- 2. Privacy concerns related to patient data security.
- 3. Initial costs of implementing AI and ML technologies.
- 4. Dependency on technology may reduce human interaction in patient care.
- 5. Need for ongoing training and education to adapt to rapidly evolving technologies.

#### CHIMERIC ANTIGEN RECEPTOR

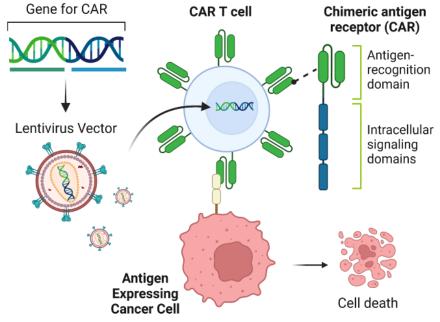
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#### (CAR) T-Cell Therapy

Chimeric Antigen Receptor (CAR) T-cell therapy is a groundbreaking immunotherapy that genetically modifies T-cells to specifically target and destroy cancer cells. By engineering a patient's T-cells to express synthetic receptors—CARs—designed to recognize tumor-specific antigens, this therapy enables the immune system to more effectively eliminate cancer. The success of CAR T-cell therapy has been particularly notable in hematological malignancies such as B-cell acute lymphoblastic leukemia (ALL) and certain types of lymphoma, with several CAR T-cell products already approved

by regulatory agencies.



#### CHIMERIC ANTIGEN RECEPTOR

CAR T-cell therapy involves extracting T-cells from a patient, modifying them ex vivo to express CARs, and then reinfusing them back into the patient. Once administered, CAR T-cells recognize antigens such as CD19 on cancer cells, initiate an immune response, and induce targeted cell death. Despite the remarkable success, the therapy is not without challenges, including severe side effects like cytokine release syndrome (CRS) and neurotoxicity, as well as potential relapse due to antigen loss or tumor heterogeneity. Recent research is focused on improving the efficacy, safety, and durability of responses by developing next-generation CAR constructs, expanding the therapy to solid tumors, and refining combination treatments.

- Isolate, activate and expand primary T cells (from healthy donors).
- Transduce T cells and check the expression of CAR by flow cytometry.
- Establish target cells stably expressing antigen of interest in a luciferase reporter CHO cell line.
- Measure IFNy production by CAR-T cells in co-culture assays using BPS Bioscience's IFNy ELISA kit.
- Assess cytotoxic cell killing using co-culture of target cells and effector CAR-T cells.

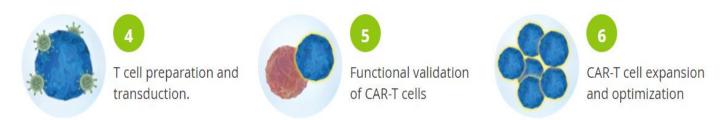
#### CHIMERIC ANTIGEN RECEPTOR

#### A Milestone-Measured Process from Concept to CAR-T

The development of custom CAR-T cells is a complex process that requires a stepwise workflow, implemented in stages:



- Design and construct lentivector for scFv-CAR of different varieties including mono-scFv, dual scFv, and tandem scFv CARs.
- Transfect lentivector and packaging plasmids in 293T cells to make high titer, concentrated virus.
- Validate CAR construct by transducing into the NFAT reporter Jurkat cell line to check for expression of CAR by flow cytometry and for functional activity by reporter assay.



Overall, CAR T-cell therapy represents a significant advancement in personalized cancer treatment, offering hope for patients with otherwise resistant forms of cancer, and its continued development holds promise for broader applications in oncology.

