



BVCPK

TechMag 2024-25

Innovations in Pharmaceutical Sciences



Bharati Vidyapeeth
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Principal's Desk



In the first instance, I congratulate the team of Bharati Vidyapeeth College of Pharmacy, Kolhapur for their consistent efforts to bring out Technical Magazine 2024-25. I appreciate the efforts in capturing the prominent advancements and events in pharmaceutical field and compiling them into this magazine. The distinctiveness of this institute in research is very well portrayed in this magazine. It will surely offer a great platform for students to explore novel pharmaceutical technologies. I wish this issue to be insightful and memorable.

Dr. H. N. More
Principal

Bharati Vidyapeeth College of Pharmacy, Kolhapur

My best wishes to the editorial board for their enthusiasm in this endeavor. The pharmacy program at every level imbibes knowledge and skills to students and exploration of advanced pharmaceutical technology will enhance holistic development and will build competency essential for successful professional career. Compliments to dear teaching faculty and PG Students for not only emphasizing on academics but also participating in several research activities that contributed overall progress of this institute. Surely, the magazine will be informative and resourceful. Once again, I congratulate team to complete this edition.



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

Editor's Note



Hello Readers!!!

It gives me a great pleasure to share Technical Magazine as BVCPK TechMag 2024-25. This magazine comprised of conventional informative scientific write ups apart from covering conventional informative scientific write ups, the issue also features Mind Lab - a brain storming section, and I encourage the readers to participate in it. I convey heartfelt thanks to all the contributors of advertisement section for sharing their firms' advert that helps to raise BVCPK TechMag quality and would helped to engage readers. I would like to appreciate the efforts taken by all faculty members and PG students for active participation in completing this TechMag.

We would welcome any feedback and suggestions for further improvement in BVCPK TechMag 2024-25 for quality hearing. Happy reading!!!

Sincerely,

Mrs. Priyanka B. Varne

Editor-In-Chief

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,

Dr. H. M. 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 colleagues and students for supporting us in making this TechMag on its completion.

OUR CONTRIBUTORS



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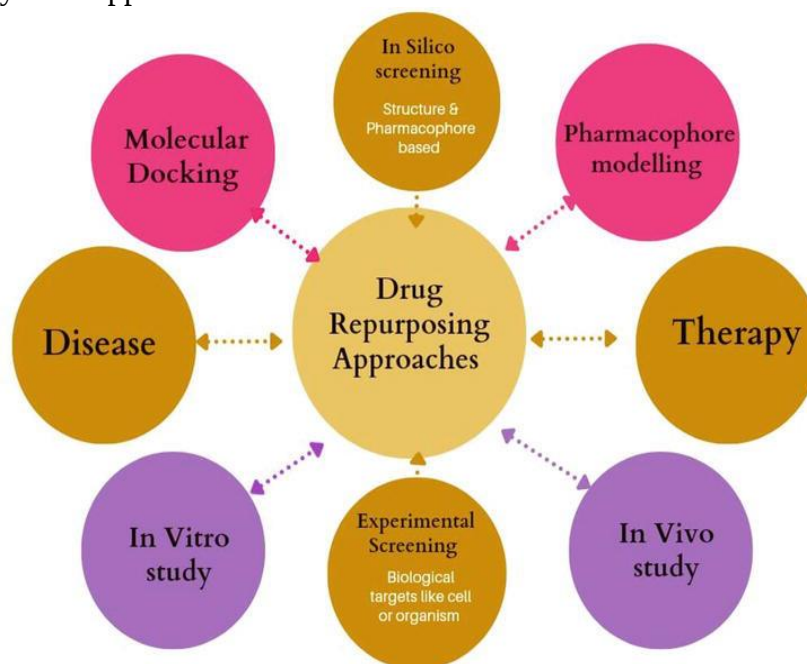
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Article 1

Drug Repurposing: A Powerful Rational Tool in Progressive Drug Discovery**Dr. Mrs. Neela M. Bhatia****Professor, Quality Assurance Department**

Drug repurposing, also known as drug repositioning or drug profiling, is defined as identification of new therapeutic uses of already existing or investigational drugs. It is an effective strategy for drug discovery or development with new pharmacological/therapeutic indications. It is especially useful where traditional de novo drug development is very costly or if cure is urgently needed for some disease, like in the search for a COVID-19 treatments. Drug repurposing strategy gained greater attention after the Food and Drug Administration accepted and granted emergency use authorization of several repurposed drugs in treatment of Covid-19. Some reports claim that that about 30–40% of new drugs and biologics approved by the US Food and Drug Administration (FDA) between 2007 and 2009 can be considered repurposed or repositioned products. Similarly, a study found that 35% of transformative drugs approved by the FDA between 1984 and 2009, approved as drugs which were both innovative and had excellent effects, were repurposed drugs. Pharmaceutical companies typically take one of three approaches to drug repurposing as part of a systematic strategy which includes drug, disease and target centric approach. Each of the approach explores the relationships between drugs, diseases and targets in various ways on the basis of therapeutic action of drug. Disease- and target-centric approaches are the most frequently used approaches.

**Fig. 1 Drug Repurposing Approaches**

Since, finding new molecular entities by traditional or de novo approach of drug discovery is a lengthy, time consuming and expensive venture, drug repositioning saves on time and resources utilizing the combined efforts using activity-based or experimental and in silico-based or computational approaches to identify new uses of drug molecules on a rational basis. It is, therefore, believed to be an emerging strategy where existing medicines, having already been tested safe in humans, are redirected based on a valid target molecule to combat particularly, rare, difficult-to-treat diseases and neglected diseases. The novel approach of drug repositioning has the potential to be employed over traditional drug discovery program by mitigating the high monetary cost, longer duration of development and increased risk of failure.

It bestow on reduced risk of failure where safety or toxicity issues in traditional drug discovery program show a failure rate of ~45% with additional benefit of saving up to 5–7 years in average drug development time. The traditional approach to drug discovery involves *de novo* identification and of new molecular entities, which include five stages: discovery and preclinical, safety review, clinical research, FDA review, and FDA post-market safety monitoring. It is a time-consuming and costly process with high risk of failure. On the other hand, there are only four stages in drug repositioning, which include compound identification, compound acquisition, development, and FDA post-market safety monitoring. With the advancement of bioinformatics/cheminformatics tools and availability of huge biological and structural database, drug repositioning has significantly decreased the time and cost of the drug development with reduction in risk of failure.

Various reviews have reported that about 30% of repurposing efforts are successful and results into product approved for marketing, as compared to 10% for new drug applications. In recent years, many pharmaceutical companies are developing new drugs with the discovery of novel biological targets by applying the drug repositioning strategy in drug discovery and development program. This strategy is highly efficient, time saving, low-cost and minimum risk of failure. It maximizes the therapeutic value of a drug and consequently increases the success rate. Many experts claim re-purposing drugs can be faster, cheaper, less risky and carry higher success rates than traditional drug development approaches, primarily because researchers can bypass earlier stages of development that establish drug safety, as they have already been completed.

The top barrier to drug repurposing was inadequate resources, especially financial, subject matter expertise, and dedicated staff focused on out-licensing. IP challenges and inadequate data access were among other leading barriers as well as value questions and assumptions on the role of repurposing as an effective tool in drug development. The major reason that promising drugs are abandoned is due to lack of efficacy or superiority over already existing therapies for a studied indication or population. Thus, drug repositioning is an effective alternative approach to traditional drug discovery process. There is need of more research on current value of drug repurposing as a core method in drug development. To facilitate it better greater attention is needed on resources to support it so that valuable results with respect to financial feasibility can be obtained and regulatory challenges can be effectively addressed.

Article 2

Molecular docking as a tool for the discovery of molecular targets of nutraceuticals in diseases management**Dr. Mrs. S. A. Arvindekar****Assistant Professor, Pharmaceutical Chemistry Department**

Molecular docking is a computational technique that predicts the binding affinity of ligands to receptor proteins. Although it has potential uses in nutraceutical research, it has developed into a formidable tool for drug development. Bioactive substances called nutraceuticals are present in food sources and can be used in the management of diseases. Finding their molecular targets helps in the creation of disease-specific new therapies. The purpose of this review was to explore molecular docking's application to the study of dietary supplements and disease management. First, an overview of the fundamentals of molecular docking and the various software tools available for docking was presented. The limitations and difficulties of using molecular docking in nutraceutical research are also covered, including the reliability of scoring functions and the requirement for experimental validation. Additionally, there was a focus on the identification of molecular targets for nutraceuticals in numerous disease models, including those for sickle cell disease, cancer, cardiovascular, gut, reproductive, and neurodegenerative disorders. We further highlighted biochemistry pathways and models from recent studies that have revealed molecular mechanisms to pinpoint new nutraceuticals' effects on disease pathogenesis. It is convincingly true that molecular docking is a useful tool for identifying the molecular targets of nutraceuticals in the management of diseases. It may offer information about how nutraceuticals work and support the creation of new therapeutics. Therefore, molecular docking has a bright future in nutraceutical research and has a lot of potential to lead to the creation of brand-new medicines for the treatment of disease.

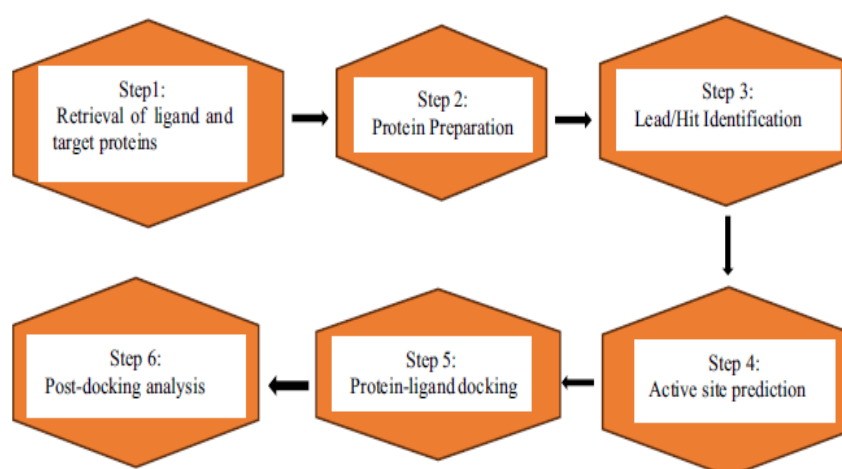


Fig. 1 A schematic representation of protocol of molecular docking study

Reference

Agu, P.C., Afiukwa, C.A., Orji, O.U. et al. Molecular docking as a tool for the discovery of molecular targets of nutraceuticals in diseases management. Sci. Rep. 13, 13398 (2023)

Article 3

Application of Mathematical Modeling and Computational Tools in the Modern Drug Design and Development Process

Dr. Mrs. S. A. Arvindekar

Assistant Professor, Pharmaceutical Chemistry Department

The traditional drug discovery process is both costly and time-intensive, but advancements in mathematical modeling and computational drug design have addressed many of its challenges. In the past, identifying small molecule drug candidates involved significant expenses and lengthy screenings against specific targets. The ongoing need to develop new therapeutic targets and drug candidates, particularly for emerging and reemerging diseases, underscores the importance of accelerating these processes. Computational and mathematical modeling approaches offer a faster, more cost-effective solution, with their predictive accuracy being a key advantage. Computer-aided drug design (CADD) leverages specialized software and mathematical models to analyze drug-target interactions efficiently. Unlike conventional methods, CADD significantly reduces the time and cost of identifying promising compounds for specific diseases. This review highlights the value of these modern approaches—such as biological target prediction, structure-based and ligand-based drug design, molecular docking, virtual screening, pharmacophore modeling, quantitative structure–activity relationship (QSAR) models, molecular dynamics simulations, and MM-GBSA/MM-PBSA techniques. It also explores the key databases and tools aiding the discovery of novel targets and therapeutics.

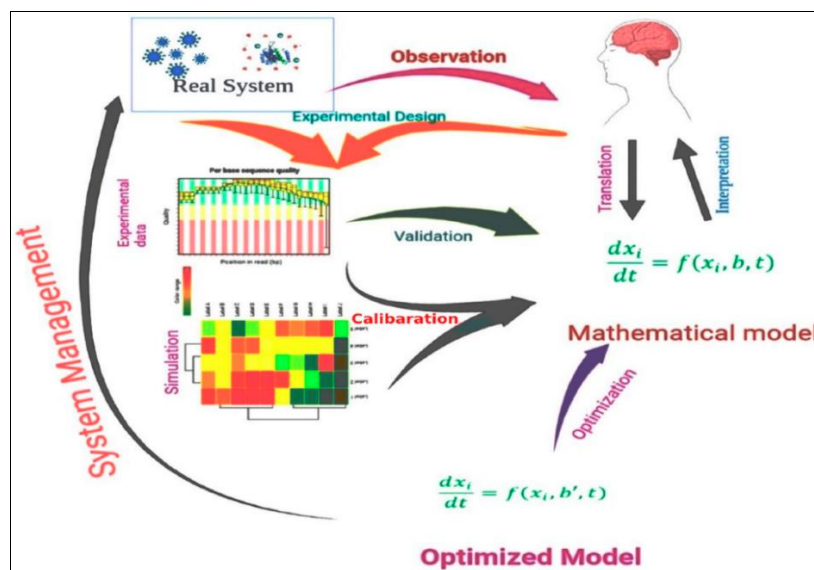


Fig.1 A schematic representation of a mathematical model, including experimental design, experimental data analysis, model optimization, and model validation, used in modern drug design approaches.

Reference

Asan, M. R., Alsaiani, A. A., Fakhurji, B. Z., Molla, M. H. R., Asseri, A. H., Sumon, M. A. A., Park, M. N., Ahammad, F., & Kim, B. (2022). Application of Mathematical Modeling and Computational Tools in the Modern Drug Design and Development Process. *Molecules* (Basel, Switzerland), 27(13), 4169

Article 4

Smart Packaging in Pharmaceuticals: Enhancing Drug Safety and Compliance**Ms. Rutuja Dattatray Chougale****Assistant Professor, Quality Assurance Department**

The pharmaceutical industry is continuously evolving, driven by the need for improved drug safety, compliance, and patient engagement. Smart packaging, which integrates advanced technologies into packaging materials, is emerging as a significant innovation in this sector. By combining traditional packaging with smart features, such as sensors and digital interfaces, smart packaging enhances the ability to monitor and communicate critical information about medications, ultimately improving drug safety and ensuring regulatory compliance. Smart packaging solutions can provide real-time monitoring of drug conditions throughout the supply chain. By incorporating temperature sensors or RFID (Radio-Frequency Identification) tags, pharmaceutical companies can track environmental factors such as temperature, humidity, and light exposure during transportation and storage. This real-time data allows for immediate corrective actions if deviations occur, ensuring that patients receive safe and effective medications.

Another essential feature of smart packaging is the ability to provide tamper-evidence. Counterfeit drugs remain a significant threat to public health, and smart packaging technologies can help combat this issue. For instance, advanced tamper-evident seals and holographic labels can signal unauthorized access to the product. By ensuring that medications are sealed securely, manufacturers can enhance consumer trust and protect patients from counterfeit products. Smart packaging also plays a vital role in improving patient compliance. Many patients struggle with medication adherence due to forgetfulness or misunderstanding dosing instructions. Smart packaging can include features like digital displays or mobile app connectivity to remind patients when to take their medications. Some packages can even provide dosage reminders or track adherence through built-in sensors, sending alerts to healthcare providers or caregivers if doses are missed. This level of engagement fosters better communication between patients and healthcare providers, ultimately leading to improved health outcomes.

Furthermore, smart packaging enhances information accessibility. It can provide patients with detailed instructions, warnings, and expiration dates via QR codes or augmented reality interfaces. This interactivity allows patients to access vital information simply by scanning the packaging with their smartphones, ensuring they have the necessary knowledge to use their medications safely and effectively. Despite the numerous benefits, the implementation of smart packaging in the pharmaceutical industry does present challenges. The cost of integrating advanced technologies into packaging materials can be significant, potentially limiting adoption, especially for smaller manufacturers. Additionally, regulatory hurdles may arise as agencies adapt to new technologies and their implications for safety and efficacy.

In conclusion, smart packaging is transforming the pharmaceutical landscape by enhancing drug safety and compliance. By enabling real-time monitoring, improving tamper-evidence, fostering patient engagement, and increasing accessibility to critical information, smart packaging addresses the industry's most pressing challenges. As technology continues to advance, the integration of smart packaging into pharmaceutical practices promises to deliver safer and more effective medications for patients worldwide.

Reference

Raman R, Dhivya K, Sapra P, Gurpur S, Maniraj SP, Murugan S. IoT-driven Smart Packaging for Pharmaceuticals: Ensuring Product Integrity and Patient Safety. In 2023 International Conference on Artificial Intelligence for Innovations in Healthcare Industries (ICAIIHI) 2023 Dec 29 (Vol. 1, pp. 1-6). IEEE.

Article 5

Blockchain in Pharmacy: Enhancing Drug Traceability and Safety

Ms. Rutuja Dattatray Chougale

Assistant Professor, Quality Assurance Department

The pharmaceutical landscape is rapidly evolving, influenced by technological advancements and a growing consumer demand for transparency. Drug traceability, defined as the ability to track a drug's journey from manufacturer to patient, is crucial for ensuring safety and regulatory compliance. Traditional tracking methods often fall short, relying on centralized databases that are vulnerable to fraud and errors. In this context, blockchain technology, with its decentralized and immutable characteristics, has the potential to revolutionize drug traceability and significantly enhance patient safety. As global supply chains grow blockchain; all participants have access to the same information, fostering trust among stakeholders. Additionally, the immutability of recorded transactions ensures data integrity, making blockchain a powerful tool for addressing critical issues in the pharmaceutical supply chain, in relation to counterfeit drugs & regulatory compliance.

The implementation of blockchain in pharmacy offers numerous advantages. One of the most significant benefits is counterfeit prevention. Blockchain is a distributed ledger technology (DLT) that enables multiple parties to maintain a shared database without a central authority. This decentralized nature mitigates the risk of manipulation, as no single entity controls the data. Transparency is a core feature of for secure tracking throughout the supply chain, ensuring that patients receive authentic medications. Unique identifiers assigned to each drug, enabling stakeholders to verify authenticity. Furthermore, blockchain facilitates real-time tracking, providing stakeholders with immediate access to a drug's status and allowing for rapid responses to recalls or quality issues, thereby mitigating risks associated with drug safety and efficacy.

Additionally, blockchain can streamline regulatory compliance processes by providing a clear, auditable trail of each drug's journey, thereby reducing administrative burdens and minimizing the risk of non-compliance. It can also enhance pharmacovigilance by enabling effective adverse event reporting through a secure, tamper-proof record of patient experiences with medications, improving overall drug safety and efficacy monitoring. Moreover, by giving patients access to their medication history via blockchain technology, individuals can make informed decisions about their treatments, which can lead to improved medication adherence and better health outcomes. Despite these promising benefits, the implementation of blockchain technology in the pharmacy sector does face several challenges. Interoperability issues arise when different blockchain platforms are unable to communicate effectively, necessitating the establishment of standards for data exchange to maximize the technology's potential. Regulatory hurdles are another concern, as the heavily regulated pharmaceutical industry may require significant adjustments to existing laws and regulations to integrate blockchain successfully. Additionally, the cost and complexity of implementing blockchain can be prohibitive, especially for smaller pharmacies lacking the necessary financial and technical resources. Finally, while transparency is a key advantage of blockchain, it is vital to prioritize patient privacy to ensure data security and confidentiality.

In conclusion, blockchain technology offers transformative potential for the pharmaceutical industry by enhancing drug traceability and patient safety. As stakeholders continue to navigate the challenges of implementation, the promise of a safer, more transparent pharmaceutical landscape remains within reach.

Reference

Zakari N, Al-Razgan M, Alsaadi A, Alshareef H, Alashaikh L, Alharbi M, Alomar R, Alotaibi S. Blockchain technology in the pharmaceutical industry: a systematic review. Peer J Computer Science. 2022 Mar 11; 8 :e840.

Article 6

Assessment of Antioxidant, Anticholinesterase and Anti-amyloidogenic Effect of Terminalia Chebula

Mr. Shedmake Abhijeet Chintaman
PG Student, Pharmaceutics Department

Alzheimer's disease is one of the most dreadful disorders of 21st century with no effective therapy till date, clinically characterized by loss of cognitive function. β -amyloid peptide ($A\beta$) is considered as the key pathogenic factor in AD, which on aggregation provokes oxidative stress mediated neuronal damage affecting activities of daily life such as learning and memory. Hence, the present study focuses on the exploration of neuroprotective potential of *T. chebula* by evaluating its antioxidant, anticholinesterase and anti-amyloidogenic activities.

Collection of Natural Compounds and Space Analysis: The bioactive natural compounds of *T. Chebula* were retrieved through extensive literature survey. The two dimensional (2D) structures of the compounds were retrieved from PubChem and Chempider databases and prepared into a library. The duplicate structures were deleted and some compounds which did not have specific structures were sketched using the Marvin Sketch v6.2.0 and saved in .mol2 format. The two dimensional (2D) structures were converted into 3D structures by using Corina 3D analysis tool in Tsar (Tools for structure activity relationships) software. Further, the three dimensional (3D) structures were converted to PDB format. The details of bioactive compounds retrieved from *T. Chebula*.

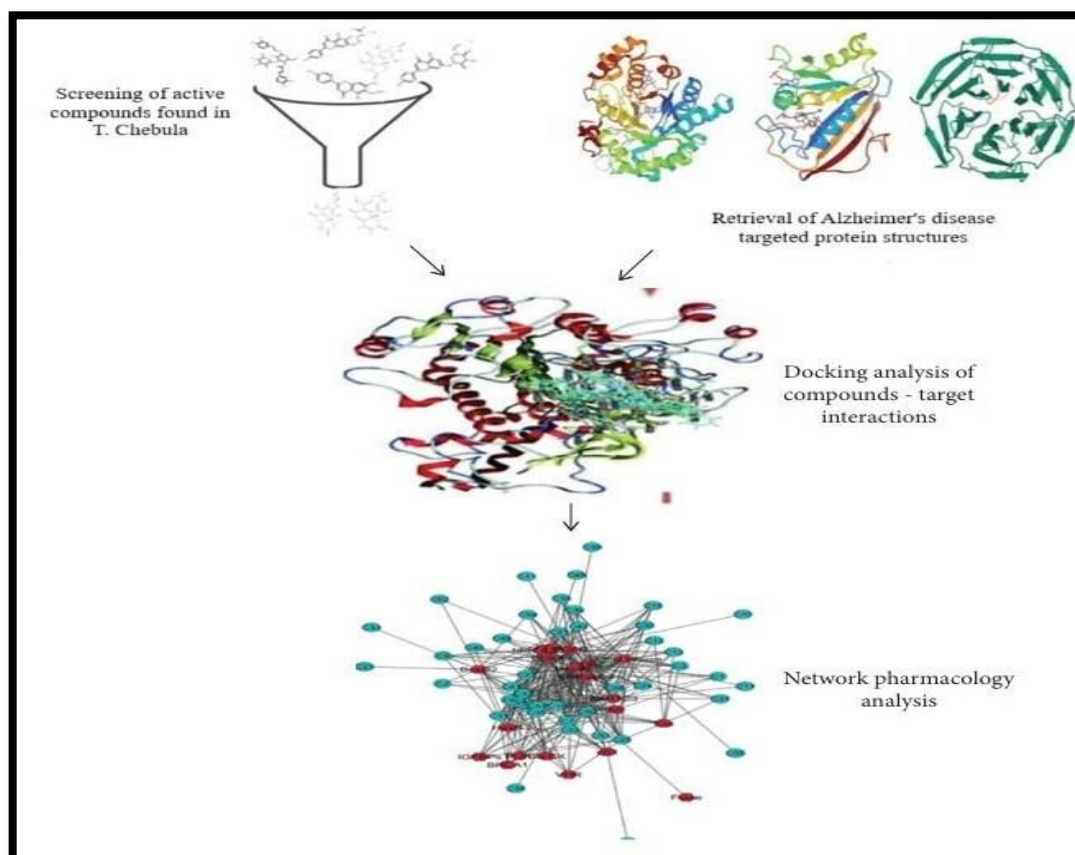


Fig. 1 Graphical representation

Retrieval of Alzheimer's disease Targets: The protein targets associated with human Alzheimer's disease were collected from four resources: (i) Therapeutic Target Database (TTD), (ii) Drug Bank, (iii) Uniport, and (iv) Protein Data Bank. The duplicates structures, structures with no active site, incomplete structures, and structures from other organisms were deleted. Finally, important drug targets from key type 'Homo sapiens' were selected.

Data Collection and Validation: Network pharmacology takes into account the aforementioned principles to optimize the efficacy and safety of a candidate drug and their potent combinations. These also represent the two important steps in any experimental study. The first step of network pharmacology is the selection of original data from the experiments to build a biological network. The second is the experimental validation for the predicted network model. The validated data can be quantified using many different integrated methods including genomics, proteomics, metabolomics, and HTS/high-content screening (HCS) technologies.

From binding site predication GLU81, ARG463, SER462, TYR465, THR438, GLU452, TYR 449, and LEU 437 were defined as the active site residues in the binding pocket of AChE protein. Among the positive ligands Donepezil has the highest docking score of 43.98 and showed interactions with GLU81 and ARG463 similar to the other positive ligands. For an effective binding of the ligand with the receptor strong hydrogen bonding is important. In the present study all the ligands are donors that have the capacity to donate their hydrogen atom to the acceptor atom of the receptor. Thus, from the docking results it was observed that among the test ligands, 7-MG has the highest dock score of 116.823 which forms a strong hydrogen bonding with ARG463 (2.62Å), GLU452 (2.96Å), GLU81 (1.12Å) and GLU421 (2.96Å) by accepting the oxygen atoms.

Results of in silico analysis illustrated 7-MG acts as potent AChE inhibitor, which has been further validated through in-vitro studies. The results of antioxidant and cholinesterase inhibitory effect of 7 MG. Results illustrated that 7-MG inhibited AChE and BuChE. The drugs with dual cholinergic activity and antioxidant capacity were considered as effective for the treatment of AD. Observation of the present study illustrated that 7-MG due to its potent antioxidant, dual cholinergic activities can act as effective candidate for the treatment of AD.

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2. Gogoi, B., & Saikia, S. P. (2022). Virtual Screening and Network Pharmacology-Based Study to Explore the Pharmacological Mechanism of Clerodendrum Species for Anticancer Treatment. *Evidence-Based Complementary and Alternative Medicine*, 2022. <https://doi.org/10.1155/2022/3106363>

Article 7

An Overview of Nanotechnology in drug delivery**Mr. Pratik Jogi****PG Student, Quality Assurance Department**

Similar to previous preceding technologies, nanomedicine has great promise for transforming medicines and diagnostics through the creation of clever nano-devices. A major component of nanomedicine is drug delivery nano systems. However, defining nanotechnology in terms of size limits is useless when discussing drug delivery because the effectiveness and utility of drug delivery systems are not solely determined by their sizes. Effective medication delivery methods encompass practically nanoscale structures (such drug-polymer combinations and polymer micelles) as well as 100 μm -sized micro-particles. The development of numerous clinically beneficial drug delivery systems has greatly benefited from the usage of both nano- and micro-scale systems. In this perspective "Nanotechnology" encompasses "micro-technology" as well as "nanofabrication" or "nano-manufacturing" and its "micro equivalent" for pragmatic reason. Because of its extraordinary potential to literally change every industry in which it is applied, nanotechnology has attracted unprecedented interest and enthusiasm. Nanotechnology is only now starting to have an effect on medicine delivery. However, a large number of the drug delivery systems that are referred to as "nano" nowadays are actually relics from traditional drug administration methods that just so happen to be in the nanoscale range. Examples of these include liposomes, polymeric micelles, nanoparticles, dendrimers, and nanocrystals.

The idea and capacity of nanotechnology to modify molecules and supramolecular structures to create devices with preprogrammed functionalities makes it significant for drug delivery. The term "nano vehicles" has replaced the previous terms for conventional liposomes, polymeric micelles, and nanoparticles. This is accurate solely in terms of size. The current nanotechnology revolution would not have occurred if those traditional medication delivery techniques had not developed to their current stage. It might be helpful to categorize drug delivery methods according to the time periods that correspond to before and after the nanotechnology revolution in order to understand the true significance of nanotechnology in medication delivery. This is because of the challenges with use of large size materials in drug delivery, some of which include poor bioavailability, in vivo stability, solubility, and intestinal absorption, sustained and targeted delivery to site of action, therapeutic effectiveness, generalized side effects, and plasma fluctuations of drugs. Of recent, several researches in nano-drug delivery have been designed to overcome these challenges through the development and fabrication of nanostructures.

Before and after nanotechnology revolution three types can be distinguished between drug delivery technologies in the context of the present nanotechnology revolution. Before nanotechnology revolution (past), Current transition period (present), mature nanotechnology (future). These efforts are still in their early stages, and numerous fabrication techniques have been created. In terms of nanotechnology, the development of nano/micro manufacturing processes that can produce nano/micro drug delivery systems is what will shape the future of drug delivery systems. The current state of nano- and micro-scale engineering material fabrication and manufacturing technology is sufficient to enable the development of nano- and micro-scale processes for the production of items other than semiconductors [3]. Assume that the nano/micro scale is used in the production of the centimeter-size soft gelatin capsules that are already in use.

