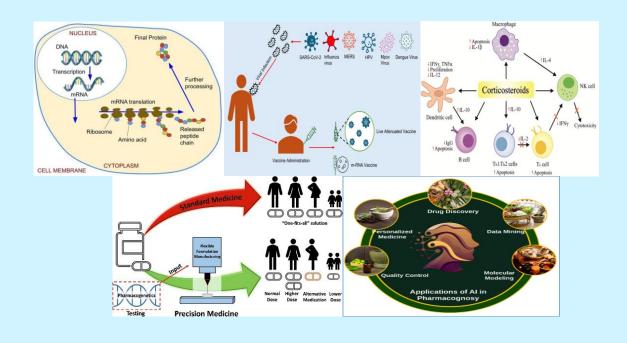








Innovations in Pharmaceutical Sciences



Principal's Desk



It is with great pride and anticipation that I extend my greetings through this edition of our technical magazine, which delves into the transformative intersection of pharmaceutical research and artificial intelligence (AI).

The pharmaceutical sciences are undergoing a paradigm shift. With AI revolutionizing how we discover, develop, and deliver medicines, we are witnessing the dawn of a new era where data-driven insights accelerate innovation, reduce timelines, and improve patient outcomes. From predictive modeling in drug discovery to personalized medicine and smart clinical trial designs, the impact of AI is profound and far-reaching.

As an academic institution, we have a vital role to play in shaping this future. We must nurture a research ecosystem that is **interdisciplinary**, **forward-thinking**, **and ethically grounded**. Our students, scholars, and faculty are the torchbearers of this mission. I am heartened by the dedication of our researchers who are not only keeping pace with global trends but also contributing original insights to the ever-evolving landscape of pharmaceutical innovation.

This "BVCPK TechMag 2025" is more than a compilation of articles; it is a reflection of the intellectual spirit that defines our institution. I encourage our budding scientists and faculty members to continue exploring the vast potential of AI in pharmaceutical research. Let us also not forget the importance of collaboration, critical thinking, and a commitment to societal wellbeing as the core values guiding our research endeavors.

To all contributors, I extend my sincere appreciation. Your work not only enriches this publication but also inspires the next generation of researchers. Let us move forward with curiosity, courage, and a collective purpose to advance science for the betterment of humanity.

Dr. H. N. More
Principal
Bharati Vidyapeeth College of Pharmacy, Kolhapur

Vice Principal's Message

I'm proud and thankful to share this message as we celebrate the publication of our "BVCPK TechMag 2025" technical magazine "Innovations in Pharmaceutical Sciences." This magazine represents a significant step forward in promoting academic excellence, scientific curiosity, and research-driven innovation within our institution.



Pharmaceutical sciences continue to evolve rapidly, driven by groundbreaking discoveries, technological advancements, and a growing emphasis on patient-centered care. In this dynamic landscape, our magazine stands as a valuable platform to disseminate original research, insightful reviews, and thought-provoking perspectives from our esteemed faculty and scholars.

I wholeheartedly congratulate the editorial team, contributors, and all who have been part of this meaningful endeavor. Your commitment to advancing knowledge and fostering a culture of inquiry is truly commendable.

Let this publication serve as an inspiration to further pursue academic rigor, interdisciplinary collaboration, and innovation that addresses real-world healthcare challenges. I encourage continued engagement with this platform, and I look forward to seeing even more impactful contributions in future editions.

Wishing the magazine continued success and a far-reaching impact in the field of pharmaceutical sciences.

Dr. M. S. Bhatia
Vice-Principal
Bharati Vidyapeeth College of Pharmacy, Kolhapur

Editor's Note



It is with great honor and purpose that we unveil this edition of "Innovations in Pharmaceutical Sciences," a technical magazine that seeks to reflect the dynamic, ever-evolving landscape of pharmaceutical research, its critical relevance to both industry and society at large.

Today, the pharmaceutical sciences are witnessing a transformative shift driven by advances in biotechnology, data science, personalized medicine,

regulatory evolution, and an increasing need for rapid, yet safe, drug development, innovation that meets real-world industry challenges and societal health needs.

This "BVCPK TechMag 2025" brings together a rich and diverse selection of articles that address contemporary issues in drug discovery, novel formulation strategies, nanotechnology, pharmacovigilance, regulatory sciences, artificial intelligence in pharma, and more. These contributions by our distinguished faculty members, dedicated research scholars, and emerging student innovators highlight the potential of academic research to translate into industrial application and social impact.

As editors, our vision is to promote a platform that fosters academia-industry synergy, encourages research with translational value, and inspires solutions for global health priorities. Each article has been curated not just for its scientific depth, but for its relevance to the current pharmaceutical ecosystem.

We extend heartfelt thanks to all contributors, reviewers, and the editorial team who made this publication possible through their hard work and intellectual contributions.

Sincerely, Dr. Mrs. P. B. Varne Editor-in-Chief BVCPK TechMag 2025

Editor's Note



It is with great enthusiasm that I welcome you to this latest edition of our technical magazine dedicated to pharmaceutical innovations. In an era where science and technology are transforming healthcare at an unprecedented pace, this issue brings you insights into some of the most ground breaking advancements in drug development, delivery systems, and regulatory science.

As Associate Editor, my commitment is to ensure the accuracy, depth, and relevance of the content we present. Each article has been carefully curated to reflect the ongoing efforts of researchers, scientists, and industry experts who are shaping the future of pharmaceuticals.

We hope this edition not only informs but inspires continued innovation and collaboration across the pharmaceutical landscape.

Warm Regards, Dr. R. R. Chavan Associate Editor BVCPK TechMag 2025

Acknowledgement

Team BVCPK TechMag is very much thankful to Bharati Vidyapeeth College of Pharmacy, Kolhapur and management for providing a wonderful platform to explore and utilize our knowledge and skills. We wish to thank our Hon'ble Secretary, Dr. Vishwajeet Kadam Sir, Dr. Shivajirao Kadam Sir, for their patronage and Dr. H. N. More Sir advising us on the importance of enhancing the visibility of workplace that stimulated us to come out with BVCPK TechMag. We also thank all our alumni, colleagues and students for supporting us in making this TechMag on its completion.

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PRECISION MEDICINE: PERSPECTIVE AND OPPORTUNITIES IN PHARMACEUTICAL PRODUCT DEVELOPMENT

Dr. Mrs. Neela M. Bhatia

Professor and Head, Department of Pharmaceutical Quality Assurance

Science has made tremendous strides in comprehending the molecular causes of illness, leading to the rapid development of novel, sensible treatments. Paradoxically, scientific advancements are making it more difficult to afford universal health care. The "evidence-based" approach to conventional medicine, also known as modern medicine, allopathic medicine, or western medicine, implies that all treatments are logical from the molecular level the ultimate therapeutic effect on patients. The enormous impact of rapid scientific and technological advancements has led to a global trend in recent decades toward the use of conventional medicine. At the same time, other ancient medical practices, like Indian and Chinese traditional medicine, have been developing and are still used today. Nevertheless, we now have a better understanding of how environmental and heritable factors affect human health. Thanks to the exponential growth of genetic, omics, and molecular biology data on humans. This has led to the term precision medicine (PM), which has the potential to transform various medical practices worldwide. The medical treatment industry is going through a radical change. Because precision medicine tailors diagnoses and treatments to each patient's particular changing health status, it has ushered in a revolutionary era in healthcare. This innovative approach takes into account individual differences in genes, environments, and lifestyles when customizing disease prevention and treatment.

Precision medicine (generally considered analogous to personalized medicine or individualized medicine) according to the US National Human Genome Research Institute, is defined as "An innovative approach that uses information about an individual's genomic, environmental, and lifestyle information to guide decisions related to their medical management. The goal of precision medicine is to provide a more precise approach for the prevention, diagnosis, and treatment of disease."

According to the US National Research Council, "personalized medicine is an older term with a meaning similar to precision medicine. However, there was concern in the word "personalized"

which could be misinterpreted to suggest that treatments and preventions are being developed uniquely for each individual. The Council therefore preferred the term precision medicine to personalized medicine" (National Library of Medicine, 2019). The goal of precision medicine however is to provide a more accurate method for disease prevention, diagnosis, and treatment. (National Human Genome Research Institute, n.d.).

Precision medicine aims to address the "five rights": the right patient, the right medication, the right time, the right dosage, and the right route. This approach, considering the patient's medical history, genes, environment, and lifestyle, defines precision medicine. This shift toward a patient-centered clinical decision-making system marks a transition from reactive medicine based on gold standards to patient-specific diagnostics and therapeutics

Although PM has many definitions, the term emphasizes the application of combined knowledge (i.e. clinical, genetic, genomic, and epigenetic/environmental) to predict an individual's susceptibility, disease prognosis, or reaction to treatment to improve their health. The P5 model, which takes into account population perspective, predictive, preventive, personalized, and participatory medicine, has emerged in precision medicine during the past 20 years. (Hood and Friend, 2011).

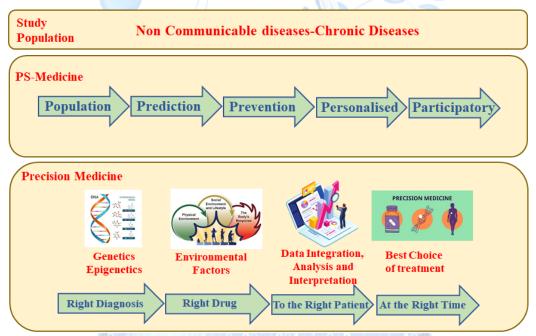


Fig. 1.1 Fundamentals of precision medicine

Benefits of Precision medicine:

It can enhance clinical management safety, lower healthcare costs by avoiding ineffective treatments, and improve patient outcomes. Better disease management techniques, individualized treatment regimens, and earlier and more accurate diagnoses are all possible outcomes of precision medicine. The development of targeted therapies that can more successfully address the disease's underlying mechanisms is made possible by precision medicine, which identifies particular molecular targets and pathways pertinent to a disease in an individual.

Drug development: Challenges and opportunities

Although it has the potential to result safer and more effective treatments. especially in fields like oncology, issues challenges with cost, accessibility, data and management, and ethics still exist. The development of medications that target particular molecular pathways or genetic mutations is made possible by precision medicine, which could result in more effective treatments with fewer adverse effects. Precision medicine approaches, including pharmacogenomics and early use of biomarkers, can potentially speed up the drug development process by identifying effective treatments more efficiently. Accessing and integrating large amounts of diverse data from various sources is a major challenge. The cost of genetic testing and specialized therapies can be a barrier to access, potentially exacerbating health disparities. Ethical issues related to data privacy, genetic discrimination, and informed consent need careful consideration. Continued research is needed to identify new biomarkers, develop more effective targeted therapies, and improve the integration of precision medicine into healthcare systems.

Although there are still obstacles to overcome, precision medicine has the potential to improve the management of chronic illnesses by determining the root causes and customizing therapies for each patient. The cost of genomic sequencing, biomarker analysis, and specialized treatments can be prohibitive, limiting access to precision medicine for many patients. Strong infrastructure and security measures are necessary to safeguard patient privacy and guarantee data integrity due to the enormous volumes of data generated in precision medicine. Unlike some cancers, chronic diseases often have complex and variable etiologies, making it difficult to identify specific targets for treatment. It takes specific knowledge and proficiency in fields like genomics, bioinformatics, and data analysis to implement precision medicine.

Revolutionizing Drug Development:

The traditional "one-size-fits-all" approach to drug development is giving way to a more personalized model. Biomarker-guided clinical trials will help identify patients who are most likely to respond to a specific drug, leading to more efficient and effective trials. Digital technologies and AI will accelerate drug discovery, optimize drug formulations, and personalize treatment plans. Multi-omics profiling (genomics, proteomics, metabolomics, etc.) will provide a comprehensive view of a patient's health status, guiding drug development and treatment decisions.

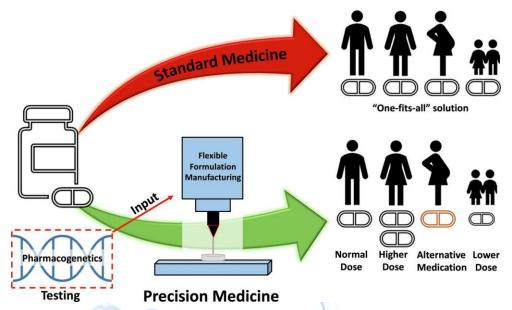


Fig. 1.2 Conventional approach Vs. Precision medicine

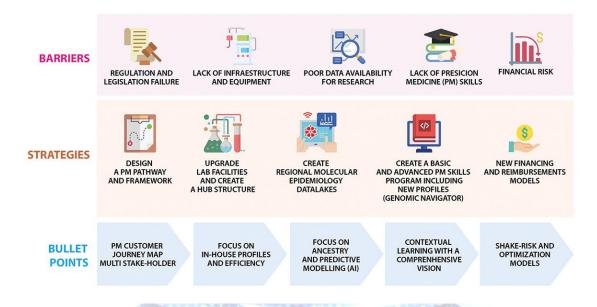


Fig. 1.3 Obstacles for the implementation of precision medicine

Precision medicine has the potential to become the gold standard for pharmaceutical therapy over the next decade, which will require a significant shift in the way novel custom drug products are designed and developed. Drug development is being revolutionized by precision medicine, which makes it possible to take a more focused, individualized, and data-driven approach. Although there are still obstacles to overcome, there are enormous potential advantages for both patients and the healthcare system. The ongoing development and application of precision medicine will surely have an impact on drug development in the future. According to the needs and genetic profile of patients, precision medicine has made it possible to develop new technologies for the creation of customized dosage forms. Several approaches have been adopted for the preparation and dispensing of personalized formulations in practice or are currently being studied. The following methods were identified as the most promising precision medicine formulation strategies: tablet splitting, liquid dispensing, compounding pharmacies, additive manufacturing, drug impregnation, drug extrusion, and orodispersible films.

Precision medicine can assist in identifying people who are more susceptible to specific diseases, enabling customized preventative measures like lifestyle changes or focused screening initiatives. People can lower their risk of contracting diseases before they even show symptoms by taking proactive measures. In summary precision medicine is enabling more effective, individualized, and efficient treatments for a variety of diseases, which is revolutionizing drug development. Even though there are still obstacles to overcome, precision medicine and formulation design have enormous potential to revolutionize healthcare.



Bharati Vidyapeeth College of Pharmacy, Kolhapur

THE UTILITY OF DIFFUSION TENSOR IMAGING FOR DIAGNOSING AND MONITORING AMYOTROPHIC LATERAL SCLEROSIS

Ms. Radhika Amol Kulkarni

Diffusion-tensor imaging (DTI) is a relatively new magnetic resonance imaging (MRI) that is used primarily to assess brain microstructural changes by measuring the mobility of water molecules in fabrics. Its visualization capabilities are based on its ability to determine the orientation and diffusion properties of white matter. Although DTI has been extensively utilized in numerous clinical scenarios, the semiquantitative aspect of DTI data analysis continues to pose a considerable limitation. The protocols for measurement and the processing of image data must be standardized to produce more precise quantitative outcomes. Enhanced DTI techniques have enabled the visualization of potential alterations in different neural pathways linked to brain injuries and clinical interventions.

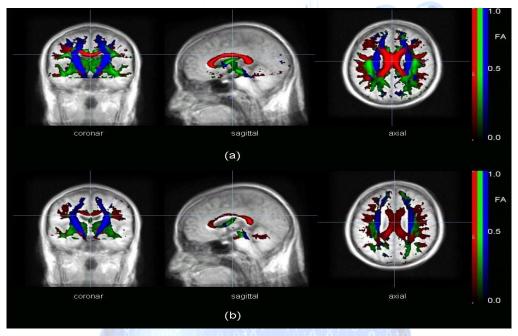


Fig. 2.1 Diffusion Tensor Imaging of Brain

Drug discovery and development are notoriously lengthy and costly processes. DTI, as part of imaging informatics, helps to accelerate these by offering detailed insights into disease mechanisms. For instance, in oncology, DTI can enable the visualization of tumor growth and

its response to potential drug candidates at a cellular level. By integrating DTI data with genomic and proteomic information, researchers can identify biomarkers that predict a patient's response to specific therapies, leading to the development of targeted treatments with improved efficacy and reduced adverse effects. One of the most significant benefits of DTI in pharma is its contribution to personalized medicine. DTI provides detailed imaging data that allows healthcare providers to tailor treatments to individual patient characteristics. For example, DTI can help identify specific molecular targets within a tumor, guiding oncologists in selecting the most appropriate therapy based on the tumor's unique profile. Furthermore, DTI can monitor the effectiveness of treatments in real-time, enabling adjustments to be made as needed, thereby ensuring optimal therapeutic outcomes with minimal side effects.

Amyotrophic lateral sclerosis (ALS) is a devastating neurodegenerative disease characterized by the progressive loss of motor neurons, leading to muscle weakness, paralysis, and ultimately respiratory failure, typically within 3–5 years of onset. Early diagnosis and intervention are critical for improving patient outcomes. Diffusion Tensor Imaging (DTI), a functional MRI technique, has emerged as a valuable tool for assessing white matter fiber tract pathology in the central nervous system, particularly in the corticospinal tract (CST), which is significantly affected in ALS. DTI parameters such as fractional anisotropy (FA) and mean diffusivity (MD) are key indicators of microstructural changes in white matter. FA measures the anisotropy of water molecular diffusion, reflecting characteristics like axon fiber number and size, and fiber density, while MD represents the mean rate of water molecular motion, indicating cellularity, edema, and necrosis, which can reflect microstructural abnormalities.

Clinical Significance

Biomarker Potential:

DTI metrics can serve as biomarkers to detect ALS pathology earlier and monitor disease progression, which is crucial for improving patient care and evaluating treatments.

Correlation with Clinical Scales:

DTI findings have been shown to correlate with clinical assessments like the Amyotrophic lateral sclerosis.

Future Directions

Machine Learning Integration:

Combining DTI data with machine learning models can enhance diagnostic accuracy and enable individualized patient stratification.

• Multimodal Imaging:

Integrating DTI with other imaging techniques, such as structural 3D MRI, can provide a more comprehensive understanding of ALS pathology and improve the power of ML models.

• Standardization and Collaboration:

Standardized DTI protocols and multi-center collaborations are necessary to validate multimodal DTI biomarkers and improve their clinical application Diffusion Tensor Imaging (DTI) plays a crucial role in the diagnosis and monitoring of Amyotrophic Lateral Sclerosis (ALS) by quantifying microstructural changes in white matter, particularly in the corticospinal tract (CST), through parameters like fractional anisotropy (FA) and mean diffusivity (MD), which correlate significantly with established neurofilament biomarkers of disease severity and progression, offering a non-invasive and clinical assessment and potentially serving as a surrogate marker for motor neuron degeneration.

Overall, while diffusion tensor imaging has demonstrated significant potential in understanding and tracking lateral sclerosis, further large-scale, longitudinal studies are needed to validate its role as a standard diagnostic and prognostic modality

Reference:

Bede, P., & Hardiman, O. (2014). Lessons of ALS imaging: pitfalls and future directions — a critical review. NeuroImage: Clinical, 4, 436–443. https://doi.org/10.1016/j.nicl.2014.02.011

FROM NETWORKS TO NEW DRUGS: HARNESSING PATHWAY MAPPING FOR SMARTER DRUG DISCOVERY

Ms. Rajnandini Vijay Patil

Network pharmacology (NP) has emerged as a revolutionary approach in drug discovery, moving beyond the traditional "one drug—one target—one disease" model. While the conventional strategy has simplified drug development, it often fails to address the complexity of multifactorial diseases such as cancer, diabetes, and neurodegenerative disorders. In contrast, NP embraces a holistic, systems-level perspective, studying diseases and therapies as interconnected networks of genes, proteins, and pathways. By integrating computational biology with traditional wisdom, NP provides cost-efficient, predictive insights that not only accelerate drug discovery but also validate ancient medical practices like Ayurveda and Traditional Chinese Medicine (TCM).

COMPUTTIONAL DRUG DISCOVERY WORKFLOW

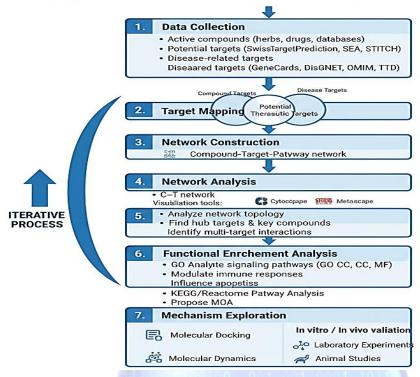


Fig 3.1: Steps used in Network Pharmacology

The roots of NP trace back to 1999, when Shao Li first connected TCM syndromes to biomolecular networks. By the early 2000s, he suggested that disease gene networks could be regulated by the multicausal and micro-effective nature of herbal formulations. In 2007, Li constructed the first biomolecular network for Cold/Hot syndromes in TCM, while Andrew L. Hopkins formally introduced the term *network pharmacology*. The field grew rapidly, with increasing publications in international databases reflecting its global recognition. In 2009, Pan Jiahu proposed a new drug discovery model using NP,

and shortly after, Li expanded the framework by creating the "phenotypic-biological-Chinese medicine network" model and introducing the concept of "network targets." By 2021, Li's team had even established the first international guidelines for NP, strengthening its credibility as a cornerstone of modern pharmacological research.