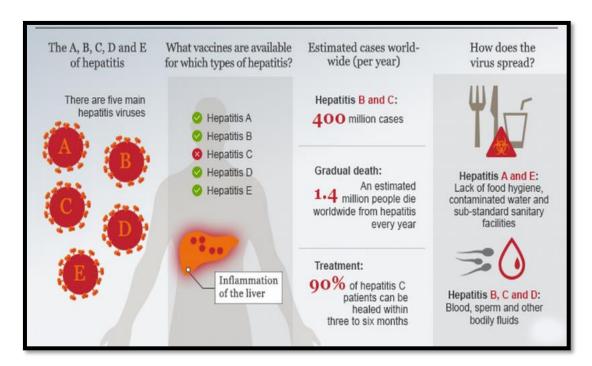
#### **HEPATITIS; CHALLENGES AHEAD**

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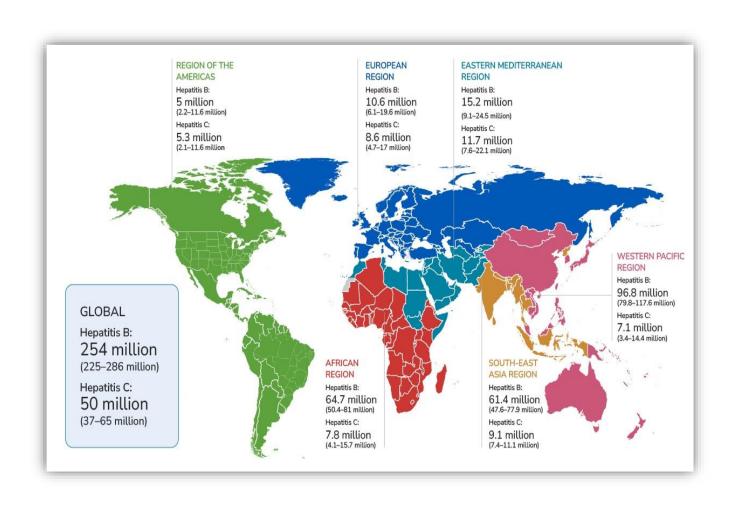
Hepatitis is an inflammatory condition of the liver, commonly caused by viral infections. It can also result from alcohol use, toxins, autoimmune diseases, or certain medications. The primary types of viral hepatitis include hepatitis A, B, C, D, and E, each caused by different viruses with varying transmission routes and long-term impacts.

Hepatitis A and E are typically spread through contaminated food or water and generally cause acute, short-term infections. Hepatitis B, C, and D are primarily transmitted through blood or bodily fluids, leading to chronic infections that can progress to severe liver diseases like cirrhosis or liver cancer if untreated.



#### **HEPATITIS; CHALLENGES AHEAD**

Hepatitis addresses the ongoing global challenge of viral hepatitis, focusing on low- and middle-income countries. Despite the availability of vaccines, diagnostics, and treatment options for hepatitis B and C, the world is far from eliminating these diseases by 2030. Viral hepatitis remains a significant cause of morbidity and mortality, with approximately **1.3 million** deaths and millions of new infections annually.



#### HEPATITIS; CHALLENGES AHEAD

Egypt's milestone in becoming the first country to achieve gold tier status for hepatitis C elimination, demonstrating that elimination is possible through robust public health approaches. However, many countries lag in service coverage, with only 13% of those with chronic hepatitis B diagnosed, and 3% receiving treatment. For hepatitis C, 36% are diagnosed, and 20% treated.

**Symptoms and Complications:** Common symptoms across hepatitis types include jaundice, fatigue, abdominal pain, and n ausea. Chronic hepatitis, notably hepatitis B and C, can lead to severe liver diseases, including cirrhosis and hepatocellular carcinoma, posing long-term health challenges.

**Prevention and Management:** Preventive measures such as vaccinations (available for hepatitis A and B), safe injection practices, and public health education are crucial in reducing transmission rates. Additionally, antiviral therapies have shown efficacy in managing chronic hepatitis infections, thereby improving patient outcomes.

**Conclusion:** Addressing hepatitis requires a multifaceted approach encompassing prevention, early detection, and effective treatment strategies. This comprehensive overview underscores the necessity for continued research and public health initiatives to mitigate the burden of hepatitis globally.