Table 1: Current nanotechnology revolution

Period	Before Nanotechnology (Past)	Transition Period (Past)	Mature Nanotechnology (Future)
Technology	Emulsion Based Preparation of nano-/micro- particle	Nano/micro fabrication	Nano/micro manufacturing
Examples	Liposomes, Polymer micelles, Dendrimers, Nanoparticles, Nanocrystals, Micro-particles	Microchip system, Microneedle, transdermal delivery systems, Layer-by-layer assembled systems, Micro-dispensed particles	Nano/micro machines for scale-up production

Nanotechnology for acceptance by the pharmaceutical industry restructuring clinical research through translational research, which makes basic discoveries easier to translate into clinical investigations, is one of the NIH Nanomedicine Roadmap Initiative's principles. The ultimate objective of using nano-drug delivery systems is to create patient treatments using formulations that are clinically effective. FDA clearance is necessary for clinical applications. When new medication delivery methods contain ingredients (also known as excipients) that are not widely accepted as safe, the pharmaceutical industry has been hesitant to adopt them. The FDA requires extensive and expensive clinical investigations before approving a new chemical entity, and the industry is reluctant to introduce any unproven ingredients that would need FDA approval.

Mature nanotechnology for drug delivery the distribution of drugs could be completely transformed by nanotechnology, but to make this happen, scientists from various fields must collaborate and funding organizations must continue to support their work. As Table 1 illustrates, the ability of nano/micro manufacturing to scale up production will determine the future of medication delivery systems based on nanotechnology. This calls for the creation of the most straightforward delivery methods feasible, which can only be accomplished by close collaboration between scientists studying medication delivery and nanofabrication. If we recognize that the true promise of nanotechnology in drug delivery lies in the usage of nano/micro fabrication and manufacturing, rather than in dealing with delivery systems in the nano/micro scale, then nanotechnology for drug delivery will evolve faster and become more helpful.

Conclusively the ideal nano vehicle for the ideal nanodrug delivery system is being sought after by drug delivery scientists. This ideal vehicle should drastically reduce drug dosage, improve drug absorption, allow patients to take smaller doses and still receive the same benefits, deliver the drug to the appropriate location in the body, increase the local concentration of the drug at the desired site, and minimize or completely eliminate side effects. The scope of this new field appears to have no boundaries as of right now. But before nanotechnology's full potential can be realized, there are still significant financial and technological barriers that the public and commercial sectors must appropriately address.

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Article 8

Graft Copolymer of Herbal Extract - An Expanding Polymer Science**Mr. Aniket Sarjerao Shete****PG Student, Pharmaceutics Department**

Naturapolyceutics is a science and technology platform that blends natural polymers and pharmaceuticals for the design and development of drug delivery systems. Natural polysaccharides and their derivatives are extensively utilized in both conventional and newer drug delivery systems due to their advantageous properties. These systems offer the benefits of maintaining optimal drug concentrations over extended periods, protecting sensitive drug from adverse conditions, and minimizing side effects by avoiding high initial blood concentrations. Compared to synthetic polymers, natural polysaccharides are often less expensive, non-toxic, biodegradable, and readily available, making them preferable for many applications. Grafting in particular, involves covalently bonding monomers onto the backbone of a natural polymer, creating a copolymer with tailored properties. This approach is especially valuable for designing new materials with specific drug release characteristics.

General mechanism Grafting has been acknowledged as the trustworthy process because it can alter the polymer's structure by reacting with synthetic monomers. This results in the creation of a new biomaterial that is much more sophisticated than the polysaccharide that occurs naturally, which is vulnerable to severe enzymatic attack as well as uncontrollably eroding and swelling. Graft copolymers are formed when a synthetic monomer and a polymer (trunk polymer) react to form a macromolecule with the help of initiator. The copolymer is formed when the monomer is continuously attached to the main chain also known as the polymer's backbone as a side chain. Graft copolymerization has a single advantage: concurrent homopolymer synthesis which is the main restriction in grafting and leads to a reduced yield while being a very beneficial and effective means of changing the polymer's properties.

Applications

- **Drug Delivery System:** Polysaccharides have extensive applications in various fields as binding, disintegrating, thickening, flocculating, and stabilizing agents in oral dosage form and also in transdermal form.
- **Controlled Drug Delivery:** Characterized by releasing the drug in specified period within pre-determined rate. Biodegradable polymers have already been used for controlled release but major problems associated with the polysaccharides.
- **Enhanced Drug Delivery:** Many dosage forms are designed to release the drug immediately or at least as quickly as possible after administration. This is useful if a faster onset of action is required for therapeutic reasons.
- **Transdermal Drug Delivery:** Beneficial due to satisfactory patient compliance, bypass of first-pass metabolism, less pain, tasteless, and controlled and sustained drug delivery over long time period.

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Article 9

GROMACS: High Performance Molecular Simulations Tool

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Abstract: CADD is a key method in current preclinical drug development exploring with different computational methods and software applications, are commonly combined for analysis in an attempt to attain the intended result. In assistance with computer-aided design and drafting, number of authorized medications has been created through the use of virtual screening terminology, software techniques, computational research and publications. GROMACS is one of the most widely used open-source and free software codes in chemistry and it is mostly used for dynamical simulations of biomolecules. It offers a wide range of preparation, analysis, and calculating tools. Version 5 brings it to even higher performance levels with a number of improved and new parallelization methods.

Introduction: One of the key strategies in modern pre-clinical drug discovery is computer-aided drug design (CADD), where a variety of software tools and computational methods are usually combined to get the desired result. Drug discovery is an expensive and time-consuming procedure. Hence with the help of CADD a number of authorized medications has been developed with accurate and with less chances of failure. The databases that were searched, the virtual screening process, molecular docking software and Molecular Dynamic (MD) simulations are interestingly used to get virtual data before clinic studies. We assessed through research that GROMACS is widely used to conduct molecular dynamics (MD) simulations, using Newtonian mechanics to improve the lead compounds' binding characteristics and efficacy that requires the use of molecular dynamics simulations. In order to illustrate the most recent trends, the most recent data available was collected between 2015 and 2020. Of the research, 38.5% used MD simulations in addition to virtual screening, and GROMACS was the most widely used MD software, with 39.3% of the studies using it. The MD simulations can provide many conformer snapshots, they are crucial for both producing finer conformations and revealing the dynamics of the protein structure. MD simulations are employed to filter and validate the results obtained from protein ligand complex docking runs by establishing the stability of the complex, interatomic interactions, the rate of system fluctuation, and binding free energies.

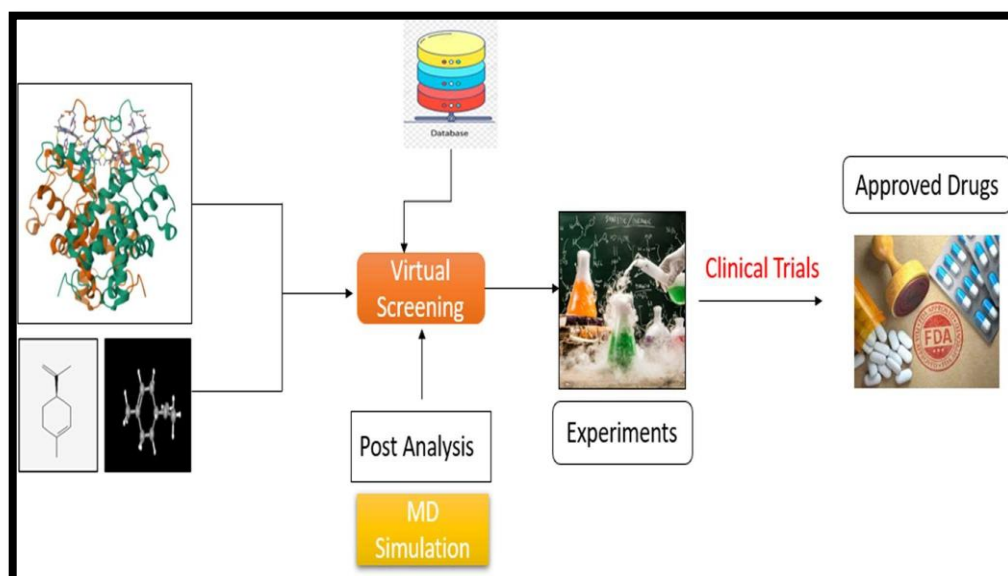


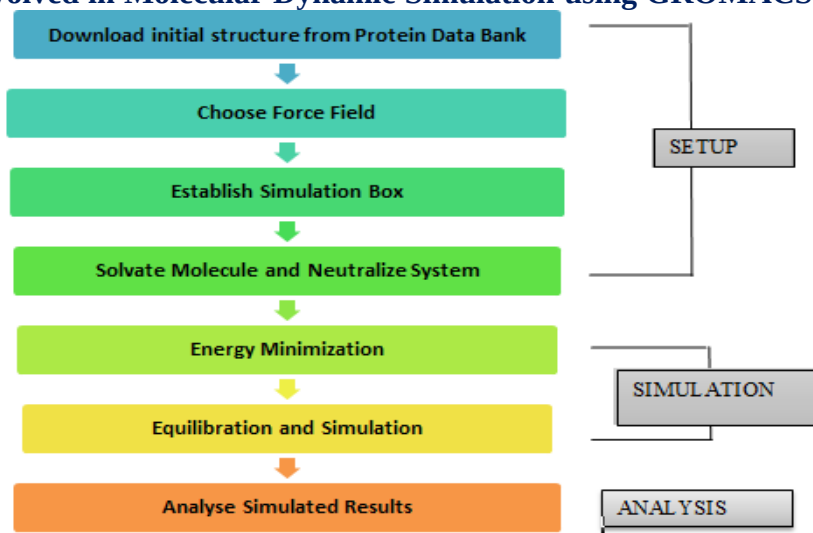
Fig. 1 Molecular Dynamic (MD) simulations

Software Description: GROMACS is one of the most widely used open-source and free software codes in chemistry and it is mostly used for dynamical simulations of biomolecules. It offers a wide range of preparation, analysis, and calculating tools. There are several sophisticated methods for computing free energy that are supported. GROMACS is a versatile package to perform molecular dynamics, i.e. simulate the Newtonian equations of motion for systems with hundreds to millions of particles and is a community-driven project. It is primarily designed for biochemical molecules like proteins, lipids and nucleic acids that have a lot of complicated bonded interactions, but since GROMACS is extremely fast at calculating the non-bonded interactions (that usually dominate simulations) many groups are also using it for research on non-biological systems, e.g., polymers and fluid dynamics.

Software functionalities: GROMACS is free software distributed under LGPLv2.1, which even allows linking into commercial applications. It requires only standards-conforming C99 and C++98 compilers, and CMake version 2.8.8. Various external libraries are either bundled for convenience, or can be detected (e.g., MKL) or even downloaded automatically (e.g., FFTW). Portability is assured via extensive automated continuous integration testing using Jenkins, deployed on Windows, MacOS and Linux, using multiple versions of compilers including those from Intel, GNU, Microsoft, LLVM and IBM. The Parallel Analysis framework provides reusable components for grid-based neighbour searching and common data processing tasks like histograms. Future development also aims to support analysing single trajectory frames in parallel, and Python bindings

Performance & scaling: GROMACS can scale to the largest machines in the world when using gigantic systems and detailed benchmarks are available on the website. All simulations use PME and initial cut-offs of 1.0 nm. All bonds were constrained with the LINCS algorithm, and the VSD uses virtual interaction sites constructed every step to extend the time step to 5 fs. The recent efforts to maximize single-core and single-node performance show benefits at all levels, which makes it even more impressive that the relative scaling has also improved substantially. The enhancements boost user throughput on all kinds and quantities of hardware, but they were focused on mature technologies. There are many other approaches open for future performance improvements to GROMACS.

Steps involved in Molecular Dynamic Simulation using GROMACS: -



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Article 10

Breast Cancer: A review of risk factors and diagnosis**Ms. Priyanka Ramesh Jogi****PG Student, Quality Assurance Department**

Abstract: Breast cancer is still a complicated and common health issue that affects millions of people globally. This review article provides an in-depth examination of the complex terrain around breast cancer, clarifying the wide range of risk factors that contribute to its incidence and examining developments in diagnostic techniques. A thorough review of the literature has revealed a number of risk factors, including hormonal impacts, lifestyle factors, reproductive patterns, and genetic predispositions such as BRCA mutations. The complex tapestry of breast cancer etiology is further woven together by environmental factors, age, and family history. This study also outlines the critical role that diagnostic tools play in the early diagnosis and treatment of breast cancer. New technologies such as genetic testing and magnetic resonance imaging complement mammography, the mainstay of breast cancer screening, to improve the sensitivity and specificity of breast cancer diagnosis. Even with these developments, it is still difficult to guarantee that screening programs are widely accessible, especially in environments with low resources.

Introduction : Collection of cancer cells known as a cancerous tumor is capable of spreading into and de Breast cancer is one of the many and common malignant tumors that harm women. Numerous internal and external variables can contribute to the development and occurrence of breast cancer. Its prevalence is associated with poor lifestyle choices, environmental variables, and social-psychological factors. Research indicates that between 5% and 10% of breast cancer cases are related to genetic abnormalities and family history, while 20% to 30% of cases are related to potentially modifiable variables. Breast cancer begins in the cells of the breast. A neighboring tissue being strayed. It can also spread across the entire body. Every now and then, breast cells experience modifications that keep them from developing or functioning correctly. These alterations may lead to atypical hyperplasia, cysts, and non-cancerous breast diseases. They could also lead to benign malignancies such as intraductal papillomas.

Risk factors for developing breast cancer among women:

Personal history of breast cancer: An increased risk of breast cancer recurrence exists in women who have previously experienced it. The second breast cancer may appear in the same breast as the first one or in a different breast. Although the majority of women who have ductal carcinoma in situ or lobular carcinoma in situ breast cancers do not recur, these women are at an increased risk of doing so.

Breast and other types of cancer in the family history: The presence of breast cancer in one or more close blood relatives indicates that the disease runs in the family. More breast cancer cases than one might anticipate randomly occur in some families. It can be difficult to determine whether a family's history of cancer is the result of coincidence, a common lifestyle, genes passed down from parents to children, or a combination of these factors. Mutations in the BRCA gene: An altered gene is referred to as a genetic mutation. Certain types of cancer may be more likely to develop as a result of some gene changes. A parent can pass on inherited gene mutations to their offspring. Only a small percentage of breast cancers (roughly 5%–10%) are brought on by inherited gene mutations. Normal human physiology includes both BRCA1 and BRCA2, which are breast cancer genes. As a result of what seems to be their involvement in regulating the growth of cancer cells, these genes are known as tumor suppressors. BRCA1 or BRCA2 gene mutations may cause them to lose their ability to regulate the development of cancer. Rarely occur these mutations. Roughly 1 in 500 people experience them. A mutated BRCA gene can be inherited by both

men and women from either their mother or father. Children of those who carry the gene mutation may also inherit it. A child has a 50% chance of inheriting the gene mutation if 1 of the 2 copies of the BRCA gene has the mutation in 1 or both parents. A child also has a 50% chance of not inheriting the gene mutation, according to this. According to studies, women who inherit BRCA1 or BRCA2 gene mutations have an 85% lifetime risk of developing breast cancer. Additionally, compared to other women, those who carry these inherited mutations are at an increased risk of developing breast cancer earlier in life. Breast cancer in both breasts is more likely to strike women who have the BRCA gene mutation. They are more likely to get cancer in the other breast if they have cancer in 1 breast. Ovarian cancer can strike a woman at any age if she carries a BRCA gene mutation. Large breasts: Compared to fatty tissue, dense breasts have more milk ducts, glands, and connective tissue. Breast density is a genetic trait. Compared to women with little or no dense breast tissue, women with dense breast tissue have a higher risk of developing breast cancer. Breast density can only be detected by a mammogram, but dense breasts also make the image more difficult to interpret. On a mammogram, dense tissue appears white, like tumors, while fatty tissue appears dark, concealing a tumor. The late menopause: The body's level of hormones, primarily estrogen and progesterone, begins to decline as the ovaries stop producing them, resulting in menopause. A woman's menstrual cycle is stopped as a result of this. Your cells are exposed to estrogen and other hormones for a longer period if you enter menopause later in life (after age 55). This raises the possibility of breast cancer. Likewise, breast tissue is exposed to estrogen and other hormones for a shorter period when menopause occurs earlier in life. A lower risk of breast cancer is associated with early menopause.

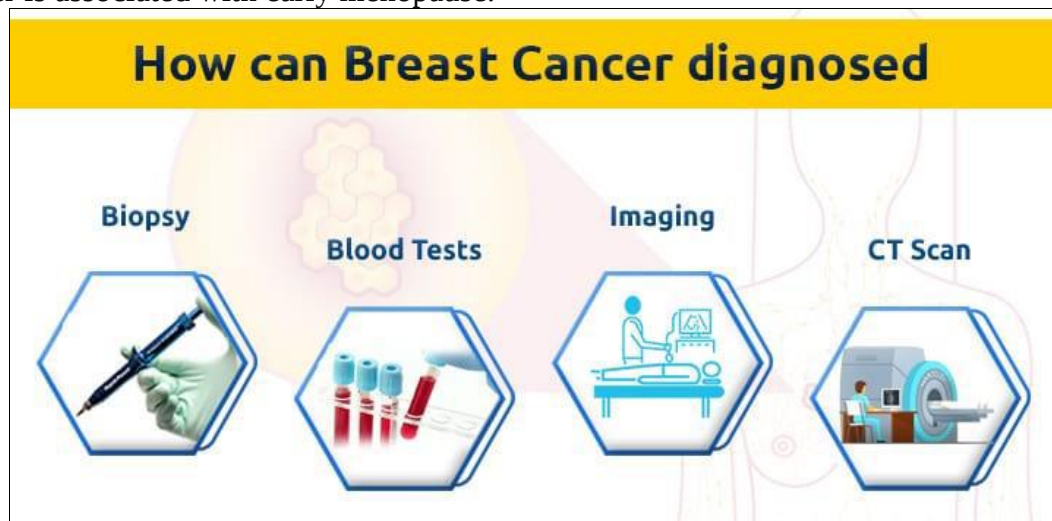


Fig. 1 Breast cancer in women: Diagnosed through appended technologic

Conclusion: Breast cancer remains a significant global health concern, impacting millions of individuals each year. This review has underscored the multifaceted nature of breast cancer, highlighting various risk factors and diagnostic approaches crucial in understanding and managing this disease. Moreover, advancements in diagnostic techniques have significantly improved early detection and treatment outcomes. Mammography, alongside emerging technologies like magnetic resonance imaging and molecular testing, plays a pivotal role in identifying breast cancer at its early stages, enabling prompt intervention and potentially improving patient prognoses. Moving forward continued research into identifying additional risk factors, enhancing screening methods, and developing targeted therapies remains imperative.

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Article 11

Preparation and evaluation of pharmaceutical co-crystals for solubility enhancement of atorvastatin calcium**Mr. Pratik Pandurang Disale****PG Student, Quality Assurance Department**

Co-crystallization is one of the important ways to improve solubility of hydrophobic medicines from the BCS class II. The goal of the study was to manufacture and characterize atorvastatin calcium co-crystals utilizing a liquid-assisted grinding process. Nicotinamide and citric acid were used as co-formers to improve the solubility of the drug. A variety of analytical techniques were used to characterize the prepared formulations, including zeta size analysis, dissolution and solubility studies, differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), powder X-ray diffraction (PXRD), Fourier-transform infrared spectroscopy (FTIR), and scanning electron microscopy (SEM).

Comparing the formulations' solubility to that of the medicine already on the market, dissolution and solubility tests revealed that the formulations' solubility was improved several times over in all mediums. To get optimal absorption, the medication must be soluble in water when it reaches the absorption site. The process that results in a saturated solution at a specific temperature is the interaction of two substances. Weakly basic and weakly acidic medicines have limited water solubility, making solubility a crucial element for improved pharmacological efficacy of medication. The medicine must be readily soluble in water and permeable across the lipophilic membrane in order to have the highest possible bioavailability.

The solubilization process consists of three steps: first, holes are created in the solvent to make room for the solute molecules; second, the solute's bonds break and its molecules migrate away from the bulk; and third, there occurs an interaction between the molecules of the solvent and the solute. The medications' particle size has an impact on their solubility since a smaller particle size results in a bigger surface area. The solvent can more easily interact with the drug particles due to the larger surface area. Similarly, solubility may be changed by adjusting the temperature and pressure. However, solubility of gases decreases with increasing temperature and pressure. The drug's water solubility plays a crucial role in determining how quickly it dissolves. The rate of dissolution, absorption, and bioavailability of medications taken orally are restricted by their restricted water solubility. In this case, increasing the medicine's dosage is necessary to get the therapeutic drug concentration in the blood.

Depending on the desired dosage form, absorption location, and drug characteristics, a variety of strategies are employed to improve the solubility of pharmaceuticals. These techniques fall into the categories of physical modification, chemical modification, and other miscellaneous ways. There are several methods in which crystal engineering is a method which improves a drug's solubility and rate of dissolution, depending on the molecular properties of the active medicinal components and the crystallization process. Co-crystals are homogeneous, structurally crystalline materials made up of two or more different molecules in a stoichiometric ratio organized so as to create a new crystal with different characteristics from the component molecules. A solid co-former at room temperature and a molecular or ionic drug are used to create pharmaceutical co-crystals. They are prepared using a variety of techniques, including co-grinding, growth from the melt, solvent evaporation, and sublimation.

Drugs that are ionizable or non-ionizable can create stable co-crystals without breaking or forming covalent bonds. The three primary processes in the design of co-crystals are co-former selection, computational analysis, and co-crystal characterization.

The drug's solubility and dissolution rate are enhanced by co-crystals, which produce and preserve the metastable supersaturated form. Ionizable or non-ionizable drugs can build covalent bonds or break them to generate stable co-crystals. Co-former selection, co-crystal characterization, and computational analysis are the three main steps in the design of co-crystals. Co-crystals, which create and maintain the metastable supersaturated state, improve the drug's solubility and rate of dissolution.

The co-crystal approach is used to improve the rate of dissolution and solubility of atorvastatin calcium (AC), a medication that is classified as a BCS class II medicine because to its high permeability and low solubility. 10–80 mg of AC should be taken once day. It results in dose-dependent adverse effects such as arthralgia, liver abnormalities, renal failure, and rhabdomyolysis. Different approaches such salt production, co-crystallization, and β -cyclodextrin complexation are employed to solve challenges of inadequate and changing oral bioavailability. Nicotinamide and citric acid, two co-formers (NA and CA), were used in varying ratios to create co-crystals by the use of a liquid-assisted grinding process.

By increasing the solubility of AC using a unique drug delivery technology, the study's goal was accomplished. Using solvent and varying amounts of co-formers, the liquid-assisted grinding approach was utilized to effectively manufacture co-crystals. CA and NA were employed as co-formers and methanol as the solvent in the co-crystallization process. Co-forms were hydrophilic, which meant that they were crucial for drug release and solubility. Co-crystals possessing enhanced solubility profiles have potential applications in medicine and bioengineering, where they can fulfil standards for pellets, tablets, and capsules.

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Article 12

Emerging Nano Formulation Strategies for Phyto-compounds Based drug Delivery**Ms. Pranali S. Takale****Assistant Professor, Pharmaceutics Department****Introduction**

Natural products have been a priceless resource for treating illnesses throughout human history. Many different types of natural resources, including plants, bacteria, fungi, and marine life, are the source of a vast array of natural goods. Among them, plants constitute an essential source of molecules with pharmacological activity, including a large number of blockbuster medications produced from plants, like morphine, artemisinin, and paclitaxel. Presently, more than 100 active phytochemicals are employed in medicine, and about 80% of people worldwide receive their main healthcare from plant-derived extracts.

Phyto-compounds

Bioactive phyto-compounds (BPCs) have demonstrated encouraging anticancer, anti-inflammatory, antioxidant, antibacterial, and anti-neurodegenerative benefits for the treatment or prevention of a number of disorders in numerous studies. Researchers from various fields like pharmacology, materials sciences, and nanoscience are utilizing nano-formulation techniques to encapsulate BPCs in order to address the limitations of BPC-based therapeutics. Nano-carriers made of lipids, proteins, polymers, and polysaccharides have demonstrated significant potential in addressing the inherent limitations of BPCs. (Figure 1.) The FDA has approved several BPC-based nano-formulations (BPC-NFs) are prescribed for clinical use. Some examples are paclitaxel-bound albumin (Abraxane®), liposomal vincristine for acute lymphoid leukemia (Marqibo®), and paclitaxel-loaded polyethylene glycol-polylactic acid (PEG-PLA) polymeric micelle (Genexol- PM®) for lung and breast cancer. There are numerous additional BPC-NFs undergoing clinical studies right now. The publishing trends over the previous ten years clearly demonstrate the great potential of BPC-NFs. As of 2019, there have been over 3000 articles on BPC-NFs. Nearly one-third of them are NFs based on nanoparticles, nano-emulsions, or lipid-based nano-carriers, aside from research on liposomal BPC-NFs. The remainders consist of solid lipid nanoparticles (SLNs) and nanostructured lipid carriers (NLCs).

Structural Design of Nano formulations

The primary objective in creating nano-formulation is to control the size of particles, surface characteristics, and how bioactive compounds are released to achieve targeted accumulation and effectiveness of drugs at the ideal rate and dosage. To enhance the characteristics of bioactive substances, nanoparticles (NFs) with a diameter typically ranging from 10 to 200 nm are produced by encapsulating drugs inside nano-carriers or attaching drug molecules covalently to nano-carriers through complexation. These nanoparticles have been used in drug delivery studies to enhance drug effectiveness, dissolvability, extended time in the bloodstream, and precise drug delivery with reduced side effects. Lipid-containing drug delivery systems are employed for transporting hydrophobic medications within the body. The encapsulation material shields the drug from breaking down and prevents damage to peripheral organs. It enhances the drug's therapeutic index, ensures stability, and improves permeability and focusing specifically on targeting at the site. Different lipid-based nano-carriers, like solid lipid nanoparticles (SLNs) and nanostructured lipid carriers (NLCs), have been created and utilized as nano-carriers, alongside the traditional liposomal formulations. SLNs and NLCs can be consistently produced using high-pressure homogenization or high-speed stirring, eliminating the need for harmful organic solvents.

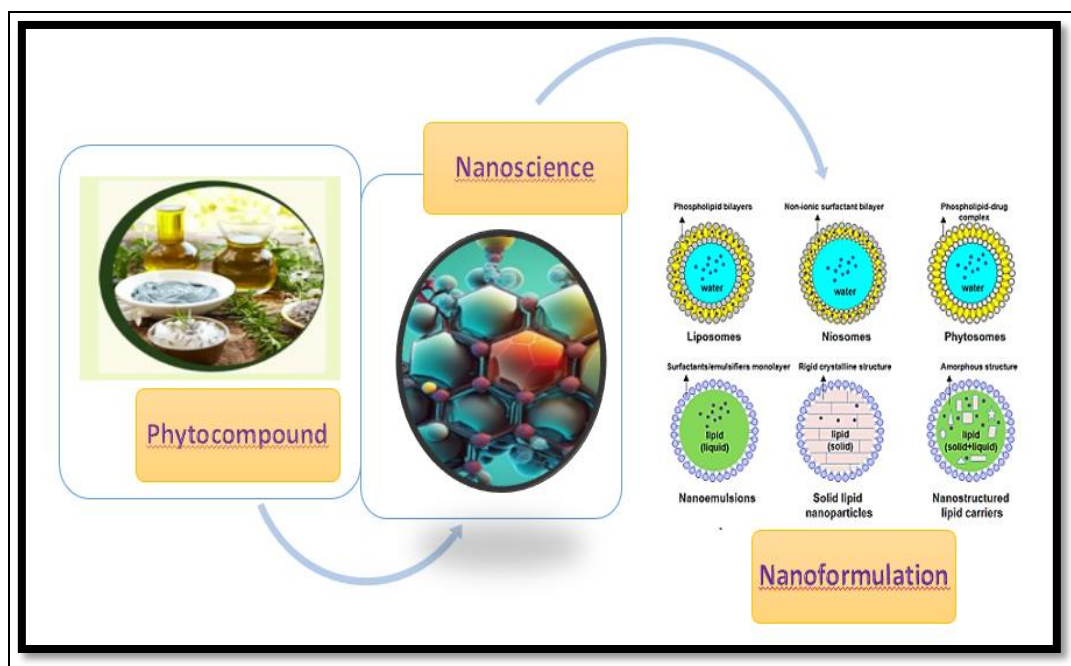


Fig. 1 Phyto-compounds based Nano Formulation

Conclusion and Perspectives:

Phytochemicals have long been a valuable resource for the creation of effective pharmaceuticals. They are acknowledged as an essential source of pharmacologically active chemicals that have been utilized in the development of numerous popular medications. Technological developments for the identification and characterization of natural products have resulted from improvements in phytochemical-based drug discovery. BPCs' poor solubility, instability, low bioavailability, off-targetability, and ensuing toxicity after injection have, however, clinically limited their use in pharmaceutical applications. As a substitute for these innate issues, NF techniques have been employed owing to advancements in nanotechnology. In general, new strategies for nanofluidics in biopharmaceutical companies can have a crucial impact on the creation of future drugs with longer therapeutic benefits. Hence, researchers and industry must work hard to advance different NF techniques and enhance them for optimal human healthcare gains.

