

**BHARATI VIDYAPEETH
COLLEGE OF PHARMACY, KOLHAPUR**

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Technical Articles

EXPLORATION OF NANOPHYTOCEUTICALS: GLOBAL NEED

Dr. Dinanath Gaikwad

Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Nature resources especially plants belong to one of the most diverse living kingdoms on earth and are represented by nearly 3,90,000 identified species. Plants produce a huge number (more than 30,000) of chemical compounds as secondary metabolites and many of them have their proven roles in the defense strategies against various pathogens and predators. Other than the direct therapeutic application against diseases, many of the plant parts are known for its disease prevention activity. The scientific literature of the 20th century showed many examples of such activity against many lifestyle diseases like diabetes, hypertension, cardiovascular diseases, kidney and liver diseases. Various plant products are available commercially to serve the purpose of nutrition and to improve the overall resistance against various diseases. In recent years, applications of nanotechnology in plant systems, such as phyto-nanotechnology, have received increasing attention. Phytoengineering deals with exploiting plants and green resources to provide solutions to various applications of science and engineering. Plant-mediated biological methods are being used by various researchers to synthesize nanoparticles of metals, metal oxides, and other materials with different size, shape, and quantity due to their easy availability and eco-friendliness. The appropriate application of nanoscience to plants and crops can provide improved outcomes and an exploration of their bioavailability and toxicity in the environment. These nanoparticles are explored for various applications as potent antimicrobial agents. They can be used as electrochemical sensors and biosensors, in medicine and health care (e.g., in vitro anticancer efficiency) and in agriculture and crop biotechnology. These nanoparticles can also be applied for pests, nutrients and plant hormones.

Nanoparticles possess unusual characteristics due to their large surface area-to-volume ratio and extraordinary catalytic activity, electronic properties, optical properties, and antimicrobial activity while they are constructed at the atomic level. Because physical and chemical methods of nanoparticle synthesis are too expensive and environmentally unsound, there is a better possibility of green synthesis of nanoparticles using plants, bacteria, and fungi, which are emerging as novel eco-friendly techniques. The growth rate of the bacterial culture, the extract of the plant secondary metabolites, and the mycelial surface area of fungus are the main comprehensible mechanisms in the green synthesis of nanoparticles. Nanofertilizers, nanopesticides, and nanoinsecticides are safe and hold a better possibility to be administered for the agricultural industry for increased food production as nutraceuticals. Phyto-nanotechnology has great potential to revolutionize agriculture and general plant sciences.

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Despite these promising perspectives, challenges are also pressing, including the impacts of diverse plant cellular structures on nanomaterial delivery and the induction of various levels of phytotoxicity to plants. Researchers have lot of opportunities in this growing area to meet the current Industrial requirements as Phytonanoparticles-based microbiological study, Phytonanoparticles drug delivery, Nanotoxicity-based studies (phytotoxicity, cytotoxicity, genotoxicity, and ecotoxicity) in plant sciences, Phytonanotechnology antioxidant activity, Nanomaterial-plant interactions, Nanofertilizers, Nanopesticides, Engineered phytonanomaterials: classification and strategies for physico-chemical characterization, Phytosynthesis of nano-scale materials, Advanced analytical techniques for the measurement of nanomaterials in plant samples,

Morphological responses of plants to nanoparticle exposure under different environmental factors, Nanoagrochemicals in plant production sector, Sensor nanotechnologies in plant sciences, Effect of nanoparticles on phytopathogens, Phytonanotechnology for sustainable agriculture etc.

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Technical Articles

MANOMETRIC TEMPERATURE MEASUREMENT: A PAT TOOL IN FREEZE DRYING

Dr. Ashok Hajare

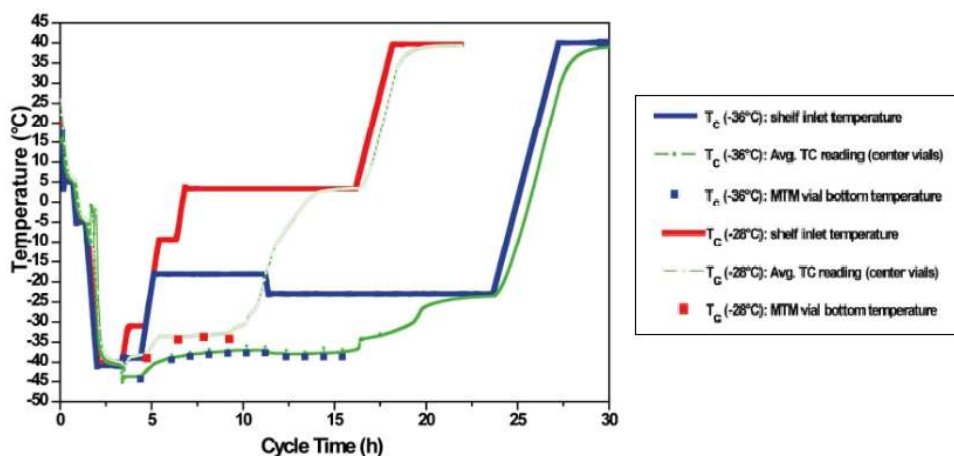
Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Over the period of time pharmaceutical manufacturers and FDA realized that testing quality in the final product slows down the pace of introducing life saving new drugs. During the past two decades the FDA has formulated an important new initiative that focused to modernization of pharmaceutical manufacturing and encouraging manufacturers to use Process Analytical Technology (PAT). The drug manufacturers who adopt advanced process monitoring and control techniques receive favourable treatment from FDA. In fact, PAT describes a method to measure quality and control in real-time the attributes that determines the quality and efficacy of a product. The key to PAT is application of a scientific approach and process understanding. PAT is used to establish a QbD approach for making a quality product that is verified in real time. Therefore, PAT control strategy is used to timely obtain a consistently high-quality product in a cost-effective way. Freeze drying (FD) is known to be a time consuming and expensive process. In order to lower costs during manufacturing, the effective cycle time must be reduced by optimizing a FD cycle at lab scale during the primary drying. It provides valuable information about product and process behaviour that may help to identify the critical process parameters (CPP) during cycle development and optimization.

