



Technical Magazine 2021-22

COLLEGE OF PHARMACY, KOLHAPUR

Near Chitrangari, Kolhapur-416013, MS. India



BVCPK TechMag

Technical Magazine 2021-22



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mRNA DELIVERY BASED ON NANOTECHNOLOGY

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The successful development of COVID-19 vaccines utilizing mRNA technology in recent years demonstrates the enormous promise of this revolutionary approach. Remarkable progress has been made in mRNA technology. There is a surge of attention in mRNA therapeutics, in addition to preventative mRNA vaccines for infectious illnesses and therapeutic mRNA vaccines for cancer. Additionally, the first possible "secreted protein" mRNA therapy was progressed into phase I trials in 2016 with the goal of delivering vascular endothelial growth factor A (VEGF-A) to cause regenerative angiogenesis in cardiovascular disease patients (NCT02935712) (Mullard, A. mRNA-based drug approaches phase I milestone). Therapy justification for individuals with ischemic heart disease, VEGF-A has long been recognized as a possible vascular and proliferative regenerative therapeutic. mRNA is significantly more effective than DNA because it can do it in the cytoplasm without going via the nucleus and initiating protein translation. Furthermore, the protein that mRNA encodes will only be made temporarily and won't be integrated into the genome. In this method, there is no risk of gene integration.

The mRNA synthesis method is simpler and less expensive than the production of proteins and viruses, making it straightforward to advance to industrial production. Since mRNA is large (104 - 106 Da) and negatively charged, very unstable, and will be absorbed by cells of the innate immune system or destroyed by nucleases. The presence of extracellular exonucleases in the target tissues, ineffective cell uptake, or failed endosomal release, however, might restrict mRNA distribution. An mRNA nano delivery technique that transfects immune cells without toxicity or undesirable immunogenicity is needed for in vivo application. Fortunately, a number of unique materials-based treatments have been developed as a result of this.

The scope of its potential applications is expanding as mRNA modifications and delivery technologies. Lipid nanoparticles (LNPs), liposomes, lipid complexes, polymer materials, micelles, polypeptides, protamine, electroporation, and others are being employed as common nano delivery techniques.



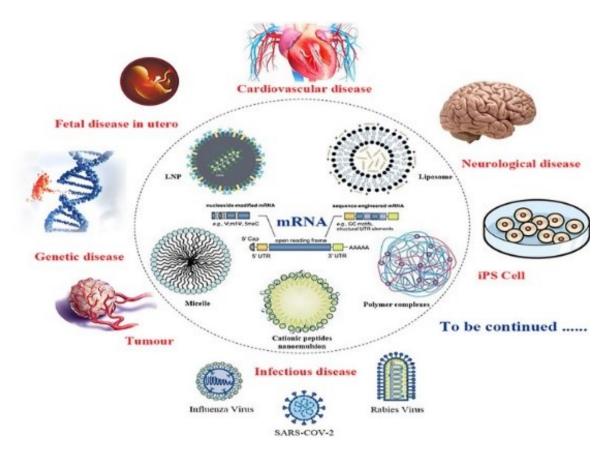


Fig.1: Nano-delivery system for mRNA and its applications

One of the most promising mRNA delivery methods uses LNPs and liposomes. Hence, the potential of random integration into the host genome with plasmid DNA, the targeted delivery of mRNA is a superior option.

Reference: Li M, Li Y, Li S, Jia, et al., The nano delivery systems and applications of mRNA. Eur J Med Chem. 2022; 227:113910.

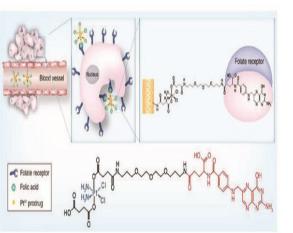


CARBON NANOTUBES IN CANCER DIAGNOSTICS AND THERAPEUTICS

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One of the nanomaterials that have seen significant use in recent years is carbon nanotubes (CNTs). They are receiving more and more attention due to their special qualities. In biological applications, CNTs are more dynamic than other nanomaterials, and they rank among the most intriguing nanocarriers in research. As innovative delivery mechanisms, CNTs have shown a clear possibility of overcoming biological barriers. In contrast to quantum dots, which have mostly been used in cancer cell imaging, CNTs can be used for thermal ablation and drug delivery. They can enter cells, and this action is unaffected by the surface functional group and cell type. As of right now, the precise methods of internalization (endocytosis or needle-like penetration) are still not fully understood. Because of the enormous surface area of CNTs, several molecular attachment sites are possible, allowing for polyvalent derivatization.



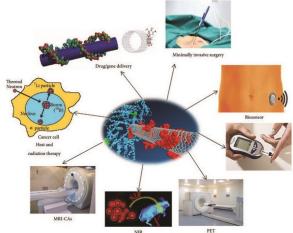


Fig: Biomedical applications of functionalized CNTs and Folate-mediated cancer targeting using single-walled carbon nanotubes conjugated with platinum-containing anticancer drug and its subsequent endocytosis

In addition, a range of chemically functionalized CNTs have the capacity for biocompatibility with the biological environment, according to the in vitro and in vivo results attained by various research groups.



These findings highlighted the importance of carefully controlling the level and kind of functionalization in vivo to control the behavior of this material. A high interfacial area with cellular membrane and the unusual ability to accommodate various functionalization's are some characteristics that CNTs possess.

Reference: Shun-rong Ji, et.al., Carbon nanotubes in cancer diagnosis and therapy, Biochimica et Biophysica Acta (BBA) - Reviews on Cancer, 2010, 1806 (1), 29-35.



