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Development and Evaluation of Taste Masked Azithromycin by Crystal Engineering

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ABSTRACT

Purpose: Cocrystallisation is a promising technique for altering important physicochemical properties of drugs such as solubility and dissolution. The present study thus aims to utilize this technique to improve the drug solubility and study its effect on taste masking.

Method: Azithromycin co-crystals were formulated by solvent evaporation technique utilizing a synthetic sweetener neotame as the cofomer. The study of microscopic characters characterized the formulated co-crystals, Fourier transforms infrared spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), Scanning electron microscopy (SEM), and Xray diffraction studies (XRD). Other evaluation parameters included taste evaluation, drug content determination, solubility, angle of repose, Carr's index, Hausner's ratio, and dissolution studies.

Results: The study revealed that the prepared co-crystals showed a marked improvement in taste and physicochemical properties. Co-crystals prepared in the ratio of 1:1 of drug and neotame displayed a nearly two-fold increase in solubility, improvement in flow properties, and a tremendous improvement in the taste as compared to the pure drug.

Conclusion: Thus, co-crystallization can be effectively used for solubility improvement and taste masking of poorly soluble bitter drugs such as azithromycin.

Keywords: Azithromycin, Bitter taste, Co-crystals, Neotame, Taste masking.

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INTRODUCTION

Drug administration by the oral route is the most popular due to the ease of self-administration, manufacturing, and good stability on storage compared to the other dosage forms. However, a major drawback of the oral dosage form is the difficulty in swallowing and bitter taste, leading to a severe pediatric and geriatric patient in compliance. Taste arises from the stimulation of taste buds present on the surface of the tongue.^{1,2} Taste masking is necessary for an active ingredient with an unpleasant taste for increased patient compliance.

Taste masking has been done by various techniques like adding flavoring and sweetening agent,³ ion-exchange resin complex,⁴ micro-encapsulation,⁵ prodrug approach,⁶ inclusion complexation,⁷ granulation, multiple emulsion technique, gel formation. However, very little work has been done using co-crystallization as a method of taste masking. This method not only improves the bitter taste but also improves the physicochemical properties of the drug.⁸ Co-crystals are coordination types of molecular complexes involving noncovalent interaction between the drug and cofomer and their complementary functional groups.⁹ Thus, it involves drug

and cofomer that self-assemble by noncovalent interactions such as electrostatic interactions and hydrogen bonding in a well-defined stoichiometry. Such a development of co-crystal of an API leads to improved properties such as stability, solubility, drug release rate and taste.¹⁰⁻¹²

Azithromycin, with an IUPAC name 9-deoxo-9a-aza-9a-methyl-9a-homoerythromycin, belongs to the *azalide* subclass of macrolides. It consists of a 15-membered ring, and methyl-substituted nitrogen at the 9a position on the aglycone ring, which is responsible for preventing its metabolism. Such a type of structure makes azithromycin different from other types of macrolides azithromycin is a broad-spectrum macrolide antibiotic having a long half-life and a high degree of tissue penetration.¹³

Azithromycin is structurally related to erythromycin¹⁴ and is commonly used for the treatment of infections of the respiratory and genitourinary tract as well as for enteric infections and may be used for sexually transmitted infections. It is a BCS Class II drug with an extremely bitter taste and a poor water solubility. Therefore the present work was aimed at using the co crystallisation technique of crystal engineering for the purpose of masking the bitter taste of the drug.

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Original Research Article

Formulation and evaluation of herbal gel for management of mouth ulcers

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ABSTRACT

Background: Aphthous stomatitis or mouth ulcers is the most common condition that we encounter. Clinically the lesions are single or multiple superficial and deep sealed and are associated with microbial invasions.

Aim: This study was conducted with the aim of evaluating the effectiveness of herbal drugs for treatment of Aphthous stomatitis.

Materials and Methods: In the research work, mouth ulcer gels were formulated incorporating the ethanolic extracts of as *Aloe barbedensis*, *Ocimum tenuiflorum* and *Azadirachta indica* using carbopol 934 as the gelling agent. Seven batches were formulated by varying the concentration of the herbal ingredients (F1 to F7). The prepared formulations were evaluated for various parameters like physical appearance, pH, Spreadability, Homogeneity and antimicrobial activity against fungi and bacteria. The antimicrobial activity was also compared with a marketed gel formulation.

Results and Discussion: All the prepared formulation using different concentration of plant extract showed the pH values in between 6.1 ± 0.2 to 7.0 ± 0.1 . The spreadability values ranged between the 5.0 to 8.0 cm. Out of all the formulations, formulation F7 containing all the three herbal extracts showed a good spreadability and very promising antimicrobial activity comparable with a marketed gel.

Conclusion: Thus stable, effective gels containing herbal ingredients for management of mouth ulcers can be developed.

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1. Introduction

Aphthous stomatitis or mouth ulcer is an ulcerative condition that is related to the oral mucosa and is characterised by repeating ulcers in the throat and oral cavity.¹ Mouth ulcers are usually generated by a number of causes, such as biting the inner layer of cheek, food allergies, hard teeth brushing, hormonal changes, vitamin deficiencies, bacterial infection and diseases.² Treatment of mouth ulcers may include soothing/ antiseptic mouthwashes, such as chlorhexidine mouthwash or povidone iodine mouthwash or use of antibiotic or anaesthetic gel formulations³

Semi-solid formulations include gel having a liquid phase which are then thickened by other components. Topical gels are intended for the application on skin or to certain mucosal surfaces for local action or percutaneous penetration of medicament preparations.⁴ A large number of Indian medicinal plants are attributed with various pharmacological activities as they contain diversified classes of phytochemicals. As the conventional synthetic drugs suffer from a numerous side effects, these herbal ingredients provide a good alternative.⁵

Leaves of *Aloe barbedensis* commonly called as aloe vera, belonging to family Asphodelaceae, are very commonly used in skin care products. They are rich in phytoconstituents such as aminoacids, anthraquinones,

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A Comparative Study of Two Different Taste Masking Approaches for Taste Masking of Azithromycin

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Abstract

Objective: Azithromycin is a BCS Class II drug having a poor water solubility and bitter taste, which leads to poor patient compliance, especially in paediatric and geriatric patients. Thus in the present work taste masking was done using two methods, solid dispersion (SD) and complexation using ion exchange resin and the two methods were compared with respect to their efficiency of taste masking. **Methodology:** In this research work, SDs were prepared by solvent evaporation method using ethanol as a solvent. Furthermore, drug resin complex containing indion 234, a weak cation exchange resin was prepared by batch method. Both, SDs and drug resin complexes were evaluated by FTIR, SEM, PXRD, and DSC studies and with respect to their micromeritic properties, solubility, drug content, dissolution, and taste evaluation. **Results and Discussion:** The study showed that both the SDs as well as drug resin complex showed improvement in taste as well as physicochemical properties. The drug content and % drug release of the optimized batch prepared by SD method was found to be more than that is $92.56 \pm 0.75\%$ and 96.77% , respectively for SD₅ (1:0.75) as compared to the optimized batch prepared by the ion exchange resin that is $67.52 \pm 0.51\%$ and 75.25% for DRC₄ (1:4). Taste evaluation studies also revealed a better taste masking with SD as compared to drug resin complex. Thus, it can be concluded that due to its versatile utility SD method was found to be the best and more efficient as compared to the ion exchange resin method for taste making of bitter tasting drugs.

Key words: Azithromycin, Bitter taste, Co-crystals, Taste masking

INTRODUCTION

Taste is an important parameter in administering drugs orally and governing compliance too.^[1] It is a crucial factor that determines the palatability of pharmaceutical oral dosage form and patient compliance.^[2] The oral administration of bitter drug is major concern for patient compliance. Several taste masking choices are accessible including sensory masking using correctives (flavors and sweeteners), chemical masking by chemical modification such as preparation of inclusion complex and prodrug by coating the particles surface, masking by using matrix and physical masking by additives. In case of pediatrics patients, unpleasant taste leads to noncompliance which decreases therapeutic efficacy.^[3]

Different techniques have been tried and employed so far for taste masking such as addition of flavors and sweeteners,^[4] microencapsulation,^[5] prodrug approach,^[6] crystallization,^[7] inclusion

complex,^[8] Ion exchange resins,^[9] and solid dispersion (SD) technique^[10] are also widely used for this purpose.