The objective of a FD cycle optimization is to keep the product temperature close to the critical (collapse) temperature during primary drying to cut cycle time. The collapse temperatures can be determined by freeze-dry microscopy (FDM). In addition, there is increasing interest in evaluating the product resistance as a CPP. The traditional problem with product temperature determination is use of thermocouple in few selected vials. It is a standard methodology used to measure product temperature in FD. However, the presence of the sensors in the product changes the nucleation behaviour of the product in vials requiring less time at primary drying. This problem is has a significant effect at manufacturing scale. Additionally, sensors measure the product temperature at the bottom of the vial and not at the sublimation interface where collapse happen during the process. There is a temperature gradient between the product at the bottom and the sublimation interface in the order of 2°C or even higher. In addition, product vials in the front row are chosen that dry irregularly relative to the rest of the vials because they receive extra heat by radiation from the walls and the chamber door of the freeze dryer and therefore run warmer and take much less time to freeze dry.

The product temperature at the sublimation interface and product resistance is most CPPs during FD. PAT technology used during cycle development should be capable of measuring of these two important parameters.

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MTM Based SMART Freeze Drying Cycle Design

(Reference: Dr. Henning Gieseler, *European Pharmaceutical Review*, Jan 2007)

The upper boundary for product temperature is always dictated by the critical temperature (T_c) of the formulation and the optimization success of the process is linked to the robustness of the formulation. Therefore, PAT (defining the critical formulation parameters) must start at the beginning. In addition, clarification about acceptance criteria (degree of shrinkage of the cake structure and the associated negative effects on cake appearance, reconstitution times, stability of the drug, etc.) for the final product must be given.

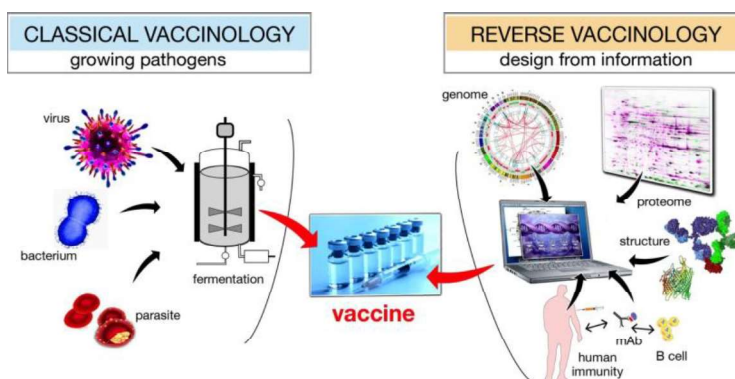
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REVERSE VACCINOLOGY: MODERN TRANSFORMATION IN VACCINE DEVELOPMENT

Mr. Rakesh P. Dhavale

Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Reverse vaccinology is an approach of development of vaccines by using entire pathogenic genomes and its screening for potential traits. The computational softwares are used to ascertain genes which indicate antigenicity and code for proteins with extracellular localization, signal peptides and B cell epitopes. Next, those genes are filtered for desirable attributes that would make good vaccine targets such as outer membrane proteins, synthesized and screened in animal models. In 2000, Rino Rappuoli and the J. Craig Venter Institute developed the first vaccine using Reverse Vaccinology against Serogroup B meningococcus. The J. Craig Venter Institute and others then continued work on vaccines for A Streptococcus, B Streptococcus, Staphylococcus aureus, and Streptococcus pneumoniae. The first successful developed vaccine using Reverse Vaccinology approach was Meningococcus B (MenB). Rappuoli and others at the J. Craig Venter Institute sequenced the MenB genome, scanned for potential antigens. 600 possible antigens were tested by expression in Escherichia coli. The antigens which proved to be functionally active and interacting with human immune system with further addition of lipopolysaccharide and adjuvants were found to be effective in adult humans. Later, Reverse Vaccinology was used to develop vaccines for antibiotic-resistant Staphylococcus aureus and Streptococcus pneumoniae. The advantage of this approach is finding vaccine targets quickly and efficiently. Traditional methods may take decades to unravel pathogens and antigens, diseases and immunity. However, in-silico can be very fast, allowing to identify new vaccines for testing in only a few years. The disadvantage is that only proteins can be targeted using this process. Conventional vaccinology approaches can find other biomolecular targets such as polysaccharides. Several softwares are used in this approach viz., NERVE, Vaxign, RANKPEP, PSSMs for epitope predictions, peptide bonding predictions and analyzing protein sequence and sequence alignment.