IN-SILICO APPROACH IN DEVELOPMENT OF MODERN VACCINE: A NEW THERAPEUTIC AVENUE

Mr. Rakesh P. Dhavale

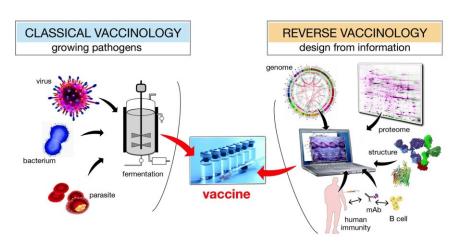
Assistant Professor, Bharati Vidyapeeth College of Pharmacy, Kolhapur

In-silico approach, alternatively named as "Reverse vaccinology" is an approach of development of vaccines 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.

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.

References: Rino Rappuoli, Reverse vaccinology, Curr. Opin. Microbiol. 2000, 3:445–450



PHARMACEUTICAL COCRYSTALS: OPPORTUNITIES AND CHALLENGES

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Although, advancement in drug discovery process lead to discovery of innumerable active pharmaceutical agents; many of them exhibit poor solubility and thus low bioavailability becomes apparent which consequently compromises therapeutic benefits of drugs. Recently, cocystallization has gained tremendous attraction from scientific fraternity owing to its uniqueness to modulate physicochemical and biopharmaceutical features without affecting pharmacological effect of API. Cocrystal; a multicomponent system incorporates two constituents i.e. drug and a coformer in a specific stoichiometric ratio by non-covalent bonding. If both these components are drugs, the system is called as 'drug-drug cocrystal' which can lead to synergistic effect thus demonstrates its potential in treatment of complex diseases like cancer, infectious diseases, diabetes etc. Interestingly, the conjugate may extend its therapeutic application in treatment of new diseases. This novel low risk and high reward approach offers numerous simple, cost-effective and green methods to overcome these major constraints. Now-a-days several cocrystals are available in market considering their superiority in many aspects like solubility, tablettability, permeability, stability, bioavailability etc.

Despite of numerous advantages, certain challenges make adoption of cocystallization approach a bit critical. Amongst them, selection of appropriate coformer is a key challenge accounting compatibility, differential solubility, molecular interactions etc. Also, dose of drug in cocrystals might differ from oral dose due to fixed stoichiometric ratio which limits its clinical application. But, many aspects of cocrystallization are yet to explore.

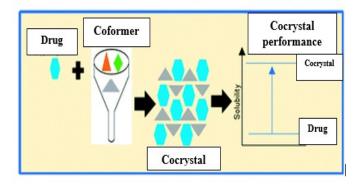


Fig: Flow of preparation of Co-crystal formation



Discovering and optimizing such features can help to overcome these challenges. Some of them include selection of suitable co-crystallization method as it influences morphology and characteristics of cocrystals. Additionally, two components can form cocrystals at more than one stoichiometric ratio. By assessing various ratios, dosage problem can be managed. In future, drug-nutraceutical cocrystal can be a novel strategy for researchers to explore.

References: Makadia, J. et.al., Artemisinin–acetylenedicarboxylic acid cocrystal: screening, structure determination, and physicochemical property characterization, Cryst. Eng. Comm, 2022, 24, 1056-1067.

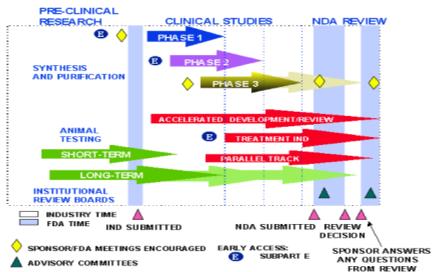


THE NEW DRUG DEVELOPMENT PROCESS: STEPS FROM TEST TUBE TO NEW DRUG APPLICATION REVIEW

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The Center for Drug Evaluation and Research (CDER) of the FDA is charged with ensuring that consumers have access to safe and efficient medications. This section contains some ideas and interactive charts that offer fundamental knowledge for small businesses and other people who are not familiar with the process of developing and approving new drugs. Access to the world's safest and most cutting-edge pharmaceutical system benefits American consumers. In this structure, CDER serves as the primary consumer watchdog. The center's most well-known function is testing new medications before they may be commercialized. In addition to preventing quackery, the center's review gives clinicians and patients the knowledge they need to utilize medications responsibly. Drugs, including brand-name and generic, must function properly and have health benefits that outweigh their known hazards, according to CDER. A medicine must undergo testing before a pharmaceutical company may sell it in the US. In order to demonstrate that the drug is both safe and effective for its intended purpose, the manufacturer subsequently provides CDER the results of these testing. A group of scientists from the CDER, including statisticians, chemists, pharmacologists, and physicians, evaluate the company's data and suggested labeling.





A medicine is authorized for sale if this impartial and unbiased examination determines that the health benefits outweigh the known hazards. Although the institute doesn't directly test pharmaceuticals, it undertakes some research on criteria for drug quality, safety, and effectiveness. The drug firm or sponsor conducts laboratory and animal experiments before a drug may be tested on humans to determine how the medicine functions and if it is likely to be safe and effective in humans. Then, a series of experiments on humans are started to see if the medication is safe when used to treat an illness and if it improves health.

Reference: fda.gov/drugs/cder-small-business-industry-assistance-sbia/new-drug-development-and-review-process

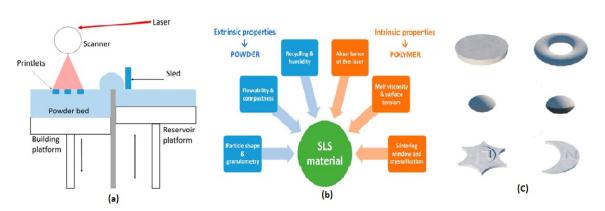


SELECTIVE LASER SINTERING (SLS), MODERN TECHNOLOGY FOR THE PRODUCTION OF SOLID ORAL DOSAGE FORMS (SOF'S) BY 3D PRINTING

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Currently, large pharmaceutical corporations generate the bulk of solid dosage forms; their approach is to produce such dosage forms which will be "one-size-fits-all". This approach is restrictive because not every patient will react similarly to the medicine. Intrinsic factors such as age, sex, and genetics as well as extrinsic factors such as environment are involved in both i.e., clinical diagnosis and pharmacological response. This is where "Personalized medicine" comes as an emerging approach to disease treatment. The main problem behind personalized medicine is it can't be produced on a large scale so industrial machines are not useful hence, 3D printing technology might be useful to produce personalized medicines based on the specific need of the patient. This technology allows the production of dosage forms of different sizes and shapes according to the design. Currently, the only pharmaceutical specialty produced by 3D printing and approved by FDA is Spritam® (Levetiracetam)., There are Different 3D printing techniques Such as binder and material jetting, fused deposition modelling (FDM), Semisolid extrusion (SSE). stereolithography (SLA), and selective laser sintering (SLS). This technology allows the production of dosage forms of different sizes and shapes according to the design.