Complexation using IERs is a simple, cost-effective technique requiring very less excipients in the formulation. IERs have excellent properties such as high ion-exchange capacity, good absorption capacity, physicochemical stability, and their insolubility in any solvents make them suitable candidates for the purpose of taste masking.^[11]

IER are insoluble polymers which carry acidic or basic functional groups and that have the capability to exchange

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**REVIEW: A THERAPEUTIC APPLICATIONS OF MICROSPONGE
DRUG DELIVERY SYSTEM****Parag A. Lekurwale***, **Dr. Kanchan P. Upadhye**, **Anup R. Thakre** and **Krutika S. Bobde**

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440016.**ABSTRACT**

More and more developments are being employed in the drug delivery systems to optimize its efficacy and cost-effectiveness of drug therapy. Peptides, proteins and DNA-based therapeutics can not be effectively delivered through conventional means. A Microsponges drug delivery system is a highly cross-linked, porous, polymeric system consisting of porous microspheres that can entrap and release them into the skin layers over a long period of time. Microsponges drug delivery system provides extended release with reduced irritation, improved thermal, physical and chemical stability. Microsponges drug delivery technology is used currently in cosmetics, skin care products,

sunscreens and prescription products. One of the best feature of microsp sponge delivery system is it is self-sterilizing. Current review is focused on the method of preparation, characterization and various therapeutic applications of microsponges.

KEYWORDS: Drug delivery System, Therapeutic Applications, Microsponges, quasi-emulsion diffusion solvent method, suspension polymerization, controlled release system.

1. INTRODUCTION

There are many classes of drugs that are being evolved day by day in evolution of the drug delivery technology. Development of the new drugs delivery system with calculated predetermined rates at different sites of action is required for the drug to be effective against any disorder. Drug delivery systems are those that can control the release rates or target drugs to a specific body site, improving the efficacy of the drug, cost-effectiveness of the drug therapy and improving patient compliance. This control of the delivery rate of active pharmaceutical ingredient (API) to a required site in the human body has become a major



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Title

CRYSTAL ENGINEERING FOR SOLUBILITY ENHANCEMENT: A REVIEW

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Abstract

Pharmaceutical cocrystals are multicomponent frameworks in which no less than one part is an dynamic drug fixing and the others are chemically acceptable Coformer. Cocrystallization of a medication substance with a coformer is a promising and arising way to deal with work on the presentation of drugs, for example, solubility, dissolution profile, pharmacokinetics and stability. This review article presents a thorough outline of drug cocrystals, choice of cofomers and screening of cocrystals have been summed up and various techniques for cocrystal development and assessment have been made sense of. Finally this article features a portion of the synthetic and herbal cocrystals alongside its preparation technique and cofomers utilized.

Key Words

Cocrystal, Coformer, Solubility, Bioavailability, BCS Class.

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**CURRENT UPDATED REVIEW ON PRONIOSOMES AS A NOVEL APPROACH FOR
DRUG DELIVERY****Meera Ingale*, Rahul Kasliwal and Yogesh Gholve**

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Proniosomes are one of the novel provesicular drug delivery systems which are dry formulations coated with carrier such as non-ionic surfactants. Proniosomes are formulated in such a manner that they can overcome the drawbacks of niosomes such as physical instabilities, fusion and aggregation. Proniosomes can be administered by various routes like oral, intravenous, buccal, topical, transdermal, ocular etc. Proniosomes are liquid crystalline compact niosome hybrids which upon hydration form niosomes. They help in reducing physical stability problems involved with niosomes such as leaking, fusion, aggregation and provide convenience in dosing, distribution, transportation and storage showing improved results than conventional niosomes.

KEYWORD: Proniosomes, provesicular drug delivery systems, niosomes, intravenous, buccal, topical, transdermal, ocular.

INTRODUCTION

Proniosomes are dry formulation of water-soluble carrier particles that are coated with surfactant. They are rehydrated to form niosomal dispersion immediately before agitation in hot aqueous media within minutes. The fundamental object of development controlled and targeted release dosage form is that improve the therapeutic effect of drug improve drug safety margin of high potency drugs by the increases plasma concentration, and also decrease side effects.^[1] Main object of Novel vesicular drug delivery system is that drug rate work on need of body throughout the period of treatment and controlled and targeted effect on the site of action, drug is encapsulated in to vesicles that manner prolonged drug action.^[2]

Various type of carriers are utilized to carry drugs at the target site in the body part like tissue organ which include, Niosomes, proniosomes, liposomes, microsphere, electrosomes, phytosomes etc.^[3] Vesicular drug delivery like a colloidal particle in which amphiphilic molecule made a concentric bilayer covered by aqueous compartment. The amphiphilic molecules like surfactants (non-ionic), phospholipid (phosphatidylcholine, phosphatidylserine etc.) is adding combination or separately with cholesterol.^[4] Proniosomes evaded the problems associated with niosomes like fusion, aggregation, physical stability, sedimentation, aggregation leakage of drug. Proniosomes are dry free- flowing formulation of surfactants- coated carrier, which can be rehydrated by brief agitation is hot water to form multilamellar niosomes.^[5]

Proniosomes can deliver both the hydrophilic and hydrophobic drug. Proniosomes can be converted into niosomes upon hydrating with hot water right before the use. As niosomes are associated with various drawbacks such as physical instabilities like fusion, aggregation of particles and leakage of the drug these are formulated into proniosomes. The principle advantage of proniosomes is that the amount of carrier required for maintaining the surfactant ratio can be easily adjusted. Proniosomal gels are the very recent provesicular drug delivery systems which offer the drug delivery through topical or transdermal route in a versatile manner. Proniosomal gels are becoming more popular because of a wide range of applications and better percutaneous absorption compared to other semi solid preparations.^[6] Niosomes have received great attention as an alternative potential drug delivery system to conventional liposomes. Niosomes are uni or multilamellar spheroid structures composed of amphiphilic molecules assembled into bi-layers. They are considered primitive cell models, cell like bioreactors and matrices for bio-encapsulation. They are alternative to liposomes as they possess greater stability and overcome the problems associated with liposomes like chemical instability, variable purity of phospholipids and high cost.^[7] The additional merits with niosomes are low toxicity due to nonionic nature, no requirement of special precautions and conditions for formulation and preparation.^[8] Niosomes are non-organic surfactant vesicles that can entrap a solute in a manner analogous to liposomes. They are osmotically active, and are stable on their own, while also increasing the stability of the entrapped drugs. The size of niosomes



A COMPREHENSIVE REVIEW ON EMULGEL: MODERN APPROACH FOR TOPICAL DRUG DELIVERY

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ABSTRACT

Considering NDDS (Novel Drug Delivery System), Emulgel is one of the recent technology used topically having characteristics of dual control release i.e. emulsion as well as gel. When gels and emulsions are used in combined form the dosage form are known as emulgel. Limitation of gels in the delivery of hydrophobic drugs through the skin. Overcome this limitation an emulsion based approach is being used so that even a hydrophobic therapeutic moiety can exhibit the unique properties of gels. Emulgel is prepared by different polymers which act as an emulsifying agent and thickening agent because the gelling capacity of these polymers give rise to stable emulsions by decreasing interfacial and surface tension while at the same time increasing the viscosity of the aqueous phase. Emulgel are having

major advantages on novel vesicular systems as well as on conventional systems considering various aspects. The emulgel provide several favourable properties for its dermatological use such as greaseless, thixotropic, easily spreadable, emollient, easily removable, non-staining, water soluble, longer shelf life, transparent, bio-friendly and pleasing appearance.

KEYWORDS: Emulgel, Emulsion based gel, Hydrophobic drugs, Topical drug delivery system.

INTRODUCTION

Topical formulations are prepared in different consistency such as solid, semisolid, and liquid. The topical delivery system is failed in the administration of hydrophobic drug. In each formulation with the active ingredients many excipients are used. Sometimes more than

**CURRENT UPDATED REVIEW ON ROLE OF PHARMACIST IN
COVID-19****Shruti C. Gotmare*, Yogesh N. Gholse and Rahul H. Kasliwal**Department of Pharmaceutics, Priyadarshini J. L. College of Pharmacy, Nagpur- 440016
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COVID-19 has become a major health problem causing severe acute respiratory illness in humans. It has spread rapidly around the globe since its first identification in Wuhan, China, in December 2019. The causative virus is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and the WHO named the new epidemic disease Coronavirus Disease 2019 (COVID-19). Italy was the first western country facing an outbreak of COVID-19. The various factors integral to the understanding of pathophysiology and susceptibility, diagnostic challenges with RT-PCR assays, therapeutic controversies, intrauterine transmission, and maternal-fetal complications. As an essential service, community pharmacists have been enacting a key role in patient counseling and supply of essential medicines and protective

equipment. Pharmacists are considered the most accessible primary care providers, so it is crucial for patients to know that pharmacists are there to support them throughout the pandemic. Pharmacists are medication experts providing patient care in a variety of settings including hospitals, clinics, community pharmacies, long-term care, physician offices, and national and public health, this included implementation of tele-health programs for comprehensive medication management. As ambulatory care clinical pharmacists continue to expand the services they provide in response to COVID-19. The COVID-19 pandemic impacts daily lives of families globally. Health extends into physical, social, emotional, spiritual, and psychological health. Interventions including mask-wearing and physical distancing are intended to prevent viral spread, but have unintended negative effects on mental health and child development and mental health and give practical interventions to foster resilience in youth and their families.