Network pharmacology begins with the collection of drug compounds and the prediction of their potential targets, alongside the identification of disease-related genes and proteins. Once the data are integrated and screened, the overlapping targets are extracted and used to build networks such as the compound–target, protein–protein interaction, and target–pathway networks. These interconnected maps are then carefully analyzed to pinpoint key compounds, hub proteins, and critical pathways. Functional enrichment analysis further links these findings to biological processes and signaling pathways, offering valuable mechanistic insights. Finally, the predictions are validated through molecular docking and experimental studies, providing a holistic perspective on drug action and paving the way for innovative approaches in modern drug discovery

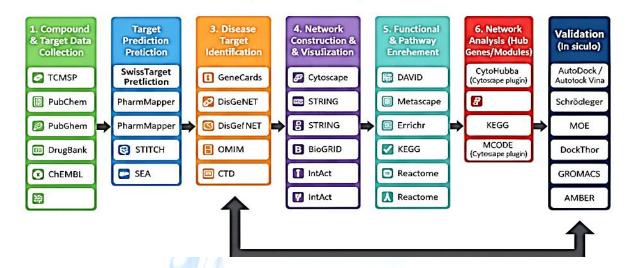


Fig 3.2: tools used for network pharmacology

At its core, network pharmacology is based on the idea that both diseases and drugs act within dynamic, interconnected biological systems rather than isolated molecules. Instead of focusing on a single target, NP adopts a multi-target, multi-component strategy capable of modulating entire networks involved in disease progression. This systems-based framework draws from protein–protein interaction networks, gene regulatory networks, metabolic pathways, and signaling cascades to reveal the deeper mechanisms of action behind therapies. In practice, NP research usually involves three steps: mapping disease-related and drug-related targets within a biomolecular network, establishing associations between them, and analyzing the overall network to understand system regulation.

The applications of NP are vast and impactful. In the realm of traditional medicine, it provides scientific evidence for Ayurvedic and Chinese herbal formulations, explains the rationale behind multi-herb prescriptions, and ensures both safety and efficacy. It also helps identify substitutes for endangered botanicals, ensures quality control through biomarkers, and uncovers the synergistic action of multiple

bioactive compounds. In pharmacology, NP aids in developing new drug leads from natural products, predicts side effects, toxicity, and drug—drug interactions, and supports drug repurposing. For modern drug research, NP facilitates the discovery of novel therapeutic targets and diagnostic biomarkers, reduces cost and time through in silico evaluations, and provides insights into signaling pathways, drug resistance, and multigene-dependent diseases. By bridging traditional wisdom with modern science, NP opens new horizons for global healthcare innovation.

Despite its immense potential, NP faces certain limitations. Much of its accuracy depends on curated databases, which can contain discrepancies due to varied sources of information. Furthermore, herbal medicines often undergo preparation methods such as boiling or mixing with vehicles like milk, ghee, or honey, which alter the chemical nature and bioavailability of bioactive—factors difficult to capture through computational models alone. Target identification is sometimes incomplete due to limited free-access databases, while the synergistic actions of multiple bioactive remain challenging to fully decode in silico. However, solutions are emerging. Advanced chemical identification methods such as UPLC-ESI-MS/MS can accurately identify bioactive, while integration of multiple datasets, combined with experimental validation through omics-based studies, can strengthen predictions. NP may not yet capture every aspect of traditional medicine, but it offers a valuable foundation for designing in vivo experiments and clinical trials, saving both time and resources.

Looking ahead, NP presents immense promise. By enabling a reverse approach—using modern computational technologies to decode traditional formulations—it not only preserves ancient knowledge but also transforms it into evidence-based solutions for present-day medical challenges. It offers the possibility of personalized medicine by tailoring treatments to individual biological network profiles and enhances drug development success rates by addressing complex, multifactorial diseases with greater safety and precision. Ultimately, NP represents a paradigm shift, merging the holistic wisdom of traditional medicine with the analytical power of modern science, and stands poised to become a cornerstone of future therapeutics.

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3D BIOPRINTING: A TECHNICAL OVERVIEW

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3D bioprinting is an advanced form of additive manufacturing that deposits bio-inks—comprising living cells, biomolecules, and scaffold materials—in a layer-by-layer fashion to create functional, tissue-like constructs. Bio-inks: Foundation of Bioprinting, Bio-inks blend cells with biocompatible hydrogels (e.g., GelMA, alginate), providing a supportive matrix for cell adhesion, growth, and differentiation. These materials must exhibit suitable rheological, mechanical, and bio-functional properties, are processed under mild, cell-friendly conditions (typically at \leq 37 °C)

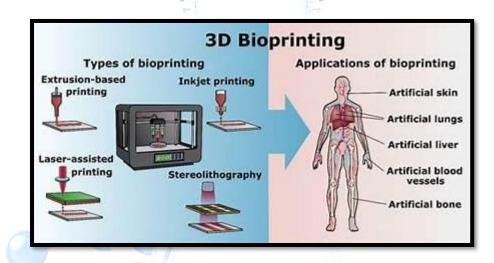


Fig. 4.1: 3DBioprinting

Printing Techniques

The main 3D bioprinting techniques include:

- Extrusion-based bioprinting Uses pneumatic or mechanical pressure to extrude continuous filaments of bio-ink, ideal for constructing soft tissues and scaffold architectures
- **Inkjet-based bioprinting** Deposits droplets of bio-ink using thermal, piezoelectric, or electrostatic forces—fast and cost-effective
- **Laser-assisted bioprinting** Employs pulsed lasers to transfer bio-ink droplets with high precision and cell viability

Materials & Process

Hydrogels, especially **cross-linked polymeric materials**, remain the dominant medium due to their cell-friendly nature and tunable properties. Recent innovations combine hydrogels with **fibers**, integrating 3D bioprinting and **touch-spinning** to replicate fibrous tissue architectures like muscle or connective tissue.

Applications

- Regenerative Medicine & Tissue Engineering: Constructs such as skin, bone, cardiac, and cartilage models are used for therapies, drug testing, and disease modeling.
- **Disease-specific Models**: Mini-tumors printed for cancer research enable side-by-side comparisons of healthy and diseased tissue.
- **Surgical Innovations**: Emerging tools like a "glue-gun" bioprints bone grafts directly onto fractures intra-operatively, enhancing fit and healing.
- **Clinical Trials**: FDA-approved bioprinting of living ear cartilage (e.g., for microtia) is progressing toward transplantation trials.

Challenges & Outlook

Major challenges include:

- Vascularization: Ensuring nutrient and oxygen delivery within thicker tissues remains a hurdle.
- Scalability & Viability: Producing organs at clinical scale demands significant technical and biological innovations.
- Ethics & Access: Ethical considerations regarding equitable access, safety, and regulation are central to responsible deployment.

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ENHANCING BONE REGENERATION: THE ROLE OF ALLANTOIN IN OSTEOGENESIS

Ms. Sagarika Sushil Yedage

Allantoin, a naturally occurring compound widely recognized for its antioxidant, antiinflammatory, and epithelial-stimulating properties, has garnered significant attention in regenerative medicine for its potential to enhance osteogenesis. Its historical use in wound healing, skin care, and tissue regeneration forms the basis for exploring its effects in bone healing processes, particularly in distraction osteogenesis where new bone formation is critical.

Experimental evidence from animal studies has demonstrated that local administration of allantoin significantly accelerates bone regeneration. In a mandibular distraction osteogenesis model in rabbits, allantoin not only increased new bone volume but also enhanced connective tissue and capillary formation. This is achieved through stimulation of mesenchymal stem cells, which are essential for osteoblast differentiation and bone matrix synthesis. Immunohistochemical analysis revealed elevated activity of RUNX2 and BMP2, key osteogenic markers, confirming that allantoin actively promotes cellular signaling pathways important for bone repair. The antioxidant effect of allantoin reduces oxidative stress at the injury site, minimizing tissue damage, while its anti-inflammatory action creates a conducive environment for efficient healing and vascularization, essential for supplying nutrients and oxygen during new bone growth.

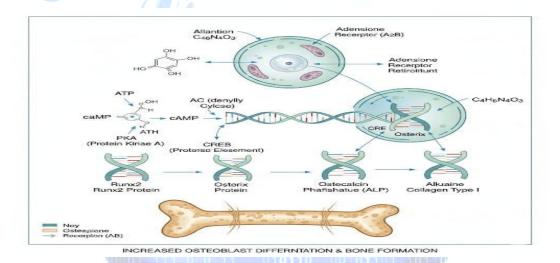


Fig.5.1: Increased osteoblast Differentiation & Bone Formation

Importantly, allantoin's influence extends to stem cell biology, where it enhances the proliferation of dental pulp stem cells and other progenitor cells involved in tissue regeneration. However, its effects on osteogenic differentiation may depend on dosage and cell type, highlighting the need for optimized application strategies in clinical contexts. Beyond experimental settings, allantoin's biocompatibility and safety profile make it a promising candidate for incorporation into bone graft scaffolds, hydrogels, or local delivery systems aimed at improving outcomes in maxillofacial surgeries and orthopedic procedures.

Clinically, allantoin's potential use as an adjunct in distraction osteogenesis and bone defect repair could revolutionize treatment protocols by shortening recovery times and enhancing bone quality. Its role in stimulating pro-collagen synthesis further supports tissue matrix strengthening and resilience, which are vital for successful regeneration. As research progresses, combining allantoin with other bioactive molecules or advanced biomaterials could pave the way for next-generation therapies in bone tissue engineering, ultimately contributing to improved patient prognosis and quality of life.

In conclusion, allantoin represents a multifaceted therapeutic agent in bone regeneration, with its ability to modulate cellular activity, reduce inflammation, and promote vascular growth making it invaluable in osteogenesis applications. Continued investigations into its mechanisms and clinical translation will be key to unlocking its full potential in regenerative dentistry and beyond.

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Article No. 6

TRENDS AFFECTING THE FUTURE OF VACCINE DEVELOPMENT AND DELIVERY: THE ROLE OF DEMOGRAPHICS, REGULATORY SCIENCE, THE ANTI-VACCINE MOVEMENT, AND VACCINOMICS

Ms. Samruddhi Pisal

Trends affecting the future of vaccine development and delivery examines the scientific, social, and cultural factors that will shape the future of vaccinology. Identified four major forces demographics, regulatory science, the anti-vaccine movement, and vaccinomics that are likely to define vaccine development and delivery in the coming decades.

Aging populations, especially in Western countries, are increasing rapidly, with projections that by 2040 up to half of these populations could be 65 or older. This is important because older adults are much more vulnerable to vaccine-preventable diseases, causing roughly 70,000 deaths per year in the U.S., compared to only about 200 in children. As people age, their immune systems weaken a process called immune-senescence making vaccines less effective. This highlights the need for research on ways to boost or bypass immune decline. Improving vaccines for older adults is critical not only to reduce illness and death but also to manage healthcare costs, especially since many chronic and respiratory diseases are linked to declining immune function.

Vaccine development is slow, expensive, and mostly done by big companies because trials are large and costly. While trials show safety and effectiveness, they often miss rare side effects or differences between groups. At the same time, misinformation and distrust fuel the anti-vaccine movement, lowering vaccination rates and causing disease outbreaks. Scientists emphasize that clear communication, transparency, and trust are as important as scientific advances, because even the best vaccines only work if people take them.

The article explains that the future of vaccines lies in vaccinomics, which uses genetics, immunology, and computer science to design personalized vaccines instead of the current "one size fits all" approach. Today, everyone gets the same dose, whether a small child or a large adult, but genetic differences can affect how people respond. Just like pharmacogenomics explains why people react differently to medicines, certain genes that control the immune system (like HLA or cytokine genes) influence how well vaccines work or whether side effects occur.

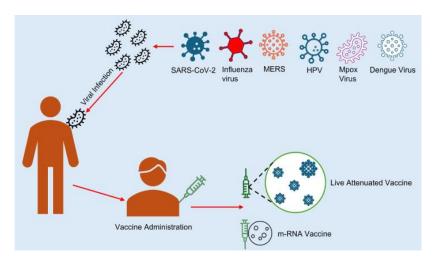


Fig. 6.1: Vaccine Development

By studying these genetic variations, scientists could make vaccines safer, more effective, and tailored to each person-for example, deciding who really needs extra doses, who might need special formulations, or who could be at risk for side effects. Future innovations may include DNA-based vaccines, plant-based vaccines, skin or nasal delivery methods, and highly precise adjuvants. This personalized approach could also help quickly develop vaccines against new or engineered diseases while protecting people more effectively.

The authors conclude that the future of vaccines will be shaped by aging populations, slow regulations, public mistrust, and advances in genomics. Tackling these challenges could lower health costs, improve adult vaccination, and build trust. Personalized vaccines through vaccinomics could create a "new golden era," making vaccination more precise and tailored to individuals. However, scientists must actively adapt to social, cultural, and scientific changes, or even the best vaccines may not reach their full potential.

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TECHNICAL APPROACHES TO RISK-BASED AUDITING IN PHARMACEUTICAL MANUFACTURING

Ms. Saniya Y. Desai

Risk-based auditing is a systematic approach applied in pharmaceutical manufacturing to evaluate processes, facilities, and quality systems based on the level of risk they pose to product quality, patient safety, and regulatory compliance. Unlike traditional audit methods that treat all operations equally, risk-based auditing (RBA) prioritizes high-risk areas, ensuring efficient use of resources while strengthening compliance with Good Manufacturing Practices (GMP). This concept has gained prominence with regulatory bodies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and World Health Organization (WHO) emphasizing quality risk management (QRM) in pharmaceutical operations. Pharmaceutical companies generally adopt different technical approaches to implement risk-based auditing.

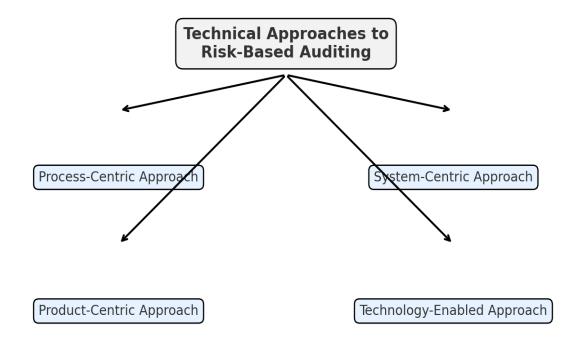


Fig.7.1: Technical Approaches To Risk-Based Auditing

Risk-based auditing in pharmaceuticals can be implemented through four main approaches. The process-centric approach targets critical operations like sterile production and aseptic filling, using tools such as FMEA and HACCP to prioritize risks. The system-centric approach focuses on quality management systems, applying risk ranking to determine audit frequency—for instance, auditing high-risk raw material suppliers more often than packaging vendors. The product-centric approach emphasizes the criticality of products, giving more attention to high-risk items such as vaccines and biologics. The technology-enabled approach leverages digital tools, data analytics, and AI to monitor emerging risks in real time. Overall, risk-based auditing improves resource efficiency, strengthens compliance with ICH Q9, enhances product safety, and allows audit plans to adapt to new processes and risks. However, Risk-based auditing, while effective, faces challenges such as reliance on reliable data, the need for skilled auditors, limited resources in smaller firms, and differing regulatory interpretations. Despite these hurdles, it marks a shift from traditional audits by enhancing compliance, efficiency, and product safety. With digital tools and analytics, it is becoming essential in pharmaceutical quality management, though its success relies on robust data, expertise, and regulatory alignment.

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TRANSDERMAL DRUG DELIVERY USING NANONEEDLES: A PROMISING ADVANCEMENT IN CUTANEOUS DRUG DELIVERY

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Department of Pharmaceutics

Transdermal drug delivery (TDD) offers a non-invasive route to deliver therapeutic agents across the skin directly into systemic circulation. Despite its advantages, the stratum corneum, the outermost skin layer, acts as a significant barrier to most drugs. In recent years, nano-needles have emerged as a revolutionary tool to overcome this challenge, providing a minimally invasive, painfree, and highly effective approach for drug transport through the skin. Nano-needles are vertically aligned, nano-scale needle-like structures usually 50–500 nm in diameter and a few micrometers in length made from materials like silicon, carbon, or biodegradable polymers. These nanostructures penetrate the stratum corneum without reaching pain nerves or blood vessels, allowing precise and safe drug administration. Unlike traditional microneedles, nano-needles offer higher surface area, deeper skin interaction, and better control over drug release kinetics.

Their mechanism involves mechanical disruption of the skin barrier, facilitating intracellular and intercellular delivery. Drugs either coated on the nano-needles or loaded into their porous structure can be released by diffusion or triggered via stimuli such as pH, temperature, or light. These systems improve bioavailability, allow controlled release, and minimize systemic side effects.

Applications of nano-needle-based TDD include delivery of peptides, insulin, vaccines, anticancer agents, and even genetic material (siRNA, DNA). Research has also shown their potential in cosmeceuticals (anti-aging, depigmenting agents) and localized therapy for skin conditions such as psoriasis and melanoma.

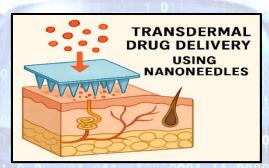


Fig. No. 8.1: Mechanism of Nano-needle-Based Transdermal Drug Delivery

A recent breakthrough is the development of dissolving or biodegradable nano-needles, which dissolve after insertion, leaving no hazardous waste behind. Furthermore, wearable nano-needle patches integrated with biosensors offer real-time monitoring and responsive drug delivery, ushering in a new era of personalized medicine.

While nano-needles exhibit enormous promise, challenges such as scalability of fabrication, regulatory compliance, cost of production, and long-term skin safety must be addressed. Advances in nano-engineering, material science, and biomedical design are key to translating lab-scale prototypes into commercially viable products.

In conclusion, nano-needles signify a transformative step in transdermal drug delivery by overcoming the formidable skin barrier while maintaining patient compliance and therapeutic efficiency. As research progresses, nano-needles are poised to redefine how we deliver medications especially those with poor oral bioavailability or narrow therapeutic indices.

Future Research Directions in Nano-needle-Based Transdermal Drug Delivery

The field of nano-needle-mediated transdermal drug delivery (TDD) is rapidly evolving. While current research demonstrates promising results in animal models and early clinical studies, several frontiers remain to be explored for its full-scale translation into clinical practice.

1. Smart and Responsive Nano-needle Systems

Future nano-needle platforms will integrate biosensors and stimuli-responsive polymers to enable on-demand drug release. These "smart patches" could detect biomarkers (e.g., glucose, inflammation levels) and respond by releasing the appropriate drug dose, enhancing therapeutic precision in diseases like diabetes or cancer.

2. Gene and RNA-Based Therapies

With the rise of gene editing tools (CRISPR-Cas9) and RNA therapies, nano-needles may offer a safer alternative to viral vectors for intracellular delivery of mRNA, siRNA, or plasmid DNA, with minimal immunogenicity. This will be especially beneficial in dermatological genetic disorders, vaccine delivery, and cancer immunotherapy.

3. High-Throughput Fabrication Techniques

Mass production of nano-needle arrays using scalable, cost-effective technologies like nano-imprinting, soft lithography, or 3D nano-printing will be critical. Research should focus on

optimizing fabrication for uniformity, mechanical strength, and biocompatibility especially for biodegradable nano-needles.

4. Personalized Transdermal Systems

Combining AI-driven diagnostics with wearable nano-needle systems could enable personalized treatment regimens. For instance, real-time feedback loops could adjust drug release based on patient response, optimizing therapeutic outcomes.

5. Combination Therapy and Vaccination

Nano-needles offer a novel route for co-delivery of multiple drugs or vaccine adjuvants in a single application. Future studies should explore synergistic payloads (e.g., drug + gene + imaging agent) for complex diseases such as melanoma or autoimmune conditions.

6. Safety, Regulatory, and Long-Term Studies

Robust toxicological, dermatological, and immunogenicity assessments are needed. Long-term studies must address repeat-dose effects, potential for skin irritation, and biodegradation by products. Regulatory pathways also need to adapt to such hybrid medical-device/pharmaceutical platforms.

7. Global Health and Low-Resource Settings

Future innovations should focus on thermostable, needle-free patches deployable without cold chains or skilled professionals. This would be transformative for vaccine campaigns in remote or underserved populations.

The intersection of nanotechnology, biotechnology, and digital health will propel nan-oneedle-based TDD from concept to clinical reality. Focused research in fabrication, biological interaction, therapeutic integration, and real-time monitoring will pave the way for next-generation, patient-centric, painless drug delivery systems.