- (a) Schema of SLS printer (b) Properties for printability of (C) Different designs of polymeric powder
- dosage forms produced by SLS technology



SLS is classified under the Powder Bed Fusion category. It includes building objects by necking powder particles using the energy provided by a laser. SLS Methods provide many benefits such as high resolution, the possibility of recycling the powder and the absence of pre-processing. The materials used for this it should be pharmaceutical-grade powders but, these materials should be printable and remain stable during the printing process. The SLS printers are equipped with a blue diode laser (445-450 nm) and some of them used the Sintratec kit. The templates of printlets were all designed using CAD software, then saved as STL files before transferring them, to the 3D printer Software. In the first stage, the powder is fed into the reservoir platform the distributed by a sled all over the building area to create a flat layer.

Prior to sintering, the printer needs to be heated to warm the powder. Printing will start by activation of the blue diode laser which scans the powder bed in a specific pattern along the X and Y-axis. Powder particles are fused partially or completely together depending on the amount of transmitted energy. After this, the printing bed is lowered, and another layer of powder is deposited over the previously sintered layer allowing the building of the object along the Z-axis. These steps are repeated until the finalization of the object at the end, the printed dosage form is removed from the build platform and then brushed off their excess powder. This is how selective laser Sintering (SLS) by 3D printing works.

Reference: Gueche Y. A. et al., A New Chapter in the Production of Solid Oral Forms (SOFs) by 3D Printing. Pharmaceutics. 2021, 13(8); 1212.



SAFETY PHARMACOLOGY- SAFE PROGRESSION OF NEW DRUGS

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A significant number of drugs withdrawn from the market were due to severe CNS adverse effects between 1960 and 1999 (Hamdam et al., 2013). Several non-cardiovascular drugs were withdrawn due to proarrhythmic effects in a large portion of the population. Detecting these adverse effects early in the drug discovery process is therefore imperative for pharmaceutical companies to save money and time. ICH (International Committee for Harmonization) has therefore established ICH S7A and S7B guidelines to identify the adverse effects of a new chemical entity prior to clinical trials.

ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner (ICH organisation), for that; ICH has produced a set of guidelines which help to maintain high quality as well as the safety of the new compound. Among these guidelines, safety pharmacology studies are the part of non-clinical pharmacology studies which must carry out to become drug from the new chemical entity.

The non-clinical pharmacological study is a part of the drug development process to survey safety, pharmacokinetic and toxicokinetic characteristics of therapeutic substances. Non-Clinical Studies include safety pharmacology, pharmacokinetics, pharmacodynamics, general toxicology, local tolerance, genotoxicity, carcinogenicity and reproductive toxicology.

Safety pharmacology is a discipline that aims to provide an integrated assessment of data that relate to risks associated with the medicinal use of a new chemical entity (Goineau et al, 2013). The adverse effect of the new compound on core battery systems, i.e. central and peripheral nervous system, cardiovascular system and respiratory system is evaluated before first in human (FiH) administration.

The detection of undesirable effects of test compound on the physiological function of many vital organ systems was not possible by the conventional preclinical toxicity testing methods conducted at the time. Preclinical toxicology testing involved the determination of the high-dose adverse event profile of a compound given at chronic, toxic doses, but would not have detected a rare lethal event liability at therapeutic dosage.



In response to this, within 4 years, Safety Pharmacology had evolved into an industry department-based discipline designed to bridge the gap between preclinical toxicology and (preclinical and clinical) drug development (Bass et al, 2015).

ICH S7A and S7B guidelines describe the various possible adverse effects of new chemical entities on the central and peripheral nervous system, cardiovascular system, and respiratory system. These studies are mainly carried out before the administration of a drug to the patient in the clinical trial (Ewart et al, 2013). This set of guidelines must be followed by all pharmaceutical companies prior to advancing a new chemical entity into clinical development.

References: Hamdam, J., et.al., Safety pharmacology - Current and emerging concepts. Toxicology and Applied Pharmacology, 2013, 273(2), 229–241.



CONTINUOUS GLUCOSE MONITORING SYSTEM FOR DIABETES: A CLINICAL UTILITY

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Continuous Glucose Monitor (CGM) is an FDA-approved system that tracks our blood sugar levels day and night. It collects readings automatically every 5 to 15 minutes. CGM is not a cure for diabetes. It's a tool which needs to be actively used for it to be helpful. Whether diabetes is managed with a pump, multiple daily injections, and oral medications or through diet and exercise CGM gives the insights to track and manage diabetes. Glucose meters are a great tool, but sometimes you need to keep a closer eye on your blood sugar levels. That's where CGM can help. It can help detect trends and patterns that give you and your doctor a more complete picture of your diabetes. Seeing glucose levels in real time can help you make more informed decisions throughout the day about how to balance your food, physical activity, and medicines. A CGM works through a tiny sensor inserted under your skin in painless fashion, either on your abdomen or arm using an automatic inserter. The sensor measures your interstitial glucose level, which is the glucose found in the fluid between the cells. A transmitter on the sensor then sends the information to a wireless-pager-like monitor that you can clip on your belt which might be a part of insulin pump or separate device.