CURRENT UPDATES AND REVIEW: SYNERGISM BETWEEN ESSENTIAL OIL WITH ANTIBIOTICS FOR MANAGEMENT OF SKIN CONDITION

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With the increase of antibiotic-resistant microorganism and the lack of recent antibiotics being delivered onto the marketplace, alternative strategies want to be observed to address infections as a consequence of drug-resistant bacteria. A feasible solution may be to combine current antibiotics with essential oil to increase the efficacy of antibiotics. A group of phytochemicals this is said to have such consequences, according to in vitro research, is important oils (EOs) and their additives. Amongst others, EOs containing phytochemical they show a synergistic effect in aggregate with antibiotics. Several modes of action were recommended by which antibiotics and the essential oil additives may additionally act synergistically, such as through affecting a multiple target; through physicochemical interactions and inhibiting antibacterial-resistance mechanisms. Many pronounced assays display additivity or moderate synergism, indicating that EOs may also provide opportunities for minimizing antibiotic use for management of skin condition.

KEYWORDS: Synergism, resistance, antibiotics, infection, microorganism.**INTRODUCTION**




Infectious diseases are the leading purpose of dying global; this has turn out to be a worldwide difficulty. The extensive use of antibiotics within the treatment of bacterial infections has led to the emergence and spread of resistant lines; even very low concentrations of antibiotics released into the environment can enrich the population of resistant strains.^[1] There is an urgent and vital need to develop novel therapeutics, new practices, and antimicrobial strategies for the treatment of infectious diseases due to multidrug-resistant microorganisms. This has intensified the search for novel healing leads towards fungal, parasitic, bacterial, and viral infections. The discovery of latest antibacterial compounds as suitable substitutes for conventional antibiotics might to be a possible solution to this problem.^[2] For many years, a various chemical and synthetic compounds have been used as antimicrobial agents in food to lessen the incidence of meals poisoning and spoiling, and to control the boom of pathogenic microorganisms. However, the full-size indiscriminate use of chemical preservatives has brought about many ecologic and clinical issues, such as allergic reaction, hypersensitivity, and immune suppression^[3] which make it vital to look for techniques which can be accessible, easy to use, and secure.^[4] There are main modes of drug discovery: the first is through using chemical synthesis for pharmaceutical purposes and the second one is the use herbal products as a basis for drug discovery.^[5] The improvement of bacterial resistance to many current antibiotics has severe outcomes, as shown in Figure1.

Antibiotics are designed to kill microorganisms, which then adapt to antibiotics, making them less powerful and resulting in antibiotic resistance through some of mechanisms of specific activity because they're notably secure, increase the shelf existence of meals, are broadly frequent via consumers, and have the potential to be exploited for multiple uses.^[6]

ANTIBIOTICS AND ITS RESISTANCE

Multidrug-resistant (MDR) microorganism have end up greater widespread in recent times because of the inappropriate and irrational use of antibiotics, which presents favourable situations for the selection of antibiotic-resistant mutants.^[7] Resistance towards all classes of antibiotics has been defined, which leads to a steady need for the development and production of new pills. However, problems inside the identity of new materials with each high effectiveness and low toxicity have led to only some new antibiotic classes being discovered because the 1970s.^[8] MDR microorganism have become abundant, especially in nosocomial infections. Many medical institution infections are now resulting from methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin resistant *enterococci* (VRE), *Escherichia coli* and *Pseudomonas aeruginosa* proof against fluoroquinolones; *Klebsiella pneumoniae* proof against ceftazidime; MDR *Acinetobacter baumannii*; and different MDR microorganism. The medical results of infections due to MDR bacteria are deteriorating, as a result of the reduced treatment options.^[9] A high incidence of nosocomial infections due

Development and Validation of Novel Analytical Simultaneous Estimation Based UV Spectrophotometric Method for Doxycycline and Levofloxacin Determination

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Abstract: The thorough literature study uncovered that none of the most perceived pharmacopeias or any journals includes a method for simultaneous estimation of Doxycycline and Levofloxacin in combination by UV/Visible spectroscopy. So, it was felt fundamental to build up a system that will serve as a solid, precise UV technique for the simultaneous estimation of Doxycycline and Levofloxacin. DOXH and LVXH showed λ_{max} at 273nm and 287nm respectively, and iso-absorptive point at 280nm in Phosphate buffer pH 6.8 prepared in Water: Methanol (80:20) dissolvable solvent system. Beer Lambert's law obeyed by both drugs within the concentration range of 2-20 $\mu\text{g/ml}$ & r^2 values of 0.9999 and 0.9998, which shows the good linearity. The method has been validated statistically and quantitatively regarding linearity, precision, LOD, LOQ, accuracy, and specificity according to the ICH guidelines. LOD for DOXH and LVXH were found to be 1.41 and 0.63 $\mu\text{g/ml}$, the LOQ was 4.30 and 1.92 $\mu\text{g/ml}$, respectively. Percent recovery at recovery level of 80%, 100% & 120% for DOXH was found to be 99.7, 99.66 & 99.69 & for LVXH 99.58, 99.66 & 99.63 respectively. Intra-day, Inter-day & precision analysis by different analyst was found to be 0.767, 0.563, 0.440 %RSD for DOXH & 0.507, 0.532, 0.708 % RSD for LVXH. Sandell's sensitivity was discovered to be adequate, and this shows that extremely less measure of the two medications can be successfully recognized by this technique. Finally, it was concluded, the developed & validated method was helpful and appropriate for regular quality analysis and simultaneous determination of drug products containing DOXH and LVXH in combination.

Keywords: doxycycline hyclate; levofloxacin hemihydrate; synthetic mixture; simultaneous estimation; UV- Visible spectrophotometric method.

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1. Introduction

Doxycycline hyclate (DOXH), $\text{C}_{24}\text{H}_{33}\text{ClN}_2\text{O}_{10}$ (CAS No. 24390-14-5), is a hygroscopic, yellowish powder, freely soluble in water & soluble in methanol[1] having Mol. Wt. 512.94 g/mol[2]. It is a wide range of effective semisynthetic[3] long-acting hydrochloride hemiethanol hemihydrate of Doxycycline got from Oxytetracycline[4, 5] having considerably more dissolvability power than doxycycline monohydrate, because of which it is broadly used in drug production[6]. It shows broad-spectrum effectiveness towards gram +ve and gram -ve microorganisms, including *Bartonella*, *Streptococcus Pyogenes*, *Hemoplasma*, *Spirochetes*, *Chlamydia Elis*, *Enterococci*, *Ehrlichia*, *Actinomyces sp.*, *Anaplasma Nocardia*, *Toxoplasma*, <https://biointerfaceresearch.com/>



Recent Updates on 3d Printing Technology: Potential Applications, Drug Design and Development

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ABSTRACT

3D printing technology has captured the attention of the medical device industry and the pharmaceutical industry because of their applications on various foundations in the healthcare industry. In three-dimensional printing technology it allows the creation of 3D objects with different geometry. However, although 3DP technology has many medical and economic potential benefits, the widespread use of 3DP technology in pharmaceutical products is still limited by certain technical and regulatory challenges. In order to overcome current barriers and promote specialized patient health care with much-needed personalized medicine in the future, continuous innovation and refinement in 3DP techniques is required. In the future, 3D-printed prostheses will likely be available, reducing waiting lists and increasing the number of lives saved. The goal of this analysis is to demonstrate an in-depth study of 3D printing applications in the medical field with the help and disadvantages and capabilities of technology. This paper sets out the regulatory agency's expectations, limitations, problems in establishing such programs for the production of drug products, benefits, disadvantages, uses and production methods. It also provides a comprehensive review of the current state of research and development in the field.

Keywords: 3D- Printing, Drug design, Materials, Development, Applications

INTRODUCTION

3D printing was introduced as a possible platform for personal medicine in the 1990s. With significant gains in 3D printed medical service, the FDA Center for Device and Space Health reviewed and deleted 3DP medical devices [1]. The first 3D printing method used in pharmaceuticals was achieved by printing an inkjet binder solution on a powdered bed, so it blends the particles together. The process was repeated until the desired final structure was obtained [2]. 3D printing has come a long way in the fields of automotive, aerospace, biomedical and tissue engineering than in the pharmaceutical industry. The FDA is promoting the development of advanced manufacturing technologies, which include 3D printing, using risk-based methods [3].