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Currently, Reverse vaccinology has caused an increased focus on pathogenic biology. However, this approach highlights many new concepts and technologies to facilitate vaccine design including contributions from proteomics, immunology, structural biology, systems biology, and mathematical modeling. Thus today, reverse vaccinology and innovations in antigen discovery has led to design of COVID-19 coronavirus vaccine. To know, SARS-CoV-2 coronavirus which is causative agent of COVID-19 was predicted for epitopes using Vaxign and Vaxign-ML which was absent in the other human coronaviruses. The entire proteome of SARS-CoV-2 was investigated to determine six proteins, including the S protein and five non-structural proteins (nsp3, 3CL-pro, and nsp8–10) were predicted to be adhesins, which are crucial to the viral adhering and host invasion. Thus, this approach has transformed designing of vaccine from conventional to modern vaccinology by virtue of computational approaches.

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Technical Articles

PHARMACEUTICAL SCIENCES IN LIGHT OF ARTIFICIAL INTELLIGENCE

Dr. Manish S. Bhatia

Vice Principal, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Pharmaceutical Sciences is a dynamic and interdisciplinary field that aims to integrate fundamental principles of organic, physical and biological chemistry along with mathematics and engineering, to understand how to design and develop drugs and optimize its delivery to the body and translate this integrated understanding into new and improved therapeutics for treating human disease. The interdisciplinary nature of this field itself makes the role of Artificial Intelligence (AI) all that more desirable and significant in achieving pharmacoeconomic outcomes. Though Artificial Intelligence is regarded as one of the promising digital transformation technologies which is evolving at a rapid pace, its usage in Pharma has been relatively slow. We have already entered a decade of machine learning and though the concept of integrating AI-assisted technologies seems far-fetched to some, the potential of its benefits is very real for the Pharma sector. Transforming drug and pharmaceutical product development process to make it commercially viable is the need of the hour and modern computing can make this possible. Artificial intelligence (AI) and machine learning (ML) tools would significantly help this transformation and the onus of spreading awareness about the same lies on the teaching community as well.

Though everyone unknowingly uses AI in some form or the other like AI-based Google searches, self-driving cars, facial recognition-based biometrics, virtual simulations and many more, its potential is yet to be fully explored in pharmaceutical industry and healthcare management. AI has transformed many industries and AI can be programmed to undertake a number of functions in the pharmaceutical and healthcare sector by utilizing appropriate type of programming for consequential capabilities. AI has a significant role to play right from the drug discovery process to product manufacturing, QA-QC and even in managing supplies and marketing.

Creation of new drugs involves leveraging millions of chemical, physical and biological data sets and in-depth analysis to generate exceptional outcomes leading to a drug like molecule and AI aids to speeds up every process in this drug discovery. Pharmacokinetics has been a critical component of drug development research and often the bottleneck in the process. By reducing human interface in the exploration of pharmacokinetics of drug products, time and expenses incurred on the process can be minimized. AI tools form the core of virtual simulations and molecular interactions for machine based pharmacokinetic and toxicity investigations. Single batch cost of production for certain new patented drugs is so high that the pharmaceutical industries are in the process of optimizing production with AI aided analytics. Various AI applications contribute to early identification of process degradation and to quality inspection optimization and thus make a dramatic impact on industries competitive advantage.

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AI has contributed immensely in the timely management of the current 'Novel Coronavirus Pandemic'. Right from diagnosis, disease surveillance, virtual healthcare assistants, information verification, intelligent robots and drones to finally the curative research for vaccine development and AI designed drug molecule for a definitive cure, all has been accelerated and aided by AI.

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UNDERSTANDING THE VARIANTS OF CORONAVIRUS: CURRENT INTERNATIONAL DEVELOPMENTS

Dr. Snehal Ashtekar

Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Viruses like SARS-CoV-2 continuously evolve as changes in the genetic code (genetic mutations) occur during replication of the genome. To inform local outbreak investigations and understand national trends, scientists compare genetic differences between viruses to identify variants and how they are related to each other.

This classification was based on the following aspects: Detection of cases attributed to coronavirus in multiple countries, including among those without travel history; The number and locations of substitutions in the spike protein; Available data for other variants with fewer substitutions in the spike protein that indicate a reduction in neutralization by sera from vaccinated or convalescent individuals; and Adata for other variants with fewer substitutions in the spike protein that indicate reduced susceptibility to certain monoclonal antibody treatments. The SIG Variant classification scheme defines four classes of SARS-CoV-2 variants:

Variant Being Monitored (VBM) so far:

- Alpha (B.1.1.7 and Q lineages)
- Beta (B.1.351 and descendent lineages)
- Gamma (P.1 and descendent lineages)
- Epsilon (B.1.427 and B.1.429)- Eta (B.1.525)
- Iota (B.1.526) - Kappa (B.1.617.1)
- Mu (B.1.621, B.1.621.1) Zeta (P.2)

Current knowledge about Omicron:

Transmissibility: It is not yet clear whether Omicron is more transmissible (e.g., more easily spread from person to person) compared to other variants, including Delta. The number of people testing positive has risen in areas of South Africa affected by this variant, but epidemiologic studies are underway to understand if it is because of Omicron or other factors.