Fig. 2: CGM device

CGM devices are complex little machines and require some upfront time to understand their technical aspects like how to insert the sensor properly, calibrate the device with fingerstick blood glucose readings, set device alarms, transfer data to a computer or your phone, etc. Certain CGM devices send an alert when your glucose levels rise or fall a certain amount. With this information, one can make changes quickly and may be able to treat or prevent highs or lows before they turn into a big problem.



The device can be used by adults and children of age 2 and older. The FDA recently approved smartphone apps to pair with the CGM. It's expected to be a great help to parents and caregivers who can't always be in the same place with the person who has diabetes. Scientists are testing new and better kinds of CGM systems in clinical trials which are also a key part of efforts to build an artificial pancreas, which could mimic the body's natural process of controlling insulin.

Reference: Bailey T. S., Chang A., and Christiansen M. Clinical accuracy of a continuous glucose monitoring system with an advanced algorithm. Journal of Diabetes Science and Technology 2014; 9(2):209-214.



NANOTECHNOLOGY ADVANCES REGENERATIVE MEDICINE: BONE FORMATION COMES DOWN TO THE NANOWIRE

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The technique relies on iron nanowires that bend in response to magnetic fields. Bone-forming stem cells grown on a mesh of these tiny wires get a kind of physical workout on the moving substrate. They subsequently grow into adult bone considerably quicker than in conventional culturing settings, with a differentiation protocol that lasts only a few days rather than a few weeks.

This is a remarkable finding," says Jasmeen Merzaban, associate Professor of bioscience. "We can achieve efficient bone cell formation in a shorter amount of time," potentially paving the way for more efficient regeneration of bone. Merzaban co-led the study together with sensor scientist Jürgen Kosel and colleagues from their labs. The scientists analyzed the bone-producing capability of their nanowire scaffold, both with and without magnetic signals. They patterned the tiny wires in an evenly spaced grid and then layered bone marrow-derived human mesenchymal stem cells (MSCs) on top. Each of the tiny wires is about the size of the tail-like appendage found on some bacteria.

The researchers discovered that adding a low-frequency magnetic field greatly accelerated the process of bone development. Within two days of incubation under mechanical stimulation, genetic markers of bone development could be detected, while genes linked to stemness, and self-renewal quickly became inactive. The scientists could also witness the cells rebuilding themselves to become more bone-like at a rapid rate under a microscope. Next, the team plans to test its system in mouse models of degenerative bone disease, with the expectation that stem cell—seeded nanowire scaffolds can be safely implanted at sites of injury and promote tissue repair. An externally applied magnetic field would be used to speed the healing process.

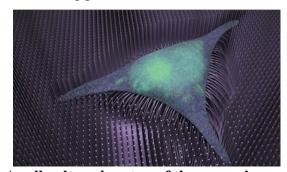


Fig: A cell cultured on top of the nanowire scaffold



There are potential applications of nanowire in other disease settings. "Varying the matrix stiffness by increasing or decreasing nanowire length and diameter could promote differential responses with MSCs or they could use other types of stem cells to, for example, promote neuronal growth and brain repair after a stroke.

We could further customize the nanowire scaffold itself or the base material for instance, by using different metals to exploit their magnetic responses or coating the nanowires with biomolecules for potential delivery upon cellular contact. For such a small technology, the possibilities are huge.

Reference: Perez, J.E., Bajaber, B., Alsharif, N. et al. Modulated nanowire scaffold for highly efficient differentiation of mesenchymal stem cells. J Nanobiotechnol, 2022, 20, 282.



MODIFIED RELEASE DRUG DELIVERY: IMPROVING EFFICACY AND PATIENT COMPLIANCE

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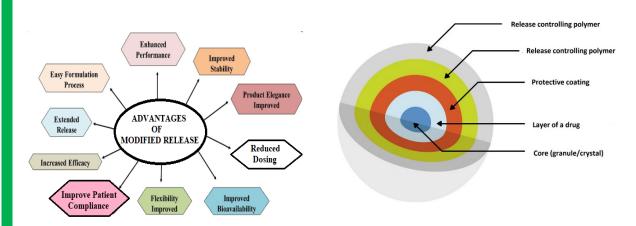
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Modified release (MR) formulations are designed by altering the drug absorption profile and site of the drug release to achieve the predetermined clinical therapeutic objective. The important therapeutic benefits of modified-release delivery include improved efficacy, reduced adverse events, increased patient compliance, and optimized performance. Modified release formulations are developed to accomplish therapeutic or convenience objectives which cannot be offered by conventional dosage forms such as conventional tablets, capsules, solutions, ointments, etc. Modified drug delivery is the one in which the drug release is characteristic of the time course, in order to achieve a desired therapeutic objective and better patient compliance.

MR dosage forms mainly include extended-release (ER) and delayed-release (DR) products. In the case of the ER formulations matrix, reservoir, and osmotic pumps are the most common delivery systems. Other MR systems include enteric, colonic, pulsatile and bimodal release systems. Promptly the MR formulations are developed to make the drug available for a prolonged period after administration, thus allowing a reduction in dosing frequency compared to the conventional dosage form and ultimately improving patient compliance by reducing dosing and preventing the adverse effects associated with the drug. The rational design of MR systems starts with identifying the clinical need, defining the target product profile, performing feasibility studies, and selecting and formulating the appropriate MR systems. By modifying the drug release, therapeutic plasma concentration can be obtained at an optimal time to counter the diurnal nature of certain diseases such as angina, hypertension, asthma, diabetes arthritis, etc.

MR means that the escape of the drug from the dosage form has been modified in some way to slow the release of the drug to reduce the medicine frequency and therefore improve patient compliance. MR formulations improve efficacy and patient compliance by providing certain advantages like sustained blood levels, attenuation of adverse effects, potential reduction in dosing frequency, and protecting acid-sensitive drugs.





Over the last decade, the approach to modified release drug delivery systems has changed from a line extension strategy to a clinically superior approach for marketed drugs as well as for new chemical entities. The common dosage forms of different modified release systems include the Matrix ER, Reservoir ER, and Osmotic ER, DR, and Pulsatile release. Modification in the drug delivery is achieved by applying the use of various release-altering excipients and polymers which affects and alters the release mechanism of the drug from the system.