Three-Dimensional Printing (3DP) is a method of creating 3D objects from digital models by assembling or inserting sequential materials, which by layer-by-layer process enables objects of different geometry to be produced. This method is also called additional production, faster prototyping, or solid production of free forms [4]

Nowadays, three-dimensional printing is one of the evolving branches of technology, arts and science, and is still expanding applications. The term three-dimensional printing was defined by the International Standard Organization (ISO) as: "manufacturing by the use of an object using a printing head, microphone, or other printing technology". In contrast to the commonly used production and creative production methods, this production method is one of the additional production methods in which parts are processed from 3D model data during the integration of a layer of building materials. The effective method of additional production is called rapid prototyping and its benefits include reducing prototyping time and cost, easy conversion of the product to a design level, the possibility of small-scale production, individual product series or impractical structures. extraction techniques [5].



Development and Validation of a Smart Analytical UV Spectrophotometric Method for Chlorhexidine Gluconate and Metronidazole Estimation in Synthetic Mixtures

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ABSTRACT

A thorough review of the literature revealed that none of the most widely used pharmacopeias or journals include a technique for simultaneous assessment of Chlorhexidine Gluconate and Metronidazole in synthetic mixtures using UV/Visible spectroscopy. As a result, it was deemed critical to construct a system that would serve as a reliable, precise UV technique for the simultaneous estimation of CHG and MTZ. CHG and MTZ showed λ_{max} at 231 nm and 320 nm respectively, and iso-absorptive point at 279 nm in Phosphate buffer pH 6.8 prepared with water: methanol (70:30) dissolvable solvent system. In the concentration range of 2-20 g/ml, both agents obey Beer Lambert's law, with r^2 values of 0.9990 and 0.9998 indicating excellent linearity. According to the ICH criteria, the technique has been statistically and quantitatively verified in terms of linearity, precision, LOD, LOQ, accuracy, and specificity. The LOD for CHG and MTZ were determined to be 1.42 and 0.64 g/ml, respectively, whereas the LOQ were 4.30 and 1.93 g/ml. The percent recovery at a recovery level of 80%, 100% & 120% for CHG was found to be 99.54, 99.56 & 99.66 & for MTZ 99.70, 99.56 & 99.44 respectively. Intra-day, Inter-day & precision analysis by different analysts was found to be 0.146, 0.112, 0.195 %RSD for CHG & 0.097, 0.125, 0.161 % RSD for MTZ. Sandell's sensitivity was discovered to be adequate and this shows that very little measure of the two medications can be successfully recognized by this technique. Finally, it was concluded that the developed validated method was helpful and appropriate for the regular quality analysis and simultaneous determination of drug products containing CHG and MTZ in combination.

Keywords: Chlorhexidine Gluconate, Metronidazole, Synthetic mixture, Simultaneous estimation, UV-Visible spectrophotometric method

1. INTRODUCTION

Chlorhexidine Gluconate(CHG)is a colorless or light yellow aqueous solution of 1,1'-hexamethylene bis [5-(4-chlorophenyl) biguanide] digluconate [1] having a Mol. wt. of 897.88, a pKa estimation of 10.3, miscible with water, and soluble in acetone and ethanol (95%) [2]. It is an antiseptic in the form of a balanced particle made up of four chlorophenyl rings and two biguanide groups linked by a focal hexamethylene bridge [3]. At pH greater than 3.5, CHG is di-cationic, having strong basic properties with two positive charges on one or the other side of the hexamethylene bridge. It displays hostility to microbial action with a demonstrated impact against gram +ve and gram-ve microorganisms such as fungi, yeasts, aerobes, and anaerobes, and has a sporicidal impact [4]. Chlorhexidine salts are successful against some lipophilic infections, for example, adeno infection, herpes infection, and flu infection, and are respectably dynamic against molds and yeast. It acts by modifying the integrity of the cell membrane of microbes. Its predominant anti-plaque movement is the consequence of its substantivity and pin-pad impact. It is broadly utilized in different clinical fields, like gynecology, urology, ophthalmology, and treatment of burns, and so forth [5].

Metronidazole (MTZ) is a 2-methyl-5-nitroimidazole-1-ethanol, having a molecular weight of 177.15, melting point is 159–163°C, pKa value of 2.6; and it is slightly soluble in water[1],synthetic antiprotozoal, anti-infective, anti-inflammatory, amoebicidal, trichomonocidal, and bactericidal drug of the nitroimidazole family, utilized fundamentally in the cure of different anaerobic contaminations, for example, vaginitis, trichomoniasis, giardiasis, Crohn's disease, intraabdominal

EFFECTS OF STABILITY PROTOCOL OF COVID-19 VACCINE ON ITS EFFICIENCYVrushali H. Talmale*¹, Dr. Rahul H. Kasliwal² and Yogesh N. Gholve³^{1,2,3}Priyadarshini J. L. College of Pharmacy, Nagpur- 440016 Dist.-Nagpur (M.S.) India.

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Dist.-Nagpur (M.S.) India.**ABSTRACT**

Vaccination is primary to controlling COVID-19. Its success relies on having safe and powerful vaccines and also on high ranges of uptake by the public over time. As mRNA vaccines became the frontrunners in high-level scientific trials to fight the COVID-19 pandemic, challenges surrounding their components and balance became without problems apparent. In this statement, we first describe company proposals, based totally on to be had public statistics, for the (frozen) storage of mRNA Covid-19 vaccine drug products across the vaccine supply chain. The need for secure and effective coronavirus disorder (COVID-19) vaccines is met with many vaccine applicants being evaluated in pre-clinical and clinical trial. The COVID-19 vaccine obtained emergency use authorization (EUA) from the USA Food and Drug Administration (FDA) and/or other regulatory agencies global require either cold (i.e., 2–8°C) or even freezing temperatures as little as –70°C for storage and distribution. Thus, present cold chain will conflict to support both the same old country wide immunization applications and COVID-19 vaccination. Although interest has focused on vaccine efficacy and evaluating the variety of symptomatic cases. In this review article we have described the cold chain management of Covid-19 vaccine and describe the efficiency of different Covid-19 vaccine.

KEYWORDS: Vaccination, Covid-19, Moderna, AstraZeneca, Efficacy, Stability.**INTRODUCTION**

Vaccination might be vitally essential in controlling future waves of the COVID-19 pandemic.^[1] Despite uncertainty concerning the specifics of a few of the capacity vaccines (e.g., efficacy and required doses), it's far clear that high tiers of ordinary public popularity may be required. In recent years, vaccination costs have fallen and public self-assurance in vaccines has been inconsistent.^[2] The term "vaccine hesitancy" refers back to the "postpone in acceptance or refusal of vaccines regardless of availability of vaccine offerings".^[3] The motives for vaccine hesitancy are multi-levelled and complex, involving mental, social, and contextual elements.^[4] Vaccine hesitancy changed into glaring at some stage in the H1N1 pandemic, which saw variable vaccine uptake, with non-uptake associated with issues approximately vaccine protection and perceptions of hazard and danger.^[5] Preliminary evidence from the modern-day pandemic suggests that a huge proportion of the public is currently both not sure or unwilling to acquire a destiny vaccine for COVID-19.^[6] The significance of high ranges of uptake turned into proven in a latest study which cautioned that a good way to "extinguish an ongoing epidemic", the efficacy of a vaccine as the sole intervention needs to be as a minimum 80% when uptake is at 75%. If uptake is lower than this, then, a fair more efficacious vaccine might be wanted.^[7]

The stability of vaccines has a chief impact at the achievement of immunization programmes global. As a part of its efforts to guarantee vaccine great, WHO has recounted the significance of clearly defining the steadiness characteristics of a vaccine and emphasizes the role of national regulatory government in general vaccine assessment. The temperature sensitivity of vaccine characteristics, in particular efficiency, caused the development of level and cold chain necessities for all vaccines. In the 1980s and the start of the 1990s, a primary WHO consciousness turned into on thermostability trying out as measured by using potency assays, as part of lot release. More lately, guidance has addressed the importance of studies executed underneath actual storage situations, actual time and different applicable environmental elements. In addition, the WHO tips for nonclinical and scientific assessment of vaccines, strain a want for stability records to assist medical trial approval. However, till now there has been no complete guidance file to be had which offers with the steadiness evaluation of vaccines at distinctive ranges of vaccine improvement, manufacturing, licensing, lot release and post-licensing research.^[8]

The wish and hype that the media and public at large are putting on having as soon as possible a vaccine that protects towards COVID-19 is the end result of the first-rate triumphs that vaccines have had and are having in

the manage of infectious sicknesses. However, there is a protracted collection of infectious diseases in which vaccines are handiest in part effective and we've a series of sensational vaccine defeats.^[9] Indeed, each disease is an immunological trouble in itself: even nowadays, with all the statistics at one's disposal, it's far hard to are expecting what type of vaccine may be really effective. This difficulty is even greater for COVID-19, a brand-new ailment wherein ongoing studies in laboratories global are adding new statistics at an extraordinary tempo. SARS-CoV2, the coronavirus liable for COVID-19 is an RNA virus, and these viruses normally have a excessive mutation price. Genetic instability has lengthy been considered to symbolize a mission to expand effective vaccines towards RNA viruses.^[10] Only a few early-level medical trials with several specific mRNA vaccine applicants, in the main focused on remedy or safety of small businesses of recipients, were in development in January 2020 at the time of the outbreak of the COVID-19 pandemic. This situation dramatically modified inside the first months of 2020, whilst mRNA vaccines 'in a single day' became COVID-19 vaccine candidates and a global pandemic needed to be tackled as fast as feasible.^[11]

DESCRIPTION OF mRNA COVID-19 VACCINE

Currently, three non-replicating mRNA vaccine applicants against COVID-19 are being examined in human clinical trials, i.e., subsidized via Moderna, Pfizer-BioNTech, and AstraZeneca.