ARTIFICIAL INTELLIGENCE IN DRUG DISCOVERY AND DEVELOPMENT

Dr. Mrs. S. A. Arvindekar

Assistant Professor Department of Pharmaceutical Chemistry

The rapid digitalization of pharmaceutical data has created challenges in analyzing and applying vast datasets. Artificial intelligence (AI) addresses these by automating complex data processing while complementing—not replacing—human expertise. AI systems learn from input data to make independent decisions and are increasingly integrated into pharmaceutical research and development. McKinsey projects that AI-driven automation will significantly reshape work culture.

AI covers domains such as reasoning, knowledge representation, and solution search, with machine learning (ML) at its core. ML identifies patterns in data, while deep learning (DL) uses artificial neural networks (ANNs)—interconnected "perceptrons" that mimic neuronal signaling. Key ANN types include multilayer perceptrons (MLPs) for pattern recognition and control, recurrent neural networks (RNNs) for memory-based tasks, and convolutional neural networks (CNNs) for image, video, and signal processing. Other variants include Kohonen, radial basis function (RBF), learning vector quantization (LVQ), counter-propagation, and ADALINE networks. Figure 1 summarizes these AI methods.

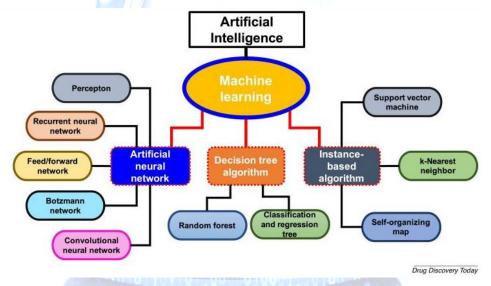


Fig 9.1. AI Method Domains and Subfields Supporting Drug Discovery and Development

Several tools have been developed based on the networks that form the core architecture of AI systems. One such tool developed using AI technology is the International Business Machine (IBM) Watson supercomputer (IBM, New York, USA). It was designed to assist in the analysis of a patient's medical information and its correlation with a vast database, resulting in suggesting treatment strategies for cancer. This system can also be used for the rapid detection of diseases. This was demonstrated by its ability to detect breast cancer in only 60 s.

Advances in artificial intelligence (AI) and its powerful tools are helping pharmaceutical companies overcome key obstacles in drug development and product lifecycle management, fueling growth in sector start-ups. Rising drug and therapy costs demand transformative solutions. Integrating AI into pharmaceutical manufacturing enables personalized medicines tailored in dose, release profile, and other patient-specific parameters. AI-driven technologies accelerate market entry, enhance product quality and production safety, optimize resource use, and reduce costs, underscoring the growing value of automation.



Article No. 10

SMART NANOPARTICLES FOR CONTROLLED AND SUSTAINED DRUG RELEASE

Ms. Shreya Patkar

Controlled and sustained drug release is critical in pharmacy to maintain therapeutic concentration over time, reduce dosing frequency, improve patient compliance, and minimize side effects. Smart nanoparticles (NPs) are engineered to respond to internal or external stimuli (pH, enzymes, temperature, light, magnetic field, etc.) to control release kinetics and location. Recent research has focused on tailoring the nanoparticle composition, surface functionalization, and structure to reduce burst release, achieve zero/near zero-order kinetics, and allow stimulus-triggered release.

Nanotechnology has emerged as a transformative tool in biomedical applications, particularly in the field of drug delivery. Among the various advancements, smart nanoparticles (NPs) have garnered significant attention due to their ability to deliver drugs in a controlled and sustained manner. These nanoparticles are engineered to respond to specific environmental cues, such as changes in pH, temperature, or enzymatic activity, enabling precise targeting and release of therapeutic agents. This approach not only enhances the therapeutic efficacy of drugs but also minimizes side effects, offering significant advantages over traditional drug delivery methods.

Smart nanoparticles are typically composed of materials like lipids, polymers, and inorganic substances, each offering distinct advantages. Their small size, typically ranging from 1 to 100 nanometers, allows for passive targeting via the enhanced permeability and retention (EPR) effect, which is particularly beneficial for tumor treatment. For instance, polymeric nanoparticles, such as those made from poly(lactic-co-glycolic acid) (PLGA) or polycaprolactone (PCL), are highly versatile due to their ease of modification and ability to encapsulate a wide range of drugs. Other types of nanoparticles, such as liposomes, dendrimers, and inorganic nanoparticles, also provide unique advantages for targeted drug delivery. Liposomes, for example, are lipid-based nanoparticles capable of carrying both hydrophilic and hydrophobic drugs, while dendrimers are branched nanostructures that allow for high drug loading capacity and surface modification. Inorganic nanoparticles, including gold and silica, offer high stability and can be engineered to release drugs in response to external stimuli, such as light or magnetic fields.

The fundamental appeal of smart nanoparticles lies in their ability to control the release of drugs over an extended period, reducing the need for frequent dosing and improving patient compliance. Various release mechanisms have been developed to enable this functionality, including pH-sensitive, temperature-sensitive, and enzyme-triggered release. pH-sensitive nanoparticles are particularly useful for delivering drugs to areas of the body with abnormal pH levels, such as tumors or inflamed tissues. These nanoparticles are designed to release their cargo when exposed to acidic environments, often found in such regions. For instance, polymers like poly(ethylene glycol)-b-poly(histidine) (PEG-b-PHis) undergo conformational changes at low pH, releasing the encapsulated drug. Additionally, enzyme-triggered release takes advantage of specific enzymes present at the target site to degrade or cleave the nanoparticles, leading to the controlled release of the drug.

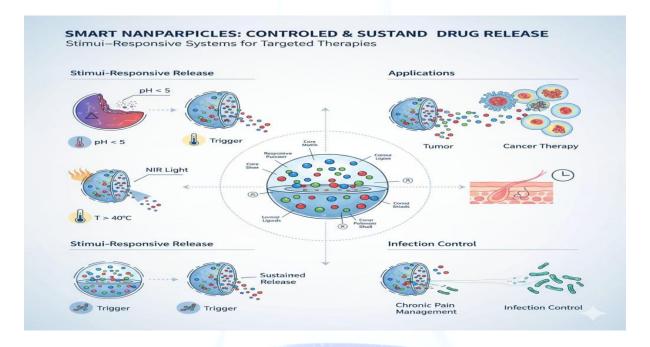


Fig. 10.1: Smart Nanoparticles for Controlled and Sustained Drug Release

The potential applications of smart nanoparticles in drug delivery are vast, with cancer therapy being one of the most promising fields. Chemotherapeutic drugs, while effective, often cause severe side effects due to their non-selective action on healthy tissues. Smart nanoparticles, by contrast, can be engineered to specifically target cancer cells, minimizing damage to surrounding healthy tissues. For example, studies have demonstrated that PLGA nanoparticles loaded with paclitaxel, a commonly used chemotherapy drug, effectively reduce tumor growth while

minimizing toxicity. Beyond cancer, smart nanoparticles are also being explored for gene therapy, where they are used to deliver genetic material like DNA or RNA to specific cells. The high precision of nanoparticle-based delivery improves gene transfer efficiency and protects the genetic payload from premature degradation. Similarly, nanoparticles offer a promising solution for sustained antibiotic delivery, ensuring prolonged therapeutic concentrations at the site of infection and reducing the risk of resistance development. Inflammatory diseases like arthritis also benefit from the controlled release of anti-inflammatory drugs, offering long-term relief with reduced side effects.

Despite their significant promise, the clinical translation of smart nanoparticles faces several challenges. One of the primary concerns is their potential toxicity, as the long-term effects of nanoparticles on human health remain poorly understood. Rigorous biocompatibility studies are essential to ensure that these nanoparticles do not cause adverse reactions when used in vivo. Another challenge lies in the scalability of nanoparticle production. Manufacturing large quantities of nanoparticles with consistent size, shape, and drug-loading capacity is complex and costly. Additionally, regulatory hurdles remain, as the approval process for nanoparticle-based drug delivery systems is still evolving. As a result, the widespread clinical adoption of these technologies has been slower than anticipated.

Looking to the future, researchers are focusing on overcoming these obstacles by developing more biocompatible materials, improving the encapsulation efficiency of drugs, and exploring new techniques for targeted and multi-stimuli-responsive drug release. Innovations in nanoparticle design and manufacturing processes will likely pave the way for smarter, more efficient drug delivery systems. In particular, the combination of multiple stimuli-responsive mechanisms could enable even more precise and effective treatments, potentially transforming the way we approach diseases like cancer, genetic disorders, and chronic infections.

Reference:

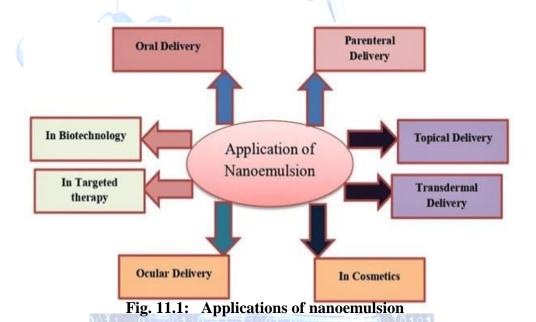
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NANOEMULSION-BASED FORMULATION OF SOPHORA ALOPECUROIDES OIL

Ms. Sneha Shahaji Katkar

Sophora alopecuroides L. (SoA) is a perennial herb from the Fabaceae family, commonly found in Northwest China. It contains several important natural compounds such as alkaloids, flavonoids, steroids and polysaccharides which are known for their health benefits like anti-tumor, antiviral, anti-inflammatory, antibacterial, pain-relieving and nerve-protective effects. The oil obtained from SoA through vacuum distillation has been traditionally used to treat skin problems like eczema, psoriasis and neurodermatitis. However, its use is limited because of poor skin absorption, low retention in skin layers, dark color, unpleasant odor and its tendency to stick to wounds which can cause discomfort.

Nanoemulsion (NE) technology offers a solution to these challenges by improving drug penetration through the skin. Nanoemulsion systems enhance permeability, hydrate the skin barrier and increase overall effectiveness. Nanoemulsion formulations also help keep the skin barrier hydrated, which makes it easier for the drug to pass through the skin and increases its effectiveness.



In this study, a nanoemulsion-based gel of SoA oil was developed to improve its skin delivery and antibacterial activity against biofilm-forming pathogens. The formulation was optimized using a

pseudo-ternary phase diagram to select the best surfactant and co-surfactant ratios, ensuring small particle size and stable dispersion. Finally, the optimized nanoemulsion was incorporated into a gel and its flow properties (rheology) were carefully studied.

Methodology:

Sophora alopecuroides (SoA) plant

 \downarrow

Extraction of SoA oil

 \downarrow

Problems with crude oil use

(poor penetration, dark color, odor, irritation)

1

Nanoemulsion-based system

1

NE gel formulation

 \downarrow

Improved skin retention, reduced irritation,

Enhanced activity against skin infections

Conclusion:

Creating a nano-emulsion-based gel with *Sophora alopecuroides* oil shows great promise for transdermal drug delivery. This formulation improves the passage of drugs through the skin, helps the drug stay longer at the target site and effectively fights biofilm-forming bacteria. While some aspects still need deeper study.

Article No. 12

3D PRINTING IN PERSONALIZED MEDICINE

Ms. Sonali. A. Chikhalwale

The goal of personalised medicine, which has the potential to completely transform the healthcare industry, is to customise medicines for each patient by taking into account their unique physiology, drug reaction, and genetic profile. 3D printing is the process of creating a three-dimensional item utilising different computer programs, layer by layer. The shape, release profile, and medication combination of pharmaceutical dosage forms can all be altered with 3D printing. The "one size fits all" mentality underlies the current medical treatment scenario, in which the majority of patients receive the same medications at the same dosages and intervals as others. The promises of personalised medicine include more accurate prescription drugs. They are less expensive, increase patient compliance, and are safer and more effective. Additionally, 3D printing has made it possible to produce customised metallic prostheses, parenteral implants, and other medical equipment.

Table: 12.1 History of 3D Printing

1970s	Initial research and patents on computer-aided additive manufacturing.		
1980s	Charles (Chuck) Hull invented and patented stereolithography (SLA).		
	SLA uses UV light to polymerize resin and form 3D objects.		
	Hull founded 3D Systems to commercialize SLA printers.		
1986s	Carl Deckard (University of Texas student) developed Selective Laser		
	Sintering (SLS), using lasers to fuse powder.		
1000	Scott and Lisa Crump (Stratasys) patented Fused Deposition Modeling		
1989s	(FDM), which heats and extrudes plastic/metal through a nozzle.		
2015s	FDA approved the first 3D-printed drug, Spritam (Levetiracetam) by Aprecia		
	Pharmaceuticals. Manufactured using Binder Jetting.		

3D Printing Technologies used in Pharmaceutical Development

3D printing includes a number of essential methods, each with its own workings and uses. Often employed for printing cells or bioinks in bioprinting, inkjet printing is the exact deposition of liquid materials through a nozzle. Binder Jet Printing, which is frequently used in prototypes and pharmaceuticals, creates items by layering a liquid binding agent onto a bed of powdered material. Using one of the most widely used techniques, fused deposition modelling (FDM), thermoplastic materials are heated and then

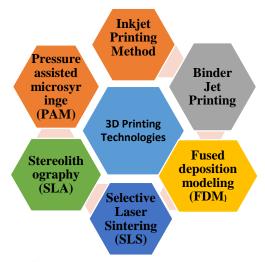


Fig.12.1:3D Printing technologies

extruded through a nozzle to create objects layer by layer. Selective Laser Sintering (SLS) offers high mechanical qualities by fusing powdered materials, including metals or polymers, using a laser without the requirement for a binding agent. Stereolithography (SLA), which is perfect for medical models and prototypes, uses UV light to cure liquid resin into solid pieces with excellent resolution and detail. Pressure-Assisted Microsyringe (PAM) printing is appropriate for bioprinting and pharmaceutical applications using semi-solid materials since it extrudes viscous materials via a microsyringe using a regulated pressure system.

Potential of 3D printing in personalized Medicine

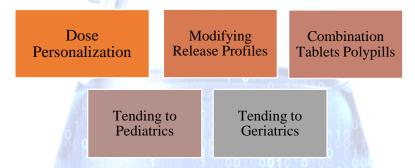


Fig.12.2: Potential of 3D printing in personalized Medicine

Reference: Vanessa Marcia Vaz, Lalit Kumar (2021), AAPS PharmSciTech (2021) 22: 49 DOI: 10.1208/s12249-020-01905-8, https://link.springer.com/article/10.1208/s12249-020-01905-8

Article No. 13

HERBOSOMAL TRANSDERMAL PATCH FOR ENHANCED WOUND HEALING

Mrs. Swapnali Dharanguttikar

Assistant Professor Pharmaceutical Chemistry Department

Wound healing is a complex biological process involving haemostasis, inflammation, proliferation, and maturation. This study investigates the development of a herbosomal transdermal patch containing ethanolic extract of Terminalia bellerica for wound healing activity. Phytoconstituents were encapsulated in herbosomes using lipid-based technology to improve bioavailability and therapeutic efficiency. The optimized formulation (F5) was incorporated into a transdermal patch and evaluated in an excision wound model. The formulation contained 50 mg of Terminalia bellerica extract, phosphatidylcholine (100 mg), and cholesterol (50 mg). The herbosomes were incorporated into a patch with polyvinyl alcohol, ethyl cellulose, PEG, and DMSO. Wound healing was assessed over a 16-day period in mice, comparing control, F5 patch, and 5% povidone—iodine ointment groups. The F5 patch demonstrated significant wound healing potential with 96.10% wound contraction by day 16, closely comparable to 5% povidone—iodine (99.24%). Control animals showed only 85.32% contraction. Epithelialization time was reduced to 15.52–16.21 days for the F5 patch compared to delayed healing in control.

Graphical Results: Percentage wound contraction over 16 days for different treatment groups: This research highlights the effectiveness of herbosomal technology in enhancing the wound healing activity of Terminalia bellerica. The F5 patch provided superior drug release, stability, and wound contraction, making it a promising herbal-based transdermal system for chronic wound management.



Bharati Vidyapeeth College of Pharmacy, Kolhapur

Article No. 14

IONOGELS: RECENT ADVANCES IN DESIGN, MATERIAL PROPERTIES AND EMERGING BIOMEDICAL APPLICATIONS

Ms. Swapnali Shivaji Khade

Ionic liquids themselves are salts that remain liquid close to room temperature. They are generally classified as protic or aprotic. Protic ionic liquids are formed when a Brønsted acid donates a proton to a Brønsted base, whereas aprotic ionic liquids are synthesized through quaternization of nitrogen, phosphorus, or sulfur compounds followed by anion exchange. Their tunable structures arise from the huge number of possible cation—anion combinations, allowing researchers to design ionic liquids with specific physical, chemical, or biological properties. Over the years, ionic liquids have progressed from the first generation (which were moisture sensitive) to the third generation, which are biocompatible, biodegradable, and task-specific. This progression has opened the way for their safe and effective use in biomedical ionogels.

Gels are soft materials made up of a three-dimensional polymer network that can hold a large amount of solvent. The network may be stabilized through covalent bonds or by weaker non-covalent forces, such as hydrogen bonding, ionic interactions, metal coordination, or hydrophobic effects. Based on the type of solvent they contain, gels are classified as hydrogels (water-based), organogels (organic solvent-based), oleogels (oil-based), and ionogels (ionic liquid-based). These versatile materials have found applications in a wide range of fields, including drug delivery, wound healing, sensors, energy storage, and soft robotics. However, challenges such as the quick drying of hydrogels and the potential toxicity of organogels still limit their use.

Ionogels are a relatively new class of gels that combine ionic liquids (ILs) with organic or inorganic supporting networks. They provide the mechanical stability of a gel while retaining the unique advantages of ionic liquids, such as non-volatility, high chemical and thermal stability, non-flammability, and good ionic conductivity. Because both the ionic liquid and the gel matrix can be chosen from a vast range of candidates, ionogels can be tailored for specific needs in areas like sensors, actuators, energy devices, and biomedical applications. Ionogels are thus promising materials that bridge the benefits of ionic liquids and polymeric

networks. Their properties such as conductivity, flexibility, and biocompatibility make them particularly attractive for future biomedical technologies.

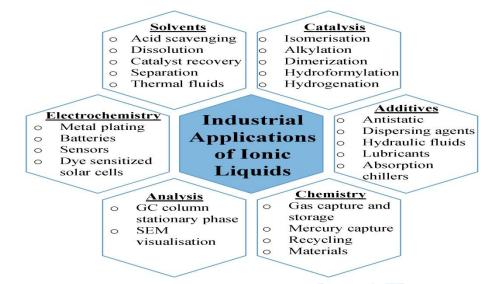


Fig.14.1: Industrial Applications of Ionic Liquid

Methodology:

- 1. Polymer/Inorganic Matrix (provides structural framework)
- 2. Ionic Liquid Phase (provides conductivity and stability)
- 3. Interaction between matrix and IL forms the Ionogel.

Conclusion:

Ionogels, formed by trapping ionic liquids within solid networks, have recently gained attention for biomedical applications. Their unique features such as ionic conductivity, non-flammability, thermal stability, and antibacterial activity make them useful for wearable sensors, wound healing, and controlled drug release. Biodegradable ionogels are particularly promising, as they can safely deliver drugs and support tissue repair. However, challenges remain, including high cost, limited biocompatibility of many ionic liquids, and the need for fully biodegradable systems.

Article No. 15

NANOCRYSTALS: A BREAKTHROUGH FOR ENHANCING ORAL BIOAVAILABILITY

Ms. Tejas Tanaji Patil

Poor solubility remains one of the major challenges in drug development, particularly for Biopharmaceutical Classification System (BCS) Class II drugs. These compounds often exhibit high permeability but limited absorption due to low solubility, resulting in reduced bioavailability. Nano-crystal technology has emerged as a promising solution, offering significant improvements in solubility, dissolution rate, and oral bioavailability. This article highlights the principles, preparation methods, advantages, challenges, and future prospects of nano-crystal-based drug formulations.

Preparation of Nanocrystals using PLH Technology

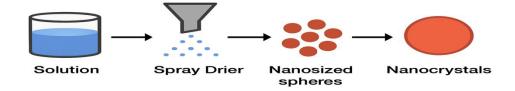


Fig.15.1: Preparation of Nano-crystals

Key Features of Nano-crystals

Nano-crystals are pure drug particles reduced to the nanometer scale, stabilized by surfactants or polymers. They improve oral bioavailability through:

- 1. Increased saturation solubility
- 2. Faster dissolution velocity
- 3. Enhanced adhesiveness to biological membranes
- 4. Potential stability improvements and reduced systemic side effects

Preparation Methods

Nano-crystals can be produced using bottom-up and top-down approaches:

- 1. Bottom-up: Precipitation and sono-crystallization techniques.
- 2. Top-down: Milling, high-pressure homogenization, and combination methods (e.g., SmartCrystal®, PLH technology).