Reference: Qiu, Yihong, and Deliang Zhou., Understanding design and development of modified release solid oral dosage forms, Journal of Validation Technology, 2011, 17 (2), 23.



New Drug Approvals in India

2022

Name of Drug	Structure	Indications
Cidofovir dihydrate	ON SHO	CMV retinitis in adults with acquired immune defeciency 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
Isavuconazolesul fate	Hoo +	Invasive Aspergillosis and Invasive Mucormycosis
Azelnidipine		Stage I hypertension



New Drug Approvals in India 2022

Name of Drug	Structure	Indications
Riboflavin		Keratoconus and corneal ecstasia
Ophthalmic	0 N	
Solution	, at an	
	06	
Pixantrone		Multiply relapsed or refractory
		aggresive Non-Hodgkins B- Cell
	\ <u></u>	Lymphomas (NHL)
	HN O NHE	
	\(\sigma\) \(\sigma\)	
	HIN	
FDC of Bilastine		Allergic rhinitis in adults
20mg and	\ \(\) \(\) \(\)	
Montelukast		
10mg tablets		
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	Y ()"	
01 1 1 1 1	0	D: 131 1 1
Obeticholic acid	HC	Primary biliary cholangitis
	Vol.	
	H _I C OH	
Favipiravir	он о	Mild to moderate Covid-19
		disease
	N NH ₂	
	N	
	F	



### **New Drug Approvals in India 2022**

Name of Drug	Structure	Indications
Pretomanid		Pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrugresistant (MDR) tuberculosis (TB
Netarsudil mesylate		Reduction of elevated intraocular pressure in patients with open angle galucoma or ocular hypertension
Risdiplam powder	N N N OH	Spinal muscular atrophy (sma)
FDC of Azelnidipine 8mg and Telmisartan 40mg	H _C C	Treatment of Stage-II hypertension
	CH ₁ CH ₂ CH ₃	

**Source:** <a href="https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/">https://cdsco.gov.in/opencms/opencms/opencms/opencms/en/Approval_new/Approved-New-Drugs/</a>



## **Patents from College**

Sr. No.	Title	Patent Application Number	Status	Name of the Inventor/s	Month & Year
01	Analytical method for beta-secretase estimation from biological fluids	201721033863	Indian Patent Granted	Gaurav Gangadhar Gadgil, Manish Sudesh Bhatia, Rakesh Pandit Dhavale	Feb. 2022
02	Transdermal ethosome composition of lanozoline	202121023742	Published	Hemlata S. Dol, <b>Ashok A. Hajare,</b> 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**

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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, <b>Durgacharan Arun Bhagwat</b> , Rahul GD, P. Jayaraman, D. Marotkar, K. Karthikayani, KB Maruthiram, S. Praveena, P. Kuchhal, R. Mishra	Aug. 2021
08	Eutectic mixture and process of preparing thereof	202121023879	Published	Namdeo Jadhav, Udaykumar Patil, Kranti Bille, Jidnyasa Pantwalawalkar	May. 2021
09	Method for determining relationships between the properties of chemical compounds and biological activity	202021026843	Published	Dr Ajit S. Kulkarni, Dr Vinod L. Gaikwad, Dr Manish S Bhatia and Mr Amit J Kasabe	Nov. 2020



- 1. Lyophilized Ethinylestradiol Nanosuspension: Fabrication, Characterization and Evaluation of in vitro Anticancer and Pharmacokinetic Study, Indian J. Pharm. Sci. 54-59, 2020.
- 2. Design and development of melt solidification of meloxicam for enhancement of solubility and dissolution Journal of Research in Pharmacy, 56-70 Jan 2020
- 3. Assessment of Structural Compatibility of Saxagliptin in Physical Mixtures with some excipient by Using HPLC Current Pharmaceutical Analysis, 1074-1082 2020
- 4. Synthesis, anticancer and antimicrobial evaluation of new pyridyl and thiazolyl clubbed hydrazone scaffolds, Synthetic Communications, 243-255, 2020,
- 5. Rust-derived Fe2O3 nanoparticles as a green catalyst for the one-pot synthesis of hydrazinyl thiazole derivatives, Organic & Biomolecular Chemistry, 4575-4582, 2020
- 6. Formulation, Characterization of Anticancer Nanoemulsion containing Trigonella foenum-graecum L. Seed oil Research Journal of Pharmacy and Technology, 2672-2680, 2020
- 7. Acrylamide grafted neem (Azadirachta indica) gum polymer: Screening and exploration as a drug release retardant for tablet formulation Carbohydrate Polymers, 115357, 2020.
- 8. Synthesis of phthalazine derivative based organic nanoflakes in aqueous solvent as a potential nano-anticancer agent: A new approach in medical field, Journal of Molecular Structure, https://doi.org/10.1016/j.molstruc.2019.127156, 2020
- 9. Fibroin-Alginate Scaffold for Design of Floating Microspheres Containing Felodipine, Journal of Pharmaceutical Innovation, 1-11, 2020
- 10. Fundamental properties of prosopis africana peel powders (papps) as drug delivery excipient African Journal of Pharmaceutical Research and Development, 119-133,2020
- 11. POC13 Mediated Syntheses, Pharmacological Evaluation and Molecular Docking Studies of Some Novel Benzofused Thiazole Derivatives as a Potential Antioxidant and Anti-inflammatory Agents, Current Chemical Biology, 58-68, 2020
- 12. Exploring the Pharmacological Potentials of Biosurfactant Derived from Planococcus maritimus SAMP MCC 3013, Current Microbiology, 452-459, 2020
- 13. Antioxidants with Multivitamin and Mineral Supplementation Attenuates Chemotherapy or Radiotherapy-induced Oxidative Stress in Cancer Patients, Indian Journal of Pharmaceutical Education and Research, 484-490, 2020