1 Many greater mRNA vaccine candidates are being evaluated in preclinical studies.

2 The first outcomes from large-scale, Phase 3 medical trials for the Moderna and Pfizer-BioNTech vaccines had been stated as very promising with high efficacy quotes (~95%). Moreover, no clinical holds due to unacceptable negative effects had been encountered up to now. As of the writing of this commentary, one mRNA-primarily based COVID19 vaccine (from Pfizer-BioNTech) has acquired conditional approval through the British MHRA (Medicines and Healthcare products Regulatory Agency) and greater regulatory our bodies are anticipated to observe soon.

3 Considering the ability of the mRNA vaccine approach to govern or maybe stop the pandemic, a rolling assessment method has been adopted through regulatory authorities which include FDA (US Food and Drug Administration) and EMA (European Medicines Agency) to make sure each a rigorous and speedy evaluation and approval procedure.

4 When accepted, a vast number of mRNA vaccine doses will need to be synthetic, shipped throughout the globe, stored at end-user web sites, after which administered in huge-scale vaccination campaigns.^[12]

Before the COVID-19 pandemic, the storage temperature of mRNA vaccine applicants in improvement had now not been given plenty interest. Typically, small batches were saved frozen at 80°C, after which thawed and administered as wished. Along with the developing

clinical promise of mRNA-based totally COVID-19 vaccines, however, there arose a developing perception that garage, transport and transport under those situations could create quite an undertaking whilst masses of hundreds of thousands (finally billions) of doses were to be administered all over the world.^[13]

We describe the cutting-edge proposals (based totally on publicly available corporation statistics) for the storage of mRNA COVID-19 vaccines across different tiers of the deliver chain including in-use balance conditions. This is followed with the aid of an outline of the literature of what is known approximately the stableness of mRNA vaccines, in particular the very last drug product.^[14] then speak attempts made to enhance their balance for the duration of storage, analytical techniques to screen their balance, and international regulatory guidelines for balance testing. Finally, summarize our current understanding base and discover outstanding challenges and possibilities with reference to enhancing the stability profile (and checks) of formulated mRNA vaccines.^[15] One of the best demanding situations encountered when developing mRNA vaccines is their terrible balance. Currently, most mRNA vaccines are administered IM, where the mRNA this is taken up with the aid of host cells ends in antigen expression.^[16] Early research on mRNA vaccines has tested that naked mRNA is quick degraded after management.^[17] Consequently, over the last few years efforts were made to enhance the in vivo stability of mRNA after administration. Another successful and presently broadly used technique is to encapsulate and shield the mRNA in LNPs.^[18] This reduces untimely mRNA degradation after management and enhances transport to the cytosol of antigen presenting cells.^[19] Although progress has been made to enhance the stableness in vivo and efficacy of mRNA-LNP vaccines, a great deal much less interest has been paid to their balance at some point of storage.^[20] In order to efficaciously distribute a vaccine worldwide, it ought to have a sufficiently lengthy shelf existence, ideally at refrigerator temperatures (2–8°C) or above. Currently, infrequently any data is to be had in the public domain on what happens while mRNA-LNP formulations are stored for lengthy intervals of time. Moreover, it's miles doubtful to what extent entrapping mRNA within LNPs impacts the storage balance of the mRNA vaccine. Additionally, very little is known about the structure and morphology of LNPs formulated with mRNA, the chemical balance of the LNP components and the colloidal balance of the mRNA-LNP machine. What is understood now could be that so one can keep the present-day mRNA COVID-19 vaccines for longer durations of time, they need to be frozen. The current mRNA COVID-19 vaccines of Moderna and BioNTech/Pfizer have to be kept among – 15 and – 25°C and among – 60 and – 90°C, respectively. the degradation techniques and the reasons why storage temperature necessities vary, are not completely understood. The requirement of storing the mRNA-LNPs in a frozen nation hampers vaccine distribution.

Especially, the very low temperature of -60 to -90°C is a main obstacle in relation to vaccine transport, storage and distribution amongst stop-customers worldwide. Most different vaccines can be stored at $2-8^{\circ}\text{C}$. Clearly, there is a want and possibility to locate ways of stabilizing mRNA-LNP vaccines to permit non-frozen storage. This overview approaches to make mRNA vaccines more stable, so they may be stored longer at less extreme temperatures. To explore the subject, the characteristics of mRNA-LNP vaccines and their effect on storage balance. are discussed.^[21] The composition of mRNA-LNP vaccines is essential to their balance. In the development of vaccines in opposition to SARS-CoV-2, a diffusion of different mRNA vaccine candidates has been created. Currently, there are 10 extraordinary mRNA COVID-19 vaccines that have improved to scientific trials (World Health Organization, 2021).^[22] The SARS-CoV-2 mRNA vaccines both use conventional mRNA or self-amplifying mRNA (SAM). There are currently three 'conventional' mRNA vaccines in use or in advanced clinical trials that encode the total S protein. These are the mRNA-1273 vaccine through Moderna, BNT162b2/Comirnaty by BioNTech/Pfizer and CVnCoV by CureVac. A particular assessment of these three mRNA COVID-19 vaccines consisting of their variations and similarities in mRNA structure and LNP layout has been provided in numerous other evaluations.^[23]

MAINTAINING THE COLD CHAIN STABILITY OF COVID-19 VACCINE

Effective cold chain management involves ensuring not only those temperatures to maintain vaccine viability are held constant, but also that adequate technologies are in place to allow stakeholders at various points in vaccine storage, transport and distribution chains to verify stability of required temperatures.^[24] Correct storage of the vaccine ensures its efficacy and the cold chain must be maintained during storage and transportation.

1. Storage requirement of each covid 19 vaccine

I. COVID-19 Vaccine Pfizer BioNTech

- Maximum shelf life is 6 months saved in a freezer at -80°C to -60°C
- 31 days at $2-8^{\circ}\text{C}$ after thaw (assign straight away after doing away with from freezer)
- In addition, as soon as removed from the refrigerator may be stored between 2 to 25°C for two hours prior to dilution
- In addition, as soon as diluted can be saved among 2 to 25°C for a further 6 hours
- Once thawed, the vaccine cannot be re-frozen
- During storage, minimise publicity to room light, and avoid publicity to direct daylight and ultraviolet mild

II. COVID-19 Vaccine AstraZeneca Vaccine

- Maximum shelf life is 6 months stored in a fridge between 2 to 8°C

- Once eliminated from the refrigerator, may be stored among 2 to 25°C for up 6 hours
- Once punctured, the vial has to be used within 6 hours
- Must now not be frozen
- During storage maintain vials in outer carton to defend from mild

III. COVID-19 Vaccine Moderna Vaccine

- Maximum shelf life is 7 months stored in a freezer at -25°C to -15°C
- Do no longer keep on dry ice or under -40°C
- 30 days at 2 to 8°C after thaw (assign right now after removing from freezer)
- Once removed from the refrigerator, may be saved between 8 to 25°C for up 12 hours
- Once punctured, the vial has to be used inside 6 hours
- Once thawed, the vaccine cannot be re-frozen
- During storage maintain vials in outer carton to shield from light.^[25]

2. Using fridges appropriately stored a covid19 vaccine

I. Monitoring temperatures

- In-constructed refrigerator thermometers usually measure the air temperature within the fridge.
- Recommendation that in addition to monitoring the air temperature of the refrigerator, a temperature probe need to be positioned right into a "mock up" product near the saved vaccines. This is called a "load probe". This probe will more accurately constitute the impact of temperature fluctuations on the temperature of the vaccine itself.
- The temperature probe within the air may also check in temporary out of restrict temperatures for the duration of regular opening and closing of the door, so the load probe thermometer can be used to provide guarantee that the vaccine itself has remained within range.
- The load probe can also be useful in establishing the lag time between the air temperature and load temperature going out of range. This information can be used to set alarm delays and alarm thresholds.
- The load probe may be useful in investigating the outcomes of a fridge failure. If the weight probe is hooked up to a datalogger rather than max/min thermometer this can provide extra beneficial records about the duration of the temperature excursion.