Combination techniques enable efficient size reduction, better homogeneity, and scalability for industrial applications.

In Vivo Performance

Nano-crystals enhance pharmacokinetic profiles by increasing maximum plasma concentration (Cmax), reducing time to peak concentration (Tmax), and improving overall absorption. They also minimize fed/fasted variability and decrease gastric irritancy compared to conventional formulations. Several marketed drugs, such as fenofibrate and aprepitant, use nanocrystal technology.

Conclusion

Nano-crystal technology represents a universal and efficient strategy to overcome the challenges of poorly soluble drugs. By enhancing solubility and dissolution rates, nano-crystals significantly improve oral bioavailability, therapeutic efficacy, and patient safety. Although concerns about nano-toxicity and long-term stability remain, future research is expected to advance targeted delivery and surface-functionalized nano-crystals, broadening their clinical applications.

Reference

Junyaprasert, V. B., & Morakul, B. (2015). Nanocrystals for enhancement of oral bioavailability of poorly water-soluble drugs. Asian Journal of Pharmaceutical Sciences, 10 (1), 13–23. https://doi.org/10.1016/j.ajps.2014.08.005

Article No. 16

IMPLEMENTING A RISK-BASED STRATEGY FOR ANALYTICAL METHOD VALIDATION IN LINE WITH ICH Q14

Mr. Venkat B. Battalwar

In the evolving landscape of pharmaceutical quality management, the International Council for Harmonisation (ICH) has issued several guidelines aimed at ensuring robust scientific approaches and regulatory alignment across regions. One of the latest additions, ICH Q14, titled "Analytical Procedure Development," introduces a structured framework for the development and validation of analytical methods. It emphasizes a risk-based approach, integrating scientific understanding and quality risk management principles throughout the lifecycle of an analytical procedure. Implementing a risk-based strategy for analytical method validation in line with ICH Q14 represents a significant shift from the traditional "one-size-fits-all" validation model toward a more flexible, knowledge-driven, and lifecycle-oriented paradigm.

The core objective of ICH Q14 is to support the development of analytical procedures that are both fit-for-purpose and capable of consistently delivering reliable data throughout the product lifecycle. Unlike previous guidelines, which focused primarily on validation at a single point in time, ICH Q14 encourages a more holistic approach. It introduces the concept of Analytical Procedure Lifecycle Management (APLM), closely aligned with ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), Q10 (Pharmaceutical Quality System), and Q12 (Lifecycle Management). This integration ensures that method development, validation, and continuous performance verification are linked by a unified scientific rationale and risk management framework.

A risk-based approach under ICH Q14 begins with the identification of critical method attributes (CMAs) and critical method parameters (CMPs) during method development. These are the elements that most directly impact the performance of the analytical procedure and its ability to measure the quality attributes of the drug substance or product. By using tools such as risk assessments, cause-and-effect (Ishikawa) diagrams, and Failure Mode and Effects Analysis (FMEA), analytical scientists can prioritize parameters based on their potential impact on method

performance. This allows for targeted development activities and validation experiments that focus resources on the most critical aspects of the method.

During method development, the use of a risk-based approach enables the definition of a Method Operable Design Region (MODR)—a multidimensional space of input parameters that consistently yield acceptable method performance. By exploring and understanding the MODR through Design of Experiments (DoE) and robustness testing, scientists can demonstrate method reliability under a variety of conditions, thereby reducing the need for frequent post-approval changes. This proactive strategy contributes to regulatory flexibility, as methods developed with a well-defined MODR can be more easily adapted within the validated range without requiring regulatory re-approval, particularly when managed within an approved post-approval change management protocol (PACMP).

Analytical method validation itself, as informed by ICH Q14, becomes a confirmation of the method's expected performance under the defined conditions, rather than an isolated set of tests. Key performance characteristics—such as accuracy, precision, linearity, specificity, detection limit, and robustness—are still evaluated, but the emphasis is on confirming that the method consistently meets the predefined acceptance criteria derived during development. Risk-based thinking ensures that the validation is not overburdened with redundant experiments and is instead focused on the most scientifically and regulatorily relevant aspects.

ICH Q 14: RISK BASED ANAYTICAL PROCEDURE LIFECYCLE MANAGEMENT



Fig.16.1: ICH Q14

Importantly, ICH Q14 introduces the concept of continual improvement and performance verification of analytical procedures throughout their lifecycle. This aligns with the principles of a Pharmaceutical Quality System (PQS) as described in ICH Q10. Risk-based approaches enable ongoing monitoring of method performance using trending tools like control charts and process capability analysis. If deviations or drifts are detected, root cause investigations can be initiated, and the method can be refined as necessary within the established MODR, maintaining regulatory compliance and product quality without unnecessary change controls.

Another significant aspect of ICH Q14 is its focus on knowledge management. Implementing a risk-based approach requires comprehensive documentation and sharing of knowledge gained during method development. This includes the rationale behind method conditions, risk assessments, control strategies, and justification for MODR. Such documentation not only supports regulatory submissions but also serves as a knowledge base for future method improvements and troubleshooting.

In conclusion, adopting a risk-based strategy for analytical method validation in line with ICH Q14 represents a transformative approach to ensuring the reliability and regulatory compliance of analytical procedures. By integrating scientific understanding, quality risk management, and lifecycle thinking, pharmaceutical companies can enhance method robustness, reduce regulatory burden, and support continuous improvement. While the transition may require upfront investment in training, process redesign, and tool implementation, the long-term benefits—in terms of efficiency, flexibility, and quality assurance—are substantial.

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1. International Council for Harmonisation. (2023). ICH Q14 Analytical procedure development (Final guideline). Retrieved from

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Article No. 17

RESVERATROL-LOADED DEEP EUTECTIC SOLVENT-BASED EUTECTOGELS: A NOVEL STRATEGY FOR ENHANCED SKIN PERMEATION

Ms. Vijaya Sahadev Satpute

Transdermal delivery of bioactive molecules has gained attention for bypassing first-pass metabolism, improving patient compliance, and enabling localized therapy. Resveratrol, a natural polyphenolic stilbene, is widely studied for its antioxidant, anti-inflammatory, anti-aging, and chemopreventive effects, making it valuable for dermatological and systemic use. However, its poor solubility, rapid metabolism, and low bioavailability limit clinical application, creating the need for novel formulations that enhance solubility and permeation while remaining biocompatible.

Deep eutectic solvents (DES) have emerged as sustainable pharmaceutical solvents to address these challenges. Formed by mixing a hydrogen bond donor (HBD) and acceptor (HBA) in specific ratios, DES exhibit lower melting points, high solubilization, tunable polarity, low volatility, and eco-friendliness. Their pharmaceutical potential lies in dissolving poorly soluble compounds and enhancing membrane permeability. A common system, choline chloride (HBA) with glycerol or polyols (HBD), shows excellent solubilization and biocompatibility.

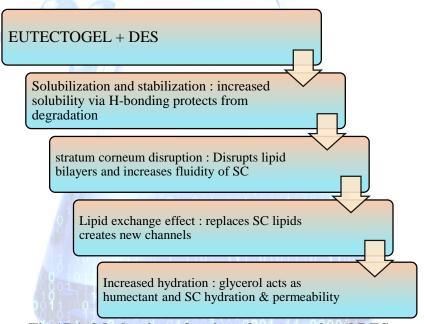


Fig.17.1: Mechanism of action of eutectogel and DES

To make DES suitable for topical use, they are incorporated into polymeric gels, creating eutectogels. These are three-dimensional polymer networks that immobilize the DES phase, combining solubilizing power with structural stability. Polymer choice is key for integrity, spreadability, and safety. Natural and synthetic polymers such as carbopol, gelatin, HPMC, and polysaccharides are preferred for clear, stable, and non-toxic gels. Dissolving resveratrol in DES and dispersing it into the polymer matrix produces eutectogels with improved solubility and mechanical stability.

The formulation of resveratrol-loaded eutectogels begins with preparing a DES, typically by mixing choline chloride and glycerol at optimized ratios to lower melting point and enhance solubility. Resveratrol is dissolved in this system, followed by dispersion and crosslinking of a suitable polymer to entrap the DES—drug mixture, forming the eutectogel. The DES-to-polymer ratio and drug concentration are optimized to balance loading, viscosity, spreadability, stability, and permeation.

Physicochemical characterization confirms eutectogel performance. Rheological tests assess viscosity, thixotropy, and spreadability, affecting dosing and patient acceptability. DSC demonstrates eutectic properties and DES-polymer interactions, while FTIR identifies hydrogen bonding between resveratrol, DES, and polymer. Microscopy or SEM shows gel homogeneity, ensuring chemical and structural stability.

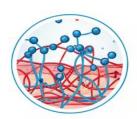
Biological evaluation focuses on skin permeation and retention. Ex vivo Franz diffusion studies demonstrate that eutectogels provide higher resveratrol permeation than conventional gels due to DES-mediated lipid disruption, hydration, and solubility enhancement. Retention studies confirm deposition in epidermis and dermis for prolonged release.

Therapeutically, enhanced delivery supports anti-aging effects via antioxidant activity and sirtuin activation, and anti-inflammatory benefits in conditions like psoriasis, eczema, and acne. Potential systemic absorption may extend benefits to cardiovascular and neurodegenerative therapy, pending further validation.

Resveratrol-loaded DES-based eutectogels offer a promising approach to overcome solubility and permeation barriers. By combining DES solubilization with gel structure, they achieve improved drug loading, enhanced dermal permeation, and superior skin retention compared to conventional formulations. While further in vivo studies are needed, eutectogels present a patient-friendly, efficient platform with potential for broader applications in topical and transdermal drug delivery.

NANOMATERIALS IN DERMATOLOGY & COSMETICS

TOPICAL SKIN APPLICATIONS



Anti-aging

- · Improves collagen syntesis,
- · Reduces wrinkles,
- · Reduces wrinklin,
- · Treats melassa & dark spots

Skin Pigimnation

- · Fights P. acnes,
- · Reduces inflammation
- · Clears skin



Wound Healing

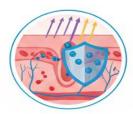
- · Promotes anginosenis,
- · Supports tissue repair
- · Keeps wounds hydrated

ADVANCED APPLICATIONS & POTENTIAL



Anti-inflanmatiory

- · Lowers cytcoinee,
- Helps in pscrasis, ezzem, & datanttis



Photogrotection

- · Shields against UV damage,
- · Prevents photoaging,
- · Works with sunscreens



Systemad Delivery (Potential)

 May allow absorption for cardivacuural & neuological benefits

Fig. 17.2: Applications of Resveratrol Eutectogel

References:

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 Supramolecular cyclodextrin deep eutectogel of resveratrol for anti-psoriasis treatment.
 International Journal of Biological Macromolecules, 299(5), 140156.
 https://doi.org/10.1016/j.ijbiomac.2025.140156

Article No. 18

BIODEGRADABLE NANO-COMPOSITE: FUTURE DIRECTION

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Biodegradable nano-composites represent an advanced category of materials created by incorporating nanoparticles into biodegradable polymers. This integration results in a composite material that not only offers improved mechanical and thermal properties but also retains the ability to degrade naturally over time. The nanoparticles used in these composites can be sourced from materials like clay, cellulose, or chitosan, each contributing to the enhanced performance of the polymer matrix. One prominent example of such a nano-composite is the combination of polylactic acid (PLA), a biodegradable plastic made from renewable resources such as corn starch, with nano-cellulose. The incorporation of cellulose nanoparticles strengthens the PLA, enhancing its flexibility and environmental resistance. As a result, PLA-based nano-composites are increasingly used in applications like eco-friendly packaging, offering a combination of durability and sustainability.

The growing concern surrounding plastic pollution underscores the critical necessity for sustainable alternatives. Conventional plastics, including polyethylene and polypropylene, can remain in the environment for centuries, inflicting considerable damage, particularly to aquatic ecosystems. These persistent, non-biodegradable materials are infamous for ensnaring marine organisms, blocking waterways, and infiltrating the food chain as microplastics. In contrast, biodegradable substances such as PLA-based nano-composites present a viable solution, as they decompose significantly faster, thereby reducing their long-term ecological footprint. Furthermore, these materials play a crucial role in promoting a circular economy by lessening reliance on products derived from fossil fuels. Sourced from renewable materials, they serve as substitutes for petroleum-based plastics, thereby encouraging more sustainable manufacturing practices. A notable illustration of their environmentally friendly capabilities is the use of biodegradable packaging for food items, which decomposes naturally in landfills without exacerbating environmental pollution.

When evaluating biodegradable nano-composites against traditional composites, the key difference is their impact on the environment. Traditional composites, such as fiberglass and polymer-based materials, are well-known for their strength and durability. However, they are highly resistant to degradation, often remaining in the environment for hundreds of years and contributing to substantial waste. A typical example is fiberglass used in construction; while it is strong, it poses recycling challenges and frequently ends up in landfills. On the other hand, biodegradable nano-composites, which include materials like polylactic acid

(PLA) combined with clay nanoparticles, are designed to break down naturally under environmental conditions, thus helping to alleviate long-term waste issues. Although traditional composites are superior in strength and longevity for certain uses, biodegradable nano-composites offer an environmentally friendly option that does not significantly sacrifice performance. For example, PLA-based nano-composites are increasingly utilized in products with shorter lifespans, such as packaging and disposable utensils, where environmental impact is prioritized over extended durability. As industries strive to lessen their ecological footprint and reduce carbon emissions, biodegradable nano-composites are becoming a practical alternative to conventional, unsustainable materials.

Natural biodegradable polymers, sourced from renewable materials, have garnered significant interest due to their environmentally friendly characteristics and ability to decompose naturally. Notable examples include starch, cellulose, chitosan, gelatine, polylactic acid (PLA), and polyhydroxyalkanoates (PHA). These polymers are primarily obtained from plants or microorganisms and are broken down by microbial activity over time, contributing to their sustainability. Starch is a readily available natural polymer, starch is typically extracted from plants such as corn and potatoes. It is biodegradable and can be transformed into films or foams suitable for packaging. Despite its susceptibility to water and relatively weak mechanical properties, starch has successfully found applications in biodegradable packaging, agricultural films, and single-use products. Cellulose is a naturally occurring polymer, found in the cell walls of plants, is one of the most plentiful organic compounds on the planet. Cellulose can be modified to create derivatives like cellulose acetate and microcrystalline cellulose, which are utilized in textiles, packaging, and medical fields. Its biodegradability positions cellulose as a promising alternative to synthetic plastics. Chitosan is extracted from the exoskeletons of crustaceans such as shrimp, chitosan is a biodegradable polysaccharide recognized for its antimicrobial and biocompatible qualities. It is frequently employed in wound dressings, drug delivery systems, and biodegradable packaging. Chitosan's ability to decompose and its non-toxic nature make it a favoured option in both medical and food sectors. Gelatine is a natural protein derived from collagen found in animal tissues, widely used in the food and pharmaceutical industries. It is biodegradable and serves various purposes, including controlled drug delivery systems, edible food coatings, and biodegradable packaging materials. Its capacity to form films and gels enhances its versatility in these applications. PLA (Polylactic Acid) is one of the most commercially popular biodegradable polymers. Made from renewable resources like corn starch or sugarcane, PLA is widely used in packaging, agricultural films, and even in medical applications such as sutures. PLA is biodegradable in industrial composting environments and offers sustainable alternative to petroleum-based **PHA** plastics. (Polyhydroxyalkanoates) is a biodegradable polymer produced by bacteria as an energy storage material. It can be synthesized from renewable resources like plant sugars or fatty acids. PHA is used in a variety of applications, including biodegradable plastics, medical implants, and controlled-release drug delivery

systems. Its unique ability to degrade in marine and soil environments gives it an advantage over traditional plastics.

Table 18.1: Types, Source and Uses Biodegradable Nano-composites

Sr. No.	Biodegradable nano- composites	Source	Uses
1.	Starch-Based	Natural	Secured with cellulose nano-crystals for food packaging and biomedical applications.
2.	Chitosan Nanoclay Composites	Natural	In wound healing and drug delivery due to their antimicrobial properties.
3.	Cellulose Nanofiber Composites	Natural	In sustainable packaging, bioplastics, and medical implants.
4.	Alginate-Based	Natural	in tissue engineering and controlled drug release systems
5.	Protein-Based	Natural	Biomedical applications like scaffolds and wound dressings.
6.	Poly(lactic acid) (PLA)	Synthetic	In food packaging, medical implants, and 3D printing.
7.	Polycaprolactone (PCL)	Synthetic	In drug delivery systems and biodegradable sutures.
8.	Polyhydroxyalkanoates (PHA)	Synthetic	Sustainable alternative for single-use plastics and medical applications.
9.	Poly(butylene succinate) (PBS)	Synthetic	In production of agriculture and eco-friendly plastic products.
10.	Polyethylene Oxide (PEO)	Synthetic	For biomedical applications as hydrogels and drug carriers.

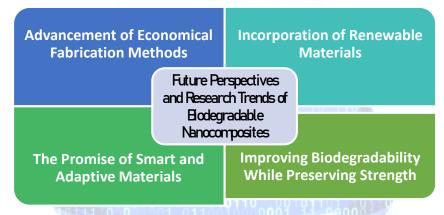


Fig 18.1: Future Perspectives and Research Trends of Biodegradable Nano-composites

Conclusion:

Biodegradable nano-composites represents combine eco-friendly polymers with nano-fillers like cellulose nanofibers, nano-clays, and metal nanoparticles to enhance strength, thermal stability, and antimicrobial properties. These materials address the limitations of traditional biodegradable plastics and are used in food packaging, agriculture, and biomedical fields. Despite challenges like high costs and scalability, ongoing research is making production more efficient. With advanced characterization tools (XRD, SEM, etc.) and rising demand for sustainable materials, biodegradable nano-composites are key to reducing plastic pollution and supporting a circular economy.

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Bharati Vidyapeeth College of Pharmacy, Kolhapur

Article No. 19

JACKFRUIT (ARTOCARPUS HETEROPHYLLUS LAM.): NUTRITIONAL PROFILE, POLYSACCHARIDE ANALYSIS, AND OPPORTUNITIES FOR PRODUCT DEVELOPMENT

Mr. Prashant Pandurang Bavadekar

Jackfruit (*Artocarpus heterophyllus Lam.*) is a large tropical fruit from the *Moraceae* family, originally native to India and Malaysia. Today, it is widely cultivated across Southeast Asia and other warm regions, including Thailand, Bangladesh, Australia, the United States (Florida), Latin America, and the Caribbean.

Nutritionally, jackfruit is considered a powerhouse. It is rich in carbohydrates, proteins, and dietary fibers along with essential vitamins and minerals such as vitamin A, B-complex, vitamin C, calcium, iron, magnesium, potassium, and sodium. Compared to other common fruits like bananas, mangoes, and pineapples, jackfruit provides a broader range of nutrients. It also contains many beneficial plant compounds, including flavonoids, tannins, phenolic acids, carotenoids, and amino acids, which give it strong antioxidant, anti-inflammatory, and antimicrobial properties. Interestingly, these nutritional and phytochemical profiles change depending on the maturity stage of the fruit, which has encouraged researchers to study the best harvest time for specific uses.

Beyond its nutritional benefits, jackfruit has drawn attention for its therapeutic value. Studies have shown that it possesses antimicrobial properties effective against certain bacteria and foodborne pathogens, as well as antiviral activity against HIV and hepatitis C. Research also suggests that jackfruit may help manage diabetes by regulating blood sugar levels and slowing down glucose metabolism. Other reported benefits include anticancer potential, immune system support, and weight management, wound healing, and antioxidant protection.

This review aims to provide a broad perspective on jackfruit covering its nutritional and phytochemical richness, therapeutic properties, culinary uses, and commercial prospects. By examining both the opportunities and challenges, it highlights jackfruit not only as a nutritious fruit but also as an emerging commodity of value in the global food industry.

Methodology:

Polysaccharides from jackfruit are usually extracted by conventional methods, but newer assisted techniques can boost yield and add functional properties. The most common approaches are microwave and ultrasound, while others include radio frequency (RF), pulsed electric field (PEF), and subcritical water extraction (SWE)

Microwave-assisted extraction (MAE): Works by rapidly increasing temperature to break plant cells and reduce viscosity. It can improve yield but may alter pectin's properties. For example, optimal conditions (66 °C, ~10 min) produced jackfruit pectin with good antioxidant and antibacterial activity. MAE combined with PEF has shown yields up to ~29.8%.

Ultrasound-assisted extraction (UAE): Uses sound waves and cavitation to disrupt cells, helping solvents penetrate faster. Optimized conditions for jackfruit peel gave yields around 13–14%. A combination of ultrasound and microwave (UMAE) further improved efficiency, with yields up to 4.3% higher than conventional methods.