- 14. Insilico Analysis of Marine Indole Alkaloids for Design of Adenosine A2A Receptor Antagonist, Journal of Biomolecular Structure and Dynamics, doi.org/10.1080/07391102.2020.1765874, 2020
- 15. Formulation and evaluation of solid lipid nanoparticle gel for topical delivery of clobetasol propionate to enhance its permeation using silk sericin as permeation enhancer. Int. J. Pharm. Sci. Res.2356-2365, 2020
- 16. QbD Based Approach to Enhance the In-Vivo Bioavailability of Ethinyl Estradiol in Sprague-Dawley Rats Acta Chimica Slovenica, 283-303, 2020
- 17. Vasorelaxant Effect of Novel Nitric Oxide-Hydrogen Sulfide Donor Chalcone in Isolated Rat Aorta: Involvement of cGMP Mediated sGC and Potassium Channel Activation, Current Molecular Pharmacology, 126-136, 2020
- 18. Synthesis and Modeling Studies of Furoxan Coupled Spiro-Isoquinolino Piperidine Derivatives as NO Releasing PDE 5 Inhibitors, Biomedicine, 121-134, 2020
- 19. Development and Validation of Novel Stability-Indicating LC Method for the Determination of Saxagliptin and Metformin, Indian journal of pharmaceutical education and research, 350-357, 2020
- 20. Design and Characterisation of Nitrendipine Nanocrystals for Solubility and Dissolution Enhancement International Journal of Pharma Science Review & Research, 66-72, 2020
- 21. Potential of NO donor furoxan as SARS-CoV-2 main protease (Mpro) inhibitors: in silico analysis, Journal of Biomolecular Structure and Dynamics, 1-15, 2020
- 22. Bioactivity Guided Antidiabetic Formulation Development of Tridax procumbens Linn Leaves ,Indian J. Pharm. Edu. Res.705-713, 2020
- 23. In silico analysis of polyphenols and flavonoids for design of human Nav1.7 inhibitors, Journal of Biomolecular Structure and Dynamics, https://doi.org/10.1080/07391102.2020.1777902, 2020
- 24. Design and development of floating pulsatile drug delivery of losartan potassium, International Journal of Applied Pharmaceutics, 218-227, 2020
- 25. Synthesis, Antimicrobial Evaluation, and Molecular Docking Study of New Thiazole-5-phenylpropenone Derivatives, Russian Journal of General Chemistry, 1523-1528, 2020.
- 26. Development of lipoprotein-drug conjugates for targeted drug delivery, Journal of Biomolecular Structure and Dynamics, 1-19, 2020



- 27. Estimation of total carbohydrate content by phenol sulphuric acid method from Eichhornia crassipes (Mart.) Solms, AJRC, 357-359, 2020
- 28. Synthesis of isoniazid-1, 2, 3-triazole conjugates: Antitubercular, antimicrobial evaluation and molecular docking study, Journal of Heterocyclic Chemistry, 3544-3557, 2020
- 29. Novel curcumin ascorbic acid cocrystal for improved solubility, Journal of Drug Delivery Science and Technology, 102233, 2020
- 30. Multi-Targeted Design and Development of Dihydroisoquinolines as Potent Antimalarials Current computer-aided drug design, 734 740, 2020
- 31. Formulation and Development of Modified Release Biphasic Compressed Tablet of Propranolol Hydrochloride, International Journal of Trend in Scientific Research and Development, 1375-1383, 2020
- 32. Carbon Dots: A Novel Trend in Pharmaceutical Applications, Annales Pharmaceutiques Françaises, Dec 2020
- 33. Capsaicin Loaded Solid SNEDDS for Enhanced Bioavailability and Anticancer Activity: In-Vitro, In-Silico, and In-Vivo Characterization, Journal of Pharmaceutical Sciences, 280-291, 2020
- 34. Pharmaceutical Applications of Electrospinning, Annales Pharmaceutiques Françaises, 1-11, 2020.
- 35. A remarkable in vitro cytotoxic, cell cycle arresting and pro-apoptotic characteristics of low dose mixed micellear simvastatin combined with alendronate sodium, Drug Delivery and Translational Research, 1122-1135, 2020
- 36. Green synthesis of silver and iron nanoparticles of isolated proanthocyanidin: its characterization, antioxidant, antimicrobial, and cytotoxic activities against COLO320DM and HT29, Journal of Genetic Engineering and Biotechnology, 1-11,2020
- 37. Validated RP-HPLC for quantification of Meloxicam in rabbit plasma using protein precipitation method: application to pharmacokinetic study, Future Journal of Pharmaceutical Sciences, 1-12, 2020
- 38. Green Synthesis ff Gold Nanoparticles Of Isolated Citrus Bioflavonoid From Orange: Characterization And In Vitro Cytotoxicity Against Colon Cancer Cell Lines Colo 320DM and HT29, Indian Drugs, 61-69, 2020



- 39. Silk industry waste protein: isolation, purification and fabrication of electrospun silk protein nanofibers as a possible nanocarrier for floating drug delivery Nanotechnology, 035101,. 2020
- 40. Stability indicating RP-HPLC method for simultaneous of zidovudine and lamivudine from their combination drug product Tropical Journal of Pharmaceutical and Life Sciences, 8(1), 11-21, 2021.
- 41. Importance of medicinal plants and herbs as an immunity booster for pandemic COVID-19 Tropical Journal of Pharmaceutical and Life Sciences 8(1), 1-9, 2021
- 42. Chyawanprash: A traditional Indian bioactive herbal medicinal formulation to boost immunity and restore youthfulness Tropical Journal of Pharmaceutical and Life Sciences 8(1), 21-28, 2021.
- 43. Comparative antioxidant study of ethanol and aqueous leaves extracts of Barleria gibsoni Dalz International Journal of Biology Research, 6(1), 14-16, 2021
- 44. Pharmacognostic studies of Phyllanthus amarus International Journal of Research in Pharmacy and Pharmaceutical Sciences, 6(2), 26-31, 2021
- 45. In vitro screening of Antidiabetic activity & Antiinflammatory activity of leaves extract of Barleria gibsoni Dalz, Research Journal of Pharmacy and Technology, 14(3), 1289-1292.2021
- 46. Formulation and evaluation of valsartan buccal patches, International Journal of Pharmaceutical Science and Research, 6(1), 30-33, March 2021
- 47. Preliminary Phytochemical screening and antimicrobial activity of Delonix regia (Bojer Ex Hook) extract, International Journal of Pharmaceutical and Clinical Research ,3(1), 13-14, 2021
- 48. Isolation of Pectin from Banana peel waste: Its Utilization in formulation of chewable lozenges International Journal of Ecology and Environmental Sciences, 3(2), 43-46, 2021