II. Using alarms

- Use of an alarm can be helpful in tracking temperature and in which deviations arise. To be effective alarms must important.
- Be set efficiently with the necessary parameters
- Sound efficiently to tell team of workers when a temperature monitoring trouble occurs

III. Fridge Maintenance

Fridges need to be maintained if they're to remain effective. This needs to consist of:

- A recurring service and protection programme
- Annual calibration of temperature sensors.^[26]

3. Transporting the covid 19 vaccine while maintain the cold chain

I. Choosing your cool box

- The cool box needs to be designed for cause of transporting and storing vaccines, and be certainly portable
- If frozen cool packs will be used, the cool field should be designed to prevent direct contact among the cool pack and the vaccine to prevent freezing
- The cool packing containers must be sourced from a acknowledged scientific deliver agency. Domestic cool bins need to not be used to transport vaccines.
- Obtain statistics to make sure that your intended use of the cool box will preserve the vaccine among +2°C to +8°C at some point of its use.

II. Preparing cool box

Cool packs should be chilled in accordance with the manufacturer's instructions, to ensure they maintain the right temperature.

- The box and cool packs must be carefully assembled in strict accordance with the manufacturer's instructions
- If frozen packs are specified by the manufacturer, a digital thermometer must be used to check the internal temperature of the cool box after the blocks are inserted and with lid closed to ensure it is between +2°C to +8°C prior to use.
- If the cool box doesn't include pockets to hold the cool blocks, a thick (1-2cm) layer of insulating material such as crumpled paper towel or bubble wrap must be used to separate the blocks from the vaccine.

III. Using your cool box

Ensure that simplest the quantity of vaccines required for each session are removed from the vaccine refrigerator & transferred to the cool container.

- The vials must be located fast into the cool bins and opening instances have to be stored to a minimal
- Vaccine vials should be packed securely to minimise movement of the vaccine. Bubble wrap or paper can be used for packing.
- Place a digital thermometer or temperature logger in with the vaccines to offer additional guarantee that the perfect storage situations are maintained.
- Any unused vaccines left over at the quit of a vaccination session must be discarded. They may not be returned for future use.
- Keep the period of time the vaccines are stored in a cold place to the minimum required.^[27]

4. Managing temperature excursions of covid 19 vaccine

Correct cold chain management will prevent temperature excursions. Where they do occur, set actions should be undertaken to gather information and seek advice.

I. Take immediate remedial action

- Return to refrigerated storage any vaccine vials that have been uncovered to temperatures outside of +2°C to +8°C
- Quarantine the affected inventory inside the refrigerator by way of attaching a "DO NOT USE" label
- Check obvious reasons e.g. The refrigerator door having been left open or a energy switch having been grew to become off.
- Confirm the refrigerator is within range or has again to +2°C to +8°C and, once documented, reset the min/max fridge reading
- Where no apparent rectifiable purpose may be identified, take the fridge out of use until a research into the motive of the excursion has been concluded. The fridge must be returned to use simplest as soon as it has been showed to be functioning efficaciously.

II. Determine and file the element

- To help recognize the situations the vaccine has been exposed to you have to:
- Determine the duration of time vaccine has been out of doors of the recommended storage conditions
- Determine the max /min temperature reached
- Examine the records of contemporary and past facts from the refrigerator
- The closing time the cold chain may be guaranteed is the point at which the min/max was closing study and found to be inside 2 to 8°C.
- Min/max facts provide constrained records to assist decision making as they only seize the extremes of temperature the fridge has reached since the last time the min/max recording turned into reset.^[28]

EFFICIANCY OF COVID-19 VACCINE

1. Pfizer-BioNTech

On December 11, 2020, this became the first COVID-19 vaccine to acquire an FDA EUA, after the company suggested tremendous clinical trial information, which included information that the vaccine become as much as 95% effective at preventing symptomatic disease. The researchers document that the vaccine changed into similarly effective across a diffusion of different kinds of humans and variables, consisting of age, gender, race, ethnicity, and Body mass index (BMI)—or presence of different scientific conditions. In clinical trials, the vaccine become one 100% effective at preventing intense ailment. In past due March, a small CDC have a look at that enrolled three, 950 fitness care personnel, first responders, and different important and frontline employees showed the vaccine to be 90% powerful upon complete immunization (at least 14 days after the second

dose) in actual-world situations. In early May, the Pfizer-BioNTech vaccine changed into observed to be greater than 95% effective towards extreme disorder or demise from the versions first detected in the United Kingdom (B.1.1.7) and South Africa (B.1.351) in two studies based totally on actual-global use of the vaccine. While the efficacy against contamination varied among the two studies, both also confirmed the vaccine gives robust safety.

2. AstraZeneca

AstraZeneca updated its records evaluation of its section three trials in March, displaying its vaccine to be 76% effective at lowering the danger of symptomatic sickness 15 days or greater after receiving the 2 doses, and 100% towards intense disorder. The business enterprise additionally stated the vaccine changed into 85% effective in stopping COVID-19 in humans over 65. The organization's update came a few days after the National Institute for Allergy and Infectious Diseases (NIAID) expressed situation over new facts AstraZeneca had submitted earlier of requesting an EUA from the FDA. So far it seems to paintings better towards the mutation that emerged in Great Britain than the one that emerged in South Africa. A paper in early February referred to 74.6% efficacy towards the B.1.1.7 variation. However, the vaccine did no longer guard as properly against mild and slight cases in humans infected with the B.1.351 variation. Therefore, South Africa halted its rollout at the same time as scientists retain to study whether the vaccine can save you extreme illness and loss of life in people infected with this version.

3. Moderna

Moderna's vaccine turned into the second one authorized for emergency use inside the U.S it acquired FDA EUA on December 18, 2020, approximately per week after the Pfizer vaccine. Moderna is likewise an mRNA vaccine, using the identical technology because the Pfizer-BioNTech one and with a further high efficacy at preventing symptomatic disorder. There are two key variations: The Moderna vaccine can be shipped and stored in long-term storage in standard freezer temperatures, and stored for up to 30 days the usage of regular refrigeration, making it less complicated to distribute and save. Also, the Moderna vaccine become slightly less effective in medical trials about 86% in folks that are 65 and older 95% effective at preventing symptomatic contamination in people with no evidence of preceding COVID-19 infection. The vaccine regarded to have high efficacy in scientific trials among people of numerous age, sex, race, and ethnicity classes and among people with underlying medical conditions (despite the fact that as referred to above, the efficacy price drops to 86.4% for people ages 65 and older). In past due March, a small CDC look at that enrolled 3,950 health care employees, first responders, and other critical and frontline workers showed the vaccine to be 90% powerful upon complete immunization (as a minimum 14 days after the second one dose) in actual-international

conditions. How properly it really works on virus mutations: Some studies has recommended that Moderna's vaccine may additionally provide safety towards the B.1.1.7 and B.1.351 versions. Researchers are still analysing this.^[29]

CONCLUSION

The mRNA vaccine from Pfizer-BioNTech, AstraZeneca and Moderna are promising frontrunners for safety in opposition to the COVID19 pandemic. Although particular efficacy and protection statistics from the clinical trials as well as required storage situations are shared with the general public via WHO suggestions, no background records on the excellent attributes that manipulate and restrict stability is to be had. In above facts we've defined balance of various Covid-19 vaccine maintain through cold chain management for the duration of storage and transformation and test its efficiency according to literature survey or clinical trial we determined the Pfizer-BioNTech Covid-19 vaccine shows higher efficacy than other Covid-19 vaccines.

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CURRENT UPDATES ON HERBAL OIL VS SYNTHETIC ANTIBIOTICS USE FOR TOPICAL APPLICATION

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ABSTRACT

Topical skin infections represent some of the most common infectious sicknesses globally. Prevention and treatment of skin infections can involve utility of a topical antimicrobial, which may be an herbal oil and synthetic antibiotic drug. However, there's restricted evidence to aid the widespread prophylactic or healing use of topical agents. Challenges concerned inside the use of topical antimicrobials encompass growing costs of bacterial resistance, local allergy reactions. We evaluate the proof for the foremost scientific makes use of herbal oil and topical synthetic antibiotics. Herbal oils are traditional herbal treatments used to deal with several situations. 5% of plant oils used for dermatological usages, pores and skin moisturizing and skin care. The benefits of this sort of therapeutics encompass properly availability, local cultural elements and individual choices. the growing demand for herbal and organic merchandise, and the already established synergistic consequences of natural oil. Synthetic antibiotics are beneficial for topical administration to treating topical skin condition rather than the oral administration because of minimising the side effect of oral administration. Nowadays topical antibiotics is widely accepted effective and safe treatment for bacterial infection. In this review article comparison of the herbal oil Vs synthetic antibiotic drug for topical use.