Severity of disease: It is not yet clear whether infection with Omicron causes more severe disease compared to infections with other variants, including Delta. Preliminary data suggests that there are increasing rates of hospitalization in South Africa, but this may be due to increasing overall numbers of people becoming infected, rather than a result of specific infection with Omicron. There is currently no information to suggest that symptoms associated with Omicron are different from those from other variants.

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Effectiveness of vaccines: WHO is working with technical partners to understand the potential impact of this variant on our existing countermeasures, including vaccines. Vaccines remain critical to reducing severe disease and death, including against the dominant circulating variant, Delta. Current vaccines remain effective against severe disease and death.

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Technical Articles

IMPORTANCE OF QUALITY BY DESIGN (QBD) IN PHARMACEUTICAL INDUSTRY

Ms. Priyanka S. Yadav

Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Pharma industries are continuously working to find the ways to ensure and enhance product safety, quality and efficacy. However, product recalls, market complaints, manufacturing failure cost, scale up issues and regulatory burden presents challenge for industry. In the traditional way, the product quality and efficacy are predominantly ensured by end product testing, with limited understanding of the process and critical process parameters. Regulatory bodies are therefore focusing on implementing quality by design (QbD), a science-based approach that improves process understanding by reducing process variation and the enabling process-control strategies.

Quality by design is a concept first developed by the quality pioneer Dr. Joseph M. Juran. The US Food and Drug Administration (FDA) encourage risk-based approaches and the adoption of QbD principles in drug product development, manufacturing, and regulation. Over the years, pharmaceutical QbD has evolved with the issuance of ICH Q8 (R2) (Pharmaceutical Development), ICH Q9 (Quality Risk Management), and ICH Q10 (Pharmaceutical Quality System) (3–5). In addition, the ICH Q1WG on Q8, Q9, and Q10 Questions and Answers; the ICH Q8/Q9/Q10 Points to Consider document; and ICH Q11 (Development and Manufacture of Drug Substance) have been issued. It serves as a bridge between industry and drug regulatory authorities to move towards a scientific, risk based holistic and proactive approach for development of pharmaceutical product.

The goals of pharmaceutical QbD is to achieve product quality specifications, increase process capability and reduce product variability and defects by enhancing product and process design, understanding, and control, increase product development and manufacturing efficiencies, enhance root cause analysis and post-approval change management. After regulatory approval, effort should continue to improve the process to reduce product variability, defects, rejections, and recalls. In a pharmaceutical QbD approach to product development, an applicant identifies characteristics that are critical to quality from the patient's perspective, translates them into the drug product critical quality attributes (CQAs), and establishes the relationship between formulation/manufacturing variables and CQAs to consistently deliver a drug product with such CQAs to the patient. The QbD does not equal to the design of experiments (DoE), but the important component of QbD. The key elements of pharmaceutical QbD can include the Quality target product profile (QTPP), product design and understanding, process design and understanding, and scale up, control strategy, and continual improvement.

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Prior knowledge, risk assessment, DoE, and Process Analytical Technology (PAT) are tools to facilitate QbD implementation. Finally, product and process capability is assessed and continually improved post-approval during product lifecycle management. This approach allows the establishment of priorities and flexible boundaries in the process. As such QbD is becoming a promising scientific tool in quality assurance in pharmaceutical industry.

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SYNTHESIS OF NOVEL ANTI-INFLAMMATORY BENZAMIDE DERIVATIVES UTILIZING SMILES REARRANGEMENTS

Smt. Swapnali Ashok Thorat

Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Chronic inflammatory disease is a medical disorder characterized by chronic inflammation, described primarily by new connective tissue formation as a prolonged and persistent pro-inflammatory state. The local response of living mammalian tissues to injury due to any agent is known as inflammation. In order to suppress or restrict the spread of injurious agents, it is a body defense reaction, accompanied by the removal of necrosis cells and tissues. In addition, to treat mild to severe pain, this class of medications is commonly used. There are restrictions on medicinal usage for most commonly used non-steroidal anti-inflammatory drugs (NSAIDs) since they cause gastrointestinal and renal side effects that are inseparable from their pharmacological activities. As potential donor ligands of transition metal ions, compounds containing carbonyl and benzamide groups occupy a significant role among organic reagents. Among these thiourea derivatives are ligands that are potentially very versatile. Thiourea derivatives oxygen, nitrogen and sulphur donor atoms give a range of bonding possibilities. A wide variety of biological activity is demonstrated by both the ligands and their metal complexes, including anti-inflammatory.