- 49. Self-Emulsifying Drug Delivery Systems: An Overview., International Journal of pharmacy and Pharmaceutical science, 3(1), 5-8, 2021
- 50. Standardization of Herbal Drugs: An Overview International Journal of Pharmacognosy and Pharmaceutical Sciences 3(1), 9-12, 2021
- 51. Comparative evaluation of Potato, Sweet potato and Maize starch as Pharmaceutical Excipient International Journal of Pharmaceutical Research and Development, 3(2), 1-3, 2021.
- 52. Use of natural polymers as excipients in the pharmaceutical industry International Journal of Advanced Scientific Research, 6(2), 55-58, 2021
- 53. Comparative studies on conventional and microwave assisted synthesis of N-(phenylcarbamothioyl) benzamide derivatives and its anti-inflammatory activity, International Journal of Chemical Science,5(3),1-3,2021
- 54. Novel extraction process use in medicinal plants: A Review International Journal of Pharmacognosy, 8(4),138-145, 2021.
- 55. Formulation and evaluation of pediatric herbal chocolate European Journal of Biomedical and Pharmaceutical sciences, 8(6), 458-462,2021
- 56. Skeletal muscle relaxant effect of Bacopa monnieri (L.) natural and micropropagated plant extracts, International Journal of Pharmaceutical Science and Research, 6(2),11-12,2021
- 57. A Review on Recent Technologies, Trending Methods and Clinical Trial of PIPAC, Annals of R.S.C.B, 25(4), 17128-17139, 2021
- 58. Nutraceuticals: Frontier in Healthcare Acta Scientific Nutritional Health 5(7), 22-26, 2021
- 59. Design and development of zolmitriptan niosomal in situ nasal gel for the treatment of migraine International Journal of Research in Pharmaceutical Sciences, 12(3), 1861-1869, 2021



- 60. Synthesis, Characterization, In Silico Analysis, and Pharmacological Evaluation of Metoprolol-Modified Saccharide Conjugates for Cardiovascular Targeting, Journal of Pharmaceutical Innovation, 1-10, 2021
- 61. Discovery of pyridoindole derivatives as potential inhibitors for phosphodiesterase 5A: in silico and in vivo studies, Natural Product Research, 1-10, 2021
- 62. In silico design and pharmacological evaluation of conjugates of atenolol with modified saccharide for cardiovascular targeting, Glycoconjugate Journal, 38 (2), 261-271, 2021
- 63. Computer Assisted Models for Blood Brain Barrier Permeation of 1, 5-Benzodiazepines, Current computer-aided drug design ,17 (2), 187-20, 2021
- 64. A review on basics and applications of modified carbohydrates in drug delivery, Indian Drugs, 58(2), 2021
- 65. Discovery of two novel hetero-tricyclic lead scaffolds as PDE5A inhibitor: virtual screening, molecular docking and pharmacophore modeling approach, Natural Product Research, 35(1), 92-98, 2021
- 66. Simvastatin and Alendronate sodium repurposing for cancer as HER2, EGFR kinase and AR potential inhibitors: In silico approach Annals of the Romanian Society for Cell Biology, 25:4, 19128-19138, 2021
- 67. Surface architectured metal organic frameworks-based biosensor for ultrasensitive detection of uric acid: Recent advancement and future perspectives, Microchemical Journal, 169, 2021
- 68. Discovery of potential inhibitors for phosphodiesterase 5A, sodium-potassium pump and beta-adrenergic receptor from Terminalia arjuna: in silico approach Journal of Biomolecular Structure and Dynamics, 39:5, 1754-1765, 2021
- 69. Green synthesis of silver, iron and gold nanoparticles of lycopene extracted from tomato: their characterization and cytotoxicity against COLO320DM, HT29 and Hella cell, Journal of Materials Science: Materials in Medicine, 32:2, 1-12, 2021
- 70. Novel curcumin ascorbic acid cocrystal for improved solubility, Journal of Drug Delivery Science and Technology, 61, 102233, 2021