#### **REVIEW ON TERPENES AS BIOACTIVES**

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#### Introduction:

Terpenes are the aromatic compounds responsible for the characteristic scents of plants. From anti-inflammatory to neuroprotective properties, terpenes are emerging as promising candidates for a wide range of therapeutic applications.

#### **Understanding Terpenes:**

Terpenes are ubiquitous in nature and found in various plants, fruits, and even insects. They are synthesized from common precursors, such as isopentenyl pyrophosphate and dimethyl allyl pyrophosphate, through the mevalonate or methyl erythritol phosphate pathway. With over 20,000 different terpenes identified to date, they exhibit remarkable structural diversity, ranging from simple monoterpenes like limonene to complex like  $\beta$ -caryophyllene.

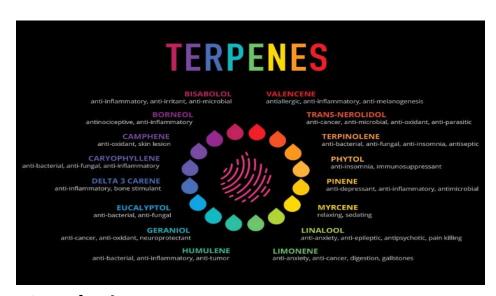
#### **Bioactivity of Terpenes:**

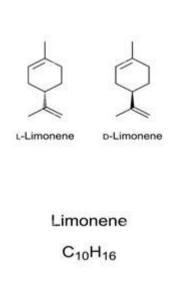
Terpenes exert their bioactivity through various mechanisms, including modulation of neurotransmitter receptors, inhibition of enzymes, and interference with cell signaling pathways. For example,  $\beta$ -caryophyllene, commonly found in black pepper and cannabis, acts as a selective agonist of the cannabinoid receptor CB2, exhibiting anti-inflammatory and analgesic effects without the psychotropic effects associated with THC.

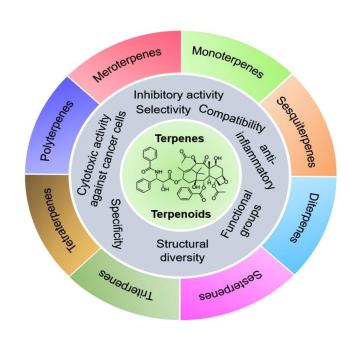
#### **REVIEW ON TERPENES AS BIOACTIVES**

#### **Clinical Implications and Future Directions**

The growing body of evidence supporting the bioactivity of terpenes has sparked interest in their therapeutic potential across various medical fields. From chronic pain management to mood disorders and neurodegenerative diseases, terpenes offer a multifaceted approach to healthcare. However, further research is needed to elucidate their mechanisms of action, optimize formulations, and explore potential drug interactions.







#### **Conclusion**

Terpenes represent nature's hidden treasures, offering a vast array of bioactive compounds with diverse therapeutic properties. As our understanding of these molecules continues to deepen, so too does the potential for innovative treatments harnessing the power of plant-derived medicine. With ongoing research and clinical trials, terpenes may soon emerge as invaluable tools in the quest for safer, more effective healthcare solutions.

#### RECENT ADVANCEMENT IN OSMOTICALLY CONTROLLED DRUG DELIVERY SYSTEM

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V semester 3<sup>rd</sup> year, B. Pharm

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#### **INTRODUCTION**

Osmotically controlled drug delivery systems (OCDDS) have garnered considerable interest due to their ability to provide controlled and sustained release of drugs, offering several advantages over conventional dosage forms. While there hasn't been any ground breaking advancement specifically in the last few months, ongoing research and development in this field continue to refine and improve the technology. Here are some recent advancements and trends in osmotically controlled drug delivery systems.