Currently, NSAIDs (Non-steroidal anti-inflammatory drugs) for example Aceclofenac, diclofenac, etc. are prescribed for previously mention medical conditions to relief from pain. However, the effect of these synthetic analogues is short-term and these 25 drugs are known to cause many side effects include serious problems like thrombosis which can be life threatening. And the carbamothioyl derivatives resist bacterial growth and cell division. Benzamide is the powerful anti-inflammatory agents used for many years to treat or prevent systemic inflammatory infections. Benzamide was synthesized and tested for anti-inflammatory sensitivity tests. Thus benzamide derivatives were further studied in the Insilco-pharmacology analysis for the synthesis by docking process where the novel thiourea ligands were docked on the receptor. In order to investigate their anti-inflammatory function, benzamide derivatives carrying urea, amide, and sulphonamide groups. Via spectral characterization using IR, NMR, and Mass, all compounds will confirm. By synthesizing the sequence of benzamide derivatives were planned and synthesized by Smiles rearrangement mechanism to develop a potential anti-inflammatory drug. Synthesized compounds have been docked with lipoxigen-3 soybean anti-inflammatory activity complex receptors.

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CARBON NANOHORNS

Mrs. Pradnya K. Mane

Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Carbon (C) Nanohorns, Single-Walled, Double Walled and Multi-Walled, are black nano scale cylindrical tubes of graphitic carbon which differ from nanotubes in their "horn-like" shape similar to a sewing thimble giving them numerous applications as both the stiffest and strongest known fibers and because of their unique shape gives them an enormous amount of surface area. Individual conical structures are typically 2–5 nm in diameter and 40–50 nm in length. During their synthesis, they tend to form about 2000 cone aggregates of approximately 100 nm diameter. They have a number of advantages over the use of carbon nanotubes-extensively utilized carbon-based structures for drug delivery such as the absence of potentially toxic metals as catalysts during the synthesis, unnecessary additional treatment with strong acids that can damage the carbon structure, and the capacity for high yield mass production at room temperature. Its discovery, multiple synthesis approaches have been developed. All methods are based on applying energy to disassemble and reorganize carbon structures, which are usually graphite rods. The different working parameters modulated during the synthesis, such as voltage, intensity, pressure and temperature can result in different SWCNH structures with different morphology, size or purity.

Three different types of nanoaggregates have been described in particular: dahlia-like, bud-like, and seed-like SWCNH. CO₂ laser ablation was the first synthetic method used for the discovery and development of SWCNH. This high-yield synthesis procedure modifies graphite targets, without any metal catalyst, producing up to 1 kg SWCNHs per day with 95% purity. Since then, it has been one of the most exploited strategies for its production. Arc-discharge has also been proposed for their relatively low-cost synthesis. An electrical discharge is emitted between two electrodes subjected to a difference in potential and placed in a gaseous atmosphere. The electric arc may be formed under air, CO or CO₂ atmospheric pressure. This technique offers the possibility to obtain purity values higher than 90%. Arc-discharge can also be performed between two graphite electrodes immersed in liquid nitrogen, resulting in a very economical alternative to the classical method. Finally, the use of reactors where graphite rings are heated by the induction of high frequency eddy currents has also been proven as a powerful and useful strategy for large-scale production of SWCNH. In general terms, CO₂ laser ablation and arc-discharge have been the most used methods since the discovery of SWCNH for its development.

SWCNHs have several interesting features that have been exploited for a multitude of applications. SWCNH display a porous structure with a very high adsorption capacity. Controlled oxidation treatments can produce nano windows within SWCNH tips and lateral walls. For this reason, they have been proposed for gas storage and gas sensing applications, such as N₂ and H₂.

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These structure windows due to oxidation can also be formed as a previous step for chemical functionalization, and then include various functional groups for other applications. The large and tuneable surface area of SWCNH, together with the great capacity for heat and electrons transport, also makes them interesting for both conversion and energy storage applications. They have also been employed in the field of electronics due to their cone structure and electric features. Several studies have revealed that SWCNH present structural defects in the tips of individual nanohorns, with a series of heptagons instead of pentagons that form the two-dimensional graphene sheets. These defects are essential to exhibit their special electronic and magnetic characteristics. Hence, they have been used for the development of electrodes and super capacitors, fuel cells, and catalyst supports. Versatile surface chemical functionalization of SWCNH has also been exploited to develop new biomedical and pharmacological strategies in recent years.

The immune response triggered by carbon nanotube-like structures could be harnessed to help treat infectious diseases and cancers, say researchers. The way tiny structures like nanotubes can trigger sometimes severe immune reactions has troubled researchers trying to use them as vehicles to deliver drugs inside the body in a targeted way. White blood cells can efficiently detect and capture nano structures; so much research is focused on allowing nanotubes and similar structures to pass unmolested in the body. A research team is planning to use nanohorns, a cone-shaped variety of carbon nanotubes, to deliberately provoke the immune system. They think that the usually unwelcome immune response could kick-start the body into fighting a disease or cancer more effectively.

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GASTRORETENTIVE DRUG DELIVERY SYSTEM: AN OVERVIEW

Dr. Anilkumar J. Shinde

Associate Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Several approaches have been proposed to retain the dosage forms in the stomach. These methods include bioadhesive system, swelling system and expanding system and floating system. In fact the buoyant dosage unit enhances gastric residence time (GRT) without affecting the intrinsic rate of emptying. Unfortunately floating devices administered in a single unit form Hydrodynamically balanced system (HBS) are unreliable in prolonging the GRT owing to their 'all- or- nothing' emptying process and, thus they may cause high variability in bioavailability and local irritation due to large amount of drug delivered at a particular site of gastrointestinal tract.