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Article 13

Exploring Plant-Derived Mucilage: Properties, Applications, and Nano-carrier Fabrication

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Plant-derived polymers are widely utilized in the paper, textile, and cosmetic sectors because of their wide range of industrial uses, including film coating, emulsifier, binder, and gelling agents. As a result, they have become extremely valuable in the food and other industries. Nowadays, individuals are very interested in plant-based, naturally generated biopolymers (glucans, gums, mucilage, and cellulose) as an efficient component for the formulation of environmentally friendly, sustainable, and reasonably priced goods because of the harmful effects that synthetic polymers have on human health. It has been discovered that plant-derived mucilage can be utilized in place of artificial polymers and additives as a natural thickening or emulsifier. Furthermore, a variety of living things, such as bacteria, fungus, plants, algae, and animals may produce an extensive number of polysaccharides. Mucilage is generally derived from a variety of plants and/or plant parts, including *Cordia dichotoma*, *Basella alba*, *Aloe vera*, *Abelmoschus esculentus*, *Trigonella foenum-graecum*, *Moringa Oleifera*, *Plantago psyllium*, *Cyamopsis tetragonoloba*, *Cactaceae*, and *Linum usitatissimum*. Several studies have reported that the extraction conditions and technique have a significant impact on the rheological, functional, and yield aspects of mucilage. Maceration and precipitation are the two successive stages that are often included in every mucilage extraction process.

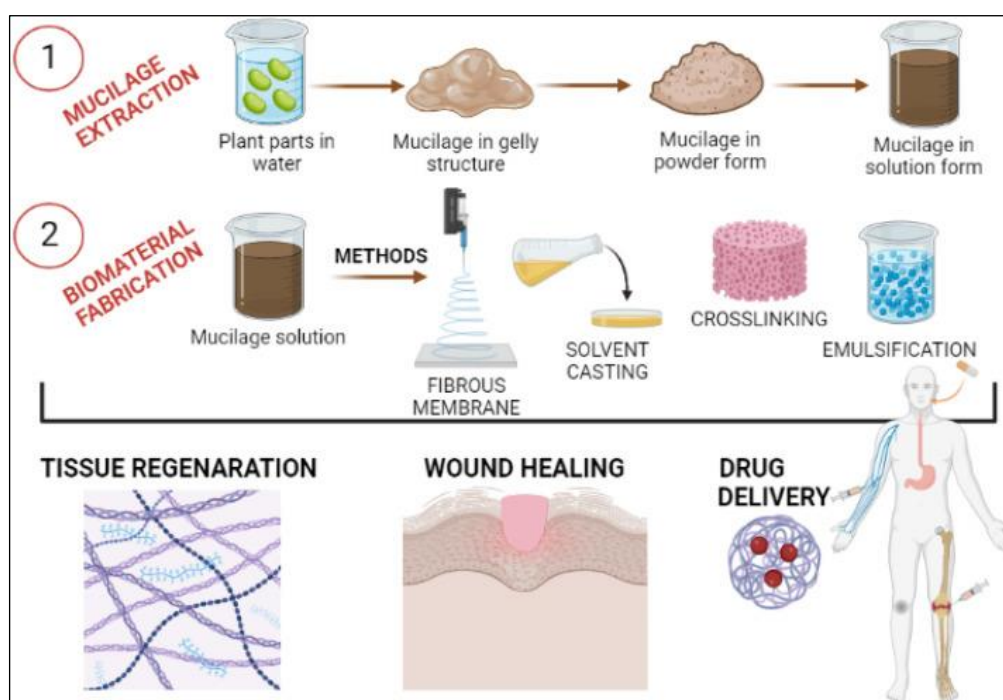


Fig. 1 Obtaining, processing and potential application areas of plant mucilage as a raw material in biomaterial production

Plant-derived mucilage is often used as an active ingredient in the formulation of pharmaceuticals, functional, and nutraceutical products because of its unique health (anticancer, angiotensin-converting enzyme inhibition extends to diabetes, and immune activation) and food qualities. In addition, it may be used to a number of techniques, including the manufacturing of tablets, edible coating, wound healing, encapsulation, water

purification, and other kinds of nano-carriers. Mucilage has good functional properties, but it also plays a significant role in the creation of films, emulsions, coated metal nanoparticles, and hydrogel because of hydrogen bonds between various functional and other polar groups. Mucilage-coated metal nanoparticles and nanostructured hydrogels have become widely employed as important delivery systems for a variety of hydrophilic and hydrophobic substances in recent years. Mucilage can function as either a main biopolymer or a cross-linking component in the formulation of nano-hydrogel. Various types of biopolymers and cross-linking polymers can be employed. Moreover, mucilage-based nano-hydrogel formulations show greater stability than that of other conventional plant-based biopolymers. The most common nano-carriers for targeted drug administration are metal nanoparticles coated with polymeric carbohydrates such as mucilage, starch, dextran, and chitosan. Because, in addition to increasing blood circulation time by hiding them from the immune system, their polymeric shells enable them to transfer and release the drug during biodegradation.

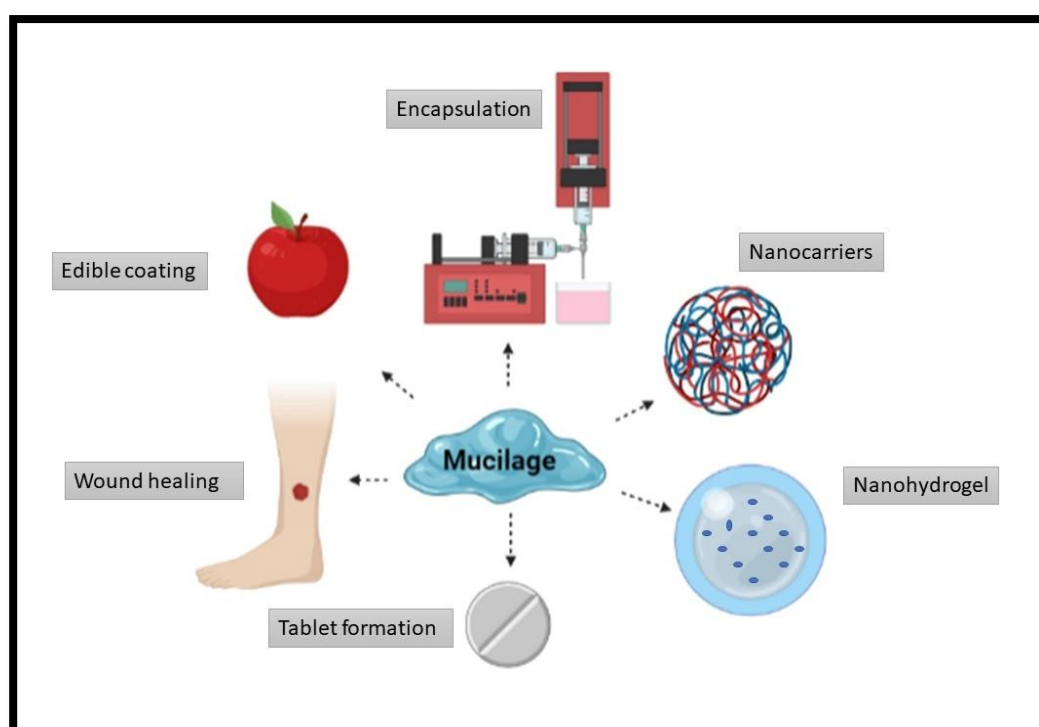


Fig. 2 Industrial Applications of mucilage

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Article 14

Dendrimers in Diagnostics: Innovations in imaging and biosensing technologies

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Dendrimers are a class of synthetically produced highly branched, spherical nanostructures that can be used as carrier molecules for imaging agents. In imaging technologies, dendrimers serve as contrast agents that enhance the visibility of specific tissues or biological markers. For example, dendrimers can be conjugated with imaging moieties for magnetic resonance imaging (MRI) and positron emission tomography (PET). Their small size and multi-valency improve binding affinity, leading to enhanced signal intensity. Recent studies have reported dendrimer-based MRI agents capable of detecting tumors at earlier stages than conventional methods, showcasing their potential in early diagnosis. Dendrimers have been investigated for various diagnostic applications, including cancer diagnosis, infectious disease diagnosis, drug delivery, and environmental monitoring.

In bio-sensing, dendrimers are also making major advancements by improving the sensitivity and specificity of detection techniques. Functionalized dendrimers can be employed in electrochemical and optical biosensors to detect biomolecules, such as proteins and nucleic acids. For instance, dendrimer-based biosensors have demonstrated exceptional performance in identifying cancer biomarkers, enabling timely interventions. Higher signal production and lower detection limits are made possible by the capacity to immobilize a large density of recognition components on dendrimer surfaces.

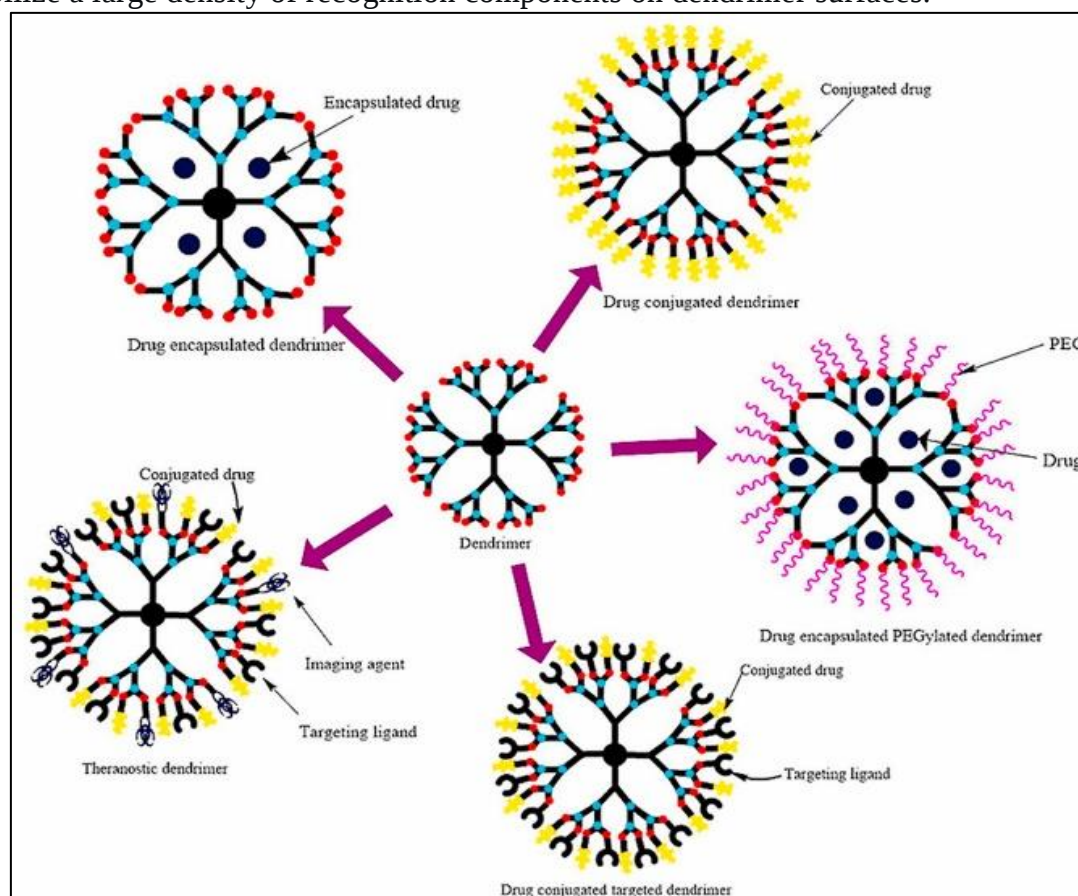


Fig. 1 Dendrimer

Dendrimer topology

(a) Illustration of general dendrimer architectural topology with the three architectural components: (i) core, (ii) interior, and (iii) terminal surface groups (Z). (b) Passive size-mediated targeting: dendrimer-based diagnostic imaging and therapy delivery nanodevices involving [A] imaging moieties, [B] small-molecule therapy components, and (Z) low-toxicity terminal surface groups. (c) Active receptor-mediated targeting: dendrimer-based diagnostic imaging and therapy delivery nanodevices involving [A] imaging moieties, [B] small-molecule therapy components, [C] receptor-mediated targeting groups, and (Z) low-toxicity surface groups. Dendrimers are revolutionizing the field of diagnostics through innovations in imaging and biosensing technologies. Their unique properties allow for enhanced detection capabilities, which could lead to significant improvements in disease diagnosis and monitoring. As research progresses, dendrimers hold the potential to transform the landscape of medical diagnostics, providing faster and more accurate tools for healthcare professionals.

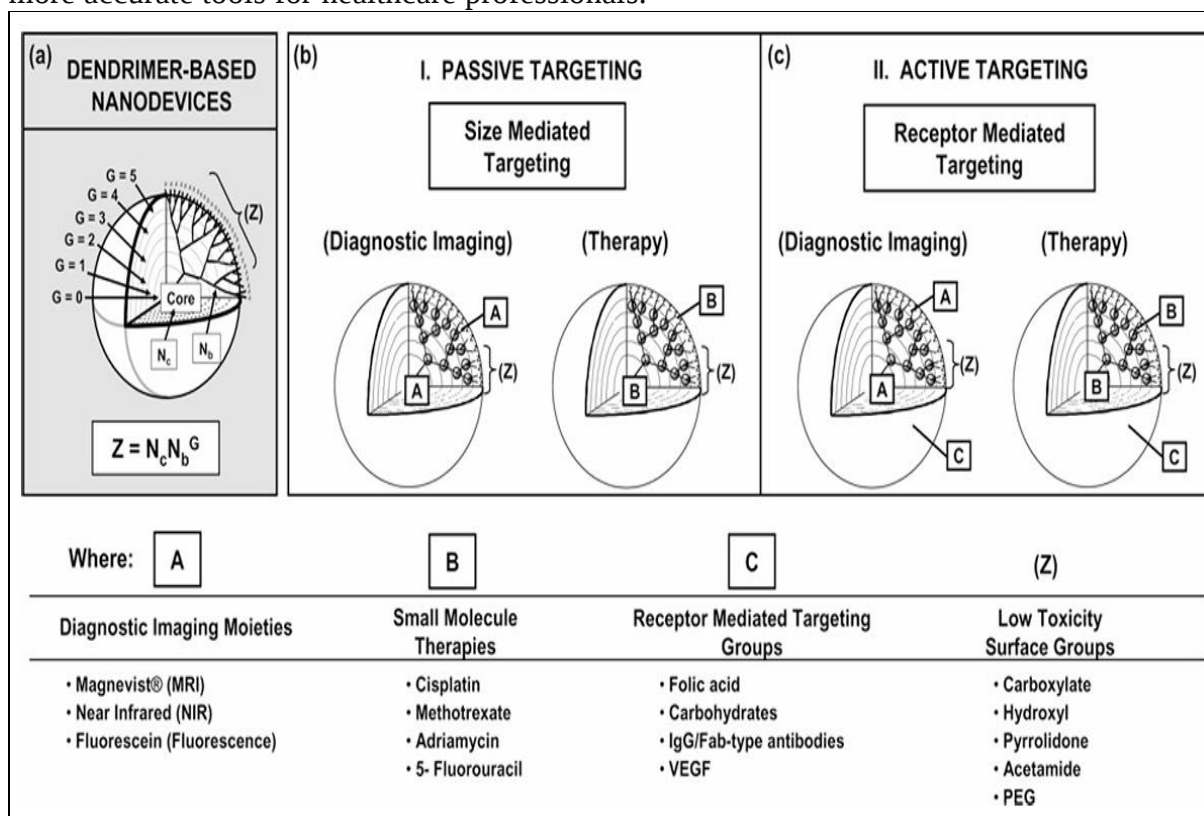


Fig. 2 Dendrimer topology

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Article 15

Cubosomes: A Novel Strategy for Enhancing Anticancer Potential of Poorly Soluble Drugs

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Abstract: Cubosomes are unique particles, either square or spherical in shape, characterized by an internal cubic lattice structure. Their discovery is an intriguing blend of disciplines like food science, differential geometry, biological membranes, and digestion processes. These particles have a "honeycombed" architecture and are thermodynamically stable. Cubosomes consist of amphiphilic lipids stabilized by polymers, allowing for diverse applications such as parenteral, oral, mucosal, and transdermal treatments for skin, hair, and other tissues. By adjusting their formation, cubosomes can be optimized for pore size or functionalized with bioactive lipids, while polymers may help in targeting specific areas. Their physiological safety, combined with the potential for drug entrapment within their internal network, makes them highly effective. Cubosomes are self-assembled nanostructured liquid crystalline particles with a cubic internal phase. Their solid-like properties and unique internal structure make them ideal for encapsulating hydrophobic, hydrophilic, and amphiphilic molecules, improving the solubility of poorly soluble drugs. Applications extend to tissue treatment, controlled release systems, and targeted cancer therapies, particularly melanoma, leveraging enhanced permeability and retention properties.

Introduction: Larsson first introduced the term "cubosomes," drawing a parallel to liposomes. Cubosomes are nanostructured particles of the bicontinuous cubic liquid crystalline phase, with discrete, sub-micron sizes. One of the key advantages of bicontinuous cubic phases is their ability to regulate membrane curvature. These particles are self-assembled liquid crystalline structures, possessing a solid-like rheology that forms quickly and efficiently. Cubosomes exhibit viscous, optically isotropic, and solid properties with cubic crystallographic symmetry similar to other liquid crystalline materials. They play a vital role in nanotechnology-based drug delivery systems. Interest in cubosomes has grown significantly, especially in pharmaceuticals, with their particle size ranging between 10-500 nm. The drug-to-polymer ratio typically varies from 1:2 to 1:1, depending on the material used. Though cubosomes share the same microstructure as their parent cubic phase, their dispersions display much lower viscosity compared to the bulk cubic phase. Cubosomes are composed of surfactant-like molecules that self-assemble amphiphilic compounds. The term "cubosome" was derived by combining 'cubic' with the suffix 'some,' denoting their cubic crystal lattice. Cubosomes form at specific temperatures and can exist in three distinct phases: the primitive (P-surface), gyroid (G-surface), and diamond (D-surface) structures.

Cubosomes Production Techniques: Cubosomes can be prepared using two main strategies: top-down and bottom-up approaches. Both methods require the use of a suitable stabilizer, such as F127, to prevent aggregation in the cubosome dispersion. The choice of the preparation method is largely influenced by the need to ensure stability, biocompatibility, and optimal drug release.

1. Top-down Approach: This method is widely adopted for cubosome preparation

It involves two primary steps:

Step 1: The lipid used to form cubosomes is mixed with a stabilizer to create bulk viscous cubic aggregates.

Step 2: High energy, such as from a high-pressure homogenizer or sonication, is applied to disperse these aggregates in an aqueous medium, forming cubosomes.

Cubosomes prepared this way are stable for up to a year without aggregation. However, this approach faces challenges in large-scale production because dispersing the cubic aggregates into smaller particles requires significant energy. Additionally, the method poses difficulties in incorporating temperature-sensitive bioactive agents, like peptides and proteins.

2. Bottom-up Approach

Also known as the solvent dilution method, this technique involves dispersing a mixture of cubosome-forming lipids, a stabilizer, and a hydrotrope in water with minimal energy input. The hydrotrope is essential as it dissolves water-insoluble lipids, forming lipid precursors, and prevents liquid crystal formation at high concentrations. Examples of commonly used hydrotropes include urea, sodium alginate, and sodium benzoate. The bottom-up approach offers advantages over the top-down method. It requires less energy and is thus better suited for temperature-sensitive compounds. The homogenous dispersion of stabilizers onto the nanovesicles' surfaces also leads to long-term stability in the resulting cubosomes.

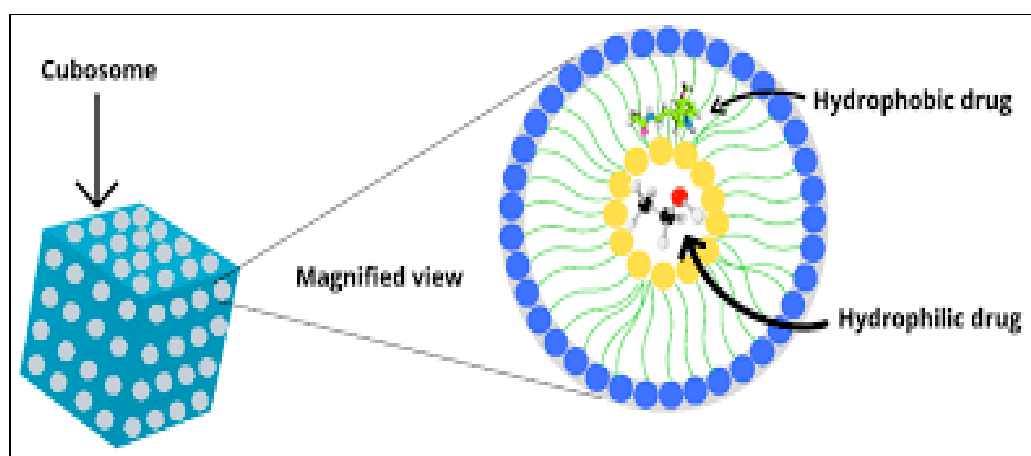


Fig. 1 Cubosomes Structure

Conclusion: Cubosomes are a unique class of lipid-based nano-vesicles characterized by their liquid crystalline nanostructure, formed by the self-assembly of amphiphilic lipids in water in the presence of a stabilizer. Recent studies have highlighted their potential as innovative drug delivery systems. In ocular drug delivery, cubosomes enhance ocular residence time and bioavailability without causing irritation. In oral applications, they can increase the absorption of poorly water-soluble drugs, shield drugs from enzymatic degradation, and facilitate targeted delivery. For transdermal delivery, cubosomes enhance skin permeation with minimal irritation. Additionally, cubosomes have been effective in delivering anticancer drugs, minimizing the side effects of chemotherapy while ensuring targeted drug delivery.

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Article 16

Herbal Drug Technology

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Introduction: Herbal drug technology involves the study and application of plant-based materials for medicinal purposes. Plants have been the primary source of medicine for centuries, and modern herbal drug technology combines traditional knowledge with contemporary scientific techniques to ensure quality, efficacy, and safety. This field integrates several disciplines such as pharmacognosy, phyto-chemistry, pharmacology, and modern pharmaceutical technology to develop and standardize herbal medicines.

Historical Context: Historically, traditional systems of medicine like Ayurveda, Traditional Chinese Medicine (TCM), and Unani have used herbal remedies to treat various ailments. These systems rely on the therapeutic potential of whole plants or plant parts. Over the years, scientific advancements have led to the isolation and characterization of active compounds from these plants, enabling a more precise understanding of their pharmacological properties.

Phyto-chemistry and Active Compound: The effectiveness of herbal drugs largely depends on the bioactive compounds present in the plant material. Phytochemicals such as alkaloids, flavonoids, glycosides, tannins, and terpenoids are commonly found in medicinal plants and possess therapeutic effects. Modern phytochemical screening methods like chromatography (HPLC, GC), mass spectrometry (MS), and nuclear magnetic resonance (NMR) are utilized to identify and quantify these compounds.

Alkaloids: Known for their analgesic and antimalarial properties (e.g., morphine and quinine).

Flavonoids: Exhibit antioxidant, anti-inflammatory, and antiviral properties.

Glycosides: Cardiac glycosides, like those found in *Digitalis*, are used in treating heart conditions.

Tannins: Possess astringent and antimicrobial properties.

Standardization of Herbal Drugs: A major challenge in herbal drug technology is the variability in the content of active ingredients in plant material, influenced by factors like geography, season, and harvesting methods. Standardization ensures consistent quality, efficacy, and safety of herbal products. Standardization involves

Authentication: Correct identification of plant species using morphological, anatomical, and chemical characteristics.

Quantification of Active Ingredients: Using techniques like HPLC, TLC, and UV-Vis spectroscopy to measure specific bioactive compounds.

Physicochemical Parameters: Determining moisture content, ash values, and extractive values to assess the quality of the plant material.

Formulation Development: Herbal drug formulations include traditional dosage forms like powders, decoctions, infusions, and modern forms such as tablets, capsules, syrups, and topical applications. The development of these formulations requires an understanding of:

Solubility and Bioavailability: Many herbal compounds have poor solubility and bioavailability, requiring enhancement techniques such as the use of bioenhancers, nanoformulations, and solid dispersions.

Stability: Herbal products must maintain stability over time to ensure efficacy. This includes protection from moisture, light, and temperature, requiring appropriate packaging and storage conditions.

Quality Control and Good Manufacturing Practices (GMP): Quality control (QC) in herbal drug technology is vital to ensure the safety and efficacy of herbal medicines. QC processes involve

Botanical Evaluation: Ensures the correct species of plants are used.

Chemical Evaluation: Determines the active constituents and ensures they meet established standards.

Microbial Limits: Testing for harmful bacteria, fungi, and other pathogens.

Toxicological Evaluation: Ensures the absence of toxic substances such as heavy metals, pesticides, and aflatoxins.

Good Manufacturing Practices (GMP) are a set of guidelines that ensure consistent production and control according to quality standards. In herbal drug technology, GMP emphasizes cleanliness, controlled environments, proper documentation, and validated procedures to ensure the production of safe and effective herbal medicines.

Regulatory Aspect: The regulation of herbal medicines varies across countries. In the US, herbal products are regulated as dietary supplements by the Food and Drug Administration (FDA), while in Europe; they are classified under the European Medicines Agency's (EMA) Traditional Herbal Medicinal Products Directive. Regulatory requirements typically include:

Safety and Efficacy Data: Preclinical and clinical studies may be required to demonstrate the safety and effectiveness of herbal drugs.

Labeling Requirements: Clear and accurate information regarding ingredients, dosage, usage, and potential side effects must be provided.

Post-market Surveillance: Monitoring adverse reactions and ensuring product recalls if safety concerns arise.

Challenges in Herbal Drug Technology

Complexity of Plant Materials: Unlike synthetic drugs, herbal products contain numerous constituents that may interact with each other, complicating the identification of active principles.

Standardization Issues: The variation in plant content makes it difficult to achieve consistent results.

Quality Control: Ensuring batch-to-batch consistency can be challenging due to variations in growing conditions.

Regulatory Hurdles: Regulatory frameworks for herbal medicines are less stringent than for conventional drugs, leading to concerns about quality and safety.

Future Trends in Herbal Drug Technology: The future of herbal drug technology lies in the integration of modern scientific tools with traditional knowledge. Current trends include:

Nanotechnology in Herbal Medicine: Nano-carriers for herbal compounds to improve bioavailability and targeted delivery.

Phytopharmaceuticals: Development of semi-purified or purified plant-based drugs that meet modern pharmacological standards.

Biotechnological Approaches: Use of plant tissue cultures and genetic engineering to produce high yields of bioactive compounds.

Personalized Herbal Medicine: Leveraging genomics and personalized medicine principles to tailor herbal treatments to individuals' genetic profiles

Conclusion

Herbal drug technology is an evolving field that bridges traditional herbal knowledge with modern pharmaceutical science. It holds the potential for developing effective, safe, and high-quality herbal medicines. However, ensuring standardization, quality control, and regulatory compliance remains crucial for the growth and acceptance of herbal drugs in the global healthcare market.

Article 17

Nanocrystals: A Novel Strategy for Enhancing Bioavailability of Poorly Soluble Drugs

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Abstract: The challenge of enhancing the bioavailability of poorly soluble drugs has driven the development of advanced strategies beyond traditional micronisation. Nanocrystals, which are sub-micron-sized particles produced through high-pressure homogenisation, represent a significant advancement in drug formulation. This article reviews the production techniques, such as DissoCubes, Nanopure, and NANOEDGE, which utilize high-energy homogenisation and precipitation methods to create nanosuspensions. These nanosuspensions can be converted into patient-friendly dosage forms like tablets and capsules, offering a solution to the bioavailability challenges of new chemical entities (NCEs) with low solubility. The principles of nanocrystal production, the impact of process parameters, and the scalability of these techniques for clinical applications are discussed, highlighting the potential of nanonisation in improving drug bioavailability.

Introduction: The solubility of many new chemical entities (NCEs) remains a significant barrier to their effective oral administration. Traditional micronisation methods often fail to sufficiently enhance the solubility and bioavailability of poorly soluble drugs. This has led to the development of nanonisation, where drug particles are reduced to the nanometer scale to improve solubility and dissolution rates. Nanocrystals, produced via techniques such as high-pressure homogenisation, offer a promising approach to overcoming these challenges.

Nanocrystal Production Techniques: Several advanced techniques have been developed to produce nano-crystals, each with distinct advantages:

Disso Cubes: This method employs water-based homogenisation to produce nano-suspensions. The process involves the use of stabilizers to maintain the stability of the nanosuspension and prevent particle aggregation.

Nanopure: This non-aqueous homogenisation technique is suitable for drugs that are sensitive to water. It involves the use of organic solvents to create a nanosuspension, which is then transformed into the desired dosage form.

Nanoedge: Combining precipitation with high-energy homogenisation, this method produces nanosuspensions with enhanced stability and bioavailability. It integrates the benefits of both precipitation and homogenisation processes.

Formulation of Nano-suspensions into Dosage Forms: Nano-suspensions can be converted into various dosage forms, including tablets and capsules. Fast dissolving oral delivery systems are particularly effective for nanocrystals. These systems are designed to dissolve rapidly in the mouth, allowing for direct absorption through the oral mucosa and bypassing the gastrointestinal tract and first-pass metabolism.

Case Study: Piroxicam (PRX) Nanocrystals: Piroxicam (PRX), a non-steroidal anti-inflammatory drug with poor water solubility, presents a significant challenge for oral administration. Recent studies have explored the use of nanocrystal technology to enhance the solubility and bioavailability of PRX. High-pressure homogenisation was employed to produce PRX nanocrystals stabilized with poloxamer 188. These nanocrystals were then formulated into orally disintegrating tablets (ODTs).

Characterisation and Performance

The PRX nanocrystal ODTs were characterized using various techniques includes Infrared Spectroscopy (FTIR), X-ray Powder Diffractometry (XRPD), Differential Scanning Calorimetry (DSC), and Photon Correlation Spectroscopy (PCS). Dissolution studies compared the performance of PRX nanocrystal ODTs with that of conventional coarse

suspension ODTs. The results demonstrated improved dissolution rates and enhanced buccal absorption of PRX.