#### **Advanced Materials:**

Researchers are exploring new materials for the construction of osmotic systems, aiming to improve drug release profiles, enhance biocompatibility, and ensure the integrity and stability of the device. Advances in polymer science have led to the development of novel polymers with tailored properties, such as better osmotic pressure generation and controlled swelling behaviour.

**Precision Engineering**: There's a focus on precise engineering of osmotic delivery devices to achieve desired release kinetics and therapeutic outcomes. This includes optimizing the design of the delivery systems, such as controlling the size, shape, and composition of the semi-permeable membrane, to modulate drug release rates.

#### RECENT ADVANCEMENT IN OSMOTICALLY CONTROLLED DRUG DELIVERY SYSTEM

Integration of Sensors and Feedback Systems: Incorporating sensors and feedback mechanisms into osmotic devices allows for real-time monitoring of physiological parameters and adjustment of drug release accordingly. This concept, known as closed-loop drug delivery, holds promise for personalized medicine by tailoring drug dosing to individual patient needs.

**Combination Therapy**: Researchers are exploring the feasibility of incorporating multiple drugs into a single osmotic system, enabling combination therapy for treating complex diseases or addressing multiple symptoms simultaneously. This approach can improve patient compliance and therapeutic efficacy while reducing the number of dosage forms required.

**Application in Novel Therapeutic Areas**: Osmotically controlled drug delivery systems are being investigated for use in various therapeutic areas beyond traditional applications. For example, there's growing interest in utilizing OCDDS for delivering biologics, peptides, and vaccines, as well as for targeted drug delivery to specific anatomical sites or tissues.

**Improved Manufacturing Processes**: Advances in manufacturing technologies, such as 3D printing and microfabrication techniques, are enabling the production of more complex and customized osmotic devices with greater precision and reproducibility.

#### RECENT ADVANCEMENT IN OSMOTICALLY CONTROLLED DRUG DELIVERY SYSTEM

**Regulatory Considerations**: Regulatory agencies are increasingly recognizing the potential of osmotic drug delivery systems and providing guidance for their development and approval. Efforts to standardize testing methodologies and establish regulatory pathways for OCDDS are ongoing, which will facilitate their translation from research to clinical practice.

Overall, the field of osmotically controlled drug delivery systems continues to evolve, driven by advancements in materials science, engineering, and pharmacotherapy, as well as growing demand for innovative drug delivery solutions that improve patient outcomes and quality of life.

GLOBAL DRUG SAFETY IN THE AGE OF ARTIFICIAL INTELLIGENCE (AI): ADVANCING PHARMACOVIGILANCE WITH PRECISION

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For over a century, pharmacovigilance has been an important tool in patient safety by monitoring and detecting adverse drug reactions at all points of the lifecycle of drugs. Recently, in post-marketing surveillance, these traditional methods often do not keep pace with the ever-escalating complexity and volume of data. With artificial intelligence in place, particularly machine learning and natural language processing, pharmacovigilance systems allow for the identification and reporting of ADRs speedily and with greater accuracy. This paper will demonstrate how Al-based methods enhance drug safety data collection at preclinical, clinical, and post-approval PMS stages to streamline detection of safety signals.

### GLOBAL DRUG SAFETY IN THE AGE OF ARTIFICIAL INTELLIGENCE (AI): ADVANCING PHARMACOVIGILANCE WITH PRECISION

Two major AI techniques that involve supervised and unsupervised learning are revolutionizing the pharmacovigilance landscape by reducing recognized patterns and improving signal detection. The classification model based on supervised learning using labeled data helps efficiently identify known ADR patterns. On the contrary, unsupervised learning models have the potential to unlock unknown hidden trends and patterns that have not been noticed before. These AI techniques significantly improve the accuracy in predicting an ADR while saving considerable time for a full safety evaluation.