Keywords: Herbal Oil, Antibiotics, Synthetic, Antibacterial, Topical, Resistance**Duration: Received-** 31/03/2021, **Reviewed-** 06/04/2021, **Revised/ Accepted-** 20/04/2021**Correspondence**Vrushali H Talmale * ✉ vrushalitalmale@gmail.com**Address -** Department of Pharmaceutics, Priyadarshini J. L. College of Pharmacy, Nagpur, Maharashtra – 440016, India.**INTRODUCTION**

The skin is the body's largest mechanical barrier against the external environment and invasion by microorganisms. It is responsible for numerous functions such as heat regulation and protecting the underlying organs and tissue.^[1] The uppermost epidermal layer is covered by a protective keratinous tissue which lets in for the removal of microorganisms through sloughing off of keratinocytes and acidic sebaceous secretions. This produces adversarial surroundings for microorganisms^[2] In addition to those defences, the pores and skin additionally includes herbal microflora which offers extra protection via inhibiting pathogenic bacterial growth by competing for nutrients and attachment sites for producing metabolic products that inhibit microbial growth.^[3] The pores and skin's natural microflora consists of species of Corinne bacterium, staphylococci, streptococci and Candida as well as Propionibacterium^[4] Topical skin infections generally require topical treatment; however, because of the potential of microbes to evolve and because of the overuse and incorrect prescribing of the modern available conventional antimicrobials, there was

emergence of resistance in not unusual pores and skin pathogens which include Staphylococcus aureus ensuing as methicillin-resistant Staphylococcus aureus (MRSA) and other such traces. Treatment has therefore emerged as a mission and is often no longer a success.^[5,6] In a few areas of the sector, infections are unresponsive to all recognized antibiotics.^[7] This risk has end up so severe that simple ulcers now require treatment with systemic antibiotics.^[8] A simple reduce at the finger or easy removal of an appendix should bring about loss of life via contamination. The World Health Organization (WHO) has warned that commonplace infections can be left without a therapy as we're headed for a future without antibiotics.^[9] Therefore, one of the answers available is to make use of one of the oldest sorts of remedy, herbal merchandise, to deal with pores and skin infections and wounds.^[10]

HERBAL OIL

Oils are one of the most ancient forms of natural herbal medicines.^[11] Since the start of civilization, herbal, animal and mineral medicaments were used to deal with

**Relationship between coronavirus and mucormycosis disease**

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ABSTRACT

As the human-to-human communicated infection, Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), has been a crisis worldwide general wellbeing event. Mucormycosis is a genuine, irregular however cosmopolitan, uncommon artful contagious contamination brought about by a gathering of molds called mucormycetes. These molds live throughout all the climate. It most normally influences the sinuses or the lungs in the wake of breathing in parasitic spores from the air. Mucormycosis is an uncommon disease, which when recognized early can be controlled. The connection among Coronavirus and mucormycosis of the paranasal sinuses should be given genuine thought. Uncontrolled diabetes and over-ardent utilization of steroids are two primary variables irritating the ailment, and both of these should be appropriately checked.

Keywords: Covid-19, Mucormycosis, Fungal infection, Corticosteroids, Diabetes mellitus

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INTRODUCTION**COVID-19**

Coronavirus disease 2019 (Covid-19) is a contamination brought about by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2)^[1,2]. Since the main case was recognized, in December 2019 in Wuhan, China, there have been different turns and contorts as far as its pathophysiology, conclusion, the board, sequelae and complications^[3-6]. The Covid-19 manifestation range has extended since the primary days of the illness show, which at first included just a dry hack and high evaluation fever, to moreover incorporate different multisystem issues like breathlessness, anosmia, ageusia, looseness of the bowels, summed up discomfort, intense cardiovascular injury and optional contaminations and a few patients were seen with asymptomatic side effects. Early recognition of these high-morbidity conditions is urgent for ideal treatment and improved outcomes^[7-9].

Covid-19 virus are positive-sense, single-stranded RNA infections having an area with the order Nidovirales, suborder Coronidovirineae, family Coronaviridae and subfamily Orthocoronavirinae^[10,11]. The subfamily Orthocoronavirinae is additionally separated into Alpha-, Beta-, Gamma and Delta-Coronavirus^[11]. Alpha- and Beta-Coronavirus are pathogenic to well evolved creatures, including individuals, bats, pigs, mice, and felines. Gamma- and Delta-Coronavirus are typically pathogenic to birds yet infrequently irresistible to mammals^[12].

As of late, we have noticed another relationship among ENT and Covid, a more perilous and conceivably destructive one: that of intrusive parasitic sinusitis coming about because of mucormycosis.

Mucormycosis

Mucormycosis is an intrusive contagious contamination brought about by mold fungi of the genus *Mucor*, *Rhizopus*, *Rhizomucor* and *Absidia*, which are in the Mucorales order of the Zygomycetes class^[13]. The most well-known sort is *Rhizopus Oryzae* and around 60% of mucormycosis cases in people; it is liable for 90% of the rhino cerebral form^[14]. It is as often as possible found in conditions where the insusceptible framework is stifled like uncontrolled diabetes, haematological malignancy (acute leukemia), solid organ relocate, undeveloped cell transplant, neutropenia, deferoxamine treatment and corticosteroid treatment. It is infrequently seen in strong individuals^[15,16].

The most well-known clinical infections are with rhinocerebral, followed by cutaneous, pulmonary, disseminated and gastrointestinal tract involvement^[16]. The space of association can be influenced by the fundamental condition. While rhinocerebral association is seen in diabetic patients. Because the development of the organisms is invigorated by a high blood glucose focus, infection is uncommon in patients with all around controlled blood glucose levels^[17]. It is a type of infection that can spread to the brain.

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Review Article

A review on synthetic study and biological activities of tetrahydropyrimidinone derivatives

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ABSTRACT

The process of drug discovery involves the identification, synthesis, characterization, screening, assay and development of new chemical entities that are suitable for pharmaceutical use. 2-thioxo-1, 2, 3, 4-tetrahydropyrimidinone (THPM) are compound & represents are markable pharmacological efficient moieties and a range of therapeutic properties. Synthetically they were synthesized using Mul reactions like Biginelli reaction or either microwave and conventional metho multiple benefits of the time consuming and get high yield. In this review, recent developments on THPMs and recently developed as antimicrobial, anti-inflammatory, analgesic, antifungal, antibacterial, anti-tubercular, anti-analgesic, anticonvulsant, antioxidant, etc. given a potent biological and pharmaceutical activity.

Keywords: Drug discovery; 2-thioxo-1, 2, 3, 4-tetrahydropyrimidinone; Biginelli reaction; antioxidant activity; antihypertensive activity

INTRODUCTION

Pharmaceutical chemistry is the core branch of pharmacy education and research. It can be categorized as synthesis of new drug molecule, its analysis and pharmacological studies. The chemistry of heterocyclic compounds is important for the discovery of novel drug. The process of drug discovery involves the identification, synthesis, characterization, screening, assay and

suitable for medical and pharmaceutical use as a result of remarkable pharmacological activity of pyrimidine derivatives, intensive research has been focused on anti-inflammatory and antimicrobial pyrimidine nucleus. The present review discusses the synthesis & biological activity of pyrimidine derivatives [2]. During the last two decades, pyrimidine derivatives have been used as chemotherapeutic agents and have shown clinical applications, which are a

SYNTHESIS AND BIOLOGICAL EVALUATIONS OF SOME NOVEL MANNICH BASES OF BENZIMIDAZOLE AND THEIR DERIVATIVES

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ABSTRACT

The present research work was carried out with a series of Mannich bases of substituted benzimidazole and their derivatives were prepared by both conventional heating and microwave assisted techniques. Benzimidazole and their derivatives were prepared through condensation between *o*-phenylenediamine and six different substituted aliphatic acids in presence of hydrochloric acid, then the product undergone Mannich reaction in presence of formaldehyde, ethanol, primary amines and ethanol to obtained six different substituted Mannich bases of benzimidazole derivatives. All the synthesized compounds were subjected to TLC to find out the purity. The synthesized derivatives were characterized by spectroscopic data and were evaluated for antimicrobial activity and antioxidant activity by using Cup plate method and DPPH free radical scavenging assay respectively. The results of antimicrobial activity (*in-vitro*) revealed that the compounds (2a, 2b, 2c & 2f) possessed significant antimicrobial activity. Among the compound tested, the compound (2d) compound (2d) had shown the highest antibacterial & antifungal activity which was comparable to that of ciprofloxacin and fluconazole respectively. The substituent of amino group on benzimidazole ring contributed significantly towards amino acid. This study suggested that microwave assisted method can be appropriate for the synthesis of benzimidazole and their derivatives with better purity, yield and ecofriendly method.