Conclusion

Nanocrystals represent a novel and effective strategy for enhancing the bioavailability of poorly soluble drugs. By utilizing advanced production techniques and formulating nano-suspensions into fast dissolving dosage forms, it is possible to overcome solubility challenges and improve therapeutic outcomes. Continued research and development in this field hold promise for the future of drug formulation and delivery.

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Article 18

Nanotechnology and Nutraceuticals

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Nutraceuticals" and "functional foods" are phrases that are commonly used interchangeably in the media and publications. The term "nutraceutical," a combination of the term's "nutrition" and "pharmaceutical," was actually coined by Stephen DeFelice, M.D., the founder of the Foundation for Innovation in Medicine in Cranford, New Jersey. There are many different products included in it, including functional foods, isolated nutrients, medicinal foods, fortified foods, and dietary supplements. A promising new avenue for improving health and wellness is presented by the combination of nutraceuticals with nanotechnology.

The application of nanotechnology to nutraceuticals is examined in this abstract, with particular attention on how it might transform bioactive substances' bioavailability, efficacy, and delivery methods. With the exact manipulation at the nanoscale provided by nanotechnology, new delivery vehicles including liposomes, nanoparticles, and nano emulsions can be designed. By enhancing nutraceutical chemicals' solubility and stability, these platforms solve problems with traditional formulations. Furthermore, targeted delivery is made easier by nano-based carriers, which guarantees the body's best possible absorption and dispersion.

Moreover, functionalization possibilities provided by nanotechnology enable the addition of bioresponsive components for site-specific targeting and triggered release. Furthermore, real-time monitoring of physiological parameters made possible by the integration of nano-sensors allows for customized interventions and accurate dosing schedules. Liposomes, nanoparticles, nano-suspensions, and polymeric micelles are examples of drug-delivery systems that use nanotechnology to improve solubility of drug, its therapeutic efficacy, permeability, stability, and oral bioavailability. Nutraceutical particles have trouble reaching to their target site for a number of reasons, including poor gastrointestinal tract (GIT) absorption brought on by problems with the solubility of active medicinal substances, like vitamin and calcium supplements.

Therapeutic activity may be impacted by interactions between nutraceutical products and chemicals, medications, and other nutraceuticals. The problems with solubility and absorption may be solved using nanotechnology. A molecule's surface area increases with size decrease, enhancing the intended biological process. Converting a nutraceutical molecule into a nano-carrier is one method of overcoming the barriers. The pharmacological approach uses nano-delivery technologies extensively.

A variety of foods incorporating nanoparticles and nano-capsules are presently on the market, albeit they are not obliged to list these ingredients on the packaging. Nanotechnology is also being used in processed foods and beverages. Nevertheless, each regulatory agency has a distinct rule. The majority of the time there have been no laws governing food safety, labelling standards, or public awareness of these foods that have undergone nano processing when they were introduced into the food chain. The majority of significant food corporations, such as Unilever, Hershey Foods, Nestle, and HJ Heinz, have made significant investments in nanotech R&D in these fields. For instance, Kraft's worldwide "Nanotek Research Consortium," which consists of 15 universities and national research labs, exemplifies a business plan to spearhead advancements for the future of nano-food.

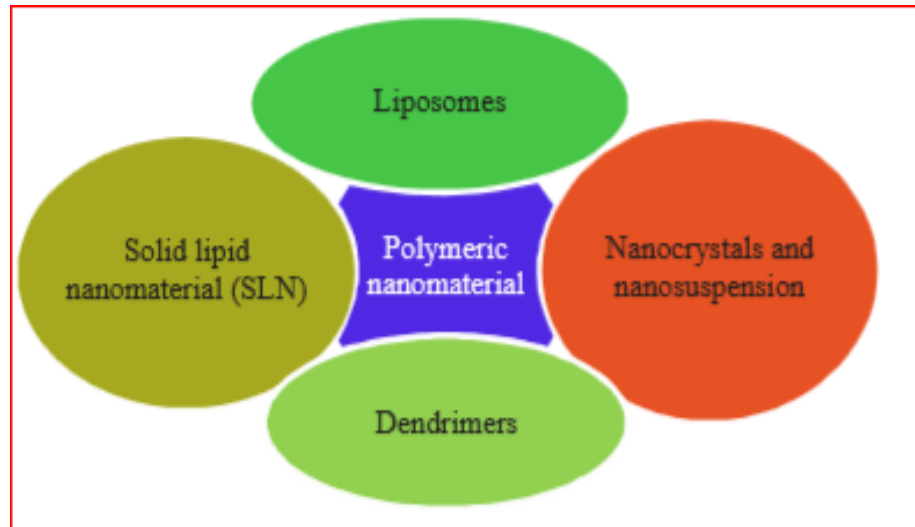


Fig.1 Types of nanoparticles

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Article 19

A Narrative Review of Autism Spectrum Disorder in the Indian Context**Mrs. Nandita A. Samudre****PG Student, Pharmacology Department**

Autism spectrum disorder (ASD) refers to “a range of conditions characterized by some degree of impaired social behavior, communication and language, and a narrow range of interests and activities that are both unique to the individual and carried out repetitively.” ASD is a neurodevelopment condition that continues to exist through childhood and adulthood. Most of the disorders are discovered during the first 5 years of life. Autism is called “spectrum” disorder because there is a wide variation in the type and the severity of symptoms that people experience. It was found that advanced paternal age, fetal distress, gestational respiratory infections, labor complications, preterm birth, neonatal jaundice, delayed birth cry, birth asphyxia, late initiation of breastfeeding, neonatal seizures, use of maternal hormonal intervention, and consanguinity as some of the identified risk factors of autism spectrum disorder. Some early theorists believed that autism is caused by emotionally detached parenting (often referred to “refrigerator mothers”); however, this idea was long ago rejected.

The diagnosis of ASD is made based on behavioral observation in 2 main categories: social communication and interaction, and restricted and repetitive behavior. According to the World Health Organization 2019 factsheet, 1 in every 100 children worldwide is diagnosed with ASD. This estimate, however, is an average figure, and reported prevalence differs substantially across studies. The prevalence of ASD in many low- and middle-income countries is still unknown. ASD can have a significant impact on family dynamics, causing caregiver overburden, and depression among other family members of children with autism. However, now many organizations such as Action for Autism in Delhi, Centre for Autism Therapy, Counselling and Help in Bhubaneswar, Communication DEALL, Assisted Living for Autistic Adults in Bengaluru, Ummeed in Mumbai, and many more are working in India for spreading awareness on autism, providing rehabilitation services for children with autism as well as offering support to individuals with ASD and their families through counselling and guidance.

The government of India has taken several initiatives to provide education for children with special needs, including those with autism. These activities include identifying and assessing children with special needs, providing aids, appliances, and corrective surgeries, developing accessible learning materials such as Braille books and large print books, offering therapeutic services, conducting training for special educators and general teachers on curriculum adaptation, creating awareness about the needs of children with special needs, implementing the Right to Education Act for children with special needs, and providing resource support to schools in the form of financial assistance for hiring special educators. Under this, the National Council of Educational Research and Training (NCERT) has developed “Barkha: A Reading Series for ‘All’” as an inclusive learning material for early reading. It follows the principles of Universal Design for Learning and includes tactile features, high-resolution visuals, and accessible text. A digital version of the series has also been created, allowing flexibility and accessibility for children. The National Institute for the Empowerment of Persons with Intellectual Disabilities (NIEPID) is a premier institute dedicated to providing training, research, and education for persons with intellectual disabilities, including autism. Although the government has introduced provisions for the education and employment of disabled individuals, the implementation and awareness among those in need remain insufficient. Additionally, there is currently a lack of government initiatives specifically targeting autism in India. Hence, there is also a need for framing effective policies as well as implementing them; the collaboration between the government and NGOs is necessary.



Fig. 1 Autism spectrum disorder (ASD)

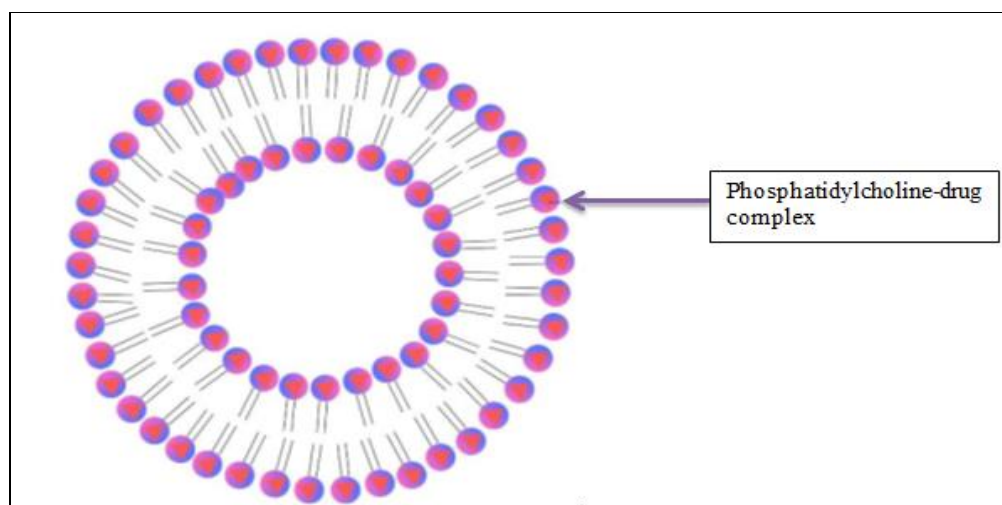
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Journal of Indian Association for Child and Adolescent Mental Health Volume 19, Issue 4, October 2023, Pages 336-343.

Article 20

Phytosomes: A Novel Approach to Improve the Bioavailability of Active Constituents**Mr. Prafull Pandurang Mane****PG Student, Quality Assurance Department**

Any pharma-cotherapeutics approach's main goal is to administer the right medicine at the right concentration at the right place as efficiently as possible using a delivery mechanism that has been carefully developed. The globe has been healing for millions and billions of years thanks to phyto-pharmaceuticals, despite the fact that their therapeutic effectiveness is called into question due to certain obstacles such as big moiety, poor stability, limited lipid solubility, and unnecessary metabolism in the stomach. Using phyto-phospholipid complexes, which combine active ingredients with label-friendly phospholipids, is a potentially effective way to boost the oral bioavailability of the contents. Phospholipid complexes are essential because of hydrogen bond interactions between phospholipids and active ingredients. "Phyto" refers to a plant, and "some" to something resembling a cell. A recently developed method called "phytosome" is used in phyto-pharmaceuticals to encapsulate and bind phyto-constituents of herbal extract in lipid. Water-soluble substances like flavonoids make up the majority of the bioactive components of phyto-medicine. Owing to their lipophilic outer layer and water solubility, phytosomes exhibit superior absorption, leading to increased bioavailability, a decrease in the clearance rate, and a greater degree of dissolution and solubility amplification of different natural products by multiple times compared to traditional herbal extracts. Because of their enhanced pharmacological and pharmacokinetic qualities, phytosomes have the potential to be employed as dietary supplements and as a treatment for both acute and chronic liver failure.

**Fig. 1 Phytosome Structure****Methods for the preparation of phytosomes:**

There are three primary methods for preparation of phytosome complexes, including solvent evaporation, freeze-drying, and anti-solvent precipitation. The stages of preparation of phytosomes includes-

- Phospholipid is dissolved in organic solvent containing drug/extract (1:1)
- Solution of phospholipid in organic solvent with drug/extract
- Drying and Formation of thin film Hydration
- Formation of phytosomal complex

Oral bioavailability enhancement using a phospholipid complex: a mechanistic outlook when administered orally, medications with poor permeability (BCS classes III and IV) or solubility (BCS class II) typically have relatively low bioavailability. The existence of metabolizing enzymes, the pH-mediated degradation of the environment, and the P-gp pump, which induces the efflux of naked medicines, are additional factors contributing to limited bioavailability. Drug delivery vehicles are therefore necessary for medications to reach the appropriate level in the systemic circulation. The same could be done with phospholipid-drug complexes, where the absorption mechanism is comparable to that of triglycerides and essential phospholipids. The method by which that the phospholipid-drug complex is absorbed is comparable to how phospholipids are absorbed naturally by enterocytes.

The phospholipid is structurally made up of two fatty acid chains that are joined to the glycerol (diacyl glycerol) moiety. The glycerol hydrolyzes to liberate fatty acid, which initiates the phospholipid's absorption. Similarly, when administered orally, the drug-diacyl glycerol combination experiences hydrolysis. At pH of approximately 1.5, the stomach undergoes minor hydrolysis, while the majority of the process takes place in the intestine, beginning in the duodenum, where juice-like secretions from the pancreas, liver, and bile bladder are produced. Because phospholipases, especially phospholipase A₂, are present in the intestine, drug-diacyl glycerol hydrolyzes, releasing fatty acids and becoming drug-monoacyl glycerol.

The bile salts and the previously used medication, monoacyl glycerol, then combine to form micellar vehicles. The formation of these micelles depends on the excretion of bile into the duodenum, which is controlled by the hormone cholecystokinin (CCK). CCK is released when the breakdown of triglycerides and diacyl-glycerophospholipids forms a larger concentration of fatty acids. But the small amount of hydrolysis that takes place in the stomach usually results in the release of a fatty acid, which sets off the release of CCK, which in turn controls the release of salts and bile acids. Enterocytes then take up the drug-monoacyl phospholipid vesicles by passive diffusion when the hydrolysis is complete. Drug-monoacyl phospholipids and endogenous diglycerides are converted to diacyl phospholipids and triglycerides, respectively, by the enzymes found in the smooth endoplasmic reticulum of enterocytes, namely acyl-CoA [3].

Additionally, apoportein B-48 integrates into the phospholipid vesicle in the golgi apparatus to generate nascent chylomicron. Through the basal membrane, the chylomicron is exocytosed from the enterocyte and enters the lacteal (lymph capillary), where it is transported out of the intestine and avoids the first pass metabolism. Once nascent chylomicron reaches the systemic circulation, high density lipoprotein distributes apolipoprotein C-II and apolipoprotein E to the nascent one, converting it to mature chylomicron. Chylomicron remnants, which are often found in the liver for endocytosis and disintegration, are produced when the matured chylomicron returns the apolipoprotein C-II after the triglycerides have been deposited [4].

Therefore, the medication phospholipid complex bypasses the first pass metabolism and reaches the systemic circulation through the chylomicron. The drug phospholipid complex's mechanism permits the absorption of medications that either exhibit substantial first-pass metabolism or are not soluble. Figure shows the schematic illustration of the same.

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Article 21

Liquisolid Compacts: A Promising Approach for Solubility Enhancement**Mr. Prasad Dilip Koli****PG Student, Pharmaceutics Department**

Introduction: At present 40% of the drugs within the development pipelines, and approximately 60% of the drugs coming directly from synthesis area unit poorly soluble. Solubility is one of the important parameters to obtain desired concentration of drug in systemic circulation. Liquisolid compacts technique is a new and promising approach to overcome this consequence and that can change the dissolution rate of water insoluble drugs and increase the bioavailability of the drugs. This technique is an efficient method for formulating water insoluble and water-soluble drugs. This technique relies upon the admixture of drug loaded solutions with applicable carrier and coating materials. Liquisolid system is characterized by flow behaviour, wettability, powder bed hydrophilicity, saturation solubility, drug content, differential scanning calorimetry, Fourier transform infra-red spectroscopy, powder X-ray diffraction, scanning electron microscopy, in-vitro release and in-vivo evaluation.

Classification

Based on the liquid medication, it divided into three sub groups:

Powdered drug solutions

Powdered drug suspensions

Powdered liquid drug

The major two is also made from the conversion of drug solutions or drug suspensions (e.g. gemfibrozil suspension in Polysorbate 80), and therefore the formulation of liquid drugs (e.g. clofibrate, valproic acid, liquid vitamins, etc.), into liquisolid systems. Based on the formulation technique, liquisolid systems is classified into two groups,

Liquisolid compacts: It refers to immediate sustained release tablets or capsules that are described under liquisolid systems.

Liquisolid microsystems: It refers to capsules ready by liquisolid systems with the inclusion of an additive resultant in a unit size that may be as much as five times less than that of a liquisolid compact.

Several mechanisms of increased drug release have been proposed for liquisolid Systems. The three main mechanisms include increased surface area of drug, increased aqueous solubility of the drug, and improved wettability of the drug particles. Formation of a complex between the drug and excipients or any changes in crystalline of the drug could be ruled out using DSC and XRPD measurements.

- Increased Drug Surface Area
- Increased Aqueous Solubility
- Increased Wettability
- Increased Drug Surface Area

If the drug within the liquisolid system is totally dissolved within the liquid vehicle it is situated in the powder substrate still in a solubilized, molecularly spread state. Therefore, the surface area of drug available for release is way larger than that of drug particles inside directly compressed tablets. Accordingly, with increasing drug content surpassing the solubility limit and so, increasing fraction of undissolved drug with in the liquid vehicle the discharge rate decreases.

Increased Aqueous Solubility of the Drug: Liquisolid systems may enhance drug solubility due to the liquid vehicle's microenvironment. Although the small amount of liquid in the compact isn't enough to improve overall solubility, it can create a favorable interface where the vehicle acts as a cosolvent, potentially increasing the drug's aqueous solubility at release.

Increased Wettability: Due to the very fact that the liquid vehicle will either act as surface chemical agent or contains a low surface tension, wetting of the liquisolid primary particles is improved.

General Procedure for Preparation of Liquisolid Compact:

- A drug substance should be initially dissolved or suspended in a suitable non-volatile solvent system to produce a drug solution or drug suspension of desired concentration.
- Then a mixture of carrier or different polymers and excipients were added to the above liquid medication under continuous mixing in a mortar. These amounts of the carrier and excipients are enough to maintain acceptable flow and compression properties.
- To the above binary mixture disintegrant like sodium starch glycolate and other reaming additives were added according to their application and mixed for a period of 10 to 20 min. in a mortar.
- The mixture was compressed manually in tableting machine to achieve tablet hardness.
- Characterize the final liquisolid granules for solubility, dissolution, flowability, compressibility and other physicochemical properties

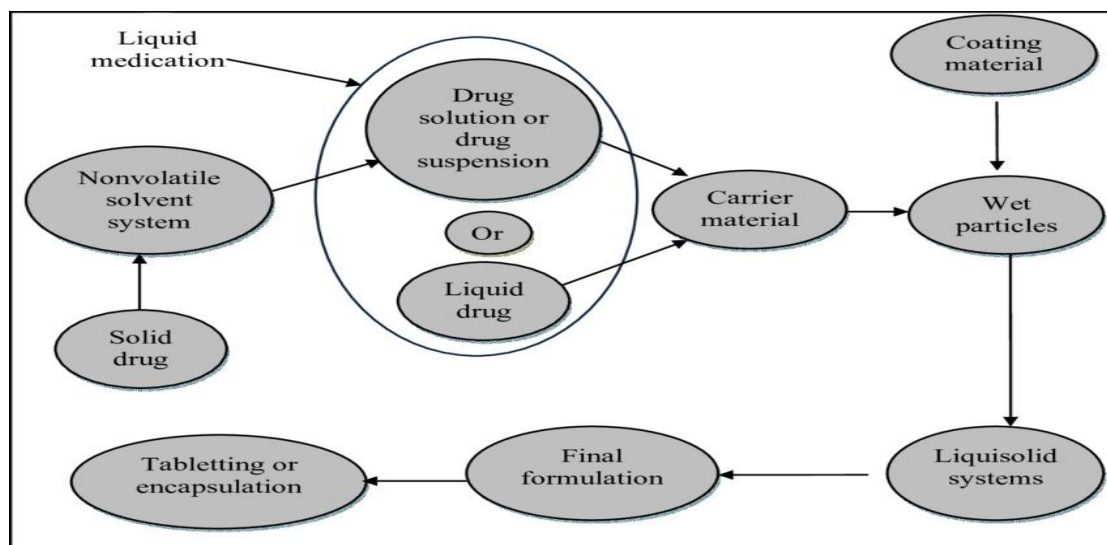


Fig. 1 Method of Preparation of liquisolid compacts

Application: -

- Rapid release rates are obtained in liquisolid formulations.
- Liquisolid compact technology is a powerful tool to improve bioavailability of water insoluble drugs. Several water insoluble drugs on dissolving in different non-volatile solvents have been formulated into liquisolid compacts.

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Article 22

Nanostructured Lipid Carriers as Potential Drug Delivery Systems for Skin Disorders**Ms. Puja Balu Pujari****PG Student, Pharmaceutics Department**

About 30 to 70% of the population worldwide suffers from skin diseases, ranging from acute to chronic and benign to life threatening diseases. The severity of the skin disease depends on the pathogen involved, the skin structure, skin layer, and the medical ailment of the patient. Skin is divided into the epidermis and dermis, external and internal layers. The epidermis consists of stratum corneum (SC). The stratum corneum (SC) protects the skin structure from environment and other things. It's providing the primary barrier against water loss and percutaneous absorption of compounds.

Nanostructure Lipid Carriers (NLCs) have effective approach to increase drug absorption through skin. The NLCs composed from solid lipid and liquid lipid. The NLCs and epidermis have similar lipid nature; due to this nature NLCs improve the drug permeation through skin. The enhanced permeation happens because NLC cause an occlusion effect through the formation of a film on the skin. The occlusive effect reduces trans-epidermal water loss, improving hydration of the skin, and increasing drug penetration. NLC components, such as lipids and surfactants, can also act as permeation enhancers by interacting with and disorganizing SC lipids, which facilitates permeation of the molecules to the deeper layers of the epidermis. Thus, inflammatory skin disorder can be successfully treated by the localized release of actives through NLC, and which are more effective than conventional formulations. NLCs used in skin disorder such as, fungal infection, Bacterial infection, Skin Cancer, Psoriasis and Dermatitis.

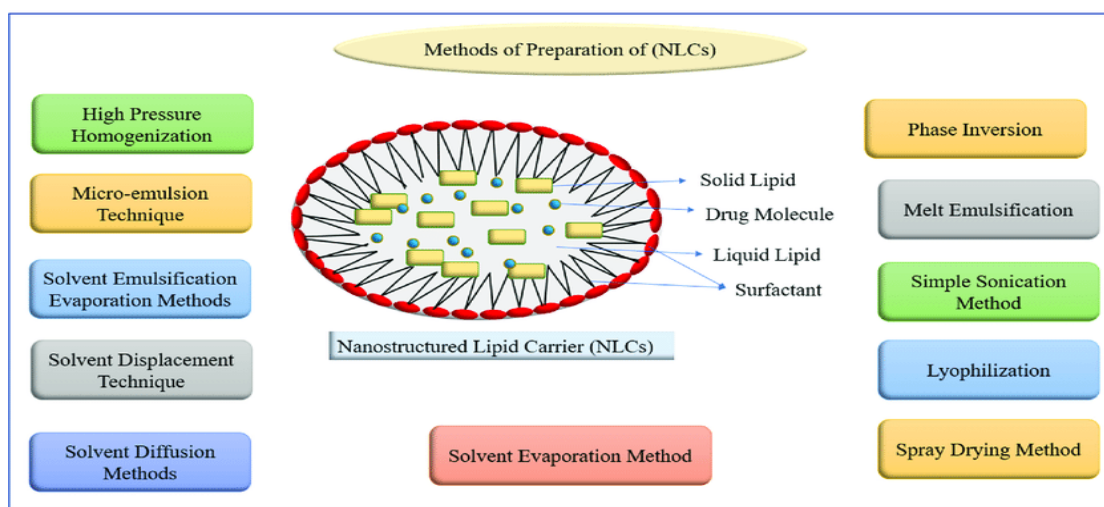


Fig. 1 Method of Preparation of Nanostructure Lipid Carriers

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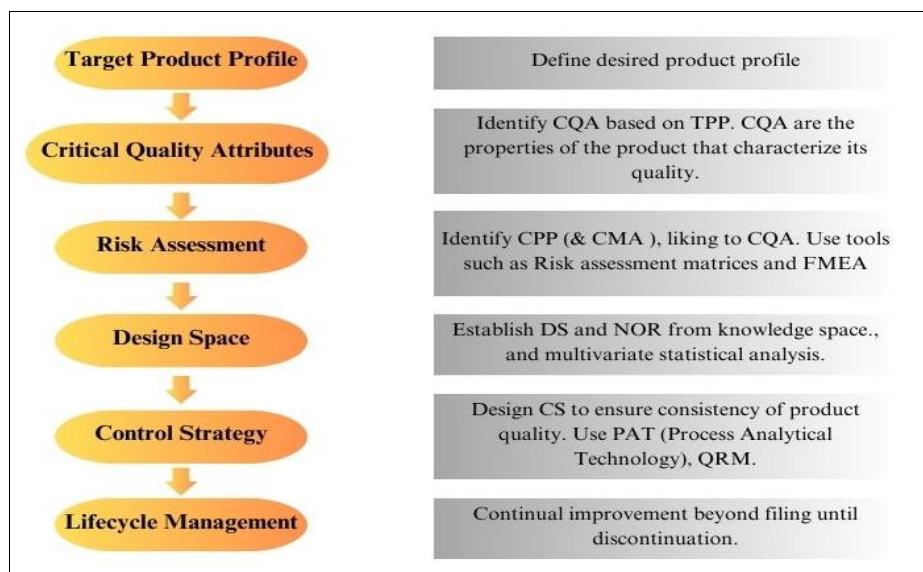
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Article 23

Quality by Design (QBD) and Process Analytical Tools (PAT) Approach in Pharmaceuticals Development**Mr. Rakesh B. Babaleshwar****PG Student, Pharmaceutical Chemistry Department**

The concept of quality by design (QbD) has been recently adopted in the pharmaceutical industry through several initiatives {e.g., ICH Q8, Q9 and Q10, and the new regulatory documents, Process Analytical Technology (PAT), FDAs cGMP for the 21st Century}. The general aim is to switch from the quality by testing (QbT) paradigm previously implemented in the pharmaceutical industry to a development aimed at improving the understanding of the processes and the products and hence improving product quality, process efficiency and regulatory flexibility. The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product. The information and knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the design space, specifications, and manufacturing controls. Information from pharmaceutical development studies can be a basis for quality risk management. It is important to recognize that quality cannot be tested into products; i.e., quality should be built in by design.

In order to meet the predetermined goals for product quality, it basically requires planning and creating the product as well as the manufacturing process from the perspective of the patient, QbD finds qualities that are crucial to quality and transforms them into the CQAs (critical quality attributes) that the product must have. It also defines the boundaries, or design space, for the significant material attributes (CMAs) and key process parameters (CPPs) that have an impact on the CQAs. It is decided to calculate the CMAs and CPPs using the new risk-based method. The technique is invariant inside the design space and produces the intended outcome. Design of experiment (DoE), a statistical method for enhancing CMA and CPP variable choices, is used to obtain design space. Making use of this data results in a manufacturing procedure that is flexible and adaptive and can consistently manufacture a product over time.

**Fig. 1 Elements of Pharmaceutical Development [ICH Q8 (R2)]**

Process Analytical Technology (PAT) estimating the impacts of CPPs on the finished product is difficult, hence process analytical technology (PAT) is intentionally used in QbD as a tool to optimize the production process. PAT is characterized as a crucial component of QbD because, even in cases when the complex interactions between process changes and their effects are unpredictable, it nevertheless permits extensive testing, monitoring, analysis, and changing of the manufacturing processes to fully control and enhance the efficacy of drug products. PAT could refer to a more comprehensive change in pharmaceutical production that involves many dynamic approaches instead than only static batch production. It entails processing the instrumentation's CPPs, producing a product that influences the product's CQAs, and controlling these CPPs at predetermined intervals. This helps producers to deliver goods of a regular standard and also contributes to reduction in waste and total costs. This waste reduction and consistent product quality manufacturing method makes a strong case for the use of continuous production technology.



Fig. 1 Process, Quality, Design and PAT

PAT tools include information management tools for data collection and analysis, process analyzers, process control tools, and tools for continuous improvement. Pharmaceutical companies frequently use Raman (RAMAN), near-infrared (NIRS), ultraviolet-visible-spectrum region (UV-VIS), and nuclear magnetic resonance (NMR) spectroscopy (NMR) for process analytical technology (PAT) applications. Applications for on-, in-, or at-line PAT are primarily focused on these criteria. Real-time release testing (RTRT), which involves in-process and/or real-time testing when making pharmaceutical products, is an essential part of Quality by Design (QbD). This strategy seeks to ensure the quality and consistency of the final product throughout the production process [4].

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Article 24

Clinical Aspects and Pathophysiology of Inflammatory Bowel Disease**Ms. Pranoti Anand Patil****PG Student, Quality Assurance Department**

The chronic inflammatory bowel diseases (IBD), Crohn's disease (CD) and ulcerative colitis (UC) are recognized as important causes of gastrointestinal disease in children and adults. IBD occurs worldwide, although it is more common in some regions (United States, United Kingdom, and Scandinavia) than in others, with incidence rates of 4 to 10/100,000 persons per year and prevalence rates between 40 to 100/100,000 persons. IBD is most commonly diagnosed between the third and fourth decades of life, with no difference noted between males and females. Approximately 20% of all patients with IBD develop symptoms during childhood, with about 5% being diagnosed before 10 years of age. About 25% of affected children have a positive family history of IBD. However, there have been no differences noted between normal children and children with IBD with regard to gender, breast feeding, formula intolerance, prior gastrointestinal illness, or emotional stresses.