Subcritical water extraction (SWE): Uses water under high temperature and pressure (100–374 °C, <22 MPa). Compared with citric acid extraction, SWE gave slightly lower yields (~15%), but the pectin had more side chains, lower viscosity, and different structure.

Radio frequency-assisted extraction (RFAE): Provides fast, uniform heating with minimal solvents. Applied to jackfruit, it achieved a yield of ~29%, much higher than conventional (~12%).

Conclusion:

Jackfruit is a nutrient-rich tropical fruit packed with vitamins, minerals, amino acids, protein, fiber and a wide range of phytochemicals that can support health and help prevent disease. Its nutritional and bioactive content changes with the stage of maturity and the part of the fruit being used, which means these factors should be considered when exploring its full benefits. Research so far shows that jackfruit has many promising properties, including antioxidant, anti-inflammatory, antidiabetic, anticancer, antimicrobial, and wound-healing effects. With the growing shift towards plant-based diets and sustainable food sources, jackfruit's unique taste and meaty texture make it an appealing meat substitute in various dishes. Beyond food, it also shows potential in non-food industries, opening opportunities for commercial use.

Article No. 20

ARTIFICIAL INTELLIGENCE IN PHARMACOGNOSY: UNLOCKING THE SECRETS OF NATURE'S PHARMACY

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Department of Pharmacognosy

Pharmacognosy the science of studying drugs derived from natural sources such as plants, microbes, marine organisms, and minerals has always been at the core of drug discovery. From aspirin (derived from Salix alba) to vincristine (Catharanthus roseus), natural products have shaped modern medicine. However, the traditional pharmacognostic process, involving plant collection, phytochemical isolation, structural elucidation, and bioactivity testing, is labor-intensive, time-consuming, and costly. This is where Artificial Intelligence (AI) is emerging as a game-changer. By combining computational tools with natural product research, AI enables scientists to rapidly screen phytochemicals, predict their biological activity, optimize formulations, and even repurpose existing natural molecules for new therapeutic indications. The integration of AI into pharmacognosy is unlocking hidden treasures of "Nature's Pharmacy," accelerating discoveries that were previously unimaginable.

1. AI in Phytochemical Discovery and Screening: Traditional phytochemical screening requires extensive chromatography, spectroscopy, and bioassays, which may take months or years. AI shortens this process through predictive modeling. Machine learning (ML) algorithms can analyze large chemical libraries of phytoconstituents and predict their potential targets in the human body. QSAR (Quantitative Structure–Activity Relationship) models powered by AI link structural features of phytochemicals to biological activities, identifying promising drug leads. Deep learning neural networks can scan thousands of phytomolecules against disease-related protein targets, providing a rational approach to prioritize candidates for lab testing.

For example, AI-driven screening has identified potential anti-COVID-19 compounds from Glycyrrhiza glabra (licorice) and Withania somnifera (ashwagandha), reducing the need for extensive trial-and-error methods.

2. AI in Standardization and Quality Control of Herbal Medicines:

One of the greatest challenges in pharmacognosy is standardization of herbal drugs, as variations in soil, climate, and harvesting methods influence phytochemical content. AI is revolutionizing this domain by:

- i. Image recognition tools that authenticate plant species
- ii. Chemometric AI models that analyze spectral fingerprints (HPLC, FTIR, NMR) to distinguish genuine extracts from adulterated or counterfeit products.
- iii. Predictive algorithms that estimate phytoconstituent stability and degradation patterns, ensuring consistent quality over time.

This reduces human error, ensures patient safety, and strengthens consumer trust in herbal medicines.

3. AI in Polyherbal Formulation and Synergy Studies:

Traditional systems like Ayurveda, Siddha, and Chinese medicine often use polyherbal formulations, where multiple plants are combined for synergistic therapeutic effects. Studying these complex interactions manually is almost impossible. AI addresses this challenge by Network pharmacology with AI integration maps the interactions between phytochemicals, targets, and disease pathways. AI-based optimization helps design polyherbal blends with maximum efficacy and minimum side effects.

For example, researchers are using AI to study synergistic anti-diabetic effects of polyherbal combinations like Gymnema sylvestre + Trigonella foenum graecum.

4. AI in Drug Repurposing of Natural Products:

Drug repurposing is the identification of new therapeutic applications for existing molecules. Natural products with known safety profiles are excellent candidates.

AI assists in:

- i. Scanning databases of phytochemicals against disease-associated targets.
- ii. Predicting alternative indications for traditional herbal remedies.
- iii. Identifying novel uses for well-known compounds (e.g., curcumin from turmeric, resveratrol from grapes).

5. Integration of AI with Omics and Big Data:

With advances in genomics, proteomics, metabolomics, and transcriptomics, vast datasets are generated from medicinal plants. AI transforms this big data into actionable insights: Metabolomics + AI identifies new secondary metabolites linked to therapeutic potential. Genomic

prediction models help identify genes responsible for biosynthesis of bioactive compounds. Cheminformatics + AI integrates structural databases of natural products, making drug discovery faster.

6. Applications of AI in Pharmacognosy beyond Drug Discovery

AI applications are not limited to discovery but extend to other aspects of pharmacognosy:

- i. Conservation of medicinal plants: AI predicts overharvesting risks and supports biodiversity management.
- ii. Smart agriculture: AI-driven monitoring of medicinal plant cultivation ensures high yield and consistent phytochemical content.
- iii. Green extraction optimization: Predictive AI models determine ideal extraction solvents, temperatures, and durations to maximize bioactive yield with minimal environmental impact.



Fig. 20.1: Applications of AI in Pharmacognosy

Artificial Intelligence is not a replacement for pharmacognosy it is a powerful enabler. By unlocking hidden patterns within complex plant-derived data, AI empowers researchers to move from slow, serendipitous discoveries toward rational, systematic, and accelerated innovation. As the demand for safer, affordable, and natural medicines grows, AI-driven pharmacognosy promises to bridge the gap between traditional knowledge and modern science, truly unlocking the secrets of Nature's Pharmacy.

Article No. 21

UNLOCKING CURCUMIN'S POTENTIAL: COCRYSTAL ENGINEERING WITH L-VALINE FOR ENHANCED SOLUBILITY AND BIOAVAILABILITY

Ms. Aishwarya Pujari

Cocrystal engineering is a supramolecular approach designed to improve the physicochemical and biopharmaceutical properties of poorly soluble active pharmaceutical ingredients (APIs) without altering their intrinsic pharmacological activity. Curcumin, a polyphenolic compound derived from *Curcuma longa*, is well known for its diverse therapeutic activities including antioxidant, anti-inflammatory, antimicrobial, anticancer, and neuroprotective effects. Despite these benefits, clinical application of curcumin is limited due to poor aqueous solubility, instability under physiological conditions, rapid metabolism, and low oral bioavailability.

Cocrystallization involves the formation of a stable crystalline lattice between an API and a pharmaceutically acceptable coformer through non-covalent interactions such as hydrogen bonding, van der Waals forces and π – π stacking. Unlike prodrugs or salt formation, cocrystals do not alter the covalent structure of the API but instead reorganize molecules into a new crystalline phase with improved physicochemical characteristics. Among several coformers, amino acids have attracted great interest owing to their safety, multifunctionality and GRAS (generally recognized as safe) status. L-valine is especially attractive due to its zwitterionic nature, ability to form multiple hydrogen bonds and its role in stabilizing supramolecular assemblies. The curcumin–L-valine cocrystal is therefore a rational design aimed at overcoming solubility and bioavailability challenges.

Characterization of the curcumin–L-valine cocrystal has been carried out using powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC), Fourier transform infrared spectroscopy (FTIR) and scanning electron microscopy (SEM). These techniques confirm the formation of a new crystalline lattice with distinct melting point, diffraction peaks and spectral shifts, which clearly differentiate it from either curcumin or valine alone. PXRD analysis provides evidence of new peaks characteristic of the cocrystal, DSC reveals a unique endothermic transition corresponding to the melting point of the cocrystal, and FTIR demonstrates hydrogen bonding interactions between phenolic hydroxyl groups of curcumin and amino/carboxyl groups of valine. SEM further highlights morphological differences between the cocrystal and its parent components

Disruption of the strong intermolecular hydrogen bonds present in crystalline curcumin accounts for the enhanced solubility of its cocrystal with L-valine. Studies report a 3–5 fold increase in aqueous solubility accompanied by faster dissolution and improved wettability, which together enhance gastrointestinal absorption and oral bioavailability. In dissolution testing across simulated gastric and intestinal media, the cocrystal consistently shows improved release characteristics compared to pure curcumin.

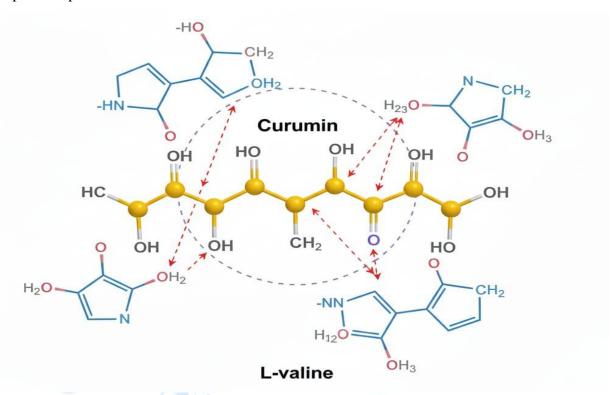


Fig.21.1 Proposed supramolecular interaction between curcumin and L-valine in cocrystal formation.

Enhanced solubility and dissolution are directly correlated with improved biological activity. The curcumin–L-valine cocrystal demonstrates higher antioxidant potential in assays such as DPPH and ABTS radical scavenging tests. Its anti-inflammatory efficacy is also greater, reflected in enhanced suppression of NF-κB signaling pathways and reduction in pro-inflammatory cytokines. In addition, cellular studies reveal increased uptake of the cocrystal leading to superior cytotoxic activity against various cancer cell lines. These results indicate that cocrystal engineering not only improves pharmacokinetics but also enhances pharmacodynamic properties.

Amino acid-based cocrystals also offer additional advantages such as safety, biocompatibility, regulatory acceptance and multifunctional stabilization of supramolecular assemblies. Amino

acids are naturally occurring, widely used in clinical nutrition, and already approved for human which favorable consumption, makes them highly for regulatory approval. Therefore, cocrystal engineering of curcumin with L-valine represents a rational and innovative approach to overcome solubility and bioavailability challenges. This strategy improves the therapeutic potential of curcumin by enabling higher bioavailability, stronger antioxidant and antiinflammatory responses, and more effective anticancer activity. The curcumin-L-valine cocrystal thus provides a platform for developing nutraceutical and pharmaceutical formulations with greater clinical impact. Future research should emphasize scale-up production, comprehensive in vivo pharmacokinetic and pharmacodynamic evaluations, and addressing regulatory requirements to translate this promising system into commercial application.

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Bharati Vidyapeeth College of Pharmacy, Kolhapur

Article No. 22

NETWORK PHARMACOLOGY: A NEW ERA IN RATIONAL DRUG DISCOVERY

Ms. Vidya Kakade

Drug discovery has historically revolved around the "one drug—one target—one disease" model. While this linear approach has produced many successful therapeutics, it often falls short when addressing complex diseases such as cancer, diabetes, neurodegenerative disorders, or inflammatory conditions. These diseases are multifactorial, involving intricate molecular networks and multiple signaling pathways. To overcome this limitation, **network pharmacology** has emerged as a cutting-edge paradigm that integrates systems biology, computational science, and pharmacology to accelerate the design of novel therapeutics.

What is Network Pharmacology?

Network pharmacology is a holistic strategy that maps the complex interactions between drugs, targets, pathways, and diseases. Unlike conventional methods that focus on isolated targets, this approach captures the dynamic interplay of biological systems, allowing researchers to understand how multiple compounds can act synergistically across multiple targets.

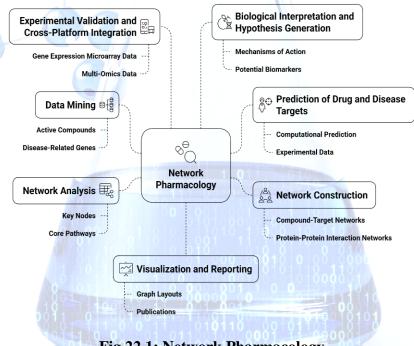


Fig.22.1: Network Pharmacology

Integration with Computer-Aided Drug Design

Modern computer-aided drug design (CADD) tools—such as molecular docking, molecular dynamics simulations, pharmacophore modeling, and quantitative structure—activity relationship (QSAR) studies—are seamlessly integrated with network pharmacology. Together, they allow researchers to:

- Predict potential drug—target interactions with higher accuracy.
- Prioritize lead molecules by evaluating their network influence.
- Explore polypharmacology, where one drug interacts beneficially with several targets.
- Identify synergistic effects of phytoconstituents or combination therapies.

By using publicly available databases (e.g., DrugBank, PubChem, STRING, and KEGG), researchers can computationally link bioactive molecules to disease pathways, providing a rational basis for experimental validation.

Applications in Drug Discovery

- 1. **Cancer Therapy:** Network pharmacology helps unravel the molecular crosstalk of tumor pathways, allowing discovery of multi-target inhibitors with fewer side effects.
- 2. **Neurodegenerative Disorders:** Mapping neurotransmitter networks enables repositioning of drugs for conditions like Alzheimer's and Parkinson's disease.
- 3. **Herbal Medicine Research:** Traditional medicine often relies on multi-component formulations. Network pharmacology helps identify active phytoconstituents, their targets, and synergistic mechanisms.
- 4. **Personalized Medicine:** By integrating patient-specific data, network models can predict individualized therapeutic responses.

Advantages over Conventional Approaches

- Captures the systems-level complexity of diseases.
- Reduces **trial-and-error** in lead identification.
- Enhances chances of success by identifying multi-target strategies.
- Facilitates **drug repurposing** by predicting novel indications of existing drugs.

Challenges and Future Perspectives

Despite its promise, network pharmacology faces hurdles such as incomplete biological databases, computational limitations, and regulatory acceptance. Translating in silico predictions into clinically validated drugs remains a major challenge. However, with the integration of artificial intelligence, big data analytics, and high-throughput experimental platforms, network pharmacology is poised to become a mainstream tool in rational drug discovery.

Conclusion

Network pharmacology, empowered by computer-aided drug design, is transforming the pharmaceutical landscape. By moving beyond reductionist models, it provides a holistic, cost-effective, and efficient pathway for discovering next-generation therapeutics. In the coming years, this approach is expected to play a pivotal role in developing safe, multi-target, and patient-tailored medicines.



Bharati Vidyapeeth College of Pharmacy, Kolhapur

Article No. 23

HERBAL NANOCARRIER SYSTEM OF HERBAL EXTRACT FOR THE TREATMENT OF GOUT ARTHRITIS

Ms. Gouri Ghatage

Gout is an excruciating inflammatory disease that is created when monosodium urate (MSU) crystals are deposited in joint spaces. It is a particular type of arthritis. The illness requires a management approach that combines preventative and therapeutic measures. A recent advancement in the treatment of gout is the use of biologic drugs that target NLRP3, such as monoclonal treatments, which block particular pro-inflammatory cytokines to enable more precise treatment. Drug delivery using nanoparticles improves biological availability and target delivery, potentially boosting therapeutic efficacy and lowering overall toxicity. Again, it is impossible to overlook the preventative strategy, which primarily consists of maintaining specific dietary and weight changes in addition to pharmaceutical treatments to lower uric acid (UA) levels and lessen the frequency of acute bouts. The development of patient genetic profiling and the discovery of biomarkers fuel the movement toward personalized medicine and care, which is rapidly overtaking one-size-fits-all approaches as the most efficient way to treat specific patients. In order to improve these strategies, the quality of life for gout patients, and the level of gout therapy, the following paper attempts to give an updated overview of gout management with an emphasis on current advancements.

Of the inflammatory arthritic disorders, gout arthritis (GA) is one of the most common, affecting 0.02% to 6.80% of adults worldwide. A clinical sign of hyperuricemia is gout, which occurs when serum uric acid (SUA) levels are higher than 6.8 mg/dL. When UA is either produced in excess or eliminated insufficiently, monosodium urate (MSU) builds up in soft tissues and joints, causing both acute and chronic inflammation. Comorbid diseases, lifestyle decisions, metabolic variables, and genetic susceptibility are important factors that contribute to the development of gout. Genetic considerations are important since the body's ability to metabolize UA might be impacted by certain genetic variants.

Lifestyle variables that promote UA production and limit excretion include excessive eating of foods high in purines (e.g., red meat, seafood), alcohol, organ meats, foods high in glutamate, foods high in RNA, and sugary beverages. Due to increased UA production and decreased renal

clearance, obesity and metabolic syndrome increase the risk of developing gout. Hyperuricemia, or high UA levels, impact 11% of adults with normal kidney function and 80% of people with stage 4 chronic kidney disease (CKD). As kidney function deteriorates, hyperuricemia becomes more prevalent. In contrast, 50% of persons with hyperuricemia and 70% of people with gout have impaired kidney function (CKD stage 2 or above), which might exacerbate each other. Because damaged kidneys are unable to adequately eliminate UA from the body, it builds up and causes this reciprocal interaction. UA is typified by painful, sporadic, and frequently recurring arthritic attacks because UA levels fluctuate during the course of the disease.

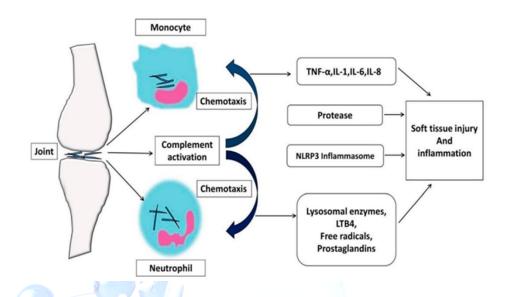


Figure 23.1: Pathophysiology of GA inflammation.

Nanotechnology creates nanoparticles that range in size from 1 to 100 mm by working with particles at the atomic and molecular level. Because of their huge surface areas and unique abilities, these particles can be used in a wide range of industries, including electronics and pharmaceuticals. A wide range of industries, including energy, nature and life sciences, agriculture, building, transportation, and environmental protection, have seen new developments as a result of the ability to interact with materials at the nanoscale. These industries also have the potential to significantly improve human well-being.

Gout treatment is advanced by nanotechnology in a number of ways, including as better drug administration, reduced inflammation, altered UA crystals, and enhanced diagnostics. Nanoparticles' primary benefits are their capacity to boost therapeutic efficacy, lower toxicity, and

improve medication pharmacokinetics. The necessity for additional research, including thorough clinical studies, as well as safety and regulatory considerations must be taken into account. A more individualized, efficient, and secure future for the treatment of gout is within our grasp as long as nanoparticle-based medicines are developed and improved.

Advantages of Nanotechnology in Gout Management

- 1. Targeted drug delivery: Nanocarriers can be designed to specifically target macrophages or inflammatory joints where urate crystals are accumulating.
- 2. Increased Bioavailability: Herbal actives, such as those found in Carica papaya, have a low water solubility.
- 3. Controlled and Sustained Release: By lowering the frequency of dose, nanoparticles can offer a sustained release profile. helps prevent flare-ups by sustaining therapeutic medication levels for prolonged periods of time
- 4. Less Toxicity and Dosage: Lower dosages of the active ingredient can be required as a result of better targeting and delivery efficiency.
- 5. Better Anti-Inflammatory Activity: By increasing the stability and activity of herbal active ingredients, nanoencapsulation can improve their anti-inflammatory qualities.

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Article No. 24

PHYTOGENIC STRATEGIES FOR ECO-FRIENDLY NANOPARTICLE FABRICATION

Mr. Prathamesh Salunkhe

Nanotechnology has become one of the fastest growing fields in science, with nanoparticles playing a central role in this revolution. Due to their extremely small size and high surface area-to-volume ratio, nanoparticles display unique chemical, physical, and biological properties that make them useful in diverse fields such as medicine, agriculture, energy, and environmental remediation. Gold and silver nanoparticles, for instance, have found roles in medical imaging, biosensing, and antimicrobial treatments, while zinc oxide nanoparticles are being used in sunscreens, catalysts, and electronics. Despite their potential, traditional methods for producing nanoparticles are often far from environmentally friendly. They usually involve toxic solvents, costly reagents, or energy-intensive processes, which contribute to pollution and limit their large-scale application. This has created a growing demand for greener, safer, and more cost-effective approaches to nanoparticle synthesis.

Among the many alternatives, plant-mediated synthesis—also known as phytogenic nanoparticle fabrication—has emerged as a promising strategy. Plants are a rich source of natural compounds such as flavonoids, phenols, terpenoids, alkaloids, tannins, and proteins, which can serve as both reducing and stabilizing agents during nanoparticle formation. This means that instead of relying on harsh chemicals to reduce metal ions into nanoparticles, researchers can simply use plant extracts, which not only trigger the reaction but also coat the newly formed particles, improving their stability and biocompatibility. This eco-friendly approach reduces harmful by-products, requires less energy, and can be easily scaled up, making it a practical solution for sustainable nanotechnology.