Requirements For Gastric Retention:

Physiological factors in the stomach, it must be noted that, to achieve gastric retention, the dosage form must satisfy certain requirements. One of the key issues is that the dosage form must be able to withstand the forces caused by peristaltic waves in the stomach and the constant contractions and grinding and churning mechanisms. To function as a gastric retention device, it must resist premature gastric emptying. Furthermore, once its purpose has been served, the device should be removed from the stomach with ease.

Need For Gastro Retention:

- Drugs that are absorbed from the proximal part of the gastrointestinal tract (GIT).
- Drugs that are less soluble or are degraded by the alkaline pH they encounters at the lower part of GIT.
- Drugs that are absorbed due to variable gastric emptying time.
- Local or sustained drug delivery to the stomach and proximal Small intestine to treat certain conditions.
- Particularly useful for the treatment of peptic ulcers caused by H. Pylori Infections.

Factors Affecting Gastric Retention:

- Density: GRT is a function of dosage form buoyancy that is dependent on the density.
- Size: Dosage form units with a diameter of more than 7.5mm are reported to have an increased GRT compared with those with a diameter of 9.9mm.
- Shape of dosage form: Tetrahedron and ring shaped devices with a flexural modulus of 48 and 22.5 kilo pounds per square inch (KSI) are reported to have better GRT 90% to 100% retention at 24 hours compared with other shapes.

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- Single or multiple unit formulation: Multiple unit formulations show a more Predictable release profile and insignificant impairing of performance due to failure of units, allow co- administration of units with different release profiles or containing incompatible substances and permit a larger margin of safety against dosage form failure compared with single unit dosage forms.
- Fed or unfed state: under fasting conditions: GI motility is characterized by periods of strong motor activity or the migrating myoelectric complex (MMC) that occurs every 1.5 to 2 hours. The MMC sweeps undigested material from the stomach and, if the timing of administration of the formulation coincides with that of the MMC, the GRT of the unit can be expected to be very short. However, in the fed state, MMC is delayed and GRT is considerably longer.
- Nature of meal: feeding of indigestible polymers or fatty acid salts can change the motility pattern of the stomach to a fed state, thus decreasing the gastric emptying rate and prolonging drug release.
- Caloric content: GRT can be increased by 4 to 10 hours with a meal that is high in proteins and fats.
- Frequency of feed: the GRT can increase by over 400 minutes, when successive meals are given compared with a single meal due to the low frequency of MMC.
- Gender: Mean ambulatory GRT in males (3.4 ± 0.6 hours) is less compared with their age and race matched female counterparts (4.6 ± 1.2 hours), regardless of the weight, height and body surface.
- Age: Elderly people, especially those over 70, have a significantly longer GRT.
- Posture: GRT can vary between supine and upright ambulatory states of the patient.
- Concomitant drug administration: Anticholinergics like atropine and propantheline, opiates like codeine and prokinetic agents like metoclopramide and cisapride.
- Biological factors: Diabetes and Crohn's disease.

Different Techniques of Gastric Retention:

Various techniques were used to encourage gastric retention of an oral dosage form. Floating systems have low bulk density, so that they can float on the gastric juice in the stomach. 2–4 The problem arises when the stomach is completely emptied of gastric fluid. In such a situation, there is nothing to float on. Different techniques used for gastric retention mentioned below.

- Hydrodynamically balanced systems (HBS):
- Effervescent systems:
- Low-density systems:
- Raft systems incorporate alginate gels:
- Bioadhesive or mucoadhesive systems:

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Evaluation of Gastroretentive Dosage Forms:

Evaluation for gastroretention is carried out by means of X-ray or gamma scintigraphic monitoring of the dosage form transit in the GI tract. The modern technique of gamma scintigraphy now makes it possible to follow the transit behaviour of dosage forms in human volunteers in a non-invasive manner.

Conclusions:

In the field of gastric retention, we have seen that there are many obstacles that need to be overcome in order to be able to claim true gastric retention. Considering the advantages for improved delivery of drugs, some companies have undertaken the considerable task of developing these types of devices, some with success and others with failure due to the unpredictability of the human GI tract. However, we are as close as we have ever been to seeing a greater transition of gastric retention devices from developmental level to the manufacturing and commercial stage.