- 71. Development of Progesterone Oily Suspension Using Moringa Oil and Neusilin US2, Journal of Pharmaceutical Innovation, 1-12, 2021
- 72. Design and development of terbinafine hydrochloride ethosomal gel for enhancement of transdermal delivery: In vitro, in vivo, molecular docking, and stability study, Journal of Drug Delivery Science and Technology, 61, 102280, 2021
- 73. Screening of effective formulation techniques for Designing and Fabrication of Terbinafine hydrochloride ethosomes, Research Journal of Pharmacy and Technology, 14,03,1353-1359, March 2021
- 74. Design, development, in silico and in vitro characterization of Docetaxel-loaded TPGS/Pluronic F 108 mixed micelles for improved cancer treatment, Journal of Drug Delivery Science and Technology, 102685, 2021
- 75. Anti-Diabetic Hypolipidemic and Histopathological Analysis of Methanolic Leaf Extract of Celosia Argentea on Alloxan Induced Diabetic Rats, International Journal of Pharmaceutical Research and Applications, 6 (1), 857-864, 2021
- 76. Evaluation of in vitro antioxidant, anticancer activities and molecular docking, studies of Capparis zeylanica Linn. leaves, Future Journal of Pharmaceutical Sciences, 7:76, 2-12, 2021
- 77. Design and in silico investigation of novel Maraviroc analogues as dual inhibition of CCR-5/SARS-CoV-2 Mpro Journal of Biomolecular Structure and Dynamics, 1-16, 2021
- 78. Synthesis, Biological Evaluation and Molecular Docking of Novel N-Acyl/Aroyl Spiro[Chromane-2,4'-Piperidin]-4(3H)-One as Potent Anti-Microbial Agents, Polycyclic Aromatic Compounds, 1-17, 2021
- 79. Synthesis, antimicrobial screening, and docking study of new 2-(2-ethylpyridin-4-yl)-4-methyl-N-phenylthiazole-5-carboxamide derivatives, Journal of the Chinese Chemical Society, 68(2), 353-361, 2021
- 80. Development of Visible Spectrophotometric Method and It's Validation for Dolutagravir in Bulk and Tablet Dosage form, International Research Journal of Modernization in Engineering Technology and Science, 3 (7), 708-714, 2021

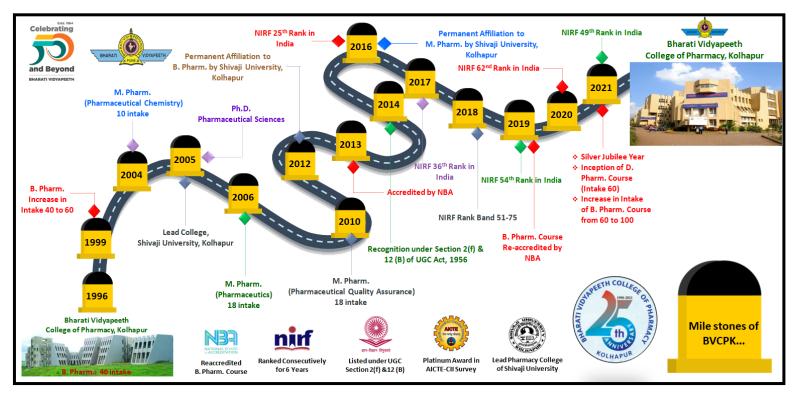


- 81. Development of Progesterone Oily Suspension Using Moringa Oil and Neusilin US2, Journal of Pharmaceutical Innovation, 1-12, 2021
- 82. Design and development of terbinafine hydrochloride ethosomal gel for enhancement of transdermal delivery: In vitro, in vivo, molecular docking, and stability study, Journal of Drug Delivery Science and Technology, 61, 102280, 2021
- 83. Screening of effective formulation techniques for Designing and Fabrication of Terbinafine hydrochloride ethosomes, Research Journal of Pharmacy and Technology, 14,03,1353-1359, March 2021
- 84. Design, development, in silico and in vitro characterization of Docetaxel-loaded TPGS/Pluronic F 108 mixed micelles for improved cancer treatment, Journal of Drug Delivery Science and Technology, 102685, 2021
- 85. Anti-Diabetic Hypolipidemic and Histopathological Analysis of Methanolic Leaf Extract of Celosia Argentea on Alloxan Induced Diabetic Rats, International Journal of Pharmaceutical Research and Applications, 6 (1), 857-864, 2021
- 86. Evaluation of in vitro antioxidant, anticancer activities and molecular docking, studies of Capparis zeylanica Linn. leaves, Future Journal of Pharmaceutical Sciences, 7:76, 2-12, 2021
- 87. Design and in silico investigation of novel Maraviroc analogues as dual inhibition of CCR-5/SARS-CoV-2 Mpro Journal of Biomolecular Structure and Dynamics, 1-16, 2021
- 88. Synthesis, Biological Evaluation and Molecular Docking of Novel N-Acyl/Aroyl Spiro[Chromane-2,4'-Piperidin]-4(3H)-One as Potent Anti-Microbial Agents, Polycyclic Aromatic Compounds, 1-17, 2021
- 89. Synthesis, antimicrobial screening, and docking study of new 2-(2-ethylpyridin-4-yl)-4-methyl-N-phenylthiazole-5-carboxamide derivatives, Journal of the Chinese Chemical Society, 68(2), 353-361, 2021
- 90. Development of Visible Spectrophotometric Method and It's Validation for Dolutagravir in Bulk and Tablet Dosage form, International Research Journal of Modernization in Engineering Technology and Science, 3 (7), 708-714, 2021



- 91. Moringa Seed Protein: Advancements and Drug Delivery Prospects, International Journal of Pharmaceutical Research, 13(3), July Sept, 2021
- 92. Quantitative structure property relationship assisted development of Fluocinolone acetonide loaded transfersomes for targeted delivery, Journal of Drug Delivery Science and Technology, 65, 102758, 2021
- 93. APTES monolayer coverage on self-assembled magnetic nanospheres for controlled release of anticancer drug Nintedanib, Scientific Reports, 11, 5674, 2021
- 94. Chitosan coated magnetic nanoparticles as carriers of anticancer drug Telmisartan: pH-responsive controlled drug release and cytotoxicity studies, Journal of Physics and Chemistry of Solids, 148, 109749, 2021
- 95. In vivo bioactivity—Guided isolation of antiasthmatic fraction of Celosia argentae Linn. leaves in rodents, International Journal of Advance Research, Ideas and Innovations in Technology, 7, 3, 2-12, 2021
- 96. Pharmacognostic account and medicinal uses of Achyranthes aspera linn. International Journal of Pharmacognosy, 8,8, 338-345,2021
- 97. Role of tinospora cordifolia as immune booster current covid -19 pandemic, International Journal of Pharmacognosy 8(8), 307-316, 2021
- 1. In vivo and in vitro hair growth-promoting effect of silver and iron nanoparticles synthesized via Blumea Eriantha DC plant extract Journal of cosmetic Dermatology, 20(4), 1283-1297, 2021







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