The basic process of phytogenic synthesis is relatively straightforward. Plant parts such as leaves, stems, roots, flowers, or fruits are collected, washed, and boiled or soaked in water or alcohol to extract their bioactive compounds. This extract is then mixed with a solution of a metal salt precursor such as silver nitrate, chloroauric acid, or zinc acetate. Within minutes to hours, a visible color change occurs, often indicating the formation of nanoparticles. For example, a pale yellow solution may turn deep red or brown due to surface plasmon resonance—a phenomenon unique to

nanoparticles. Under microscopic and spectroscopic analysis, the newly formed particles often exhibit desirable shapes such as spheres, rods, or triangular plates, depending on the plant used and the reaction conditions.

A wide variety of plants have been successfully employed for nanoparticle synthesis. Neem leaves, aloe vera, tulsi, hibiscus, and green tea are some of the most studied examples. Gold nanoparticles synthesized using neem extracts have demonstrated potential in targeted cancer therapy, while silver nanoparticles derived from tulsi have shown strong antimicrobial activity against bacteria and fungi. Aloe vera extracts have been used to produce zinc oxide nanoparticles, which are now being tested for use in sunscreens and photocatalytic degradation of pollutants. These examples highlight how common plants, some even considered household herbs, can function as "green factories" for advanced nanomaterials.

The advantages of phytogenic nanoparticle synthesis extend well beyond environmental safety. One of the most significant benefits is biocompatibility. Because plant metabolites act as natural capping agents, the nanoparticles they produce are often safer for biological applications. This makes them ideal for medicine, where nanoparticles are used for drug delivery, diagnostic imaging, or as therapeutic agents themselves. Another advantage is cost-effectiveness. Plant extracts are inexpensive and widely available, especially in countries rich in biodiversity. This means that large-scale production is possible without heavy investment in specialized equipment or chemicals. Additionally, phytogenic methods are relatively quick, with nanoparticles sometimes forming within minutes, which makes them practical for commercial production.

Applications of these green nanoparticles are rapidly expanding. In healthcare, phytogenic silver and gold nanoparticles are being investigated as antibacterial coatings for medical devices, as agents in cancer treatment, and as carriers for drugs that need precise delivery within the body. In agriculture, nanoparticles synthesized from plants are being incorporated into nano-fertilizers and nanopesticides, which promise to improve crop yields while reducing chemical usage and soil pollution. In the environmental sector, green nanoparticles are being tested for their ability to degrade toxic dyes, capture heavy metals, and neutralize industrial pollutants in water. Beyond these fields, plant-derived nanoparticles are being explored in renewable energy applications such as solar cells, fuel cells, and batteries, where their unique optical and electrical properties can be harnessed.

NANOMATERIALS: DIVERSE APPLICATIONS

DRUG DELIVERY SYSTEMS DIAGNOSTIC IMAGING & BIOSENSING Targeted Paylsad Release · Molecular Probes Controlled Release Kintetics In Vio Imaging Agents CANCER THERAPY FICESORS · Photohermal/Photodyamic Tx Moleculal Probes Cntifungal Treastments In Vio Imaging Agents Antifiral Therapies · Biomarker Detection ANTIMICROGIAL AGENTS NANO-FERTLIZERS & NANOPESICIDES · Photthermal/Photodyramic Tx Slow-Release Nutrients Chemo-Sensiizaations Pest-Resistant Coatings · Immuntorapty Adjuvants · Improved Crop Yield ENVIRONMENTAL REMOCATIVION ANTIMICROGIAL AGENTS Antibacterial Nucrients Pollunt Rate Enhacenen Antt-Resistant Coatings Water Purfication Chemical Synstesis Improved Crop Yield COSMETICS & PERSONAL CARE CATALYSIS & PHOTOCATALL'AS UV Protection (Nano-ZO/TIO₂) Reaction Rate Enhacement · Water Purfication Anti-Aging Formulations · Transdermal Drug Delivery · Chemical Synstesis

Fig. 24.1: Nanoparticles applications

Despite their promise, phytogenic strategies face several challenges. One of the biggest hurdles is variability. The concentration and type of phytochemicals in a plant extract can differ depending on the plant species, the part of the plant used, the season in which it was harvested, and even the geographic location. This makes it difficult to ensure reproducibility, which is a key requirement for commercial and clinical applications. Another challenge lies in scaling up the process. While phytogenic synthesis works efficiently in small laboratory settings, industrial-scale production requires optimization of parameters such as temperature, pH, concentration, and reaction time to ensure uniformity of nanoparticle size and shape. Furthermore, while the general mechanism of nanoparticle formation is understood, the precise molecular interactions between specific phytochemicals and metal ions remain unclear, and more detailed research is required.

Safety and regulatory approval also represent critical barriers. Although phytogenic nanoparticles are considered more biocompatible than their chemically synthesized counterparts, their long-term effects on human health and the environment are not fully known. Regulatory bodies will require thorough toxicity and biosafety assessments before these materials can be widely used in medicine or agriculture. Intellectual property and commercialization also present challenges, as many traditional plant species are involved, raising questions about ownership and benefit-sharing.

Looking forward, the future of phytogenic nanotechnology appears bright, provided that these challenges can be overcome. Researchers are now working on integrating biotechnology and molecular biology techniques to better understand and control the synthesis process. Artificial intelligence and machine learning are also being applied to predict the behavior of plant extracts in nanoparticle formation, which could significantly speed up the discovery of optimal synthesis conditions. Interdisciplinary collaboration will be crucial, as chemists, material scientists, botanists, and engineers must work together to develop standardized, scalable, and efficient methods. Governments and industries, too, will need to invest in infrastructure and regulatory frameworks that support the adoption of green nanotechnology.

In conclusion, phytogenic strategies for nanoparticle fabrication represent a sustainable, innovative, and highly promising alternative to conventional chemical synthesis. By harnessing the natural power of plants, scientists can create nanoparticles that are not only effective but also safer for humans and the environment. The approach reduces chemical waste, minimizes energy consumption, and enhances biocompatibility, making it particularly attractive for medicine, agriculture, and environmental applications. While challenges of reproducibility, scalability, and regulation remain, the continued advancement of green nanotechnology is likely to establish phytogenic synthesis as a mainstream approach in the near future. In a world that is increasingly demanding sustainable solutions, plant-mediated nanoparticle fabrication exemplifies how ancient natural wisdom can be combined with modern science to shape a cleaner and more responsible future for technology.

Article No. 25

ANTIMICROBIAL RESISTANCE: A CRITICAL CHALLENGE TO PUBLIC HEALTH WORLDWIDE

Dr. Mrs. S. A. ArvindekarAssistant Professor
Department of Pharmaceutical Chemistry

Antibiotics, once hailed as 20th-century "magic bullets," revolutionized therapy and continue to save millions of lives. Beyond medicine, they have long been used in animal husbandry and food production, particularly in developing nations. However, widespread and often inappropriate use has fuelled antimicrobial resistance (AMR)—the ability of bacteria, viruses, fungi, and parasites to survive drugs designed to kill them. AMR infections are harder to treat and carry higher risks of severe illness and death.

Antimicrobials include antibiotics, antifungals, antivirals, disinfectants, and preservatives, but antibiotic resistance is the most prevalent. Resistance arises through natural genetic mutations as microbes adapt to selective pressure. Escalating antibiotic use, especially in low- and middle-income countries, accelerates this process, increasing global morbidity and mortality. AMR now represents a "silent pandemic," threatening health, food security, and economies worldwide. Its spread is driven by factors spanning healthcare, agriculture, pharmaceuticals, waste management, trade, and finance. Drug-resistant "superbugs," such as methicillin-resistant *Staphylococcus aureus* (MRSA) and multidrug-resistant or extensively drug-resistant tuberculosis (MDR/XDR-TB), exemplify the crisis.

The World Health Organization ranks AMR among the top three global health threats. In 2019 alone, an estimated 1.27 million deaths were directly attributable to AMR and nearly 5 million associated with it; projections warn of up to 10 million annual deaths by 2050, surpassing cancer mortality. Overuse of antibiotics in livestock feed further accelerates resistance, demanding tighter surveillance and regulation. AMR undermines both treatment and prevention, compromising procedures such as cancer chemotherapy, transplantation, and invasive surgeries.

Despite urgent need, antibiotic discovery has stalled since the 1980s, with only a few new drug classes emerging since fluoroquinolones in 1987. Preserving existing antimicrobials through prudent use is therefore critical.

This disproportionate ratio between drug-resistant pathogens and number of available antibiotics has given sufficient reasons to critics for their prediction of an imminent postantibiotic era. The timeline of major antibiotics discovery and their resistances is depicted below (Figure 1).

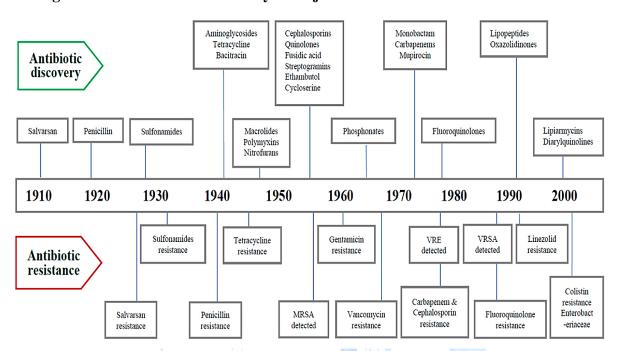


Figure 25.1: Timeline of discovery of major antibiotics and antibiotic resistance

Combating antimicrobial resistance (AMR) demands urgent, coordinated global action. Governments, international agencies, healthcare professionals, researchers, pharma and agriculture sectors, and the public must work together to slow its spread and reduce health and economic impacts. Key measures include antimicrobial stewardship, strict antibiotic policies, surveillance, limiting over-the-counter and livestock antibiotic use, ensuring access to quality medicines, vaccines, and diagnostics, and enforcing legislation. Prevention through rational antibiotic use, rapid diagnostics, new vaccines, and development of novel antimicrobial or alternative therapies is critical. Without swift, united efforts and strong political commitment, rising AMR could soon undermine modern medical advances such as surgery, organ transplantation, neonatal care, and cancer treatment.

Article No. 26

THE ROLE OF ARTIFICIAL INTELLIGENCE IN THE PHARMACEUTICAL INDUSTRY

Mr. Koushal K. Kadam

Artificial Intelligence (AI) is changing the way industries work, and healthcare is one of the most impacted sectors. Specifically, the pharmaceutical industry is seeing huge advancements with the help of AI. Whether it's speeding up drug discovery, improving clinical trials, or enhancing patient care, AI is driving major changes that are reshaping the way pharmaceutical companies operate. It's making processes faster, smarter, and more cost-effective.

AI can sift through massive amounts of data, identify patterns, and predict outcomes, which helps pharmaceutical companies make better decisions. This not only speeds up the development of new drugs but also makes the entire process more accurate and effective. The potential benefits are enormous, particularly when it comes to getting life-saving medicines to patients faster than ever before.

According to Precedence Research, the AI-driven pharmaceutical market is expected to grow from USD 908 million in 2022 to a staggering USD 11813.56 million by 2032, at a compound annual growth rate (CAGR) of 29.30%. This rapid growth highlights just how vital AI is becoming in revolutionizing drug development and improving healthcare overall.

In fact, the rise of AI-driven pharmaceuticals is increasingly being recognized as one of the top AI business ideas. The intersection of AI and pharma is paving the way for breakthrough innovations, making it an attractive area for businesses and investors alike.

With this exciting growth in mind, let's explore the specific ways AI is transforming the pharmaceutical industry—from speeding up drug research to offering better patient care.

1. Drug Discovery and Development

One of the most significant impacts of AI is in drug discovery:

- Target Identification: AI can analyze large datasets from genomics, proteomics, and clinical trials to identify potential biological targets for new drugs.
- **Molecule Generation**: Generative AI models can design new drug-like molecules with specific properties, significantly speeding up early-stage research.

• **Predictive Modeling**: Machine learning can predict how a drug will interact with the body and forecast its potential side effects or toxicity.

Example: Companies like Atomwise and Insilico Medicine are using AI to identify new compounds for diseases such as cancer and fibrosis

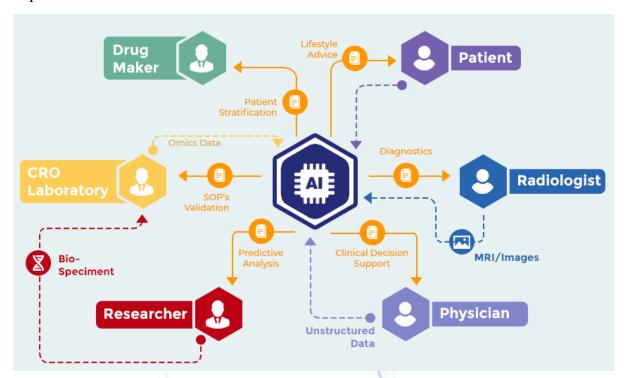


Fig.26.1 AI in P'ceutical Industry

2. Clinical Trials

AI streamlines clinical trials, which are often time-consuming and costly:

- **Patient Recruitment**: AI algorithms can scan electronic health records to find eligible participants faster and more accurately.
- **Trial Design**: AI helps design adaptive trials that can adjust based on interim results, improving success rates.
- **Data Monitoring**: AI enables real-time monitoring of trial data, identifying adverse effects or anomalies promptly.

3. Drug Manufacturing

AI is improving efficiency and quality in pharmaceutical manufacturing through:

- **Predictive Maintenance**: Machine learning models can forecast equipment failures, reducing downtime.
- **Process Optimization**: AI helps in real-time optimization of manufacturing processes to ensure consistency and reduce waste.
- **Quality Control**: Computer vision systems can inspect products for defects more accurately than human workers.

4. Personalized Medicine

AI supports the shift toward personalized treatments:

- By analyzing patient data (e.g., genetic profiles), AI can help tailor drug treatments to individual needs, improving outcomes and minimizing side effects.
- AI also plays a role in developing **companion diagnostics**, tests used to determine which patients are likely to benefit from a specific drug.

5. Market Access and Drug Repurposing

- **Drug Repurposing**: AI can analyze vast biomedical databases to find new uses for existing drugs, potentially shortening the development timeline.
- Market Analysis: AI tools are used to predict market trends, understand competitor landscapes, and optimize pricing strategies.

Benefits of AI in Pharma

- Faster Drug Development: AI reduces the time required to identify and test new drugs.
- Cost Reduction: By automating complex tasks, AI lowers R&D and operational costs.
- Improved Accuracy: AI minimizes human error in data analysis and clinical predictions.
- **Informed Decision-Making**: AI provides insights based on large datasets that would be impossible to analyze manually.

Despite its promise, AI in pharma faces several hurdles:

- Data Quality and Availability: High-quality, standardized data is essential for effective AI models.
- Regulatory Compliance: Regulatory bodies like the FDA require transparency and validation of AI algorithms.

• Ethical and Privacy Concerns: Using sensitive health data raises concerns about patient privacy and data protection.

The future of AI in pharma is bright, with continued growth expected. Emerging areas include:

- **AI-powered robots** for lab automation.
- **Digital twins** of patients to simulate responses to drugs.
- **Real-world evidence generation** using AI to analyze data from wearable devices and health apps.

Conclusion

AI is transforming the pharmaceutical industry by enhancing every stage of the drug lifecycle—from discovery and development to manufacturing and market delivery. While challenges remain, the integration of AI offers unprecedented opportunities to accelerate innovation, reduce costs, and ultimately improve patient care. With responsible adoption and continued investment, AI will remain a cornerstone of pharmaceutical advancement in the coming decades.

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Article No. 27

MACHINE LEARNING IN DRUG DESIGN: FROM DATA TO DISCOVERY

Ms. Priyanka Kiran Sutar

Over the last decade, machine learning (ML) has emerged as a transformative research paradigm across a wide range of scientific and engineering disciplines. Its capability to effectively analyze large, complicated datasets and discern both linear and nonlinear relationships among variables has positioned it as a powerful tool. While classical algorithms such as linear regression and principal component analysis (PCA) have long been staples, more advanced algorithms like Gaussian regression processes (GPR) and artificial neural networks (ANNs) have significantly expanded the scope of what is possible. This new data-driven approach offers a compelling alternative to traditional research methods, particularly in fields like drug discovery, which have historically relied on tedious and often inefficient experimental processes.

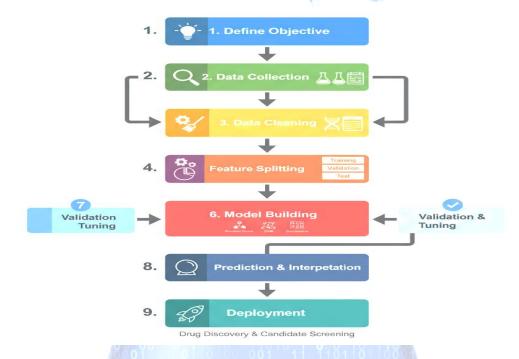


Fig.27.1: Stepwise Procedure for Machine Learning in Drug Design

Traditionally, the mathematical modeling of drug release and other related processes has been predicated on analytical, semi-analytical, or numerical methods. These approaches often necessitate idealized assumptions, such as homogeneous matrices, perfect sink conditions, and

constant diffusion coefficients, while frequently neglecting complex factors like degradation dynamics. The resulting models, while useful under specific constraints, often lack the necessary predictability to accurately model complex release behaviors or be reliably extrapolated to new experimental conditions.

In contrast to conventional methods, the ML approach is inherently data-driven, thereby eliminating the need for idealized assumptions. This allows ML algorithms to accurately and adaptively model complex systems and release mechanisms. Once an ML model is established, it can be readily utilized with various parameter values, providing an inexpensive and environmentally friendly approach that minimizes the reliance on repetitive, error-prone experiments. This not only optimizes manpower and resources but also enables continuous model improvement as new data become available, enhancing accuracy and adaptability over time.

Machine Learning (ML) encompasses a range of computational techniques that enable systems to learn from data, identify patterns, and make decisions with minimal human intervention. At its core, ML is grounded in the idea that machines can learn from and adapt to data, improving their accuracy over time. This section outlines the fundamental principles of ML, focusing on concepts critical to drug discovery, including supervised and unsupervised learning and deep learning.

- Supervised Learning: Supervised learning algorithms are trained on labeled datasets, meaning each training example is paired with an output label. This type of learning is akin to learning with a teacher who provides the algorithm with the correct answers during training. In drug discovery, supervised learning can be used for predictive modeling tasks such as predicting the activity of compounds against specific targets based on their chemical structures
- Unsupervised Learning: Unlike supervised learning, unsupervised learning algorithms deal with datasets without labeled responses. The goal is to uncover hidden patterns or intrinsic structures within the data. Unsupervised learning is particularly useful in drug discovery for tasks such as identifying novel drug-like compounds or grouping compounds based on similarity in their molecular structures, without prior knowledge of their activities
- Deep Learning: A subset of ML, deep learning uses neural networks with many layers (hence "deep") to model complex patterns in data. Deep learning is particularly adept at handling vast amounts of data and can automatically discover the representations needed for detection or

classification. In drug discovery, deep learning has shown promise in areas such as virtual screening of compounds, predicting drug-target interactions, and generating novel chemical entities.

Machine Learning (ML) has emerged as a powerful tool across the spectrum of drug discovery, offering innovative approaches to overcome traditional challenges. Its applications range from the initial stages of identifying and validating drug targets to optimizing lead compounds and assessing their safety profiles. This section comprehensively explores these applications, highlighting the transformative impact of ML.

AI IN DRUG DISCOVERY & DEVELOPMENT

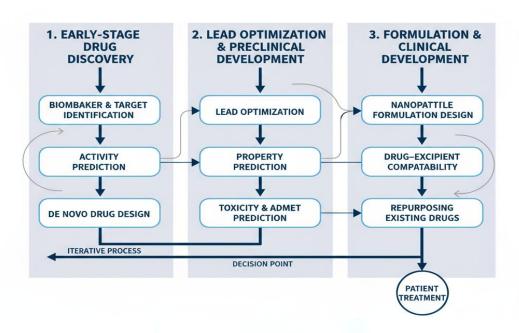


Fig.27.2: AI in Drug Discovery & Development

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Article No. 28

GLAUCOMA: THE SILENT THIEF OF SIGHT

Ms. Samiksha Vishnu Kamble

Glaucoma is a group of eye diseases that damage the optic nerve, which carries visual information from the eye to the brain. If left untreated, this damage leads to permanent vision loss and possibly blindness. It's often referred to as the "silent thief of sight" because early stages frequently have no noticeable symptoms. Many people are unaware until significant vision loss has occurred. Glaucoma is often called the "silent thief of sight" because it typically progresses with little or no noticeable symptoms until significant, irreversible vision damage has already occurred. Its hallmark is damage to the optic nerve, often associated with elevated intraocular (eye) pressure, which leads to loss of retinal ganglion cells and characteristic visual field defects.