UC is a condition in which the inflammatory response and morphologic changes remain confined to the colon. The rectum is involved in 95% of patients, with variable degrees of proximal extension. Inflammation is limited primarily to the mucosa and consists of continuous involvement of variable severity with ulceration, edema, and hemorrhage along the length of the colon. The characteristic histologic findings are acute and chronic inflammation of the mucosa by polymorphonuclear leukocytes and mononuclear cells, crypt abscesses, distortion of the mucosal glands, and goblet cell depletion.

CD, in contrast to UC, can involve any part of the gastrointestinal tract from the oropharynx to the perianal area. Diseased segments frequently are separated by intervening normal bowel, leading to the term "skip areas." Inflammation can be transmural, often extending through to the serosa, resulting in sinus tracts or fistula formation. Histologic findings include small superficial ulcerations over a Peyer's patch (aphthoid ulcer) and focal chronic inflammation extending to the submucosa, sometimes accompanied by noncaseating granuloma formation. The most common location is the ileocecal region, followed by the terminal ileum alone; diffuse small bowel, or isolated colonic disease in decreasing order of frequency.

UC and CD are associated with both intestinal and extraintestinal manifestations. Extraintestinal manifestations are usually related to intestinal disease activity and may precede or develop concurrently with intestinal symptoms. While UC and CD have a number of similarities in their clinical presentations, characteristic features are emphasized below. IBD is a common disease that causes considerable morbidity in the United States and Europe. In recent years, important advances have been made in our understanding of the immune mediators of intestinal inflammation. This information has led to new therapeutic approaches to IBD. Furthermore, considerable data point to the significance of genetic factors, which may predispose patients to a dysregulated immune response, in the development of IBD. The commensal bacterial flora also appears to be a critical element, particularly with respect to CD. While the precise role of the commensal bacteria and the genetic factors involved in the pathogenesis IBD remain ill defined, research in the next decade promises to yield fresh insights into these areas.

Table 1 Tests used to diagnose IBD

Test	Finding
Complete blood counts	Microcytic anemia, leukocytosis with band forms, thrombocytosis
Acute-phase reactants	Elevated sedimentation rate and serum orosomucoid, and C-reactive protein levels
Chemistries	Low serum iron level, hypoalbuminemia, elevated liver enzyme levels
Special serologic tests	pANCA, ASCA
Stool examinations	Exclude bacterial pathogens, ova and parasites, occult blood, and fecal leukocytes
Endoscopic evaluation	Esophagogastroduodenoscopy with biopsy, colonoscopy with biopsy
Radiologic evaluation	Upper gastrointestinal tract with small bowel follow-through, enteroclysis (as indicated), barium enema

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Article 24

Powder Solution Technology: An Overview**Mr. Sambhaji Shivaji Jadhav****PG Student, Pharmaceutics Department**

Oral drug administration has been one of the most convenient and widely accepted routes of delivery for most of the therapeutic agents. It is one of the most extensively used routes of drug administration because of its obvious advantages of ease of administration, improved patient compliance, and convenience. Most of the newly developed drug candidates are lipophilic and poorly water-soluble. Enhancing the dissolution and bioavailability of these drugs is a major challenge for the pharmaceutical industry. Liquisolid technique, which is based on the conversion of the drug in liquid state into an apparently dry, non-adherent, free flowing and compressible powder, is a novel and advanced approach to tackle the issue. The objective of this article is to present an overview of liquisolid technique and summarize the progress of its applications in pharmaceutics. Low cost, simple processing and great potentials in industrial production are main advantages of this approach. In addition to the enhancement of dissolution rate of poorly water-soluble drugs, this technique is also a fairly new technique to effectively retard drug release. Overall, liquisolid technique is a newly developed and promising tool for enhancing drug dissolution and sustaining drug release, and its potential applications in pharmaceutics are still being broadened.

Spireas et. al. developed a mathematical approach for formulation of liquisolid compact. This approach is mainly to calculate required amount of carrier and coating material in liquisolid technique. As a powder can retain only limited amount of liquid while maintaining acceptable flow and compression properties, this approach is based on the flowable (Φ -value) and compressible (Ψ -number) liquid retention potential. Flowable liquid retention potential (ϕ -value) is defined as the maximum weight of liquid that can be retained per unit weight of powder material in order to produce an acceptably flowing liquid/powder admixture. Compressible liquid retention potential (ψ -value) is defined as the maximum weight of liquid that can be retained per unit weight of the powder material in order to produce an acceptably compressible liquid or powder admixture.

The excipient ratio (R) or the carrier: coating material ratio is represented as follows:

$$R = Q / q \quad \dots\dots (1)$$

Depending on the excipient ratio (R) of the powder substrate an acceptably flowing and compressible liquisolid system can be obtained only if a maximum liquid load on the carrier material is not exceeded. This liquid/carrier ratio is termed "liquid load factor (Lf) [w/w] and is defined as the weight ratio of the liquid formulation (W) and the carrier material (Q) in the system:

$$Lf = W/Q \quad \dots\dots (2)$$

The liquid load factor that ensures acceptable flow ability (ΦLf) can be determined by:

$$\phi Lf = \phi + \phi \cdot (1/R) \quad \dots\dots (3)$$

Where ϕ and ϕ are the Φ -values of the carrier and coating material respectively. Similarly, the liquid load factor for production of liquisolid systems with acceptable compactability (ψLf) can be determined by:

$$\psi Lf = \psi + \psi \cdot (1/R) \quad \dots\dots (4)$$

Where Ψ and ψ are the Ψ -numbers of the carrier and coating material respectively. Therefore, the optimum liquid load factor (L0) required to obtain acceptably flowing and compressible liquisolid systems is equal to either ϕLf or ψLf , represents the lower value.

Advantages

Low production cost. The Bioavailability of BCS class II and IV drugs can be improved manufacturing cost of formulations is lowest as compared to soft gelatin capsules drug release modification is achieved with the help of suitable ingredients. They are very ductile. Improves the drug release by using certain hydrophobic carriers and surface-active agents thus enhance the dissolution profile. The manufacturing capability can be increased. The extent of absorption is better than conventional tablets

Limitations

The technique is successfully applied for low dose water-insoluble drugs, whereas the incorporation of high dose water-insoluble drugs into liquisolid systems is its main limitation. As these drugs require large quantity of liquid vehicle, therefore, in order to obtain liquisolid powder with good flow and compressible properties, large amounts of carrier and coating material are required. This may increase tablet weight over the limit, which is difficult for patients to swallow.

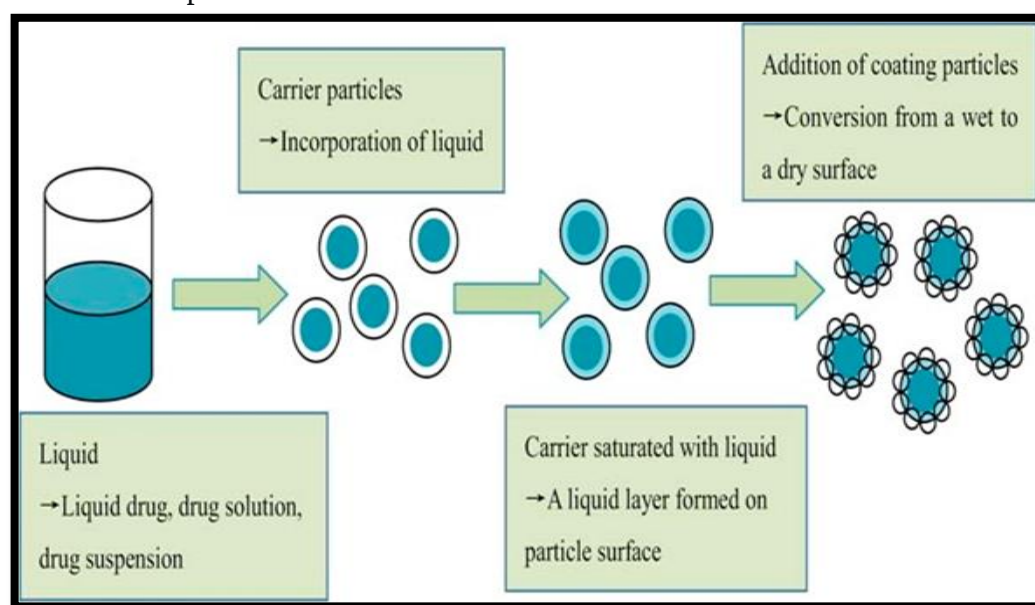


Fig. 1 Liquisolid system technique

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Article 25

Grafting modification of okra mucilage: Recent findings, applications, and future directions

Ms. Divya Ganesh Gavhane

PG Student, Quality Assurance Department

Okra polysaccharides, which include D-galactose, L-galacturonic acid, and L-rhamnose units, are naturally present in the fruit of the *Hibiscus esculentus* plant, which is a member of the Malvaceae family. Okra polysaccharide motif repeats as (1,4)-galacturonic acid and (1,2)-rhamnose residues with side chains of disaccharides; the polymeric chain shows a particular level of acetylation. Okra polysaccharides are non-toxic, biodegradable, chemically inert, and biocompatible polymers. They function as hydrophilic natural polymers in a variety of medicinal formulations because they include polyhydroxy groups, which make them soluble in water. Okra polysaccharides have been shown to have antibacterial, antidiabetic, anticancer, antiulcer, antifatigue, and antioxidant properties. Okra polysaccharides have a wide range of uses, which makes them useful in many industries. Surface modification using natural polysaccharide grafting has been used to create superior materials with enhanced functionality.

Regarding the grafting modification of okra polysaccharides, which have important uses in medication delivery and other sectors, there isn't a thorough recent update accessible. Slices of okra fruit devoid of stems were used to extract and isolate the okra polysaccharide. These pieces were made identical. Any insoluble particles were then separated using centrifugation for 30 minutes at 4 °C and 15,000 rpm. Double-distilled water or phosphate-buffered saline solution was used to transfer the supernatants. The polysaccharide from okra was extracted using anion-exchange chromatography. Recently, a technique using ultrasonic assistance was created to extract water-soluble polysaccharides from okra fruits using polysaccharide extraction.

The optimum scenario involved extracting the sample at 59 °C for 30 minutes, 522 W of ultrasonic power, and an extraction period of 30 min. To extract okra polysaccharides using microwave-assisted extraction (MAE), 5.0 g of okra powder was refluxed for one hour at 80 °C with 50 mL of 80% ethanol. Grafting is a widely recognized technique for enhancing the surface characteristics of polymeric materials, making them appropriate for a variety of uses. Using the free-radical approach, several monomers have been grafted on polysaccharides, including acrylamide, methacrylamide, N-acrylonitrile, methylmethacrylate, N-polyvinylpyrrolidone, and tert-butylacrylamide.

Polar bonds are specifically excited by microwave radiation, and no polar C-C sequence is left unchanged. Thus, microwave radiation cleaves polar hydroxyl bonds, producing free radical "active sites" on the polymeric backbone. Later on, these active sites may react with vinyl monomers, extending the polymeric chains in the process. It was recently revealed that microwave radiation might be used to graft poly-acrylamide into the mucilage of okra. Utilizing a 3-factor 2-level central composite design, optimization was performed. Ammonium persulfate was used as the redox initiator in a combination of acrylamide monomer and okra mucilage polysaccharide. For three minutes, the mixture was subjected to microwave radiation. To get rid of any unreacted reagents, the final product was precipitated using acetone and then washed three times with aqueous CH₃OH.

It was discovered that the grafting okra copolymer had a good yield. Another crucial method for adding specific functional groups to the polymer backbone is enzyme-mediated polymer grafting. It is anticipated that this technology will not have any negative impacts on human health because it does not require any potentially dangerous species, such as electromagnetic radiation or free radicals. Consequently, enzyme-mediated grafting is very beneficial for enhancing thermal stability, water solubility, pH sensitivity, and

safety. Okra polysaccharides' inherent qualities, which include their ability to work as a gel forming, coating agent, and controlled-release matrix, make them popular choices for drug administration in a variety of ways. They also improve tissue penetration to demonstrate a drug's oral bioavailability and can take the place of synthetic polymers to improve mucoadhesion. Because of their biological activity and uses in the food sector, pharmaceuticals, and wastewater treatment, okra polysaccharides provide a unique way to modify and use natural polysaccharides. Even though grafting modification using a single monomer was done on the surface of okra polysaccharides, there is still a lot of room to improve their distinctive features. Strong biological properties, including antimicrobial, anticancer, and antidiabetic action, have been shown for okra polysaccharides. They have also been shown to be beneficial against various metabolic disorders. Their uses are versatile due to their hydrophilic nature and high solubility at neutral pH.

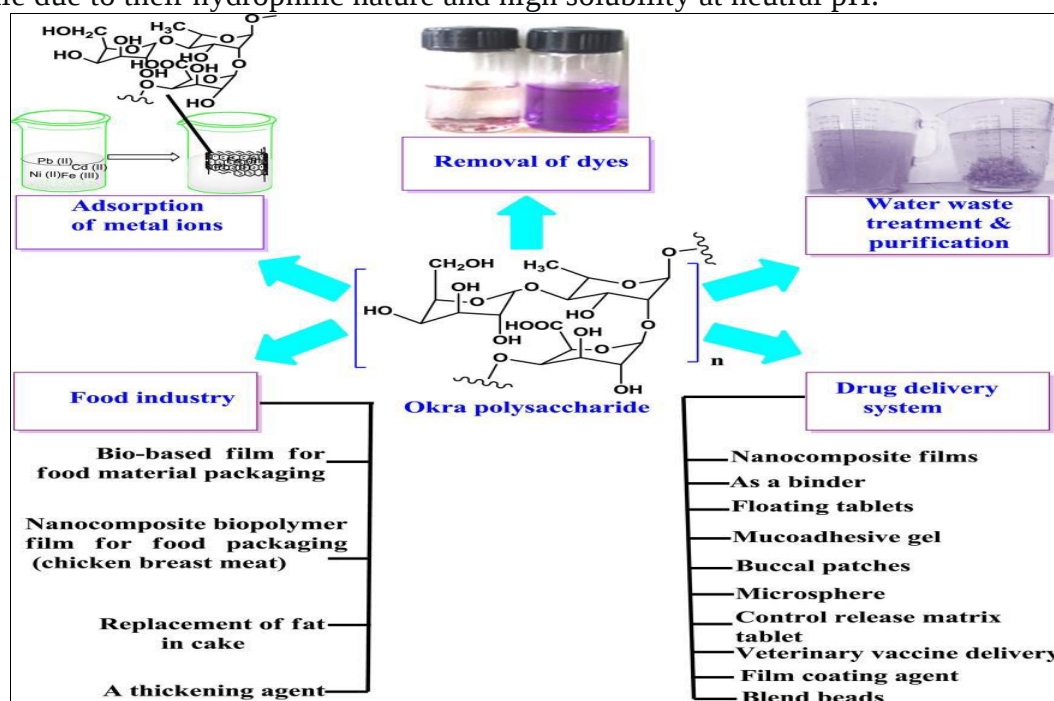


Fig. 8 Applications of okra polysaccharides in different fields

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Article 26

Artificial Intelligence in Pharmaceutical Technology and supply chain management: mapping the territory**Mr. Vaibhav Shivaji Padolkar****PG Student, Pharmaceutics Department**

Artificial intelligence (AI) has become an effective tool that utilizes personal knowledge and offers quicker solutions for difficult problems. Significant developments in machine learning and AI technologies offer a game-changing chance for the drug discovery, the creation and evaluation of dosage formulations for pharmaceuticals. Through the use of AI algorithms that with the aid of vast biological data, such as proteomics and genomes, researchers are able to predict the interactions between potential treatment candidates and disease-associated targets. This makes it possible for a more effective and focused strategy to drug discovery, raising the possibility of successful drug permissions. Additionally, AI can lower development costs by maximizing research and procedures for development. Algorithms for machine learning support the design of experiments and can forecast the toxicity and pharmacokinetics of potential medications. This capacity reduces the need for extensive and expensive animal research by enabling the prioritization and optimization of lead compounds. Artificial intelligence (AI) algorithms that evaluate real-world patient data can support personalized medicine strategies, improving patient adherence and treatment outcomes.

The broad range of uses of AI in drug discovery, drug delivery dosage form designs, process optimization, testing, and pharmacokinetics/ pharmacodynamics (PK/PD) investigations is examined in this thorough overview. This analysis highlights the advantages and disadvantages of the several AI-based techniques used in pharmaceutical technology. However, the pharmaceutical industry's ongoing exploration and investment in AI present great opportunities for improving patient care and drug development procedures. In order to improve company adaptability, a number of pharmaceutical businesses are looking forward to new developments in their supply chain as well as creative solutions to these problems. Global operations, including ongoing clinical studies, have been severely disrupted by the coronavirus disease epidemic of 2019 (COVID-19). Supply chain disruptions are made worse by pandemics, natural disasters, price adjustments, cyberattacks, delays in logistics, and problems with products. The epidemic's effects on transportation caused damage on global industries and the supply chain. Price fluctuation delays are caused by supplier decision-induced delays for price updates because of confusion about whether to use the new price or the current price for goods or materials [1].

Countries' strategies for collaborating on cross-border trade give birth to new challenges, including a growth in criminal activity and unstable supply of essential resources for production and operation. Customized footprints must be manufactured to meet patient requirements and ensure compliance. A large number of COVID-19 vaccinations produced by the pharmaceutical industry were rendered useless during the pandemic because to issues with cold chain maintenance. The main reason for the disruption of the supply chain that came about as a result of the delayed response is that industrial and commercial operations lack innovation and make inaccurate forecasts. Disruptions to the pharmaceutical industry's supply chain can have a big impact on prospective revenues, corporate reputation, and consumer happiness [2].

Artificial Intelligence (AI) has the potential to significantly alter how the pharmaceutical business manages its supply chain. In order to provide practical answers for a range of supply chain problems, it also synthesizes a number of AI research initiatives from the previous few decades. The report also makes recommendations for

future research directions that can improve supply chain management decision-making tools [3].

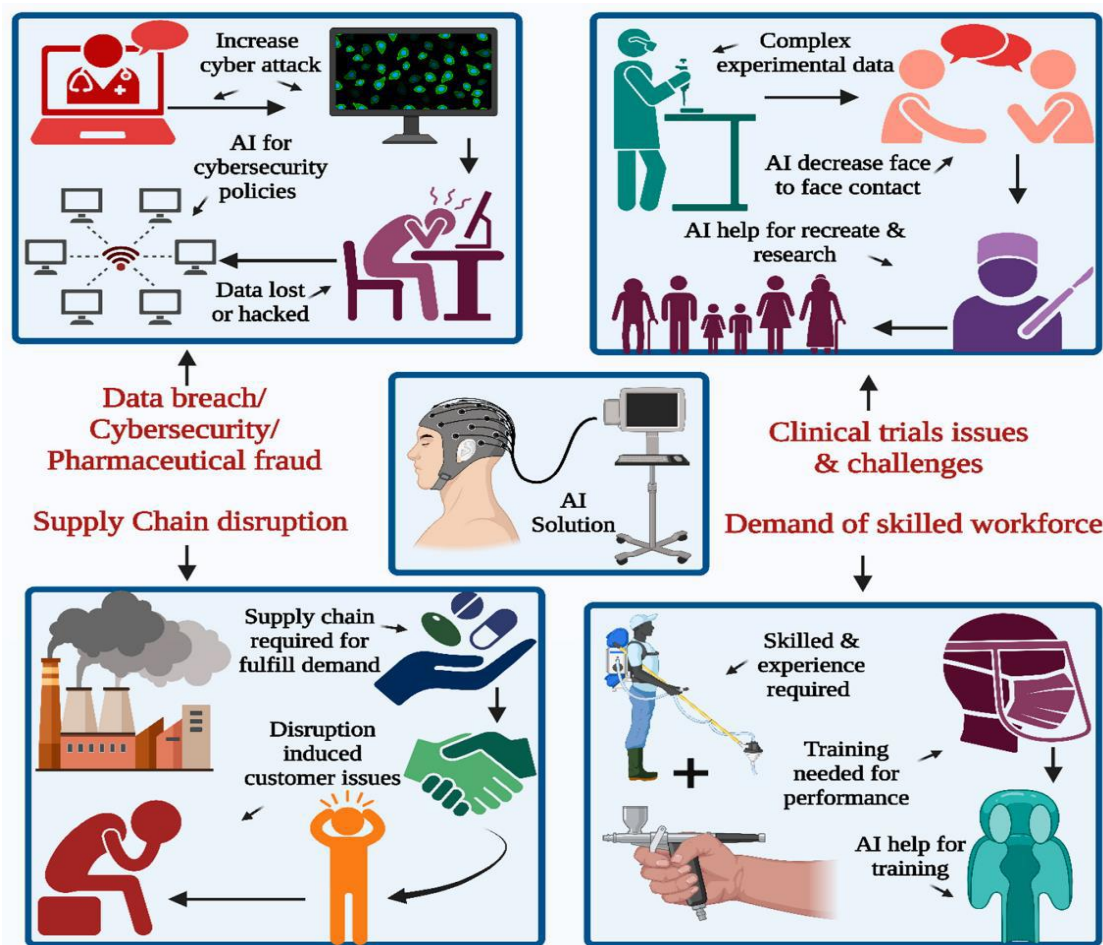


Fig. 1 Illustrates a potential artificial intelligence (AI) remedy for the problems facing the pharmaceutical industry: all industries need to have skilled workers in order to take advantage of their knowledge, skills, and ability to innovate new products. The second deals with issues related to disruptions in the supply chain and clinical trial experiments. Cyberattacks are becoming more common, and security and data breaches are becoming major issues for business.

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Article 27

A Cutting-Edge Platform for Advanced Cancer Therapy with Nanostructured Lipid Carriers

Mr. Vaibhav Shivaji Padolkar
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The development of cancer is linked to unusual, uncontrolled proliferation of cells and has a major negative social and economic impact on society. The aging population and rising rates of risk factors like stress, obesity, altered reproductive patterns, and smoking have led to an increase in the global statistics of various malignancies. If cancer is discovered early, there is a good chance of recovery. For the clinician, late-stage diagnosis remains a significant difficulty nevertheless. Radiation therapy is usually used after surgery and chemotherapy. The most commonly used treatment approach for treating cancer is chemotherapy. Its primary drawback, meanwhile, is the inadequate delivery of anticancer therapies to certain cancer-targeted tissues or cells. By using an active or a passive targeting strategy, nanomedicines—in particular, Nanostructured lipid carriers, or NLCs—can increase the effectiveness of encapsulated medicines against various cancer types. Targeted nanomedicine may be useful in delivering medication carriers to the precise tumor-targeted tissue or cells while avoiding harming healthy tissue or cells. By using the binding of a particular tumor ligand to the NLCs' surface-active targeting increases the effectiveness and safety of cancer treatments [1]

When it comes to developing efficient targeted therapy for cancer chemotherapeutics, one of the most promising nano-carriers is nanostructured lipid carriers (NLC). Solid and liquid lipids are spread in a surfactant solution to form a core matrix for these biocompatible and/or biodegradable lipid-based nanoparticles. The majority of hydrophobic cancer treatments become easier to dissolve in water because to NLC. Through site-specific targeting for improved efficacy and decreased dose-related toxicity, their surface modification can be utilized to overcome drug resistance in cancer chemotherapy [2].

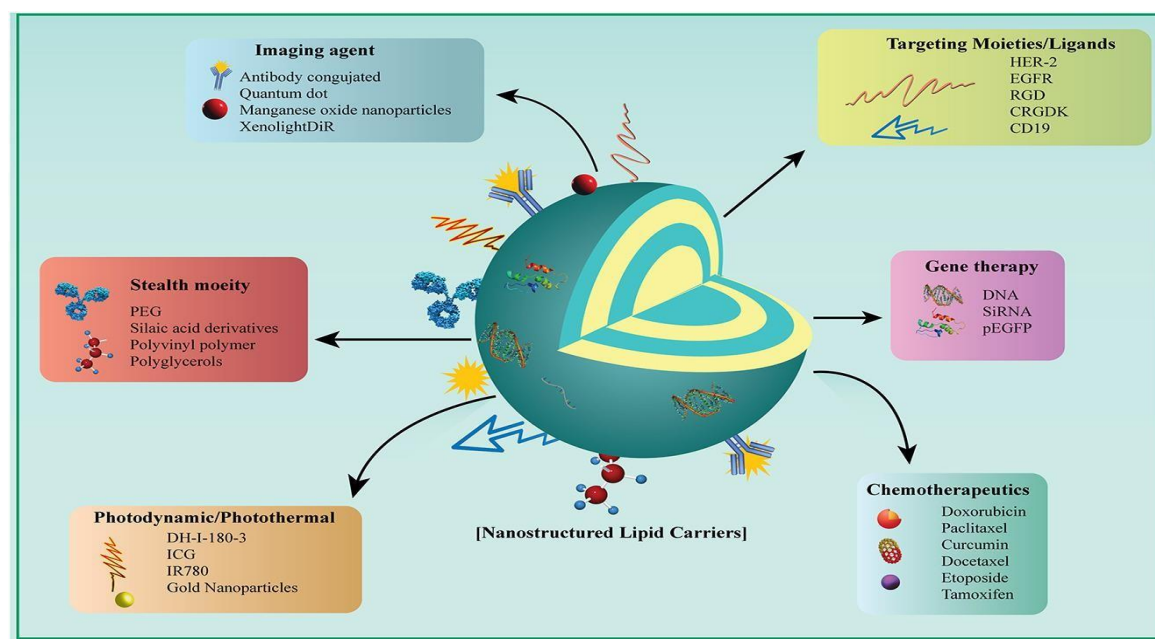


Fig.1 Nanostructured Lipid Carriers

NLCs represent a significant opportunity for the development of novel pharmacological products with therapeutic value due to their different applicability. They are a particular type of drug carrier for cancer therapy since they are biodegradable, biocompatible, safe, and simple to reach the appropriate nanometric dimension. NLCs are a system used to encapsulate and conjugate various functionalized modalities and treatments, such as nucleic acid, aptamers, photosensitizers, particular genes, peptides, and tiny bioactive compounds, for the treatment of various malignancies. Moreover, the NLCs system has been used to co-deliver genes and/or anticancer medications. Multiple studies are creating and improving distinct synthetic approaches to functionalize NLCs with a range of targeted ligands and bioimaging indicators for multimodal cancer treatments.

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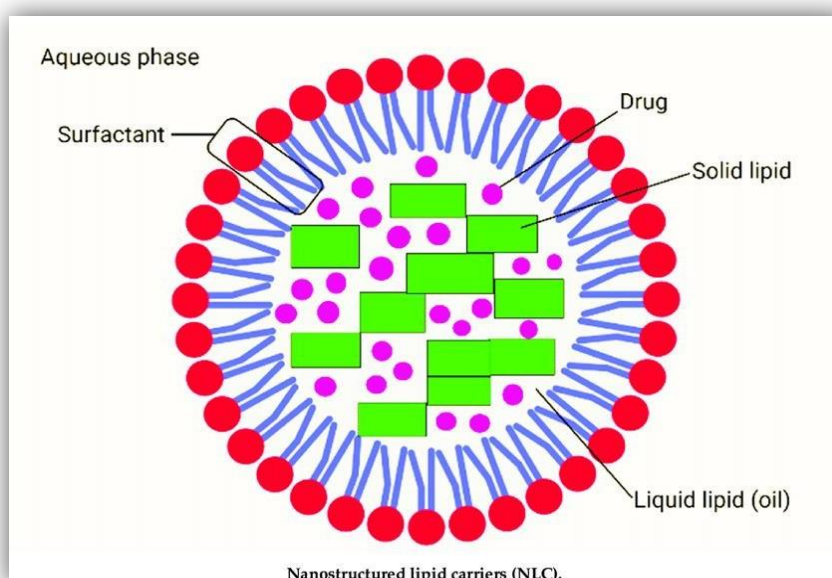
Article 28

Nanostructured Lipid Carriers: A Novel Drug Targeting Strategy for Anticancer Activity

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Nanostructured Lipid Nanocarriers are second-generation lipid carriers formulated to address issues with Solid Lipid Nanoparticles and are used in a variety of medicinal applications. NLCs were originally developed for the delivery of lipophilic medicines although their applicability for hydrophilic pharmaceuticals is now well proven. The biocompatibility of lipids has led to their development as a possible medication delivery method. It was discovered to have better properties than other lipid compositions. NLCs are designed to increase the oral bioavailability of medicines that are weakly water soluble. Nowadays, NLCs included cosmetic goods and dermal creams are being sold. The formulation of medicines into NLCs for medication targeting in various disorders is widely investigated. NLCs are being explored as possible lipid nanocarriers for enhancing bioavailability and selectivity as well as reversing multidrug resistance [1]

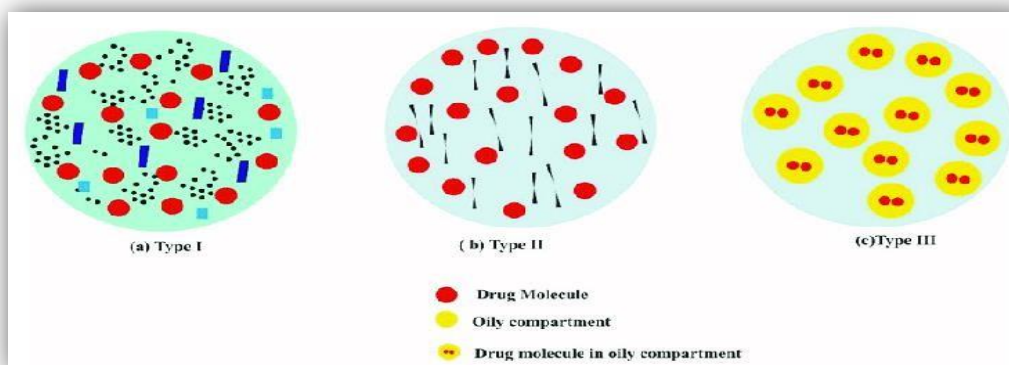
Structure of NLCs: The structure of NLCs are very and somehow similar to SLNs, NLCs



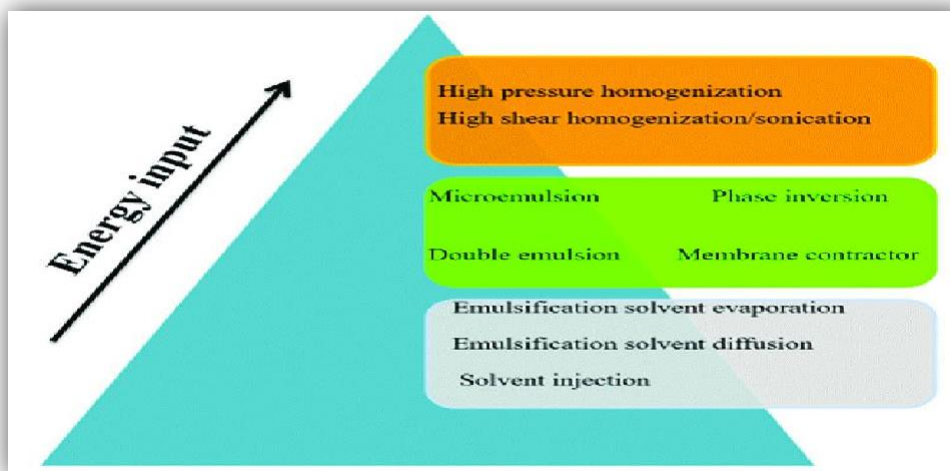
have three very specific features these properties are based up on the location the drug is going to be integrated three different methods were adopted for a development and formulation of nanostructure NLCs.