Real-life examples show the potential of AI in the field of pharmacovigilance. Programs like the FDA's Sentinel Initiative and EMA's EudraVigilance, introduced AI-based systems to analyze wide amounts of health data from sources as diverse as electronic health records (EHRs), social media, and patient-reporting outcomes. This allows for nearly real-time monitoring of drug safety more rapid responses to emerging safety concerns and, similarly, a more proactive approach to patient care.

### GLOBAL DRUG SAFETY IN THE AGE OF ARTIFICIAL INTELLIGENCE (AI): ADVANCING PHARMACOVIGILANCE WITH PRECISION

Although promising, Al-driven pharmacovigilance also has some significant challenges head-on. Major among them is data standardization; huge amounts of data used in these systems are sourced from other places and forms. Transparency of algorithms as well as conformity of algorithms with ICH E2E and MedDRA standards and the rest become a pressing issue in the best interest of surveillance in this healthcare-related system. The challenge today is the design of models that can not only serve as safety signal detectors but also meet the regulatory expectations of ICSR and PSUR.

This paper also discusses Al's ability to interact with the pharmacogenomics of ADRs, that genetic factors determine how an individual metabolizes a drug and reacts to it. For instance, the variations of the CYP450 enzyme family may lead to differences within patients' abilities to metabolize particular drugs, resulting in the onset of ADRs with certain genetic subgroups. Integration of pharmacogenomics data may therefore enable AI models to deliver more personalized insights for healthcare providers to predict and prevent ADRs. Another special population where a drug response may vary from that of the general population is children, pregnant women, and the elderly.

### GLOBAL DRUG SAFETY IN THE AGE OF ARTIFICIAL INTELLIGENCE (AI): ADVANCING PHARMACOVIGILANCE WITH PRECISION

Surprisingly, the regulatory landscape does not work in isolation. Organizations such as CIOMS (Council for International Organizations of Medical Sciences) play an important role regarding the globally accepted guidelines that determine pharmacovigilance practices. The CIOMS Form takes center stage regarding the standardization of safety data collection. The central drug authority for pharmacovigilance in India is CDSCO, governing this under the Drugs and Cosmetics Act 1940 and Schedule Y. This paper summarizes key differences between Indian and global pharmacovigilance requirements, and AI systems to ensure the accuracy of data and compliance with regulations.

Conclusion: Such vast promise of AI promises a safer future for pharmacovigilance, especially so, with regard to the detection of ADR, pharmacogenomics, and regulatory compliance. However, there are insurmountable hurdles that need to be cleared. These include data standardization to ensure that transparency within algorithms is ensured and regulatory alignment is achieved. As AI technology advances, the coordination of industry and regulators will be an integral part of crafting a much safer and more efficient pharmacovigilance framework that can reach benefits of worldwide patients and healthcare systems.

### PHARMA Info



### OVERVIEW OF NATIONAL GOOD LABORATORY PRACTICE (GLP) COMPLIANCE MONITORING AUTHORITY {NGCMA}



On April 24, 2002, of the National GLP Compliance Monitoring Authority (NGCMA)

The Union Cabinet approved the creation by the Department of Science & Technology (DST), Government of India.

March 3, 2011, India is a full member of the OECD's Working Group on GLP for Mutual Acceptance of Data (MAD).

### OVERVIEW OF NATIONAL GOOD LABORATORY PRACTICE (GLP) COMPLIANCE MONITORING AUTHORITY {NGCMA}



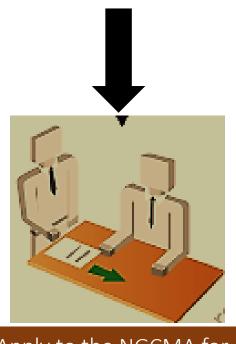
36 OECD members and six non-member MAD adherent nations recognize the non-clinical health and safety research and data produced by Indian GLP facilities.

This makes it easier to export chemicals, medications, insecticides, and other goods to these nations, particularly the developed markets of the United States, United Kingdom, Australia, Japan, and the European Union.