Glaucoma is one of the leading causes of irreversible blindness globally. Many people with glaucoma are undiagnosed, especially in early stages, because symptoms are minimal or absent. The number of affected individuals is expected to increase due to aging populations worldwide. In certain populations, the burden is high, especially where screening and access to ophthalmic care are limited. Glaucoma is not just high eye pressure the mechanism of damage involves multiple interacting factors:

Intraocular Pressure (IOP) and mechanical stress the fluid inside the eye, aqueous humor, is produced and drained through pathways (mainly the trabecular meshwork). If drainage is impaired or production increases, pressure can rise. Elevated pressure can physically deform structures like the lamina cribrosa (a sieve-like structure at the back of the eye through which optic nerve fibers pass). The pressure gradient deforms pores, compresses axons, and affects blood flow to nerve fibers. This leads to disruption of axonal transport (flow of nutrients / waste) in retinal ganglion cell axons, and eventually cell death (apoptosis). Non-pressure-related factors Some people develop glaucoma even with "normal" IOP (normal-tension glaucoma), pointing to other contributing mechanisms Structural changes As nerve fibers are lost, the optic nerve head shows characteristic "cupping" (i.e. the "cup" in the optic disc becomes larger relative to the disc) and thinning of the neuroretinal rim. The retinal nerve fiber layer (RNFL)

becomes thinner, which can be measured by imaging modalities. While existing damage is generally irreversible, aim is to slow or halt progression and preserve remaining vision. The main principle is lowering the intraocular pressure (IOP) (or reducing stress on the optic nerve).

Medical Therapy (Eye Drops / Medications):

First-line in many cases are topical ocular hypotensive medications (eye drops). Classes include: Prostaglandin analogues, Beta-blockers, Alpha-agonists, Carbonic anhydrase inhibitors, Rho-kinase inhibitors, Combination drops. Oral medications sometimes used (e.g. systemic carbonic anhydrase inhibitors) when additional pressure lowering is needed. Adherence (correct use, timing) is crucial — noncompliance is a major cause of treatment failure.

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Jarag, R., Jarag, R., & Dhule, G. (2023). Formulation and evaluation of polyherbal in-situ gel for glaucoma. International Journal of Pharmaceutical Sciences & Research, 14(12), 5880-5894.



Article No. 29

DRUGS, DIET AND AI: THE 'GAME CHANGER' NEW FINDINGS ON TACKLING HEART CONDITIONS

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The 2025 European Society of Cardiology Congress held in Madrid unveiled a series of transformative findings that collectively mark a new era in tackling cardiovascular diseases through the synergistic integration of drugs, diet, and artificial intelligence (AI). Central to this progress is the advent of novel pharmacological therapies such as AstraZeneca's baxdrostat, a drug that directly inhibits aldosterone production and has demonstrated significant efficacy in patients with hypertension resistant to standard treatments. Clinical trials reveal that baxdrostat effectively lowers systolic blood pressure, thereby substantially reducing the risk of heart attacks and strokes, conditions that remain leading causes of morbidity and mortality worldwide.

This breakthrough is complemented by emerging weight-loss medications that not only facilitate significant reductions in body weight but have also been linked to a halving of hospitalization rates and premature death among heart patients, underscoring the critical importance of metabolic health in cardiovascular risk management. Further pharmacological advances challenge existing paradigms, with studies suggesting that clopidogrel may offer superior protection compared to aspirin in preventing adverse cardiovascular events, potentially reshaping clinical guidelines for antiplatelet therapy. Parallel to pharmaceutical innovations, nutritional research presented at the congress reaffirmed and expanded our understanding of diet's pivotal role in cardiovascular health. Potassium-rich foods, including avocados, bananas, and leafy greens, were shown to reduce the incidence of heart-related complications by approximately 24%, highlighting the value of dietary modifications as a cost-effective and accessible intervention. The findings reinforce the long-standing advocacy for a heart-healthy diet, emphasizing not only macronutrient balance but also micronutrient optimization as a critical component of prevention strategies. Lifestyle factors, particularly regular physical exercise, were also emphasized for their ability to facilitate cardiac recovery and improve long-term cardiovascular outcomes. This holistic approach recognizes that

effective heart disease prevention extends beyond medication adherence, integrating behavioral and environmental factors that collectively influence health trajectories.

Perhaps most strikingly, the congress showcased the rapidly evolving role of AI as a game changer in cardiovascular diagnostics and management. An AI-powered stethoscope now capable of diagnosing complex heart conditions in just 15 seconds exemplifies how machine learning algorithms and digital signal processing can dramatically accelerate clinical decision-making while enhancing diagnostic precision. These technologies not only augment the clinician's capabilities but also hold promise for expanding access to expert-level cardiac assessment in resource-limited settings. Additionally, AI-driven tools are being harnessed to improve stroke recovery outcomes by enabling personalized rehabilitation programs and facilitating real-time access to updated clinical guidelines, thereby optimizing care pathways. One of the more innovative developments is the use of AI to calculate vascular age, a novel digital biomarker that surpasses traditional risk scores by providing individualized assessments of arterial health. This advancement enables earlier intervention and more tailored treatment plans, embodying the principles of precision medicine. Advances were not limited to adult populations; paediatric cardiology also benefited from innovative technologies.

A non-invasive, two-minute cheek-swab test was introduced for the early detection of arrhythmogenic cardiomyopathy (ACM), a condition that can cause sudden cardiac death in young individuals. This early diagnostic tool allows for intervention years before clinical symptoms appear, potentially saving countless lives through timely management. This breakthrough underscores the expanding scope of cardiovascular research to include genetic and molecular diagnostics, which promise to revolutionize preventive cardiology from childhood onward. The congress also addressed emerging public health challenges, notably the cardiovascular risks associated with youth vaping, which continues to gain popularity despite mounting evidence of its harmful effects. This underscores the need for ongoing public health campaigns and policy interventions to mitigate these risks, particularly in vulnerable populations.

Moreover, research highlighted the ancillary cardiovascular benefits of vaccinations; notably, the shingles vaccine was shown to reduce the risk of heart attacks and strokes by up to 18%, revealing a compelling link between infectious disease prevention and cardiovascular health.

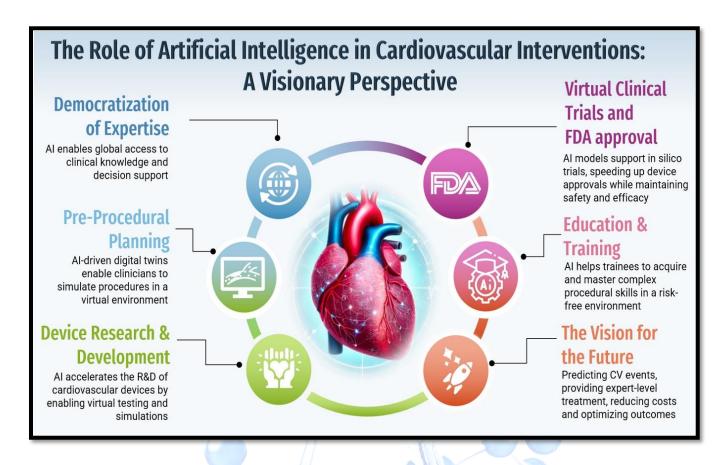


Fig.29.1: Role of AI in Cardiovascular Interventions

There is a convergence of pharmacological innovation, nutritional science, and artificial intelligence that collectively herald a paradigm shift in cardiovascular care. These advances embody a multifaceted strategy that not only targets the biological underpinnings of heart disease but also leverages technology and lifestyle modifications to enhance prevention, diagnosis, and treatment. As the integration of AI continues to evolve, it promises to democratize access to high-quality cardiac care and enable personalized medicine approaches that were once aspirational. Meanwhile, novel drugs and dietary insights provide powerful tools to reduce the global burden of cardiovascular disease, a leading cause of death worldwide. Together, these developments chart an optimistic path toward more effective, efficient, and equitable management of heart conditions, with the potential to save millions of lives and improve quality of life on a global scale.

Article No. 30

ENHANCING SKIN-LIGHTENING: ROLE OF CORTICOSTEROID IN MELASMA

Ms. Siddhi Ashok Lawand

Melasma is a prevalent, acquired hyper-pigmentary disorder characterized by the appearance of symmetrical, brown-to-gray patches on sun-exposed areas, particularly the face. Hydrocortisone is BCS Class II (High Permeability & Low Solubility) drug which diffuses into the cytoplasm and binds to the glucocorticoid receptor (GR) & it can reduce the activity of tyrosinase, the enzyme responsible for melanin synthesis, thereby decreasing pigmentation. The drug exerts it's pharmacological action by penetrating and binding to cytoplasmic receptor protein and causes a structural change in steroid receptor complex. This structural change allows it's migration in to the nucleus and then binding to specific sites on the DNA which leads to transcription of specific m-RNA and which ultimately regulates protein synthesis. It exerts both glucocorticoid and mineralocorticoid actions. The drug exerts anti-inflammatory and immunosuppressant actions as follows: -

- Induce lipocortins in macrophages, endothelium, and fibroblasts which inhibits phospholipase A2 and thus decreases the production of Prostaglandins, leukotriens (LT), and platelet activating factor.
- Causes negative regulation of genes for cytokines in macrophages, endothelial cells and lymphocytes and thus decreases the production of interleukins (IL-1, IL-2, IL-3, IL-6), TNFalpha, GM-CSF (granulocyte macrophage colony stimulating factor), Gama interferon and suppresses fibroblast proliferation and T-lymphocyte functions and interferes chemo taxis.
- Decreases the production of acute phase reactants from macrophages and endothelial cells and interferes complement function.
- Decreases the production of ELAM- 1(Endothelial leukocyte adhesion molecule-1) and ICAM-1(intracellular adhesion molecule- 1) in endothelial cells.
- Inhibit IgE mediated histamine and LT-C4 release from basophiles and the effects of antigenantibody reaction is not mediated.
- Reduces the production of collagenase and stromolysin and thus prevents tissue destruction.

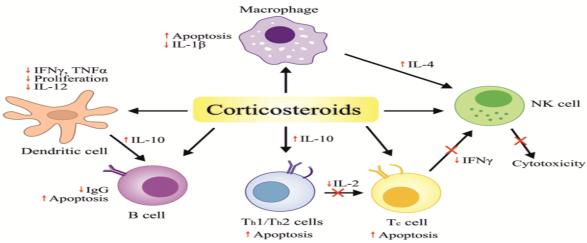


Fig.30.1: Corticosteroids

Since their introduction, topical corticosteroids have become indispensable in the treatment of various dermatoses. Hydrocortisone was the first compound. Modifications in the basic structure generated in vivo activity and thus different topically active compounds were discovered. Apart from the Stoughton vasoconstrictor assay, various other methods are used for potency assessment of topical corticosteroids. Topical corticosteroides are classified based upon potency and action of these molecules. Mechanism of action at the cellular level and indications of topical corticosteroid use have been discussed. Various adverse effects often occur as an extension of their activity combined with inappropriate usage. Tachyphylaxis and contact allergy are potential problems in clinical practice. Newer compounds with improved risk-benefit ratio are available.

In conclusion, the management of melasma patients remains a significant challenge to patients and dermatologists. While triple-combination HQ cream is the gold standard, numerous non-HQ agents have been studied in the treatment of melasma or other hyperpigmentation and may be considered as potential adjuncts or alternatives. Well- designed, large-scale randomized controlled trials in melasma and hyperpigmentation of various skin types are needed. As additional agents are being investigated, the dermatologist should be up to date with new and emerging therapies to better inform tailored treatments that may enhance treatment outcomes.

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Article No. 31

mRNA TECHNOLOGY: SHAPING THE FUTURE OF VACCINE DELIVERY AND THERAPEUTICS

Miss. Dipali Ashok Navadkar

Messenger RNA (mRNA) technology has emerged as a groundbreaking innovation in the field of vaccine delivery, rapidly transforming how we approach immunization and treatment. Unlike traditional vaccines, which often use weakened or inactivated pathogens, mRNA vaccines teach cells to produce a specific protein that triggers an immune response. This novel approach has not only accelerated the development of COVID-19 vaccines but also opened new doors for tackling a range of infectious diseases, cancer, and genetic disorders

Traditional vaccines typically rely on weakened or inactivated viruses, or pieces of viral proteins, to trigger an immune response. mRNA vaccines take a different approach. The synthetic mRNA is encapsulated in protective lipid nanoparticles (LNPs), which protect the fragile mRNA molecules and help them enter human cells. Once inside the cell, the mRNA is translated by ribosomes into viral proteins (like the spike protein of SARS-CoV-2). These proteins are displayed on the cell surface or released, alerting the immune system to produce antibodies and activate T cells. This primes the immune system to recognize and attack the actual virus if it infects the body in the future.

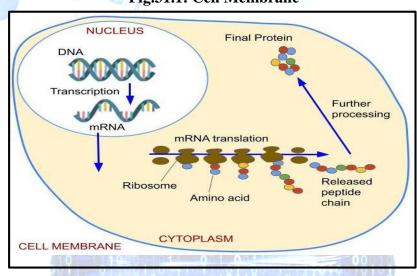


Fig.31.1: Cell Membrane

Advantages over Traditional Vaccine Platforms

- **Speed and flexibility:** Once the genetic sequence of a pathogen is known, mRNA vaccines can be designed and produced rapidly, bypassing the need to grow live virus or proteins in cell cultures. This was evident during the COVID-19 pandemic where vaccines were developed in under a year.
- **Safety:** mRNA vaccines do not contain live virus, cannot cause infection, and do not integrate into the human genome, reducing risk.
- **Adaptability:** The mRNA sequence can be quickly adjusted to respond to emerging variants or new diseases, making it ideal for fast-evolving pathogens.
- **Potent immune response:** mRNA vaccines stimulate both antibody production and T- cell mediated immunity, which is crucial for long-lasting protection.

Therapeutic Potential beyond Vaccines

- Cancer therapies: Personalized mRNA vaccines are being developed to encode tumor- specific antigens, enabling the immune system to specifically target and destroy cancer cells. This approach can be tailored to the unique mutations present in a patient's tumor.
- Protein replacement therapies: For genetic disorders caused by missing or defective proteins, mRNA can provide instructions to produce the functional version temporarily. Diseases like cystic fibrosis or enzyme deficiencies are targets for this approach.
- Immunomodulation: mRNA can be used to produce cytokines or antibodies within the body, modulating immune responses for autoimmune diseases or chronic inflammation.

Challenges and Limitations

- Stability: mRNA molecules are inherently unstable and prone to degradation by enzymes called RNases. This requires specialized cold storage (e.g., -70°C) and formulation in lipid nanoparticles for protection.
- Delivery: Efficient delivery to target cells while avoiding unwanted immune

- activation or toxicity is complex and an active area of research.
- **Manufacturing:** Scaling up production to meet global demand requires advanced infrastructure and stringent quality controls.
- **Distribution:** Cold-chain requirements pose logistical hurdles, especially in resource-limited settings.

Future Directions and Innovations

- Self-amplifying mRNA (saRNA): These constructs can replicate inside cells, producing more antigen from a smaller initial dose, potentially reducing side effects and cost.
- **Circular RNA:** Circularized mRNA is more stable and may sustain protein production longer, enhancing therapeutic potential.



Article No. 32

PREDICTING COGNITIVE DECLINE WITH AI-ENHANCED EEG: A NEW FRONTIER IN PRECLINICAL NEURODIAGNOSTICS

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In 2025, a pioneering study marked a significant milestone in the early detection of memory decline and neurodegenerative disorders by harnessing the power of artificial intelligence (AI) applied to electroencephalogram (EEG) data. The research, conducted by a multidisciplinary team of neuroscientists, data scientists, and clinicians, leveraged advanced machine learning algorithms to analyse EEG recordings from a diverse cohort of middle-aged and elderly participants. These individuals were followed longitudinally, allowing researchers to correlate specific neural patterns with the onset and progression of memory impairment over several years. The core innovation of this study was the ability of AI models to detect subtle, complex changes in brainwave activity such as alterations in neural oscillations, connectivity between brain regions, and spectral power distribution—that are often imperceptible to conventional EEG analysis or clinical evaluation. These electrophysiological signatures were found to reliably predict future memory decline long before the appearance of overt cognitive symptoms or clinical diagnoses, such as mild cognitive impairment (MCI) or Alzheimer's disease (AD). This early identification is crucial, as it opens a valuable window for intervention when therapeutic strategies are most likely to be effective in slowing or preventing disease progression. The methodology involved recording resting-state and task-related EEG data, capturing the brain's electrical activity in various cognitive states.

The AI algorithms utilized deep learning architectures capable of handling high-dimensional timeseries data, extracting meaningful features, and differentiating between normal aging patterns and early pathological changes. By training these models on large datasets and validating them on independent cohorts, the researchers ensured robust predictive performance and generalizability. One key finding was the alteration in the synchronization of neural networks associated with memory consolidation, particularly within the hippocampus and prefrontal cortex, regions critically involved in learning and memory processes. The AI detected disruptions in theta and

gamma oscillations, frequencies known to support memory encoding and retrieval, as well as weakened functional connectivity that presaged cognitive decline. Importantly, these changes were evident several years prior to clinical diagnosis, suggesting that EEG combined with AI could serve as a sensitive biomarker for preclinical neuro-degeneration.

The implications of this research are profound and multifaceted. Clinically, it offers a noninvasive, cost-effective, and widely accessible screening tool that could be deployed in routine health assessments to identify individuals at elevated risk for memory disorders. Early detection through AI-enhanced EEG analysis could facilitate timely interventions—whether pharmacological, lifestyle-based, or cognitive therapies—aimed at preserving cognitive function and improving quality of life. Furthermore, this approach could revolutionize the design and enrolment criteria of clinical trials by enabling the selection of participants in the earliest stages of disease, thereby increasing the likelihood of successful therapeutic outcomes. From a public health perspective, widespread adoption of such predictive technology could help reduce the societal and economic burdens of dementia by shifting the focus toward prevention and early management. Beyond its immediate clinical utility, the study exemplifies the transformative potential of integrating AI with neurophysiological data.

It demonstrates how machine learning can uncover hidden patterns within complex brain signals that traditional methods might overlook, offering novel insights into the pathophysiology of memory decline. This integration paves the way for personalized medicine, where individual brain profiles can guide tailored interventions. Additionally, the research sparks interest in combining EEG-based predictions with other biomarkers, such as neuroimaging, cerebrospinal fluid analysis, and genetic risk factors, to build comprehensive models of cognitive health. Such multimodal approaches could further enhance accuracy and provide a more holistic understanding of disease mechanisms.

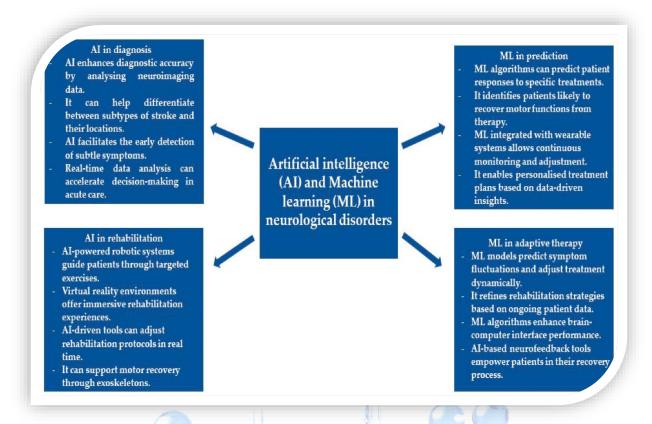


Fig. 32.1 Role of AI in neurological disorders

While the findings are promising, the study also highlights challenges that warrant attention. Standardization of EEG acquisition protocols, validation across diverse populations, and ensuring the interpretability of AI models are critical steps before widespread clinical implementation. Ethical considerations around data privacy, informed consent, and the psychological impact of early diagnosis must be carefully managed. Nevertheless, this research marks a paradigm shift in memory disorder diagnostics, showcasing how AI-driven EEG analysis can move the field closer to pre-emptive neurology—where proactive monitoring replaces reactive treatment. In conclusion, the 2025 AI-EEG study stands as a landmark achievement in the quest to detect memory decline at its nascent stages. By revealing electrophysiological biomarkers predictive of future cognitive impairment years before clinical manifestation, it offers hope for earlier, more effective interventions against neurodegenerative diseases. This fusion of neuroscience and artificial intelligence heralds a new frontier in cognitive health, promising to transform how memory disorders are diagnosed, monitored, and ultimately managed, with the potential to improve outcomes for millions worldwide.