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DRUG REPURPOSING FOR COVID-19: OPPORTUNITIES AND CHALLENGES

Dr. D. A. Bhagwat

Assistant Professor, Dept. of Pharmaceutics & Head, Diploma Pharmacy, Bharati Vidyapeeth College of Pharmacy, Kolhapur

Drug repurposing is the process to identify the new indications for existing drugs and considered as an efficient and economical approach. It is also known as repositioning, re-profiling, re-tasking and rescue of drugs. It has been considered that 75% of known drugs could be repositioned for various diseases.^{1, 2} In future, chloroquine and hydroxychloroquine require a large number of research studies to reach a conclusion for its use in COVID-19 patients. Further, ACEIs and ARBs could be the potential supportive therapy against this infection. Some drugs are in the early phase of investigation like ivermectin and auranofin to be used against the COVID-19 and these agents could be potential therapeutic agents in future. Molecular docking would be the central technique to identify the probable therapeutic agents against COVID-19 patients and the screened agents, thereby, could be verified for their effectiveness in in-vitro and in-vivo studies.³

Advantages of drug repurposing:⁴

- Reduced risk of failure as safety and dosing profile typically well established
- Product manufacturing and supply chains already available
- Patients are often more willing to take part in clinical trials due to the appeal of the 'known' factor
- Faster development times and reduced costs

Potential challenges:⁴

- May need to fill in the gaps on safety, exposure & preclinical data on the mechanism of action
- Identifying the optimal drug & formulation
- Feasibility of clinical trials given unlicensed/off-label access
- Existing intellectual property (IP)/patents on product

The value of drug repurposing is to speed up the traditional process of drug discovery by identifying a novel clinical use for drugs that have already proven to be safe and effective in humans and are approved for other indications. This strategy can also reduce the costs required for the development of new drugs, with notable savings in preclinical phase I and II. Repurposing has several implications in the drug regulatory setting as well as in the scientific setting, especially if it occurs during a public health emergency such as the COVID-19 pandemic.⁵

Technical Articles

Although drug repurposing has the potential to decrease the time usually required for a drug to reach the market, it is a process that is still associated with many challenges, whether from a regulatory or a scientific perspective. Close collaboration between various stakeholders is needed to leverage and critically evaluate existing evidence and strategically plan the generation of new pre-clinical, clinical and observational evidence to investigate the efficacy/effectiveness and safety of drug for potential repurposing.⁶

Computational approaches make use of machine learning and algorithms to model disease and drug interaction, while experimental approaches involve more traditional wet-lab experiments. This review would discuss in detail various ongoing drug repurposing strategies and approaches to combat the current COVID-19 pandemic, along with the advantages and the potential challenges.⁷

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New Drug Approvals in India

2020

Name of Drug	Structure	Indications
Cidofovir dihydrate		CMV retinitis in adults with acquired immune deficiency syndrome (AIDS)
Dacomitinib		Metastatic non-small cell lung cancer
Alpelisib		Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer
Isavuconazolesulfate		Invasive Aspergillosis and Invasive Mucormycosis
Azelidipine		Stage I hypertension

New Drug Approvals in India 2020

Name of Drug	Structure	Indications
Riboflavin Ophthalmic Solution		Keratoconus and corneal ecstasia
Pixantrone		Multiply relapsed or refractory aggressive Non-Hodgkins B- Cell Lymphomas (NHL)
FDC of Bilastine 20mg and Montelukast 10mg tablets		Allergic rhinitis in adults
Obeticholic acid		Primary biliary cholangitis
Favipiravir		Mild to moderate Covid-19 disease
Pretomanid		Pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrugresistant (MDR) tuberculosis (TB)

New Drug Approvals in India 2020

Name of Drug	Structure	Indications
Netarsudil mesylate		Reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension
Risdiplam powder		Spinal muscular atrophy (sma)
FDC of Azelnidipine 8mg and Telmisartan 40mg		Treatment of Stage-II hypertension

Source: https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/

Patents from College

Sr. No.	Title	Patent Application Number	Status	Name of the Inventor/s	Month & Year
01	Method for determining relationships between the properties of chemical compounds and biological activity	202021026843	Filed	Dr Ajit S. Kulkarni, Dr Vinod L. Gaikwad, Dr Manish S Bhatia and Mr Amit J Kasabe	Nov. 2020
02	Transdermal ethosome composition of lanozoline	202121023742	Filed	Hemlata S. Dol, Ashok A. Hajare , Trupti A. Powar, Kiran S. Patil	May, 2021
03	Machine Learning Based Diagnosis Of Chronic Kidney Disease In Diabetes Patients	2021107110	Granted	Dr.Pokkunuri Pardha Saradhi, Dr.Raghava Yathiraju, Sreedevi S., Dr. Usha Bhanu.N, Chitransh Dixit, Pankaj Sahu, Rakesh Patel, Dr Binod Kumar, Dr Anil Maheshwari, Dr. Durgacharan Arun Bhagwat , Saravanakumar C, Dr. S. Pothalaiah	Oct. 2021
04	Artificial Intelligence Based Smart Touch Less Medicine Dispensing System For Pharma Field	202141038793	Published	Mr. A. Kumaraswamy, Bhaskar Kapoor, Dr.Sumanth V., Nalini Kanta Sahoo, Dr. Chinmaya Keshari Sahoo, Dr. Banavath Heeralal, Dr. Sujata Mallapur, Dr. Jagadeesh Kumar Ega, Dr. Durgacharan Arun Bhagwat , Dr. Rahul Shivaji Adnaik, Pratibha Rahul Adnaik, V Gopu	Aug. 2021