- NLC type I also called as imperfect crystal-
 - ✓ Imperfectly structured solid matrix
 - ✓ Spatially different lipids are mixed creating imperfections in the crystal order of lipid nanoparticles; Show high-drug pay load
- NLC type II also called as multiple type-
 - ✓ Multiple oil in fat in water
 - ✓ Solubility of drug in lipophilic phase decreases during the cooling process after homogenisation and crystallisation process during storage
- NLC type III also called as amorphous type-
 - ✓ Structure less solidamorphous matrix
 - ✓ Formed by mixing solid lipids with special lipids like hydroxyoctacosenyl

hydroxystearate, isopropyl myristate or medium chain triglycerides



Preparation Methods for NLCs: Lipid nanoparticles such as SLN and NLC do not vary much in their methods of preparation. The difference is just about the absence and presence of liquid lipids in the formulation. Highpressure homogenization emulsification-ultrasonication film ultrasonication solvent emulsification is some of the commonly preferred methods for preparation of NLCs [2]



Application of NLCs

- Oral drug delivery: NLCs can improve the bioavailability of drugs by protecting them from the gastrointestinal environment, bypassing hepatic metabolism, and blocking P-gp efflux.
- Targeted drug delivery: NLCs can be used to deliver drugs to specific sites in the body, such as the liver, brain, and cancer ulcers.
- Gene therapy: NLCs can be used to deliver genetic material for gene therapy.

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Article 29

Overcoming Solubility and Dissolution Challenges in Drug Development: An In-depth Analysis of Solid Dispersion Technology

Mr. Umesh Ganesh Bhavsar
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The pharmaceutical industry has substantial hurdles in medication formulation, particularly in producing molecules with poor water solubility and dissolution profiles. These challenges are especially important for oral dosage forms, because solubility and dissolution rates directly influence drug absorption and bioavailability. Compounds with a water solubility of less than 0.1 mg/mL frequently present severe challenges in drug research and product development, compromising the medicine's therapeutic efficacy. As a result, formulation scientists are focusing heavily on improving these chemicals' solubility and dissolution rate. Common Approaches for Enhancing Solubility and Dissolution Rates Various techniques have been employed to address solubility and dissolution limitations, such as:

Formation of soluble salts	Particle size reduction	Prodrugs	Use of amorphous forms	Co-solvency, super disintegrant, and inclusion
A common strategy, but it is limited to drugs that can form salts. Neutral compounds and weak electrolytes cannot be improved through this method.	Reducing the particle size increases the surface area available for dissolution. However, fine hydrophobic powders challenging due to poor wettability.	Modifying the drug to create a more soluble precursor compound that converts to the active drug in the body.	Amorphous forms of a drug, being less thermodynamically stable than crystalline forms, often exhibit improved solubility.	These methods enhance solubility through various chemical and physical modifications.

Despite these options, each technique has limitations. For example, salt formation does not apply to all drugs, and micronization can lead to issues in drug formulation due to poor powder flow or compressibility. This is where solid dispersion (SD) technology provides a robust alternative, especially for enhancing the dissolution rate and bioavailability (BA) of poorly water-soluble drugs. By boosting the drug's wettability and reducing particle size, the SD technique improves oral bioavailability. SD technique is particularly useful for pharmaceuticals that crystallize easily. The SD approach entails integrating an active pharmaceutical ingredient (API) into a polymer matrix resulting in a more desirable amorphous form. SDs are typically prepared through techniques such as Melting (fusion), Solvent evaporation, Melt extrusion, Spray drying, Supercritical fluid technology. These methods have proven successful in increasing the in vitro release of drugs compared to traditional dosage forms, often leading to improve in vivo performance.

Case Study: Spironolactone (SPL) Solid Dispersions: SDs were created utilizing PEG 4000 as the hydrophilic carrier in a recent work to improve the solubility and dissolution of spironolactone (SPL), a poorly soluble medication. SPL was formed into SDs using the traditional fusion technique, which entails heating the carrier (PEG 4000) to a molten state and dispersing the medication within the polymer. The study sought to compare SPL's solubility and dissolution profile in SD form to its commercial version.

Preparation of Physical Mixtures and Solid Dispersions: Physical mixtures of SPL and PEG 4000 were prepared by simple mixing in different ratios of 1:1, 1:3, and 1:5 (w/w). To prepare SDs, PEG 4000 was heated to 60°C until it melted, and SPL was gradually added

with continuous stirring until the drug was fully dissolved. The mixture was allowed to solidify at RT, then pulverized and sieved to ensure uniform particle size.

Solubility Studies: Solubility studies were conducted using distilled water and 0.1N HCl, following the method described by Higuchi et al. saturated solutions of the drug, PMs, and SDs were shaken for 72 h at 37°C. After filtration, the solubility of the samples was analyzed using UV spectrophotometry at 242 nm. The results displayed increase in solubility for the SDs compared to both the pure drug and PMs, particularly in acidic conditions (0.1N HCl).

Differential Scanning Calorimetry (DSC) and Fourier Transform Infrared Spectroscopy (FTIR): DSC was used to assess the degree of crystallinity in SPL and its SDs. A reduction in crystallinity was observed in the SDs, indicating the transformation of SPL into an amorphous form. This amorphous state is crucial for improving solubility and dissolution. FTIR spectroscopy was used to confirm any interactions between SPL and PEG 4000. The FTIR spectra indicated no significant chemical interaction between the drug and the polymer, ensuring the stability of the formulation.

In Vitro Dissolution Studies: Dissolution studies were performed using a USP Type-II apparatus with 0.1N HCl as the dissolution medium. Both SDs and PMs were tested, with each sample containing 25 mg of the equivalent drug. The SD formulation exhibited a significantly enhanced dissolution rate compared to both the pure drug and the PMs, likely due to the improved wettability and amorphous nature of the drug in the SDs.

Stability Studies: Stability studies were conducted as per ICH guidelines by storing the samples at 40°C and 75% relative humidity for three months. The drug content and dissolution rate were evaluated at predetermined intervals, demonstrating that the SD formulation remained stable over the testing period, with no significant loss in drug content or dissolution performance.

Conclusion: Solid dispersion technology has been shown to be a successful method for increasing the solubility, dissolution rate, and bioavailability of weakly water-soluble medicines. The case study of spironolactone indicates how SDs can improve medication performance by using amorphous carriers such as PEG 4000. The fusion approach used in this work provided a simple yet effective way to create SDs, which was a considerable advance over previous dose forms. As the pharmaceutical industry continues to create novel medications with difficult solubility profiles, solid dispersion technology will undoubtedly remain an important tool in overcoming these barriers.

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Article 30

Crystal Engineering: Shaping the future of pharmaceuticals**Mr. Mihir M Vaidya****PG Student, Pharmaceutical Chemistry Department**

The subject of crystal engineering firstly used in the 1970s with the study of topo-chemical reactions in the solid state. A broad chemical definition of crystal engineering was published in 1989, and the supramolecular synthon concept was proposed in 1995 followed by hetero-synthons and their potential applications for the design of pharmaceutical co-crystals in 2004. Crystal engineering is a novel approach used in the formation of Pharmaceutical co-crystals. The co-crystal formation between an active pharmaceutical ingredient and suitable co-former can help to modify the physicochemical properties of the drug without change in the molecular structure of the drug. Pharmaceutical co-crystals are solid state forms of drugs which exist in single or multicomponent system in crystalline and amorphous state. The various methods such as spray drying, freeze drying, hot melt extrusion, rotary evaporator method and vapour assisted tumbling methods are used for formation of pharmaceutical co-crystals. The researchers can perform various processes such as design, synthesis, and characterization of a pharmaceutical co-crystal. Crystal engineering has several critical applications in the field of pharmacy, particularly in drug design, formulation, and delivery. Some of the key applications include:

Improving Drug Solubility: Crystal engineering is used to design co-crystals and polymorphs that enhance the solubility of poorly water-soluble drugs, improving their bioavailability.

Enhancing Drug Stability: It helps in stabilizing drugs by selecting stable crystal forms (polymorphs or salts) that resist degradation due to environmental factors such as humidity, light, or heat.

Controlled Drug Release: The release rate of a drug can be controlled by altering the crystalline structure for sustained or delayed release formulation

Polymorph Selection and Formulation: Crystal engineering can be used to select specific polymorphs of a drug that exhibit desired physical and chemical properties, such as solubility, stability, and bioavailability.

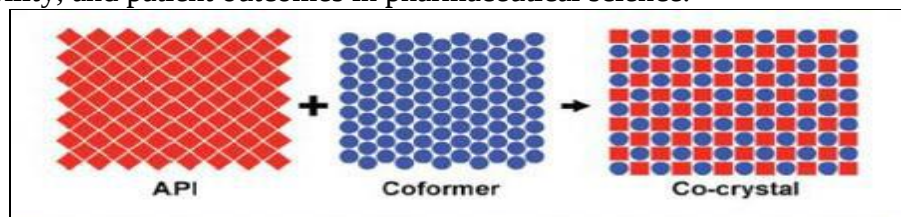
Co-Crystal Design for Multi-Drug Formulation: Co-crystals can be engineered to include multiple active pharmaceutical ingredients (APIs), enabling combination drug therapies in a single dosage form.

Masking Unpleasant Drug Taste: Crystal engineering can modify the crystal form to mask the bitter taste of certain drugs

Improved Compressibility for Tablet Formation: Crystals can be engineered to improve the compressibility and flow properties of powders, facilitating the manufacturing of tablets.

Targeted Drug Delivery: Crystal structures can be designed to interact with specific biological targets, enhancing the precision of drug delivery to diseased tissues or cells.

These applications show the diverse role that crystal engineering plays in enhancing drug performance, stability, and patient outcomes in pharmaceutical science.

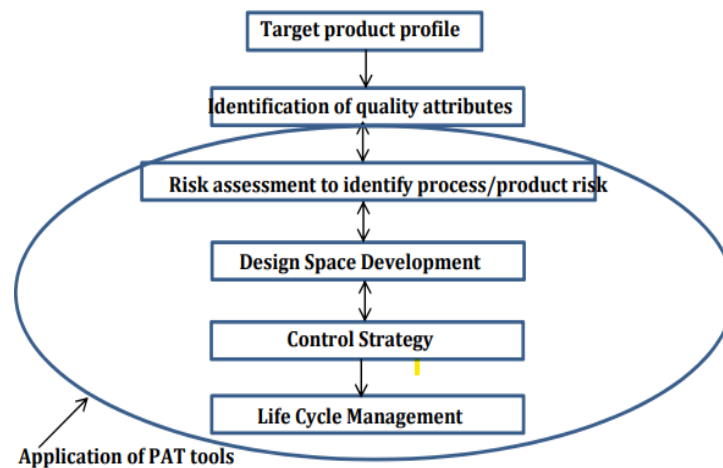
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Article 31

Quality by Design (QbD): A new concept for development of quality pharmaceuticals**Rachana Ravindra Patil****PG Student, Quality Assurance Department**

Quality by Design (QbD) is a new development concept for of quality pharmaceutical product, I essential part of the new approach to pharmaceutical quality product, QbD is a solution to build a quality in all pharmaceutical products but it is also a challenge to the Pharmaceutical industry whose processes are fixed in time, despite inherent process and material variability, Under this concept of QbD is designing and development of a product, it is essential to define desire product performance profile [Target product Profile (TPP), Target Product Quality Profile (TPQP)] and identify critical quality attributed (CQA). quality cannot be tested into products, i.e., quality should be built in by design". ICH Q8 QbD is defined as a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. Pharmaceutical Quality by Design: ICH Q8 defines quality as the suitability, of either a drug substance or drug product for its intended use. It refers term includes such attributes as the identity, strength and purity.



In additional to providing information on the drugs at a certain stage of development, the TPP states the overall objectives of the drug development program. The TPP generally relates drug development activities to certain ideas meant for inclusion in the drug labeling and is organized in accordance with the major parts of the labeling. A CQA has been defined as “a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality” (1).

Key Aspects of Qbd



Figure 1: Overview of QbD

Design of experiments (DOE) is a structured and organized method to determine the relationship among factors that influence outputs of a process. When DOE is applied to pharmaceutical process, factors are the raw material attributes (e.g., particle size) and process parameters (e.g., speed and time), while outputs are the critical quality attributes such as blend uniformity, tablet hardness, thickness, and friability. Any measurable input (such as an operational parameter or an input material attribute) or output (such as a process state variable or an output material attribute) of a process step that has to be controlled in order to achieve the required process uniformity and product quality is referred to as a critical process parameter, or CPP. Every item would be a process parameter (2).

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Article 32

Nanotechnology: A Formulation Technology Revolutionizing Drug Delivery and Diagnostics**Ms. Rupali S. Waghmare****PG Student, Quality Assurance Department**

Nanotechnology is considered the most rapidly growing technology in the world. Considering the enormous applications of nanotechnology in various fields, including biomedicine, it is believed to be the beginning of a new era and industrial revolution of the twenty-first century. Nanotechnology has proved its potential in providing completely novel and unique concepts and approaches in medicine which facilitate the development of efficient, rapid, and sensitive diagnoses, as well as treatment strategies with the least number of possible interventions and almost without adverse effects. Various inorganic and organic nanomaterials have been synthesized and developed which can be directly used as potential antimicrobial agents or as nanocarrier systems for different drugs and biomolecules for efficient, target-specific delivery in a wide range of diseases. Nanotechnology has proven beneficial in the treatment of cancer, AIDS and many other diseases, also providing advancement in diagnostic testing. Nanotechnology in combination with artificial intelligence has vast variety of applications.

The development of nanoparticles has provided a new avenue for chemotherapy. With smartly designed nanoparticles, targeted drug delivery at the tumor site or a certain group of cells do largely avoid the toxic effects to other normal tissues and organs. Micelles and liposomes offer another option for delivery of chemotherapeutic agents. Additionally, micelles are also a great way to make insoluble drugs soluble due to their hydrophobic core and hydrophilic shell. If the micelle's surface is further PEGylated, it increases the ability of the nano-carriers to get through fenestrated vasculature of tumors and inflamed tissue through passive transport, thus resulting in higher drug concentration in tumors. E.g. several polymeric micelles containing anticancer drugs, NK012, NK105, NK911, NC-6004, and SP1049C are under clinical trials and one such system, Genexol-PM (paclitaxel) is approved for breast cancer patients.

DNA nanostructures have surfaced as intriguing entities with vast potential in biomedicine, notably in the drug delivery area. Tetrahedral DNA nanostructures (TDN) have received worldwide attention from the array of different DNA nanostructures due to their extraordinary stability, great biocompatibility, and ease of functionalization. TDN could be readily synthesized, making them attractive carriers for chemotherapeutic medicines, nucleic acid therapeutics, and imaging probes. Their varied uses encompass medication delivery, molecular diagnostics, biological imaging, and theragnostic. Here extensively highlights the mechanisms of functional modification of TDN and their applications in cancer therapy. Additionally, it discusses critical concerns and unanswered problems that require attention to increase the future application of TDN in developing cancer treatment. Nanotechnology in coordination with AI gives wide range of applications shown in Fig.1

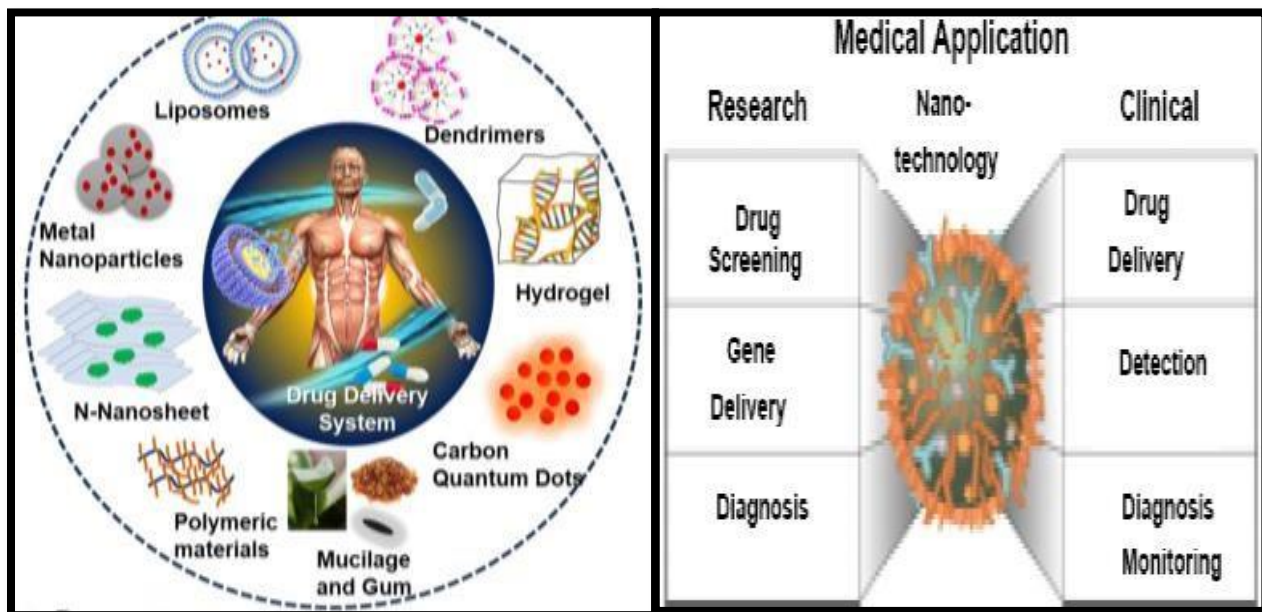


Fig. 1 AI contribution to drug development and research

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Article 33

Review of the efficacy of nanoparticle-based drug delivery systems for cancer treatment

Ms. Sharayu Rajkumar Gajewar
PG Student, Quality Assurance Department

Introduction:

Nanotechnologies are a promising field for creating tailored medication delivery methods for a variety of disorders, most notably cancer. Lipid-based drug delivery encapsulates and delivers medications to specific cells or tissues, with cancer cells receiving special attention due to their high growth rates and resistance to established treatment approaches. [1] Cancer treatment involves the use of many types of nanoparticles. Nanoparticles can transport chemotherapeutic medications directly to cancer cells, increasing efficacy while minimizing side effects. [2] They can also use hyperthermia to heat up and kill cancer cells. Nanoparticles can also improve medical imaging procedures by allowing for better tumor surveillance and location. Overall, nanoparticles have the potential to significantly improve patient outcomes and advance oncology. [3] Discovering techniques to improve nanoparticle stability and reduce organ accumulation will be critical to their effective translation into therapeutic applications. [4]

The importance of drug delivery in nanomedicine:

Encapsulating pharmaceuticals within nanoparticles shields them from degradation, transports them directly to the target region, and releases them in a regulated manner to maximize therapeutic effects. [5]. This breakthrough in nanomedicine has transformed drug delivery and has enormous promise to improve patient outcomes. Healthcare experts may now accurately manage the quantity and timing of pharmaceutical release utilizing nanoparticle-based drug delivery systems, resulting in more tailored and effective treatments. [6]

Nanoparticle-based drug delivery systems:

Nanoparticles can also actively overcome drug-resistant systems seen in cancer cells, allowing medications to reach their targeted sites and have therapeutic effects. Nanoparticles can be created to release medications in a regulated manner, resulting in sustained drug levels and fewer side effects. Furthermore, ongoing research is aimed at increasing the specificity of nanoparticle-based systems, allowing them to target cancer cells while preserving healthy organs. This holds considerable promise for developing more customized and effective cancer treatments in the future. [7]

Mechanisms of nanoparticles targeting cancer cells:

These mechanisms use ligands or antibodies to attach to cancer cells' overexpressed receptors, allowing nanoparticles to accumulate in tumor tissue while avoiding healthy cells. Furthermore, pH-responsive nanoparticles can detect the acidic environment of tumors and release their payload selectively in certain areas, increasing the efficacy and safety of cancer treatments.

Conclusion:

Targeted drug delivery systems have showed interest in improving cancer treatment, however tumor heterogeneity and micro environmental issues restrict their effectiveness. Additional research and development are required to optimize targeted therapy delivery. Nanotechnology provides a promising technique for precisely targeting cancer cells while causing minimal damage to healthy tissues. Nanoparticles can transport therapeutic medicines directly to the tumor site, overcoming the hurdles posed by the tumor microenvironment. Modifications to nanoparticle surfaces can boost stability, circulation time, and cellular absorption, further increasing their efficiency. The use of nanoparticles in targeted therapy can also overcome obstacles such as drug resistance and limited

therapeutic penetration into solid tumors. These nanoparticles can be made to deliver therapeutic substances in a controlled manner, ensuring long-term and successful treatment. Furthermore, current advances in nanotechnology have the potential to transform cancer treatment by enabling personalized medicine techniques suited to specific patients' needs.

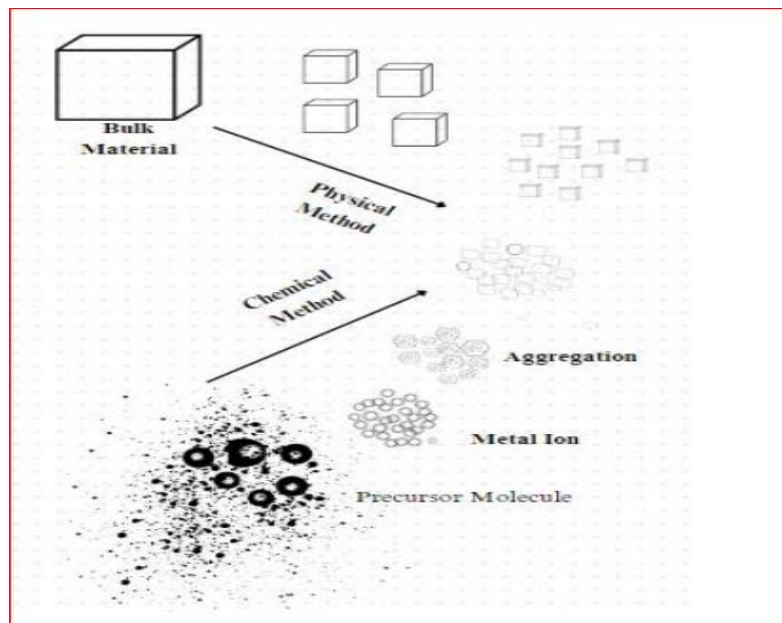


Fig. 1 Nanoparticle Synthesis

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Article 34

Bioactive Loaded Cream for Diabetic Wound Healing**Mr. Nikhil Pratap Nalavade****PG Student, Pharmaceutics Department**

Wound is defined as the disruption of cellular, anatomical, and functional continuity of a living tissue. Wounds represent a significant burden on the patients and health care professionals worldwide. They not only affect physical and mental health of millions of patients but also impose significant cost on them. Current estimates indicate that worldwide nearly 6 million people suffer from chronic wounds. Delayed wound healing is producing high economic burden on the society and is generally associated with Diabetes mellitus or related complications thus need needing safe treatment like herbal formulation Therefore, researchers in the field have shown an increasing interest in using natural compounds as constituents for such systems.

Plants, as an important source of so-called “natural products” with an enormous variety and structural diversity that still exceeds the capacity of present-day sciences to define or even discover them, have been part of medicine since ancient times. However, their benefits are just at the beginning of being fully exploited in modern dermal and transdermal delivery systems. Thus, plant-based primary compounds, with or without biological activity, contained in gums and mucilages, traditionally used as gelling and texturing agents in the food industry, are now being explored as valuable and cost-effective natural components in the biomedical field. Their biodegradability, biocompatibility, and non-toxicity compensate for local availability and compositional variations. Also, secondary metabolites, classified based on their chemical structure, are being intensively investigated for their wide pharmacological and toxicological effects. Their impact on medicine is highlighted in detail through the most recent reported studies. Innovative isolation and purification techniques, new drug delivery devices and systems, and advanced evaluation procedures are presented.

The skin, as the body's largest and most exposed organ, can provide a readily accessible delivery route for therapeutic substances. In fact, the topical application of remedies has been practiced for thousands of years. From Galen, the Father of Pharmacy, who introduced herbal ingredients into the formulation of drugs, the evolution of skin wound dressing/healing (WD) and transdermal delivery (TD) took an interesting path, which continues, and grows nowadays with the help of modern scientific techniques Most topical drug delivery systems (DDSs) were traditionally designed for the local administration of active pharmaceutical ingredients (APIs), with numerous applications in the field of skin tissue healing.

However, the concept of soft (permeable) drugs that can also affect the tissues/organs beneath the skin originates from Ibn Sina (Avicenna), the great Persian physician and philosopher, born in 980 AD in the village of Afshanah This is now believed to be the oldest conceptualization of transdermal drug delivery (TDD). Currently, there is a constant search for new materials and new medical devices (wound patches, scaffolds, and transdermal delivery systems) that can provide effective treatment through the unique, controlled, and targeted delivery of APIs. New methods are sought to replace conventional drug delivery routes gastric, intravenous, and intradermal.

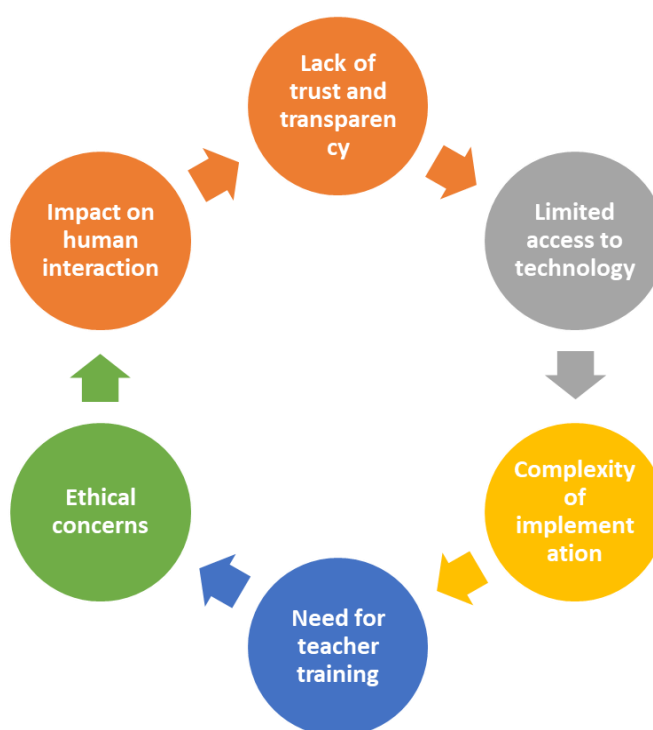
Article 35

New Education Policy (NEP) 2020 and Artificial Intelligence (AI)**Mr. Rohankumar R. Chavan****Assistant Professor, Pharmaceutical Chemistry Department****Key points related to AI in the NEP 2020:**

1. **Technology integration:** According to NEP 2020, technology may serve to increase educational quality, expand educational opportunities, and offer individualized learning experiences. AI in the curriculum: Starting in class 6, the NEP 2020 suggests incorporating coding and AI into the educational program. The goal is to educate students for the professions of the future and provide them with the skills they need to engage in the digital economy.
2. **Artificial Intelligence in Teacher Training:** This aims to support educators in utilizing technology in the classroom and staying current with emerging technologies.
3. **AI-powered assessment:** According to the NEP 2020, AI-powered assessment systems may decrease subjectivity and bias, speed up and increase assessment accuracy, and provide students fast feedback.
4. **National Educational Technology Forum (NETF):** It will provide as a forum for the sharing of concepts, insights, and best practices around the integration of technology into the classroom. Additionally, it will help the successful integration of technology in education and make it easier to design solutions based on technology.