Article No. 33

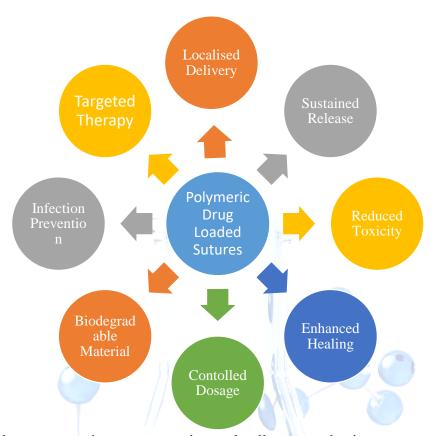
POLYMERIC DRUG-LOADED SUTURES: A PLATFORM FOR SUSTAINED THERAPEUTIC DELIVERY IN SURGICAL WOUND HEALING

Ms. Urmila Sudhakar Rathod

Drug-loaded surgical sutures represent an innovative biomedical advancement integrating wound closure with localized therapeutic drug delivery. These specialized sutures are engineered to release pharmacologically active agents at the surgical site, offering controlled, sustained, and targeted therapeutic effects. The concept aligns with the emerging field of "smart biomaterials," where the suture serves as both a mechanical and a pharmacological tool for enhanced post-operative care. Traditional sutures merely approximate tissues and provide mechanical support; however, polymeric drug-loaded sutures advance beyond this by combining wound approximation and drug elution in a single platform. The integration of polymers such as polyglactin 910 (Vicryl®), polyglycolic acid (PGA), polylactic-co-glycolic acid (PLGA), polycaprolactone (PCL), and polydioxanone (PDS) enables tunable degradation rates and drug release kinetics. These polymers are biocompatible, bioabsorbable, and can encapsulate a variety of therapeutic molecules including antibiotics, anti-inflammatory agents, growth factors, and analgesics.

Depending on the polymer-drug interaction, the release profile can range from hours to several weeks, ensuring prolonged drug availability at the surgical site and minimizing systemic side effects. Drug loading onto sutures can be achieved by several methods such as dip coating, solvent casting, electrospinning, or melt extrusion. Dip coating involves immersing prefabricated sutures into a drug-polymer solution, whereas electrospinning allows uniform nanofiber coating with high surface area for efficient drug adsorption. These techniques ensure uniform drug distribution and controlled release without compromising mechanical integrity, knot security, or tensile strength of the sutures. The therapeutic intent of polymeric drug-loaded sutures extends to reducing postoperative infections, inflammation, and pain, while accelerating wound healing. Antibiotic-loaded sutures such as triclosan-coated Vicryl have already been commercialized, demonstrating reduced microbial colonization. Similarly, incorporation of

anti-inflammatory drugs like ibuprofen or diclofenac aims to control local inflammation and pain without systemic adverse effects. Growth factor or herbal extract incorporation has also



been explored to promote tissue regeneration and collagen synthesis.

Fig. 33.1: Advantages of Polymeric Drug-Loaded Sutures in Sustained Therapeutic Delivery and Wound Healing

Characterization of drug-loaded sutures involves a multi-dimensional evaluation including morphological (SEM), chemical (FTIR, DSC, TGA), and mechanical (tensile strength, knot pull, elongation) studies. In vitro release studies in phosphate buffer saline (PBS) or simulated body fluid (SBF) are carried out to determine the kinetics and mechanism of drug release, often following Higuchi or Korsmeyer–Peppas models. Biodegradation and biocompatibility studies further confirm the safe degradation of polymers into non-toxic byproducts.

Reference: -

Khalid, G. M., et al. "Drug-Eluting Sutures by Hot-Melt Extrusion: Current Trends and Future Potentials." *Materials*, vol. 16, no. 22, 2023.

Article No. 34

ANALYTICAL QUALITY BY DESIGN: A SYSTEMATIC APPROACH TO MODERN HPLC METHOD DEVELOPMENT

Mr. Sanket N. Kumbhar

High-Performance Liquid Chromatography (HPLC) remains one of the most essential tools in pharmaceutical analysis, widely used for the quantification, identification, and purity assessment of drug substances and products. Traditionally, HPLC method development relied heavily on trial-and-error experimentation and expert intuition, which often led to time-consuming processes, suboptimal robustness, and poor method understanding. To overcome these challenges, the pharmaceutical industry has increasingly adopted Analytical Quality by Design (AQbD), a systematic, risk-based, and science-driven approach that aligns with the broader principles of Quality by Design (QbD) used in manufacturing.

AQbD starts with the definition of the Analytical Target Profile (ATP), which clearly outlines the purpose of the method and its performance requirements. The ATP serves as a strategic foundation, detailing aspects such as the specific analytes to be quantified, the required levels of accuracy, precision, specificity, and acceptable limits for performance criteria. For instance, an ATP may state that the method should quantify the active pharmaceutical ingredient (API) with 98–102% accuracy and a precision of less than 2% relative standard deviation (RSD). This ensures that the method's development is focused and goal-oriented from the beginning.

Once the ATP is defined, developers identify Critical Method Attributes (CMAs)—such as resolution, retention time, and tailing factor—and the Critical Method Parameters (CMPs) that influence them. In HPLC, CMPs typically include mobile phase composition, buffer pH and strength, flow rate, column temperature, and, in gradient methods, the gradient profile. A deep understanding of the relationships between CMPs and CMAs is crucial for developing a method that consistently meets ATP criteria. To prioritize the most influential factors, a risk assessment is conducted using tools such as Ishikawa (fishbone) diagrams and Failure Mode and Effects Analysis (FMEA). This helps identify high-risk parameters that are likely to impact method performance and thus deserve detailed investigation.

The core of AQbD is the application of Design of Experiments (DoE), which enables a systematic study of multiple variables simultaneously. By using statistical models, DoE helps identify significant factors, interactions between parameters, and their effects on method performance. From these experiments, developers can establish a Method Operable Design Region (MODR)—a multidimensional range within which the method is proven to meet its performance criteria. Operating within the MODR ensures method robustness and flexibility, allowing future method changes (e.g., slight pH or temperature adjustments) without the need for regulatory re-approval.

After establishing the MODR and optimizing the method, a control strategy is implemented to maintain method performance during routine analysis. This includes setting specific ranges for CMPs, incorporating system suitability tests, and performing robustness studies to evaluate the method's sensitivity to minor changes. Method validation is then carried out following ICH Q2(R2) guidelines to confirm parameters such as accuracy, linearity, specificity, limit of detection (LOD), limit of quantitation (LOQ), and precision. However, unlike traditional validation approaches, AQbD treats validation as part of a broader lifecycle management strategy, as described in ICH Q14 and ICH Q12. The method continues to be monitored during routine use, with tools such as control charts and statistical process control used to detect trends and prevent performance drift.

Analytical Quality by Design (Qbd) for HPLC Method Development

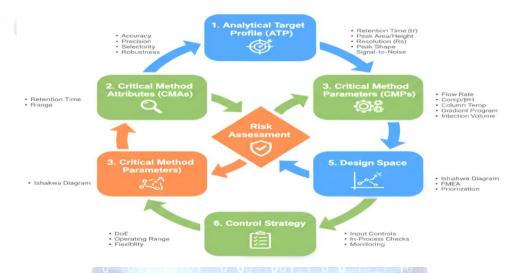


Fig.34.1: Analytical quality by design for HPLC method development

The adoption of AQbD in HPLC method development offers numerous benefits. It significantly improves method robustness and reliability, reduces the risk of method failure during validation or routine use, and enhances regulatory flexibility by allowing post-approval method adjustments within the MODR. Additionally, AQbD shortens development timelines by replacing guesswork with systematic experimentation and provides a greater level of scientific understanding and control.

Application of Analytical Quality by Design (AQbD) in HPLC Method Development:

1. Risk Assessment:

- Identify Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs).
- Evaluate how parameters (e.g., mobile phase, flow rate, temperature) impact method performance.

2. Design of Experiments (DoE):

- o Use DoE to systematically study and optimize method parameters.
- o Identify interactions between parameters to determine the optimal conditions.

3. Design Space Creation:

- Define a "design space" where method parameters are optimized for robust and reliable performance.
- o Provide flexibility for operational changes while maintaining consistent results.

4. Robustness Testing:

- Assess and optimize method robustness to minor variations in parameters (e.g., column, flow rate).
- o Ensure method reliability across different operational conditions.

5. Method Validation:

- Validate methods within the defined design space to ensure regulatory compliance.
- o Confirm method performance (accuracy, precision, etc.) under varying conditions.

6. Lifecycle Management:

- Continuously monitor and improve HPLC methods to adapt to changes in technology or regulatory standards.
- o Ensure long-term consistency and performance of the analytical method.

7. Regulatory Compliance:

Ensure the method development process meets regulatory requirements,
 minimizing risks and ensuring product quality.

AQbD ensures a more systematic, efficient, and predictable approach to HPLC method development.

In conclusion, Analytical Quality by Design marks a transformative step in modern HPLC method development. By applying structured risk assessment, statistical design, and lifecycle management principles, AQbD leads to better-designed methods that are more robust, regulatory-compliant, and capable of consistent performance. As the industry moves toward continuous improvement and enhanced regulatory expectations, AQbD will continue to evolve as the standard approach for developing high-quality analytical methods.

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Article No. 35

MICRONEEDLES: A BREAKTHROUGH IN TRANSDERMAL DRUG DELIVERY

Mrs. Pradnya Mane

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Microneedles represent an innovative and minimally invasive technology that has transformed the landscape of transdermal drug delivery. Unlike conventional hypodermic needles, microneedles are tiny projections, typically ranging from 50–900 µm in length that can painlessly penetrate the stratum corneum to deliver therapeutic agents directly into the epidermis or dermis.

Types of microneedles include solid, coated, dissolving, and hollow designs, each engineered for specific applications such as vaccine delivery, insulin administration, or cosmetic treatments. The advantages of microneedle systems include improved patient compliance, reduced risk of infections, and the ability to bypass first-pass metabolism.

Recent research has expanded the potential of microneedles by integrating nanoparticles, biodegradable polymers, and biosensors, enabling controlled release, targeted drug delivery, and real-time monitoring of therapeutic outcomes. These innovations hold promise for addressing global healthcare challenges, particularly in resource-limited settings. As this field continues to evolve, microneedles are expected to play a pivotal role in personalized medicine, vaccination campaigns, and painless therapeutic interventions.

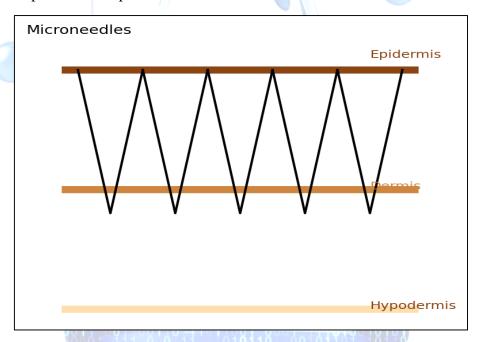


Fig.35.1: Schematic representation of microneedles for drug delivery

Microneedles function by creating microscopic channels through the stratum corneum, the outermost barrier of the skin. These micro-channels allow drugs, vaccines, or biomolecules to be delivered directly into the underlying layers without pain or bleeding. Unlike hypodermic injections, microneedles target the epidermis or dermis, which is rich in immune cells and capillaries, enabling both local and systemic therapeutic effects.

Key Advantages:

- Pain-free and patient-friendly administration.
- Eliminates needle phobia and reduces medical waste.
- Bypasses gastrointestinal degradation and first-pass metabolism.
- Potential for self-administration and large-scale immunization.

Future perspectives include smart micro needles integrated with biosensors for real-time drug release monitoring and responsive delivery systems for personalized therapy.



Article No. 36

MOBILE-FREE MINDSET FOR A BALANCED LIFE

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In the modern world where everything is empowered, mobile phones have become an essential part of our life, and they can be used to communicate, learn, entertain, and even track our health. Although technology has certainly made life more convenient and connected, excessive use has also brought with it the increased concerns regarding physical and mental health. Overuse of screens is associated with strain to eyes, sleep disorders, lack of concentration, anxiety, and lack of physical activities (Kushlev & Dunn, 2019). In the case of college students who undergo an entirely different form of pressure in their academic environment and in social surroundings. Being always online may lead to the disruption of emotional balance in college students.

The so-called mobile-free time a period when people do not use their mobile devices during certain hours is a solution which seems to be rather easy and effective to restore their control over their health and lifestyle. Research indicates that digital disconnection, which involves limiting mobile phone use before sleep or even at the dinner table, can enhance the quality of a person in terms of sleep, social engagement and overall wellbeing (Roberts & David, 2020). The use of mobile free space also allows other activities, such as hobbies or exercise, or face-to-face interactions, which are usually dwarfed by digital use.

Being mobile-free does not have to do with renunciation of technology per se, but with being mindful of it. Students who intentionally pull out in specific hours usually report increased productivity, enhancement of their concentration in school and the improvement of personal relationships. In addition to the above, mobile-free time leads to self-control and strength an attribute that is crucial to success in the long run and a healthy life.

During the time when mobile technology has become both our academic and personal life, being mobile-free is not only a lifestyle decision but also a health requirement. Through nurturing

mindfulness and harmony, learners will also be able to gain the advantages of technology without compromising their mental acuity, physical and emotional wellbeing.



Fig.36.1: Digital Detox for Inner Peace

- 1. Mental Health Benefits: It has been found that stress, anxiety and lack of attention span are associated with high mobile use. Digital anxiety is the result of constant messages and the desire to look at them. A rest allows the brain to recharge and brings emotional equilibrium. Study Insight: A 2019 study published in Frontiers in Psychology found that students who practiced daily mobile-free periods reported lower stress levels and improved mood.
- 2. Better Sleep and Rest: The light of the mobile screens disturbs the natural sleeping cycle of the body (circadian rhythm). Late night mobile use slows down the release of melatonin which results in poor sleep and caused daytime fatigue. Tip: Keep your phone away at least one hour before bedtime to enjoy restful sleep. Evidence: According to the Journal of Clinical Sleep Medicine (2018), students who reduced mobile use before sleeping had better academic performance due to improved rest.
- 3. Promotes Physical Exercise: Overuse of phone encourages an unhealthy lifestyle, exposing one to obesity, backache, and poor posture. These students can play outdoor games, yoga or even just walks in nature which will refresh the body by switching off the screens. Health Note: The World Health Organization (WHO) recommends at least 150 minutes of moderate physical activity per week. Mobile-free time can help meet this target naturally.
- 4. Enhances Social Skills and Relations: Family glue and friendships are made stronger when time is spent together without mobiles. The discussions are more meaningful and students get the ability

to listen and communicate better- aspects that are mostly diminished by being digital. Observation: A survey by Pew Research Center (2020) revealed that over 60% of young adults feel mobiles distract them during face-to-face interactions.

5. Enhances Efficiency and Attention: Mobile free time will enable students to devote themselves to studies, hobbies and creative outputs. The level of concentration would be higher without being interrupted every time with digital distractions, which translates to better learning. Practical Tip: Try the "Pomodoro Technique" — 25 minutes of focused study followed by 5 minutes of rest, with your phone kept away.

Practical Ways to Create Mobile-Free Time

- No-Phone Zones: Dining tables, bedrooms, and classrooms.
- Digital Detox Hours: Fix 1–2 hours daily for offline activities.
- Screen Alternatives: Read books, practice meditation, or engage in sports.
- Tech Tools: Use apps that limit screen time and track usage patterns.

Conclusion: Mobiles are powerful tools, but they should not control our lives. By consciously practicing mobile-free time, students can protect their mental health, sleep better, stay physically active, and build stronger social connections. In a world dominated by screens, the ability to disconnect is the real sign of balance and well-being.

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81.	Virtual Screening and Network Pharmacology- Based Study to Explore the Pharmacological Mechanism of Vitis Venifera (Grapes) for Anti-Breast Cancer Treatment	Asma Mokashi, Neela Bhatia Dilnawaz Pathan Hemant Jain	International	Comprehensive Health and Biomedical Studies,	July 2024

LIST OF PATENTS FILED, PUBLISHED AND GRANTED IN ACADEMIC YEAR 2024-25

Sr. No	Title	Filed (Provide Patent Application Number)	Awarded (Provide Patent Grant Number)	Name of the Inventor/s	Month & Year (DDMMYYYY)
1	A topical skin tissue regeneration composition of bael fruit gum material, chitosan and gelatin	202421007438	563496	Dr. Dinanath T. Gaikwad	25/03/2025
2	Device for Fabrication of Transdermal Patch	Indian Design Patent No. 427803-001, Filed Date: 22/08/2024	Indian Design Patent No. 427803-001 Granted: 07/10/2024	Dr. Durgacharan Arun Bhagwat, Vishin Ashish Patil	07/10/2024
3	Portable Device used for Breast Cancer Detection	Indian Design Patent No. 456067-001, Filed Date: 21/04/2025	-	Dr. Durgacharan Arun Bhagwat, Dr. Sachin S. Mali, Vishin Ashish Patil, Mr. Harshvardhan D. Patil	21/04/2025
4	Novel Anticonvulsant Drugs: Synthesis, And Evaluation Of Oxadiazole Derivatives	202421046390	-	Mr.Vipul Patil, Dr, Harinath More	19/07/2024
5	Laboratory Organ bath for monitoring Tissue Activity	20/10/2023	09/02/2024	Dr.Avijit Choudhary, Dr.Pankaj Pradhan, Dr.Sayed Ali, Satish Patil, Nandita Samudre, Avik Das,Kore Jagganath, Arun Soni,Ajay Sharma.	February 2024
6	Evaluation Of Some Bamboo Varieties Forpotential Compomnents Of Nutritional And Femalhealth Benef	202421051659	Published	Dr. Mrs. Neela M. Bhatia, Ms. Shamali Shashikant Rane And Ms. Manasi Siddheshwar Zade	05/07/2024
7	Portable Digital Ultrasonic Probe Sonicator	438191-001	438191-001	Miss Pranali Shankar Takale	13/01/2025
8	Formulation of Fast Dissolving Axitinib Liquisolid Tablet	202321054776	Published	Mrs. Priyanka Bhushan Varne Dr. Ashok Ananda Hajare Dr. Kiran Shivaji Patil	21/02/2025

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9	"Polyherbal Multipurpose Hair Cleanser"	20252109154A	Published	Dr. Hemlata Suhasrao Dol Ms. Girija Ajitsingh Ghatage Ms. Rani Shantilal Dhole Mr. Dnyaneshwar mahadev Mrs. Priyanka bhushan varne Ms. Girija abhijit gatade Ms. Shravani shrikant sanagar Ms. Rohini tanaji sarade Dr. Ashok ananda hajare Mr. Bhushan shrikrishana varne Ms. Sakshi dinkar	21/03/2025
10	Saline Level Alert Signalling AI device	416843-001	416843-001	khade Mr. Adwait pranesh tole 1. Mr. Mohammad Tayfur Jameer Patvegar 2. Dr. Abhinandan Ravsaheb Patil 3.Prof. Ravindra Jagannath Jarag	05/07/2024
11	Anti-tubercular herbal composition of colocasia esculenta thereof	202421067021		Dr. Savita Sandeep Satpute Mrs. Rekha Ravindra Jarag Ms. Jotsna Mohanlal Gandhi Mrs. Swapnali Sachin Patil Ms. Chitra G. Rajput Ms. Swapanali Arun Mohite Mrs. Madhura Mahesh Karale Ms. Satwasheela Shahajirao Kadam Mr. Vinayak Yashwant Rohile Mr. Abhishek Vilas Desai	11/10/2024

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12	Fabrication And Evaluation Of Antioxidant And Hepatoprotective Activity Of Litsea Polyantha Extract In HEPG2 Cells	202441092265	Published	Dr. J. Sangeetha, Dr. R. V. Valli Kumari, Dr. N. Satheesh Kumar, Dr. Rashmi Mohapatra, Dr. B. Bhargavi, Dr. G. Jaya Vasavi, Ms. Vidya Krushna Kakade, Mr. Hemant Sunil Mali, Mr. Somnath Vishwanath Kalegaonkar.	29/11/2024
13	Noninvasive device for Prediction of blood glucose levels	453210-001		Mr Vishal thorat	27/03/2025
14	Digital hot plate for monitoring rodent activity	Design Patent No: 429166-001	429166-001	Kritika Sachan Vishin Ashish PatilAlka Dr.Vinay.P.Tikare .Bharatbhusan Sahu Dr. Sanmati Kumar Jain Rahul Nimba Patil Md Kaish Shantanu Ranjan .Raghwendra R.Waghmode	03/09/2024
15	Pharmaceutical drug dispensing device	Design Patent No: 434226-001	434226-001	Dr. Sachin A. Nitave Mrs. Vishin A. Patil Ms. Sayali S. Patil Dr. Swapnil A. Phade Ms. Pranali S. Mahajan	14/10/2024

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