### OVERVIEW OF NATIONAL GOOD LABORATORY PRACTICE (GLP) COMPLIANCE MONITORING AUTHORITY {NGCMA}

**GLP Certification is valid for a period of three years** 

#### How to apply for GLP?



Apply to the NGCMA for a pre-evaluation.

**Surveillance inspection at 18 months** 

**GLP** certification is voluntary in nature

Conduct an inner audit
( non-compliance identification).

Endure a inspection according NGCMA.

Implement corrective measures implemented

Receive a GLP certificate ifapproved in final inspection



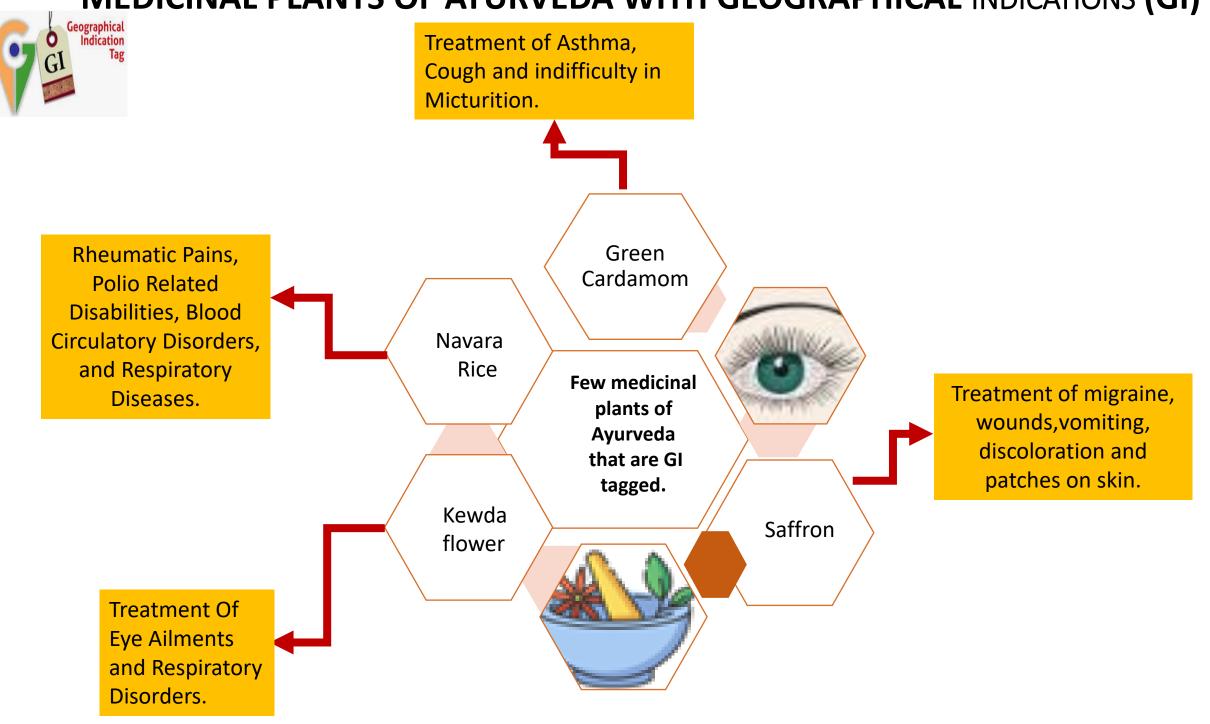


MEDICINAL PLANTS OF AYURVEDA WITH GEOGRAPHICAL INDICATIONS (GI)

A Geographical Indication (GI) is a sign or tag used on agricultural, natural or manufactured products which correspond to a specific geographical location

They are part of the intellectual property rights that comes under the Paris Convention for the Protection of Industrial Property.