Issues/Challenges of Using AI in Education

While there are many potential benefits of using AI in education, there are also several issues and challenges that need to be addressed such as –



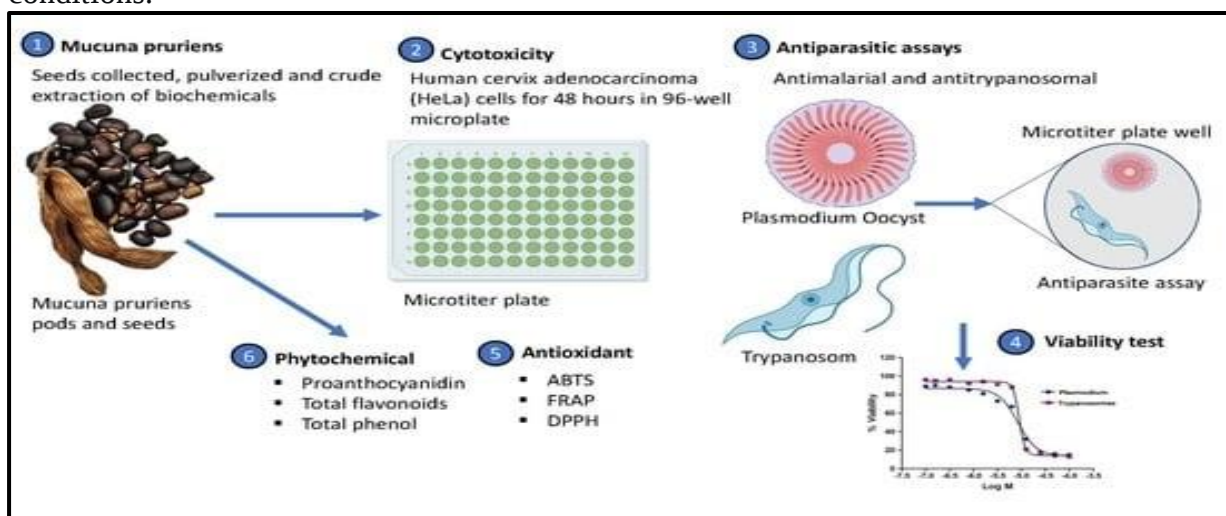
Article 36

Development of Mucuna Pruriens Loaded Herbosomes as Mast Cell Stabilizer

Mrs. Swapnali Vyankatesh Dharanguttikar

Assistant Professor, Pharmaceutical Chemistry Department

This study explores the development and characterization of Mucuna pruriens loaded herbosomes as a novel approach for mast cell stabilization. Mucuna pruriens, a tropical legume known for its neuroprotective and anti-inflammatory properties, was encapsulated in phospholipid-based herbosomes to enhance its bioavailability and efficacy. The herbosomes were evaluated for their physicochemical properties, in vitro release profile, and mast cell stabilizing activity. Mast cells play a crucial role in allergic and inflammatory responses. Stabilizing these cells can potentially alleviate symptoms associated with various allergic disorders. Mucuna pruriens, rich in L-DOPA and other bioactive compounds, has shown promise in managing inflammatory conditions. However, its poor bioavailability limits its therapeutic potential. This study aims to overcome this limitation by developing Mucuna pruriens loaded herbosomes and assessing their efficacy as mast cell stabilizers. Mucuna pruriens loaded herbosomes were prepared using the thin film hydration method, combining the extract with phosphatidylcholine and cholesterol in a chloroform-methanol mixture, which was evaporated and then hydrated with phosphate buffer (pH 7.4). The resulting herbosomes were characterized using dynamic light scattering for particle size (180 ± 15 nm) and zeta potential (-25 ± 3 mV), ultracentrifugation and HPLC for encapsulation efficiency ($78 \pm 4\%$), and transmission electron microscopy for morphology, revealing spherical vesicles with a lipid bilayer structure. In vitro release studies using a dialysis membrane method showed a sustained release pattern, with approximately 65% of the encapsulated extract released over 24 hours. Mast cell stabilizing activity was evaluated using rat peritoneal mast cells pre-treated with herbosomes and challenged with compound 48/80, demonstrating significant improvements compared to the free extract: 62% reduction in histamine release and 58% reduction in β -hexosaminidase release. These enhanced effects can be attributed to improved cellular uptake, sustained release of bioactive compounds, and potential synergistic effects between phospholipids and the Mucuna pruriens extract, highlighting the promise of this herbosomal formulation for managing allergic and inflammatory conditions.

**Reference**

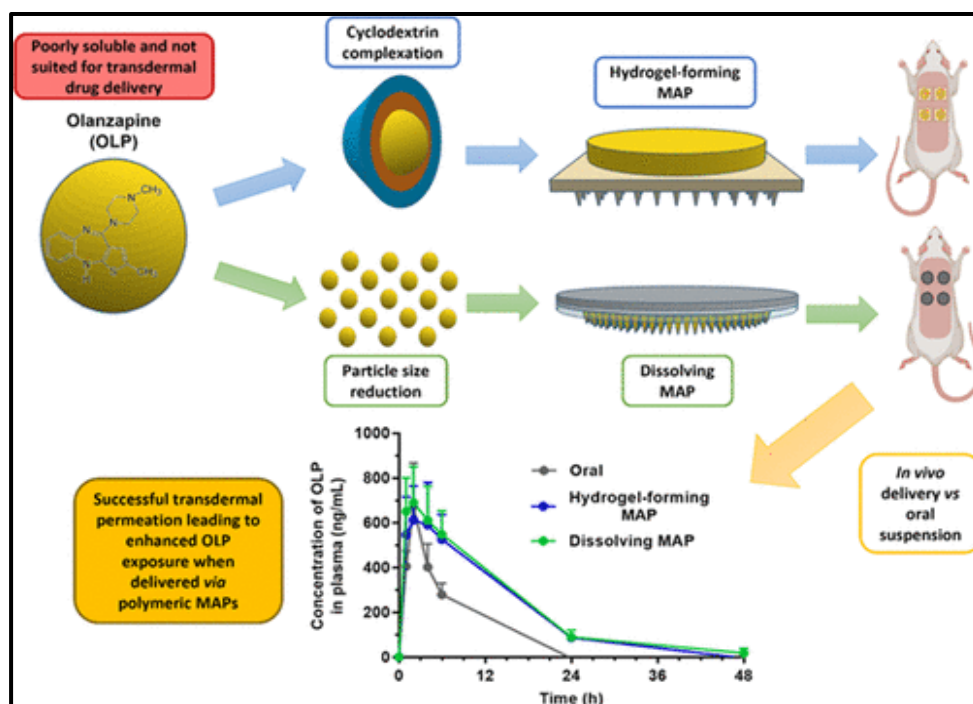
Karekar P, Killedar S, More H, Shaikh A, Joshi S, Waghmare S, Walvekar A, Buchade R, Patil S. Accelerated Stability Studies of Mucuna pruriens Hydroalcoholic Extract Phytosome Formulation, and Evaluation of its Capsule Dosage Form.

Article 37

Herbosomal Transdermal Patch with Terminalia Bellerica for Enhanced Wound

Mrs. Swapnali Vyankatesh Dharanguttikar
Assistant Professor, Pharmaceutical Chemistry Department

Wound healing, a complex biological process, faces challenges such as slow healing rates, scarring, and infection with traditional methods, necessitating innovative approaches. Terminalia bellerica, an Ayurvedic medicinal plant with potent wound healing properties, can be effectively delivered using herbosomes, lipid-based vesicles that offer improved skin penetration, enhanced bioavailability, sustained release, and reduced systemic side effects. The development of a herbosomal transdermal patch involves extracting Terminalia bellerica, preparing herbosomes using phospholipids and cholesterol, formulating the patch, and characterizing its properties. In vitro and in vivo evaluations, including release studies, skin penetration assessments, wound healing efficacy in animal models, and histological analysis, are crucial to determine the patch's effectiveness. This innovative delivery system has the potential to accelerate wound closure, reduce scarring, improve tissue regeneration, alleviate pain and inflammation, reduce infection risk, and enhance patient compliance. By combining the benefits of herbosomes with the therapeutic properties of Terminalia bellerica, this herbosomal transdermal patch offers a promising approach to address unmet needs in wound care and improve patient outcomes.

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Article 38

Exploring Endophytic Microorganisms in Pharmacognosy: A New Frontier in Drug Development

Mrs. Vishin A. Patil

Assistant Professor, Pharmacognosy Department

Introduction

Pharmacognosy, the study of medicinal drugs derived from natural sources, has long focused on plants as a primary resource. However, the emergence of endophytic microorganisms as a new frontier in drug development has transformed this field. Endophytes are microorganisms, primarily fungi and bacteria that reside within plant tissues without causing any harm to their host. These symbiotic organisms are gaining attention for their potential in drug discovery, especially in producing bioactive compounds with therapeutic benefits. This article explores the exciting world of endophytic microorganisms in pharmacognosy, discussing their role in drug development, the mechanisms they use to produce bioactive compounds, and the future implications for natural product-based therapies.

The Role of Endophytes in Drug Development

Endophytes have emerged as a promising source of novel bioactive compounds. These microorganisms have evolved alongside their host plants, often sharing the same metabolic pathways and producing similar secondary metabolites. This unique relationship makes endophytes valuable for drug discovery, as they can produce a wide range of biologically active substances, including antibiotics, anticancer agents, immune-suppressants, and antiviral compounds. One notable example is the discovery of paclitaxel, an anti-cancer compound initially derived from the Pacific yew tree. Researchers later found that endophytic fungi within the tree could also produce paclitaxel, offering a sustainable and scalable source of this vital drug. Such findings highlight the immense potential of endophytes in drug development. Endophytes also offer a solution to the over-harvesting of medicinal plants. By cultivating endophytes in the laboratory, scientists can produce valuable compounds without depleting natural plant populations. This sustainable approach is crucial in preserving biodiversity and ensuring the long-term availability of essential drugs.

Mechanisms of Bioactive Compound Production

The ability of endophytes to produce bioactive compounds is linked to their complex interactions with host plants. These microorganisms often engage in a symbiotic relationship with plants, providing benefits such as enhanced resistance to pathogens, improved growth, and stress tolerance. In return, the plants offer a protective environment and access to nutrients. Endophytes produce bioactive compounds as a defense mechanism, helping their host plants fend off pathogens, herbivores, and environmental stressors. These compounds, which include alkaloids, terpenoids, flavonoids, and polyketides, have been found to possess a wide range of pharmacological activities.

Recent studies have revealed that endophytes can produce compounds identical to those found in their host plants. For example, the endophytic fungus *Colletotrichum gloeosporioides* has been shown to produce camptothecin, a potent anticancer alkaloid originally isolated from the plant *Camptotheca acuminata*. This discovery opens up new possibilities for drug development, as it suggests that endophytes can be harnessed to produce plant-derived compounds in a more controlled and sustainable manner. In addition to mimicking plant compounds, endophytes can also produce unique bioactive molecules not found in their host plants. These novel compounds often exhibit potent pharmacological activities and represent a valuable source of new drug candidates.

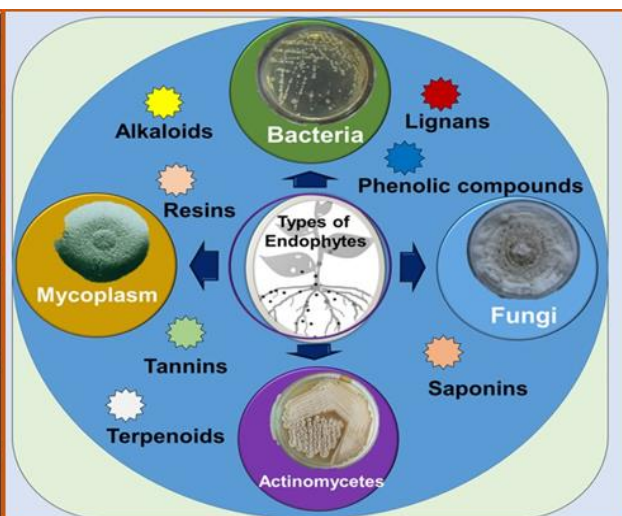
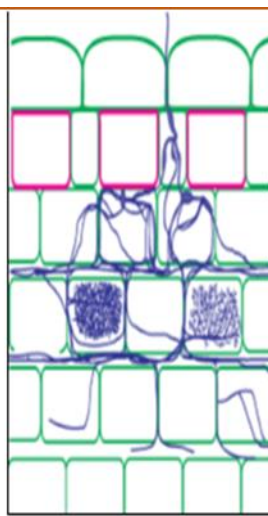


Fig 1: Endophytes inside the cell

Fig 2: Types of Endophytes

Current Research and Applications

Research into endophytic microorganisms is rapidly expanding, with numerous studies investigating their potential in various therapeutic areas. Some of the most promising applications include:

Antibiotic Production: With the rise of antibiotic-resistant bacteria, the need for new antibiotics has never been greater. Endophytes have shown significant potential in producing novel antibiotics that can combat resistant strains. For example, the endophytic bacterium *Streptomyces* sp. has been found to produce antibiotics with activity against methicillin-resistant *Staphylococcus aureus* (MRSA).

Anticancer Agents: Endophytes are being explored for their ability to produce anticancer compounds. The aforementioned paclitaxel-producing fungi are just one example. Other endophytes have been found to produce compounds that induce apoptosis (programmed cell death) in cancer cells, offering new avenues for cancer treatment.

Immuno-suppressants: Endophytes are also being studied for their potential in producing immunosuppressive compounds. These substances can modulate the immune response and are valuable in treating autoimmune diseases and preventing organ transplant rejection.

Antiviral Compounds: In the wake of viral pandemics, the search for new antiviral agents is critical. Endophytes have shown promise in producing compounds with antiviral activity, offering new tools in the fight against viral infections.

Future Directions and Challenges

While the potential of endophytic microorganisms in drug development is immense, several challenges must be addressed to fully realize their benefits. One of the primary challenges is the cultivation of endophytes in the laboratory. Many endophytes have complex growth requirements and may lose their ability to produce bioactive compounds when removed from their natural environment. Advances in microbial culture techniques and genetic engineering may help overcome these obstacles. Another challenge is the identification and isolation of bioactive compounds. The chemical diversity of endophytes is vast, and the process of screening for useful compounds can be time-consuming and resource-intensive. High-throughput screening methods and advanced analytical techniques are being developed to streamline this process and accelerate the discovery of new drugs. The future of endophytic research also lies in exploring the vast diversity of endophytes in nature. Many plant species, particularly those in unexplored ecosystems, likely harbor endophytes with unique and valuable properties. Collaborative efforts between botanists, microbiologists essential in uncovering the full potential of these microorganisms

Conclusion

Endophytic microorganisms represent a new frontier in pharmacognosy and drug development. Their ability to produce a wide range of bioactive compounds, combined with their symbiotic relationship with plants, makes them a promising source of novel drugs. As research into endophytes continues to expand, we can expect to see new breakthroughs in the treatment of diseases and the development of sustainable natural products. The future of pharmacognosy is undoubtedly intertwined with the exploration of these remarkable microorganisms, and their potential to revolutionize medicine is just beginning to be realized.

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Article 39

The Evolution of Computational Chemistry and Its Impact on Modern Drug Discovery**Ms. Vidya K. Kakade****Assistant Professor, Pharmaceutical Chemistry Department**

In the 19th century, Auguste Comte dismissed the application of mathematical methods in chemistry, viewing them as irrational. However, just a few decades later, in 1888, Gay-Lussac predicted that computation would eventually revolutionize chemistry. This shift in perspective set the stage for major breakthroughs in the field, particularly with the development of computational chemistry.

In 1998, the Nobel Prize in Chemistry was awarded to Walter Kohn and John Pople for their pioneering contributions to computational chemistry. Kohn developed the density-functional theory, while Pople introduced computational methods in quantum chemistry. These developments allowed scientists to perform complex energy calculations on molecules and multi-atom systems. Chemists could now predict the dynamics of chemical reactions and better understand molecular interactions, marking a turning point in how chemistry was studied and applied.

The role of computational approaches in drug discovery gained prominence again in 2013 when Martin Karplus, Michael Levitt, and Arieh Warshel were awarded the Nobel Prize for developing multiscale models that could simulate complex chemical processes. These models allowed for predictions of chemical reaction outcomes even before conducting experiments, a revolutionary advancement. Their work forms the foundation for modern simulations used in industries such as drug development and industrial chemistry, enabling more precise control of chemical processes and reducing the need for trial-and-error experiments.

With the rapid advancements in computing power, fueled by Moore's Law and the advent of GPUs and parallel CPUs, computational chemistry became more accessible and efficient. Modern computers now enable high-throughput virtual screening (HTVS), allowing researchers to evaluate millions of compounds in a single day. This capability was notably demonstrated during the COVID-19 pandemic, where researchers used the SUMMIT supercomputer to conduct ultra-large virtual screenings to find potential inhibitors for the SARS-CoV-2 virus.

Computational tools such as molecular docking, molecular dynamics, and QSAR (Quantitative Structure-Activity Relationship) modeling have become indispensable in drug discovery. These methods help scientists identify promising compounds by simulating molecular interactions, predicting binding affinities, and optimizing drug candidates in silico, reducing the need for costly and time-consuming laboratory experiments.

Recent advancements in machine learning and artificial intelligence have further transformed drug discovery. These technologies, combined with the growing availability of protein-ligand interaction data from databases like the Protein Data Bank (PDB), have significantly improved the accuracy and speed of predicting drug-target interactions. Additionally, the integration of receptor-ligand affinity data has created ideal scenarios for both academic and industrial research, accelerating the early phases of drug discovery.

A number of recent studies have highlighted the practical application of computational methods in drug discovery. For example, researchers have used molecular docking and pharmacophore modeling to identify novel modulators for orphan receptors and potential inhibitors for enzymes like dihydrofolate reductase (DHFR) and Arginase 1 and 2. These computational approaches have helped narrow down large libraries of compounds to identify promising candidates for in vitro and in vivo testing. Molecular dynamics simulations have also been instrumental in understanding the detailed

mechanisms of drug interactions. For instance, they have provided insights into the binding mechanisms of histamine receptors, anti-parasitic drugs, and protease inhibitors for SARS-CoV-2. These studies illustrate the importance of computational chemistry in predicting not only the binding of drug candidates but also their dynamic behavior in biological systems.

Moreover, machine learning-driven QSAR models have allowed researchers to predict the biological activity of novel compounds before synthesis, further streamlining the drug development pipeline. Studies have shown that these models can guide decision-making in selecting anti-leishmanial compounds and other therapeutics, making the discovery process more efficient and targeted.

In summary, the integration of chemistry, mathematics, and computing has fundamentally transformed drug discovery. From the early skepticism of applying mathematics in chemistry to the Nobel Prize-winning advancements in computational chemistry, the field has evolved to enable unprecedented accuracy and speed in predicting chemical reactions and designing new drugs. Today, computational methods are at the forefront of drug discovery, driving the development of new therapies and ensuring that the next generation of drugs is more efficient and precisely targeted. With the continued progress in hardware and AI, computational chemistry will likely play even more prominent role in future scientific breakthroughs, especially in personalized medicine and targeted therapies.

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Article 40

From Nature to Medicine: The Evolution of Natural Therapies**Ms. Vidya K. Kakade****Assistant Professor, Pharmaceutical Chemistry Department**

The journey from natural products to clinical practice has shaped modern drug development in profound ways. For centuries, nature has provided a vast "toolbox" of small molecules, many of which have evolved into therapeutic agents for combating chronic diseases. Despite advances in synthetic chemistry, recent trends in research have re-emphasized natural products, not only for their medicinal potential but also for their cost-effectiveness and safety. Historically, efforts in drug discovery, particularly in the 1990s, focused on combinatorial chemistry and high-throughput screening. However, these approaches yielded limited success, prompting researchers to revisit natural compounds for new drug candidates. Natural products have since gained renewed attention, especially for their pharmacokinetic and pharmacodynamic properties.

Recent studies have highlighted the potential of natural molecules like catechin and honokiol, which demonstrate blood-pressure-lowering effects via novel mechanisms. Other research delves into natural antibiotics, such as azalomycin F, which has poor oral bioavailability but offers promise in treating systemic infections through intravenous administration. Furthermore, natural products have shown efficacy in addressing inflammation and oxidative stress, with phytochemicals from sources like *Ficus religiosa* and green apple flavonols exhibiting significant antioxidant properties. These findings not only enrich our understanding of natural substances but also push them closer to clinical use.

The integration of cutting-edge technologies, such as LC-MS/MS, has also enhanced our ability to analyze these compounds with precision, bringing us one step closer to translating laboratory research into practical, clinical solutions. From herbs like *Withania somnifera* to synthesized peptides inspired by natural sources, these advances exemplify the potential of nature-derived treatments. As researchers continue to explore natural products, they promise to play a key role in future biomedical innovations, offering safer, more effective therapies for a wide range of conditions. The path from the laboratory to clinical practice is long, but with nature as our guide, the future of medicine looks promising.

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Article 41

Abnormal Uterine Bleeding**Dr. Mrs. Neela M. Bhatia****Professor and HOD Quality Assurance Department**

Abnormal uterine bleeding earlier more commonly called as dysfunctional uterine bleeding occurs when an individual has vaginal bleeding which is not part of regular menstrual cycle. A result of an imbalance in sex hormones, many other conditions can lead to abnormal uterine bleeding. Abnormal uterine bleeding is a broad term which describes irregularities in the menstrual cycle. These irregularities may involve frequency, regularity, duration, and volume of blood flow. Studies have revealed that about one-third of women will experience abnormal uterine bleeding in their life time with irregularities most commonly occurring at menarche and perimenopause. Frequency of a normal menstrual cycle has a frequency of 24 to 38 days and lasts for 2 to 7 days, with 5 to 80 milliliters of blood loss. Variations in any of these 4 parameters constitute abnormal uterine bleeding. The main cause of dysfunctional uterine bleeding is an imbalance in the sex hormones. Girls in the phase of puberty and women approaching menopausal age can have imbalanced hormone levels for months or even years. This can cause sporadic bleeding, heavy bleeding, and spotting. Older terms such as oligomenorrhea, menorrhagia, and dysfunctional uterine bleeding now should be discarded to describe the nature of abnormal uterine bleeding. Revisions to the terminology were first published in 2007, followed by updates from the International Federation of Obstetrics and Gynecology (FIGO) in 2011 and 2018.

Abnormal uterine bleeding (AUB) can also be divided into two namely acute versus chronic. Acute AUB is excessive bleeding that requires immediate intervention to prevent further blood loss. Acute AUB can occur on its own which refers to irregularities in menstrual bleeding for a period of about 6 months. The prevalence of abnormal uterine bleeding among reproductive-aged women internationally is estimated to be between 3% - 30% with a higher incidence occurring around menarche and perimenopause. Many studies are limited to heavy menstrual bleeding (HMB), but when irregular and intermenstrual bleeding are considered, the prevalence rises to 35% or greater. Medical conditions that often cause dysfunctional uterine bleeding include Hormone changes, polycystic ovary syndrome (PCOS), Endometriosis, Uterine polyps, uterine fibroids, Sexually transmitted diseases (STDs), Pregnancy etc. The various symptoms included are heavy menstrual bleeding, bleeding that contains many clots or large clots, bleeding that lasts more than 7 days, bleeding that occurs less than 21 days from the last cycle, bleeding that occurs later than 35 days from the last cycle, spotting, bleeding between periods etc. generally with pelvic pain or pressure.

To understand abnormal uterine bleeding it is necessary to realise the pathophysiology of uterus. Blood is supplied to uterus through uterine and ovarian arteries. These arteries become the arcuate arteries which send off radial branches supplying blood to the two layers of the endometrium, the functionality and basalis layers. Level of progesterone hormone falls towards the end of menstrual cycle, leading to enzymatic breakdown of the functional layer of the endometrium. This breakdown causes blood loss and sloughing, which leads to menstruation. Various functioning platelets, thrombin, and vasoconstriction of the arteries to the endometrium controls blood loss. Any derangement in the structure of the uterus (such as leiomyoma, polyps, adenomyosis, malignancy, or hyperplasia), derangements to the clotting pathways (coagulopathies or iatrogenically), or disruption of the hypothalamic-pituitary-ovarian axis (through ovulatory/endocrine disorders or iatrogenically) can affect menstruation and lead to abnormal uterine bleeding. The cause of abnormal uterine bleeding can be diagnosed with

the help of ultrasound, blood tests, hysteroscopy, magnetic resonance imaging and endometrial biopsy.

Treatment of abnormal uterine bleeding depends on multiple factors, such as the etiology of the AUB, fertility desire, the clinical stability of the patient, and other medical comorbidities. Treatment must be individualized on the basis of various factors. In general, medical options are preferred as initial treatment for AUB. Medical management options include a levonorgestrel-releasing intrauterine device (IUD), GnRH agonists, systemic progestins, and tranexamic acid with non-steroidal anti-inflammatory drugs (NSAIDs). For acute abnormal uterine bleeding, hormonal methods are the first line in medical management. Intravenous (IV) conjugated equine estrogen, combined oral contraceptive pills (OCPs), and oral progestins are all options for treating acute AUB. Tranexamic acid prevents fibrin degradation and can be used to treat acute AUB. Coagulopathies leading to AUB can be treated with tranexamic acid or desmopressin (DDAVP). Ovulatory dysfunction can be treated through lifestyle modification in women with obesity, PCOS, or other conditions in which anovulatory cycles are suspected.

Endometrial disorders have no specific treatment, as mechanisms are not clearly understood. Surgical options include uterine artery embolization, endometrial ablation, or hysterectomy. Complications of chronic abnormal uterine bleeding can include anemia, infertility, and endometrial cancer. Acute abnormal uterine bleeding, severe anemia, hypotension, shock, and even death may result if prompt treatment and supportive care are not initiated. Health professionals should initiate and coordinate due care to evaluate and treat women with abnormal uterine bleeding. Nurses and physicians in primary care, such as family medicine and internal medicine, might be the first to discover AUB and should consult with obstetrics and gynecologists as early as possible. Patients should be informed of all of their options for control of AUB based on etiology. Physicians and pharmacists should educate patients concerning any possible side effects of medical management. A timely diagnosis and early treatment can help prevent other further complications for females.

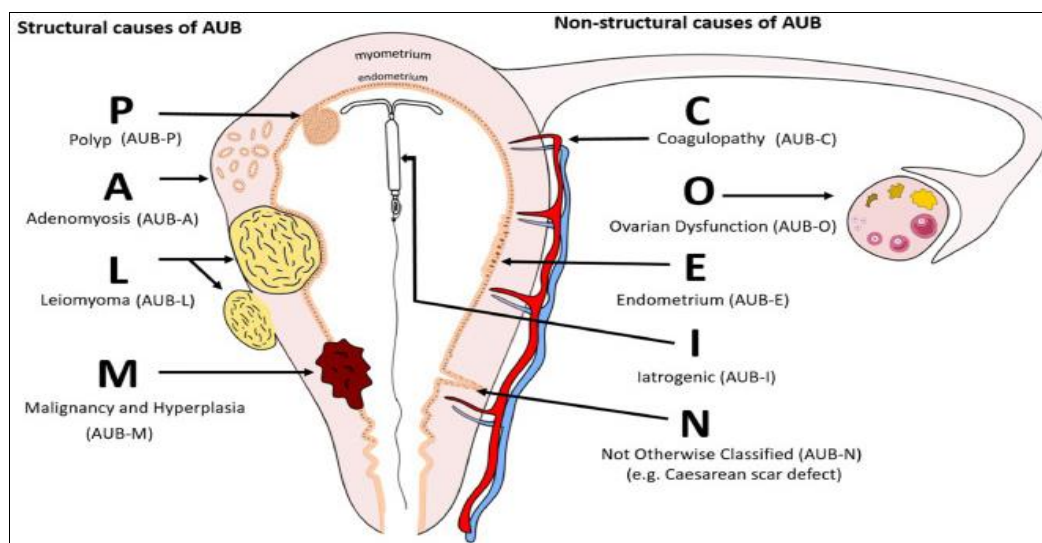


Fig. 1 abnormal uterine bleeding (AUB) – structural and non-structural causes

Article 42

Floating Drug Delivery System

Ms. Nisha Sanjay More

PG Student, Pharmaceutics Department

Floating drug delivery system (FDDS) is the main approach to prolonging the gastric residence time in the stomach in which the bilayer floating tablet has the main role. It is more suitable for the treatment of local infections such as peptic ulcer, gastritis, Zollinger-Ellison syndrome, indigestion, and other local infections related to the gastrointestinal tract and also used for systemic applications. FDDS provides protection for those drugs which are acid labile and have a short half-life. It also improves bioavailability, reduces drug waste, and enhances the residence time of drugs. Nowadays, various technologies are being used for the development of FDDS. Novel drug delivery systems incorporation into bilayer floating tablets has also broadened the role of FDDS. Polymers have the main role in the development of FDDS, which serve as carriers for the drug and determine the gastric retention time and drug protection. FDDS is also an easy, cheap, and more convenient method for dual drug delivery of drugs.

Materials and Methods for the floating mix matrix tablets include stavudine were prepared by melt granulation method. Beeswax was used as hydrophobic meltable material. Hydroxypropyl methylcellulose (HPMC), sodium bicarbonate, and ethyl cellulose were used as matrixing agent, gas generating agent, and floating enhancer, respectively. The prepared tablets were evaluated for physicochemical parameters such as hardness, weight variation, friability, floating properties (floating lag time, total floating time), drug content, stability study, and in vitro drug release. The drug-polymer interaction was studied by Differential Scanning Calorimetry (DSC) thermal analysis and Fourier transform infrared (FT-IR).