Patents from College

Sr. No.	Title	Patent Application Number	Status	Name of the Inventor/s	Month & Year
05	Water Purifying and Flavor Infusion Devices	347809-001	Published and Queries addressed	V.Vandhana Devi, A. Sreenivasulu, R.S. Shinde, Durgacharan Arun Bhagwat	Aug. 2021
06	Machine Learning and Image Processing Based Smart Prediction of Human Emotions and Character	202141035789	Published	Durgacharan Arun Bhagwat , Jagadish R M., S. Violet Beaulah, Siddappaji .M. R., Arulkumar N., Bharath V G., P. Sudarsanam, Dr. K. Maheswaran, Appasami G., Sushma Jaiswal, Chetan Nagar, Minimol R.	Aug. 2021
07	Microstrip Patch Antenna Based Detection of Breast Cancer using Microwave Breast Images	202141035114	Published	Mittal, R. R. Rath, S. Ayub, Durgacharan Arun Bhagwat , Rahul GD, P. Jayaraman, D. Marotkar, K. Karthikayani, KB Maruthiram, S. Praveena, P. Kuchhal, R. Mishra	Aug. 2021
08	Analytical method for beta-secretase estimation from biological fluids	201721033863	Published and Queries addressed	Gaurav Gangadhar Gadgil, Manish Sudesh Bhatia, Rakesh Pandit Dhavale	Aug. 2021
09	Eutectic mixture and process of preparing thereof	202121023879	Filed	Namdeo Jadhav, Udaykumar Patil , Kranti Bille, Jidnyasa Pantwalawalkar	May. 2021

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3. Assessment of Structural Compatibility of Saxagliptin in Physical Mixtures with some excipient by Using HPLC Current Pharmaceutical Analysis, 1074-1082 2020
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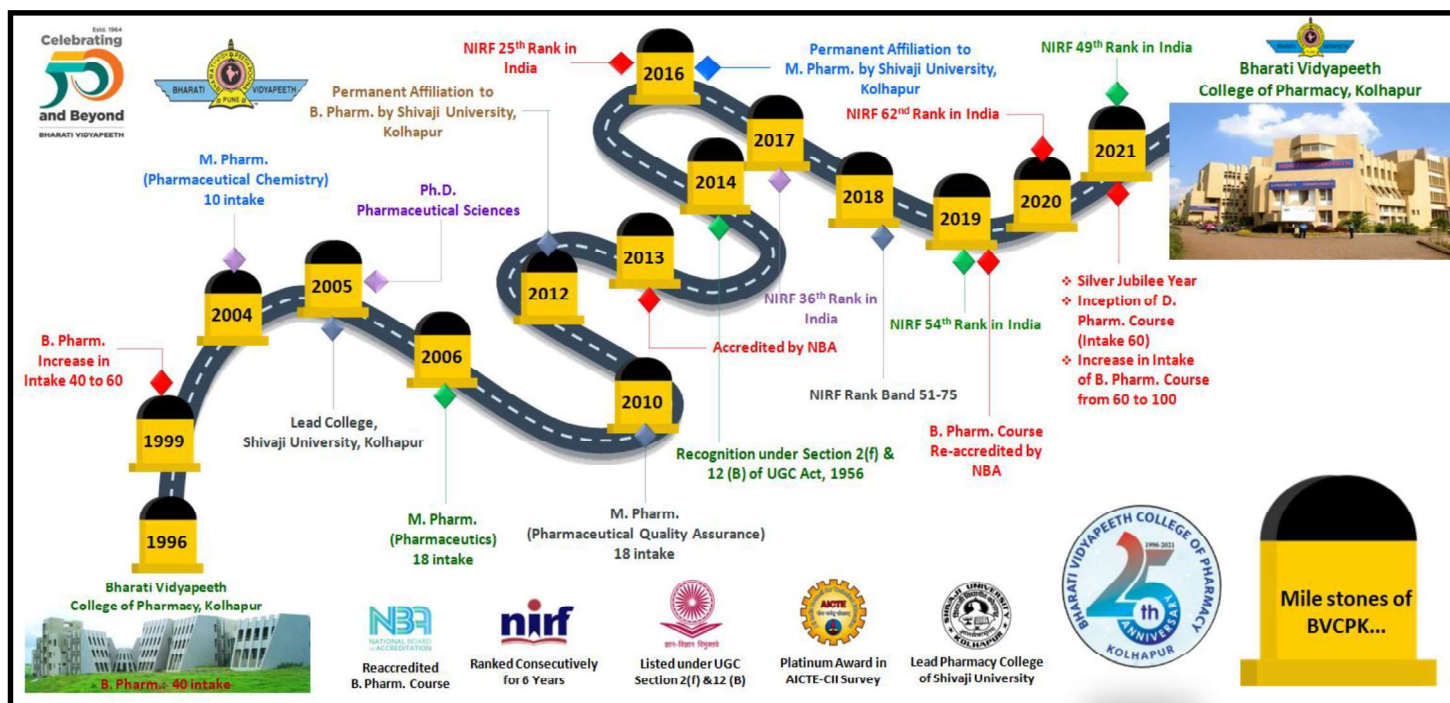
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Near Citranagari, Morewadi, Kolhapur. M.S. India. Pin: 416 013
 Phone: +91-231-2637286, Fax: +91-231-2638833
 E-mail: copkolhapur@bharatividyaapeeth.edu
 Website: copkolhapur.bharatividyaapeeth.edu