#### MEDICINAL PLANTS OF AYURVEDA WITH GEOGRAPHICAL INDICATIONS (GI)



### (PHARMACY INSTITUTE)

#### LIST OF NEW DRUG CANDIDATES APPROVED BY FDA (JULY-DECEMBER 2024)

Drug Name	Active Ingredient	Approval Date	FDA approved use
<u>Alhemo</u>	concizumab-mtci	12/20/2024	For routine prophylaxis to prevent bleeding episodes in hemophilia A and B
<u>Alyftrek</u>	vanzacaftor, tezacaftor, and deutivacaftor	12/20/2024	To treat cystic fibrosis
<u>Tryngolza</u>	olezarsen	12/19/2024	To treat familial chylomicronemia syndrome
<u>Ensacove</u>	ensartinib	12/18/2024	To treat non-small cell lung cance
Crenessity	crinecerfont	12/13/2024	To treat classic congenital adrenal hyperplasia
<u>Unloxcyt</u>	cosibelimab-ipdl	12/13/2024	To treat cutaneous squamous cell carcinoma
<u>Bizengri</u>	zenocutuzumab-zbco	12/4/2024	To treat non-small cell lung cancer and pancreatic adenocarcinoma
<u>lomervu</u>	iomeprol	11/27/2024	For use as a radiographic contrast agent

Drug name	Active ingredient	Approval date	FDA approved use
Rapiblyk	Landiolol	11/22/2024	To treat supraventricular tachycardia
Attruby	Acoramidis	11/22/2024	To treat cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis
<u>Ziihera</u>	Zanidatamab-hrii	11/20/2024	To treat unresectable or metastatic her2-positive (IHC 3+) biliary tract cancer
<u>Revuforj</u>	Revumenib	11/15/2024	To treat relapsed or refractory acute leukemia
<u>Orlynvah</u>	Sulopenem etzadroxil, probenecid	10/25/2024	To treat uncomplicated urinary tract infections (uuti)
<u>Vyloy</u>	Zolbetuximab-clzb	10/18/2024	To treat gastric or gastroesophageal junction adenocarcinoma
<u>Hympavzi</u>	Marstacimab-hncq	10/11/2024	To prevent or reduce bleeding episodes related to hemophilia A or B
<u>Itovebi</u>	Inavolisib	10/10/2024	To treat locally advanced or metastatic breast cancer

Drug name	Active ingredient	Approval date	FDA approved use
<u>Flyrcado</u>	Flurpiridaz F 18	9/27/2024	A radioactive diagnostic drug to evaluate for myocardial ischemia and infarction
<u>Cobenfy</u>	Xanomeline and trospium chloride	9/26/2024	To treat schizophrenia
<u>Aqneursa</u>	Levacetylleucine	9/24/2024	To treat niemann-pick disease type C
<u>Miplyffa</u>	Arimoclomol	9/20/2024	To treat niemann-pick disease type C
<u>Ebglyss</u>	Lebrikizumab-lbkz	9/13/2024	To treat moderate-to-severe atopic dermatitis
Lazcluze	Lazertinib	8/19/2024	To treat non-small cell lung cance
Niktimvo	Axatilimab-csfr	8/14/2024	To treat chronic graft-versus-host disease (cgvhd
Livdelzi	Seladelpar	8/14/2024	To treat primary biliary cholangitis (PBC

Drug Name	Active Ingredient	Approval Date	FDA Approved Use
<u>Nemluvio</u>	Nemolizumab-ilto	8/12/2024	To Treat Prurigo Nodularis
<u>Yorvipath</u>	Palopegteriparatide	8/9/2024	To Treat Hypoparathyroidism
<u>Voranigo</u>	Vorasidenib	8/6/2024	To Treat Grade 2 Astrocytoma Or Oligodendroglioma
<u>Leqselvi</u>	Deuruxolitinib	7/25/2024	To Treat Severe Alopecia Areata
<u>Kisunla</u>	Donanemab-azbt	7/2/2024	To Treat Alzheimer's Disease



# "See you in the Next Edition" Stay Safe, Stay healthy, and Keep Learning

















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