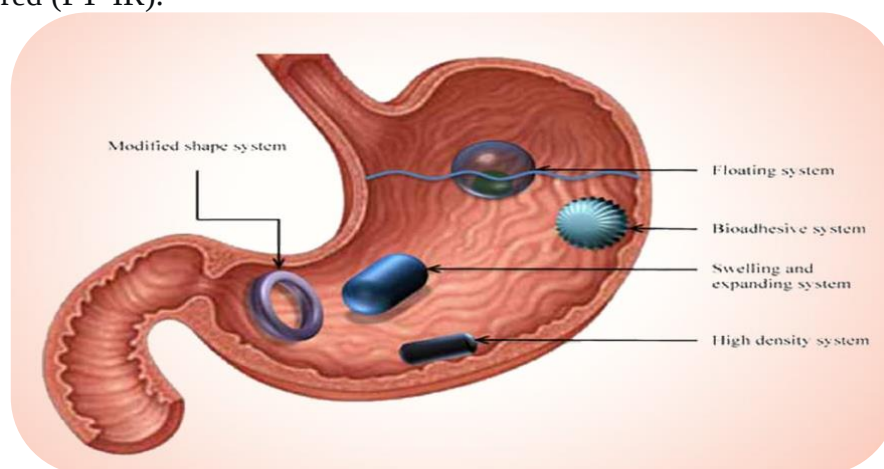
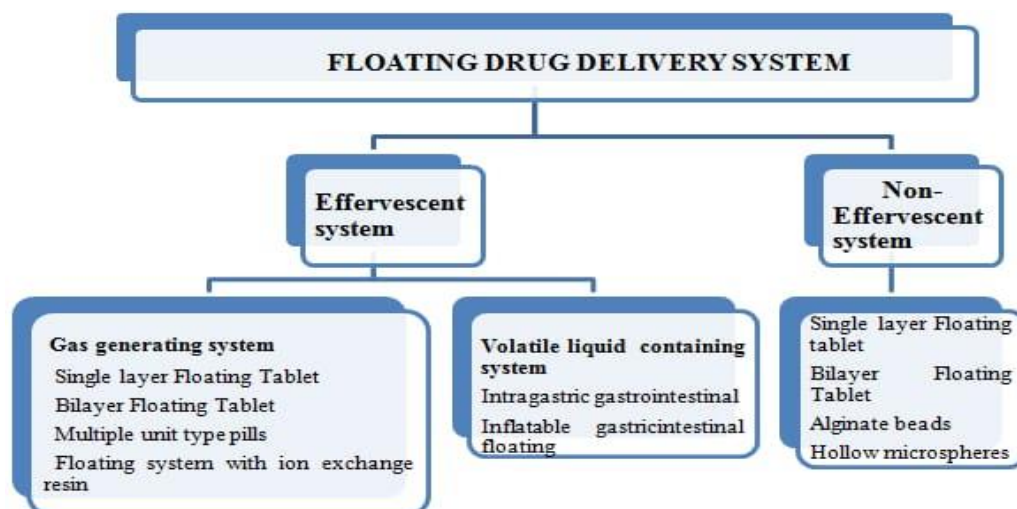


Fig. 1 Floating Drug Delivery System

Applications of Floating Drug Delivery System:

Floating drug delivery offers several applications for drugs having poor bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract. These are Sustained Drug Delivery and Site-Specific Drug Delivery. These systems are particularly advantageous for drugs that are specifically absorbed from stomach or the proximal part of the small intestine, e.g., riboflavin and furosemide.



FDDS can protect drugs that are acid labile or have a short half-life. It can also be used for dual drug delivery. FDDS requires a certain level of fluids in the stomach to work properly. FDDS uses bilayer floating tablets to prolong the time a drug spends in the stomach. The tablets are less dense than stomach fluids, so they float and slowly release the drug over time. This increases the amount of time the drug spends in the stomach, which improves bioavailability and reduces drug waste. Evaluation Tests include in-vitro and in-vivo test. In-vitro include Floating lag time, Floating time, Dissolution study, Resultant weight test evaluation and in-vivo test include X ray method, Gamma-scintigraphy, Gastroscopy, Ultra sonography. Mechanism of Floating Drug Delivery System: FDDS has bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for prolonged period of time.

$$F = F_{\text{buoyancy}} - F_{\text{gravity}} (D_f - D_s) gV$$

Where,

F-total vertical force, D_f -fluid density, D_s -object density, V-volume, g-acceleration due to gravity

FDDS promises to be a potential approach for gastric retention. Dosage form with prolonged GIT will bring about new and important therapeutic actions. These systems offer the gain of better absorption and bioavailability. Floating drug delivery system guarantees to be a technique for gastric retention. Although there are a wide variety of complications to be laboured out to gain extended GI retention, many companies are focusing in the direction of commercializing this approach. A wide variety of industrial product patents and recent research on floating drug delivery system are briefly studied here.

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Article 43

A review of regulatory submissions for pharmaceutical continuous manufacturing**Mrs. Priyanka B. Varne****Assistant Professor, Pharmaceutical Chemistry Department**

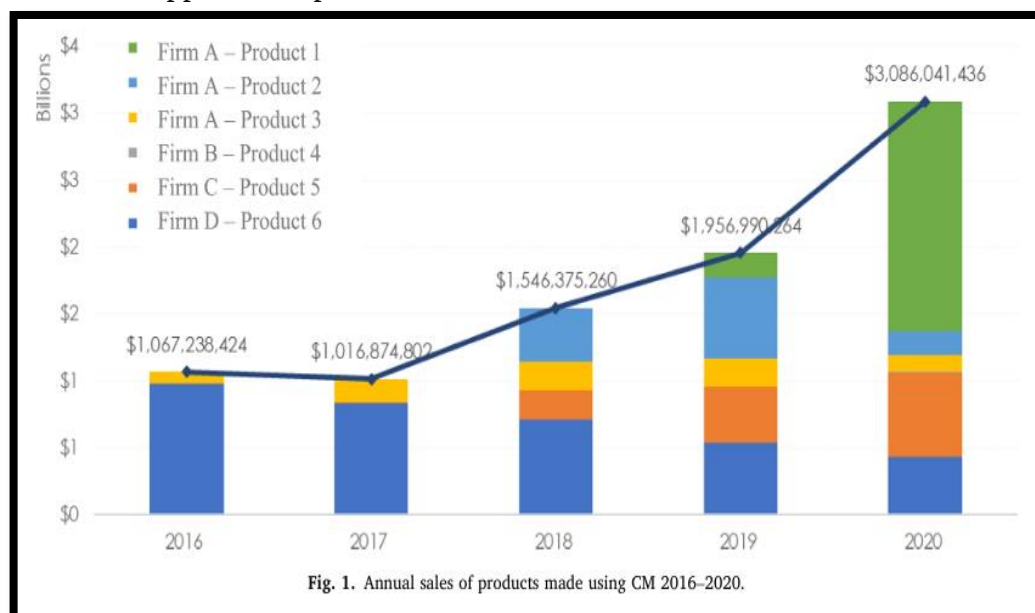
Continuous manufacturing (CM) is a technology that sends materials produced during each process step directly and continuously to the next step for further processing. In such a process, input materials are continuously fed into production and transformed, and processed output materials are continuously removed. CM has been adopted in many industries (e.g., petroleum, commodity chemicals), while the pharmaceutical industry has been slower to adopt CM. The U.S. landscape of prescription drug products made using a CM process was roughly \$3.09B in 2020 (Fig. 1), representing a small but growing portion of the \$172B total market for branded, solid oral prescription drugs. The leading firm in the CM sector captures around 65% of total sales, with 20% of sales captured by the next largest firm. Many have pointed to the slow adoption of advanced manufacturing technologies, including CM, as one of the reasons that the pharmaceutical industry has not achieved the consistent six sigma manufacturing capability.

The United States Food and Drug Administration (FDA) has long championed the development and implementation of advanced manufacturing technologies like CM for drug substances and finished drug products because of the potential to improve product quality and reliability, lower manufacturing costs, reduce waste, decrease inventory, and increase manufacturing flexibility and agility in response to fluctuations in product demand. The cumulative effects of CM adoption could reduce or mitigate drug shortages. CM can be applied to all classes of products: new drugs submitted in New Drug Applications (NDAs) generic drugs filed in Abbreviated New Drug applications (ANDAs), drug substances filed in Drug Master Files (DMFs), biotechnology products filed in Biologics License Applications (BLAs), and nonprescription drugs. There is now a rich source of scientific literature describing the benefits of CM in pharmaceutical manufacturing relating mostly to decreases in production/operating costs and improvements in product quality and reliability. Perhaps most importantly for patients and consumers, CM has the potential to impact product availability; for example, by avoiding drug shortages due to manufacturing problems or expediting patient access through improved Manufacturing agility and easier scale-up to commercial production.

The FDA's Center for Drug Evaluation and Research (CDER) has several visible commitments to facilitate the adoption of CM. Perhaps most visible is the Draft Guidance for Industry: Quality Considerations for Continuous Manufacturing published in 2019, which provides FDA's current thinking on the quality considerations for the continuous manufacturing of small molecule, solid oral drug products (FDA. Quality Considerations for Continuous Manufacturing Guidance for Industry. In.; 2019). CDER's Emerging Technology Program seeks to promote the adoption of innovative approaches to pharmaceutical product design and manufacturing, such as CM, through direct engagement with industry representatives (FDA. Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization Guidance for Industry. In.; 2017). Under this program, FDA staff and participants discuss, identify and resolve potential technical and regulatory issues regarding the development and implementation of a novel technology prior to the filing of a regulatory submission

CDER approved the first application employing CM in 2015 following extensive engagement between the applicant and the Emerging Technology Program. CDER has funded a large and growing scientific knowledge base for CM fueled by intramural and extramural research on topics such as process modeling, formulation, bioprocesses, and integrated (i.e., inclusive of drug substance and drug product) continuous processes. Recognizing that global regulatory harmonization can be significant barrier to CM adoption, the FDA leads international regulators in developing a harmonized international guideline on CM (ICH Q13) to further lower regulatory uncertainty regarding implementation across multiple regulatory regions (ICH, 2021). There are known perceptions in the pharmaceutical industry of regulatory barriers that reduce the attractiveness of advanced manufacturing technologies, such as CM. Some key regulatory concerns relate to increased time to approval and market entry, more difficulty implementing and submitting post-approval changes, and increased inspectional scrutiny. While the benefits of CM adoption in the context of capital and operating expenditures have been explored extensively in the literature; regulators have not yet described or quantified the regulatory outcomes of products made using CM. Here we self-audit the approved U.S. regulatory submissions to CDER that employ CM and analyze the relevant regulatory outcomes, at approval and during the product lifecycle, as compared to applications that employ traditional batch processes by examining:

- Time to approval and market entry
- Manufacturing process changes reported in Annual Reports
- Manufacturing-related post-approval application supplements
- Pre-approval inspections



Reference

Fisher, Adam C., et al. "An audit of pharmaceutical continuous manufacturing regulatory submissions and outcomes in the US." *International Journal of Pharmaceutics* 622 (2022): 121778.

Research Publications in Indexed Journals 2023-24

Sr. No.	Title of Paper	Journal name	Category	Impact Factor
1.	Identification of potential biogenic chalcones against antibiotic resistant efflux pump (AcrB) via computational study	Journal of Biomolecular Structure and Dynamics	Drug Discovery Processes	4.4
2.	Identification of potential hits against fungal lysine deacetylase Rpd3 via molecular docking, molecular dynamics simulation, DFT, in-silico ADMET and drug-likeness assessment	Chemistry Africa,	Drug Discovery Processes	2.6
3.	In Silico Exploration of Phytoconstituents and Identification of Hits Against α -Amylase for Antidiabetic Potential	Research Journal of Pharmacy and Technology	Drug Discovery Processes	0.9
4.	Synthesis of Glycoconjugates in Potentiating Pharmacological and Pharmaceutical Activity	Drug Formulation Design	Drug Discovery Processes	-
5.	Active constituents of herbal medicines for breast cancer:Current status	Journal of Applied Pharmaceutical Science	Drug Discovery Processes	0.26
6.	Biosynthesis of Silver Nanoparticles using Annona squamosa L Seed and Leaves Extract: Evaluation of the Anti-inflammatory, Antifungal, and Antibacterial Potency	International Journal of Pharmaceutical Quality Assurance	Drug Discovery Processes	-
7.	Morphological, Histological and Phytochemical Features of Nephrolepis cordifolia (L.) C. Presl	National Academy Science Letters	Drug Discovery Processes	1.1
8.	Exploring α , β -unsaturated carbonyl compounds against bacterial efflux pumps via computational approach	Journal of Biomolecular Structure and Dynamics	Drug Discovery Processes	4.4
9.	Benzylpyrazolyl naphthoquinones as potential VEGFR-2, GPCR and PPAR inhibitors: synthesis, anti-cancer evaluation, molecular docking and DFT studies	Journal of Molecular Structure	Drug Discovery Processes	3.8
10.	Novel jellyfish-shaped resorcinarene macrocyclic cocrystal via collaboration of macrocyclic chemistry and co-crystal engineering:	Journal of Molecular Structure	Drug Discovery Processes	3.8

Technical Articles

	Insight into structural, noncovalent interactions and computational chemistry			
11.	Design, synthesis and antitubercular assessment of 1, 2, 3-triazole incorporated thiazolylcarboxylate derivatives	Bioorganic & Medicinal Chemistry Letters	Drug Discovery Processes	2.7
12.	Design, Synthesis, and Optimization of Silver Nanoparticles Using an Artocarpus heterophyllus Lam. Leaf Extract and Its Antibacterial Application	Nano Biomedicine and Engineering	Drug Discovery Processes	0.323
13.	Molecular docking, QSAR, pharmacophore modeling, and dynamics studies of some chromone derivatives for the discovery of anti-breast cancer agents against hormone-dependent breast cancer	Journal of Biomolecular Structure and Dynamics	Drug Discovery Processes	2.8
14.	Nanophytosomes Loading Andrographis paniculata Hydroalcoholic Extract: Promising Drug Delivery for Hepatoprotective Efficacy	Journal of Pharmaceutical Innovation	Drug Delivery Applications	2.6
15.	Physicochemical Evaluation and Standardization of Traditional Healing Herb Sonchus asper Linn	Research Journal of Pharmacy and Technology	Drug Delivery Applications	0.8
16.	Stimuli-Responsive Design of Metal–Organic Frameworks for Cancer Theranostics: Current Challenges and Future Perspective	ACS Biomaterials Science & Engineering	Drug Delivery Applications	5.7
17.	QbD-steered fabrication of lisinopril ion-pair gel for improved skin permeability and bioavailability in rabbits.	Journal of Research in Pharmacy	Drug Delivery Applications	-
18.	Comparative Evaluation of Formulations Designed using Chemically Modified Pectin and Eudragit for Sustained Release of Nateglinide	Research Journal of Pharmacy and Technology.	Drug Delivery Applications	0.8
19.	Evaluation of curcumin-loaded chitosan nanoparticles for wound healing activity	ADMET DMPK	Drug Delivery Applications	2.5
20.	Exploring anticancer potential of nintedanib conjugated magnetic nanoparticles: In-vitro and in-silico studies	Journal of Drug Delivery Science and Technology	Drug Delivery Applications	5.0

Technical Articles

21.	Formulation and evaluation of polyherbal in-situ gel for glaucoma	International Journal of Pharmaceutical sciences and research	Drug Delivery Applications	-
22.	Preparation, statistical optimization, in-vitro evaluation and characterization of solid lipid nanoparticles of an anti-retroviral drug Nevirapine	Research Journal of Pharmacy and Technology	Drug Delivery Applications	0.27
23.	In vitro, in silico and in vivo screening of non-oncology drugs for repurposing in osteosarcoma.	Journal of Research in Pharmacy	Drug Delivery Applications	-
24.	Development and in vitro evaluation of folate conjugated polydopamine modified carmustine-loaded liposomes for improved anticancer activity	Journal of Drug Delivery Science and Technology	Drug Delivery Applications	5
25.	In vitro and in silico exploration of newly synthesized triazolyl-isonicotinohydrazides as potent antitubercular agents	Journal of Biomolecular Structure and Dynamics	Drug Delivery Applications	4.4
26.	Oral self-nanoemulsifying drug delivery systems for enhancing bioavailability and anticancer potential of fosfestrol: In vitro and in vivo characterization	European Journal of Pharmaceutics and Biopharmaceutics	Drug Delivery Applications	4.4
27.	Challenges and Opportunities with Drug Repurposing: An Emerging Technique in Drugs Discovery	Indian Drugs	Drug Delivery Applications	0.148
28.	Synthesis, In-Silico, In Vitro and DFT Assessments of Substituted Imidazopyridine Derivatives as Potential Antimalarials Targeting Hemoglobin Degradation Pathway	Journal of Computational Biophysics and Chemistry	Drug Delivery Applications	2
29.	Synthesis, Computational, and In Vitro Antimycobacterial Studies on Benzofuran based Sulphonamide Derivatives (Part II)	Russian Journal of Bioorganic Chemistry	Drug Delivery Applications	1.1
30.	Formulation development and pharmacological evaluation of polyherbal formulations for the treatment of ovarian cancer	European Chemical Bulletin	Drug Delivery Applications	0.5
31.	Development of Doxazosin mesylate liquisolid system for improved manufacturing processability and bioavailability: in vitro and in vivo	Journal of Dispersion Science and	Drug Delivery Applications	2.2

Technical Articles

	evaluation for tailored hypertension treatment approach with modified dissolution rates	Technology		
32.	Design and development of Fujicalin-based axitinib liquisolid compacts for improved dissolution and bioavailability to treat renal cell carcinoma	European Journal of Pharmaceutics and Biopharmaceutics	Drug Delivery Applications	4.4
33.	A Systematic Review on Chemical Actives from Plant Sources, Targets and Chemotherapy for Triple-Negative Breast Cancer	Pharmaceutical Chemistry Journal	Bioactivity assessment	0.9
34.	Bioactive Natural Products for Breast Cancer Chemoprevention and Treatment	Current Bioactive Compounds	Bioactivity assessment	0.2
35.	Glycosylated heterocycles emulsified with antifungal fraction of Moringa oleifera for potentiation of mycolytic activity	Natural Product Research	Bioactivity assessment	2.4
36.	Exploration of bioactive molecules from Tinosporacordifolia and Actinidia deliciosa as an immunity modulator via molecular docking and molecular dynamics simulation study	Natural Product Research	Bioactivity assessment	2.2
37.	Biological evaluation, molecular modeling and dynamic simulation of IDQ bulk and IDQNPs: Organo nano-bio interface in the medical field	Journal of Molecular Structure	Bioactivity assessment	3.8
38.	Development and Validation of a Novel Bioanalytical Method for Estimating Epigallocatechin 3 Gallate in Wistar Rat Plasma by RP-HPLC Employing Gradient Elution Techniques.	Journal of Research in Pharmacy	Product Development	-
39.	Developed and Validated RP-HPLC Method for Concurrent Analysis of Some Cardiovascular Drugs	International Journal of Pharm. Quality Assurance	Product Development	-
40.	HPLC Method Validation for Quantification of Lisinopril	International Journal of Pharma. Quality Assurance	Product Development	-

Patents from College till 2024

Sr. No.	Title	Status Granted/Publication Date	Names of Faculty	Date with National/International
1.	Novel Approach For The Enhancement of Solubility of antidepressant Class II Drug.	Published 202421044157	Mrs. Priyanka B. Varne	07/06/2024 National
2.	Spectrophotometric Apparatus for instant estimation of blood glucose level	Design No: 399318-001 Mumbai	Mrs. Vishin Ashish Patil	06-11-2023 National
3.	AI based pill dispensing device	UK Design No. 6322573	Dr. Firoj A. Tamboli	07/11/2023 International
4.	Novel Ketoconazole loaded NLC Gel for management of Skin Diseases	Filed 202321043227 A	Dr. H. N. More	15/09/2023 National
5.	Formulation of Fast Dissolving Axitinib Liquisolid Tablet	Filed 202321054776M Mumbai	Mrs. Priyanka B. Varne	16/08/2023 National
6.	Advanced liquid chromatography apparatus	Indian Patent Design No. 392021-001	Dr. Firoj A. Tamboli	05/08/2023 National
7.	A topical skin tissue regeneration composition of bael fruit gum material, chitosan and gelatin	Filled 202421007438	Dr. D. T. Gaikwad	03/02/2024 National
8.	A posaconazole nanosuspension composition and its preparation process by solvent-antisolvent precipitation for enhanced oral bioavailability.	Published	Dr. M. S. Bhatia, Dr. P. B. Choudhari	11/8/2023 National
9.	A FA-CS-DS-Nanoparticles composition and its synthesizing process thereof	Granted 2023/00808	Dr. M. S. Bhatia	29/3/2023 International
10.	A system for the pharmacological evaluation of conjugates of atenolol with modified saccharides for cardiovascular targeting	Granted 202023100257	Dr. M. S. Bhatia	07/2/2023 International
11.	Coolant Liquid Assembly for Preservation of API	Granted 6294311	Mr. R. J. Jarag	13/07/2023 International
12.	Formulation and Evaluation of Enalapril Loaded Solid Lipid Nanoparticles for Therapeutic Application	Published 202321040518 A	Dr. D. A. Bhagwat	04/08/2023 National
13.	Advanced Liquid Chromatography Apparatus	392021-001 (Design)	Dr. F. A. Tamboli	5/8/2023 National
14.	Portable Lyophilizer for Improving Stability of Compounds	Granted 6303370	Dr. D. A. Bhagwat	22/8/ 2023 International

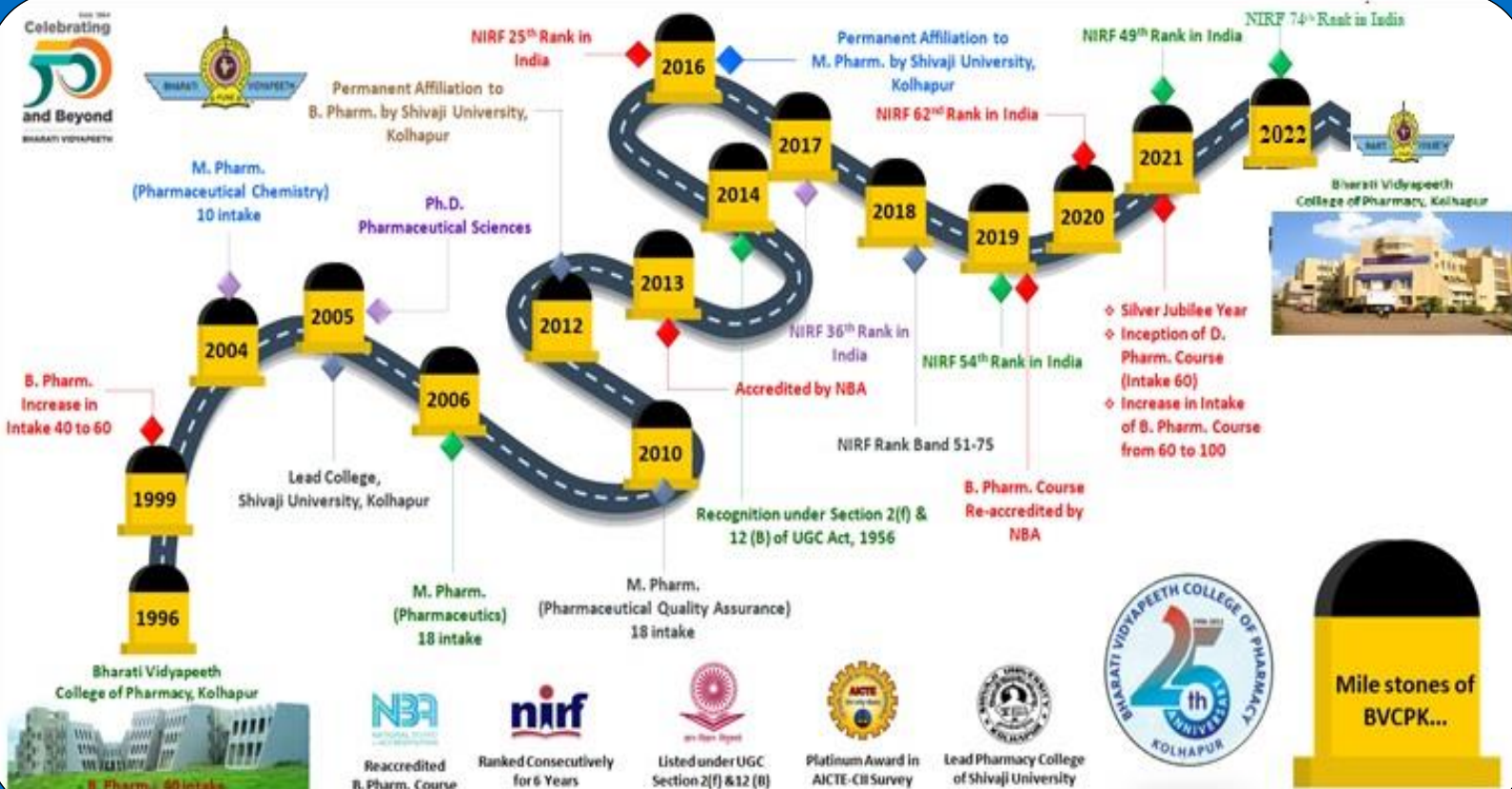
Technical Articles

15.	Novel Menstrual Regulation Activity Of Macrotyloma Uniflorum On Albino Rats	Published 202321051150	Mr. R. J. Jarag, Mrs. R. R. Jarag	22/09/2023 National
16.	Novel Ketoconazole loaded NLC Gel for management of Skin Diseases	Published 202321043227 A	Dr. A. A. Hajare, Dr. H. N. More	15/09/2023 National
17.	AI Based Pill Dispensing Device	Granted 6322573	Dr. F. A. Tamboli	29/10/2023 National
18.	Construction of Curcumin-Bael Fruit Gumelectrospun Nanofibers	Published 202221030754	Dr. D. T. Gaikwad	30/05/2022 National
19.	Analytical Method For Beta-Secretase Estimation From Biological Fluids.	Published 201721033863	Dr. M. S. Bhatia, Mr. R. P. Dhavale	25/02/2022 National
20.	An Empirical System For Risk Assessment Of Mental Illness Disorders Using Neural Network Diagnostic	Granted South Africa Patent Application No 2022/02141 09/12/2021	Dr. D. A. Bhagwat	12/02/2022 National
21.	Virtual Doctor to Detect Patent Heart Beat and Body Temperature Monitoring	Granted Indian Patent Application No. 202141057189	Dr. D. A. Bhagwat	04/02/2022 National
22.	A Tissue- Based Study For Analysing The Effect Of Drugs Applied Externally	Published 202221007261	Ms. S. A. Thorat	10/02/2022 National
23.	A Process For Preparing Stable Sustained Release Topical Composition Of Euphorbia Tithymaloides.	Published 202221024039	Ms. S. A. Thorat	06/05/2022 National
24.	Novel nanoemulgel formulation containing extract of <i>Clerodendrum inerme</i>	Published	Dr. A. J. Shinde, Dr. H. N. More	24/06/2022
25.	Artificial intelligence based approach along with nanoscale for accurate diagnosis and detection of skin cancer using biometric sensors	Published 202231054865	Dr. F. A. Tamboli	30/09/2022
26.	Integrating the techniques of computer vision along with machine learning algorithms to detect the disease of plant based on leaf structure	Published 202241054867	Dr. F. A. Tamboli	30/09/2022
27.	The Composition Of Polyherbal Soap For Skin	Published 202221051622 A	Dr. F. A. Tamboli	7/10/2022
28.	Green synthesized silver nanoparticles by using natural mucilage for anticancer potential	Published 202221058516 A	Dr. D. T. Gaikwad, Mr. R. R. Chavan	11/11/2022 13/10/2022

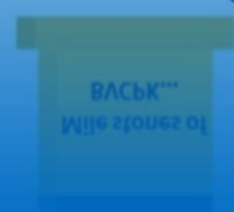
Technical Articles

29.	Promising antidiabetic composition of <i>Terminalia arjuna</i>	Published 202221059364 A	Dr. D. T. Gaikwad, Mr. D. P. Mali, Mr. V. H. Thorat	11/11/2022 18/10/2022
30.	Polyherbal tablet composition for anti-inflammatory and immunomodulatory potential	Published 202221066689	Dr. D. T. Gaikwad	9/12/2022
31.	Transdermal ethosome composition of lanazoline	Published 202121023742	Dr. A. A. Hajare	May, 2021
32.	Machine Learning Based Diagnosis of Chronic Kidney Disease In Diabetes Patients	Granted 2021107110	Dr. D. A. Bhagwat	Oct, 2021
33.	Artificial Intelligence Based Smart Touch Less Medicine Dispensing System For Pharma Field	Published 202141038793	Dr. D. A. Bhagwat	Aug, 2021
34.	Water Purifying and Flavor Infusion Devices	Published 347809-001	Dr. D. A. Bhagwat	Aug, 2021
35.	Machine Learning and Image Processing Based Smart Prediction of Human Emotions and Character	Published 202141035789	Dr. D. A. Bhagwat	Aug, 2021
36.	Microstrip Patch Antenna Based Detection of Breast Cancer using Microwave Breast Images Mishra	Published 202141035114	Dr. D. A. Bhagwat	Aug, 2021
37.	Eutectic mixture and process of preparing thereof	Published 202121023879	Dr. N. R. Jadhav, Mr. U. S. Patil	May, 2021
38.	Method for determining relationships between the properties of chemical compounds and biological activity	Published 202021026843	Dr. M. S. Bhatia	Nov. 2020
39.	Lyophilized myeloperoxidase from mammalian heart	Published 201921023861	Dr. Mrs. N. M. Bhatia, Dr. M. S. Bhatia	July 2019
40.	Myeloperoxidase bioassay kit	Published 201921023862	Dr. Mrs. N. M. Bhatia, Dr. M. S. Bhatia	July 2019
41.	Predictive computational model for selection of suitable grade of polymer for desired formulation property	Published 201921010545	Dr. M. S. Bhatia	Oct 2020
42.	Herbal Composition for Transdermal Delivery	Published 201721044914	Dr. D. T. Gaikwad,	21-06-2019

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