CURRENT SCENARIO IN ANTICANCER DRUG THERAPY

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Abstract:

Disease is presently the subsequent driving reason for death internationally and is relied upon to be answerable for around 9.6 million passings in 2018. With a remarkable comprehension of the atomic pathways that drive the turn of events and movement of human diseases, novel focused on treatments have become an energizing new improvement for hostile to malignancy medication. These focused on treatments, otherwise called biologic treatments, have become a significant methodology of clinical therapy, by acting to hinder the development of disease cells by explicitly focusing on atoms needed for cell development and tumorigenesis. Because of their particularity, these new treatments are required to have better adequacy and restricted unfriendly results when contrasted and other treatment choices, including hormonal and cytotoxic treatments. Various advancements are right now under assessment in clinical preliminaries or have been now brought into clinical practice. While nanomedicine is adding to the improvement of biocompatible materials both for demonstrative and remedial purposes, bioengineering of extracellular vesicles and cells got from patients has permitted planning impromptu frameworks and univocal focusing on methodologies. In this audit, we will give a top to bottom investigation of the most creative advances in essential and applied malignancy research.

Keywords: Cancer, tumorigenesis, vesicles, targeted therapy, immunotherapy, gene therapy, thermal ablation, radiomics, pathomics

Introduction:- Malignant growth is one of the primary driver of death around the world, and in the previous decade, many exploration considers have zeroed in on discovering new treatments to diminish the results brought about by customary treatments.

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PharmacologyJournal homepage: <https://www.ijcap.in/>

Review Article

Bioentrepreneurship: A venture for commercializing biotechnological knowledgeShailju G Gurunani¹, Shubhada V Mangrulkar^{1,*}, Dhanashri T Jawal¹,
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ABSTRACT

The term "biotechnology" is widely used and encompasses many different technologies. Consulting firms provide common definitions of modern biotechnology. The term "modern biotechnology" refers to all innovative methods, processes or products, including the use of living organisms or their cellular compartments, and the use of biochemistry, molecular biology, immunology, virology, microbiology, cell biology or environmental sciences and engineering. Biotechnology and entrepreneurship are intrinsically linked together, and are studied biotechnology at the regional, firm, and individual level of analysis. The concept of "bioentrepreneurship", is described as a wealth created by applying the life sciences to a business environment. Bioentrepreneurs seek business value in the technologies they use to conduct biotechnology research. Some well-known bio startups are based on multiple companies. Biotechnology and entrepreneurship are essentially linked. In recent years, a large number of articles in the business literature have studied biotechnology at the level of analysis of regions, companies and individuals. This review article will encourage stakeholders to address the research space which have been recognized and will help more progress in this captivating area of interest in the field of biotechnology and entrepreneurship.

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1. Introduction

In the current years, entire world is in the surge of innovation. Everyday new ideas lead to the development and reformation of any material which can be natural or synthetic. Biotechnology is one of those areas where wave of new ideas brought several products of agricultural, environmental, medical and pharmaceutical applications.

2. Definitions and Concepts

2.1. Biotechnology

The term "Biotechnology" was first used by "Karl Ereky" in 1919, meaning the production of products from raw materials with the aid of living organisms.¹The era of biotechnology-enhanced agriculture began in the 1990s with government approval for commercial deployment of biotech soybeans, corn, cotton, canola, and papaya. Because of their tremendous production advantages, biotech crops have become the most rapidly adopted technology in the history of agriculture.

The word "biotechnology" is extensively applied and covers a number of different technologies. A commonly used definition of modern biotechnology is provided by the

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PharmacologyJournal homepage: <https://www.ijcap.in/>

Review Article

A review on current strategies and emerging treatments in management of silicosis: An ayurveda perspective

Dhanashri Tikaram Jawal¹, Shubhada V Mangrulkar^{1,*}, Prasad Sherekar²,
Dinesh R Chaple¹¹Priyadarshini J. L. College of Pharmacy, Nagpur, Maharashtra, India²Priyadarshini Institute of Engineering and Technology, Nagpur, Maharashtra, India

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ABSTRACT

Background: Silicosis is a possibly deadly, irreversible, fibrotic pneumonic sickness that may create resulting to the inward breath of a lot of silica dust over the long haul. As a rule, silicosis just creates resulting to significant word related presentations. The sickness has a long idleness period and may clinically present as an intense, quickened, or ongoing infection.

Main Body: In this audit the medicines that can lessen the aggravation and scarring in which are as nodular injuries in the upper projections of the lungs. The principle point of audit is to the likely home grown treatment for silicosis. This survey zeroed in on different medicines which incorporate natural plants, neutraceuticals, polyherbals, and herbominerals and furthermore cell based treatment for silicosis.

Conclusion : From that review we presume that the natural treatment which is utilized in treatment of silicosis is potential treatments which incorporate huge quantities of home grown plants, polyherbals, neutraceuticals and herbominerals likewise incorporate the new treatment for silicosis is the cell based treatment.

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1. Introduction

Silicosis is a type of word related lung infections brought about by inward breath of glasslike silica. It is set apart by irritation and scarring as nodular injuries in the upper projections of the lungs. It is a kind of pneumoconiosis. Silicosis (especially the intense structure) is portrayed by windedness, hack, fever, and cyanosis (somewhat blue skin). It might regularly be misdiagnosed as aspiratory bowel purge (liquid in the lungs), pneumonia, or tuberculosis.¹ Silicosis brought about 102 passings in USA.²

Silicosis is a possibly lethal, irreversible, fibrotic pneumonic infection that may create resulting to the inward

breath of a lot of silica dust over the long haul. The sickness has a long inertness period and may clinically present as an intense, quickened, or ongoing infection.

The pathophysiology of constant silicosis includes persistent aggravation emerging because of the gathering of different fiery go between and fibro genic variables. Affected by these variables, aspiratory silicoproteinosis (a rapidly fatal pneumoconiosis occurring several weeks to months after massive exposure to silica dust, characterized by the presence of proteinaceous fluid in the air spaces) creates as eosinophilic proteinaceous material aggregates in the pneumonic alveolar spaces. The pace of illness movement seems to rely on the pace of silica affidavit in the lungs, just as the aggregate sum of glasslike silica that is really held in the lung. At times, silicosis might be related with the attending improvement of different


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Research Article | [Published: 21 October 2021](#)

Amalgamation of Solid Dispersion and Melt Adsorption Technique: Improved *In Vitro* and *In Vivo* Performance of Ticagrelor Tablets

[Mukesh Yadav](#), [Jayant Sarolia](#), [Bhavin Vyas](#), [Manisha Lalan](#),
[Shubhada Mangrulkar](#) & [Pranav Shah](#) 

[AAPS PharmSciTech](#) **22**, Article number: 257 (2021)

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Abstract

Ticagrelor (TG) suffers from low peroral bioabsorption (36%) due to P-gp efflux and poor solubility (10 µg/mL). TG solid dispersion adsorbates (TG-SDAs) were formulated using an amalgamation of solid dispersion and melt adsorption techniques which were simple, economic, scalable, and solvent-free. FTIR indicated no incompatibility between drug and excipients. DSC, XRD, and SEM suggested a reduction in TG crystallinity. $Q_{30\text{min}}$ from TG-SUSP and TG-conventional tablets was only 2.30% and 6.59% respectively whereas TG-SDA-based tablets exhibited a significantly higher drug release of 86.47%. Caco-2 permeability studies showed 3.83-fold higher permeability of TG from TG-SDAs. TG-SDA-based tablets exhibited relative bioavailability of 748.53% and 153.43% compared to TG-SUSP and TG-conventional tablets respectively in rats. TG-SDA-based tablets were devoid of any cytotoxicity as indicated by MTT assay and



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Research Articles

Prospecting for *Cressa cretica* to treat COVID-19 via *in silico* molecular docking models of the SARS-CoV-2

Sapan Shah  , Dinesh Chaple, Sumit Arora , Subhash Yende , Chetan Mehta  & Usha Nayak 

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Abstract

The severe acute respiratory syndrome COVID-19 declared as a global pandemic by the World Health Organization has become the present wellbeing worry to the whole world. There is an emergent need to search for possible medications. *Cressa cretica* is reported to show antitubercular, antibacterial and expectorant property. In this research, we aim to prospect the COVID-19 main protease crystal structure (M^{pro}; PDB ID: 6LU7) and the active chemical constituents from *Cressa cretica* in order to understand the structural basis of their interactions. We examined the binding potential of active constituents of *Cressa cretica* plant to immensely conserved protein M^{pro} of SARS-CoV-2 followed by exploration of the vast conformational space of protein–ligand complexes by molecular dynamics (MD) simulation.

Pharmaceutical Comparison of Generic and Branded Tablets from the Indian Market

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ABSTRACT

The concept of generic drug prescription becoming popular all over the globe. The government of India started BhartiyaJanaushadhiPariyojna. Innovators drugs are under patent period and within 180 day of expiry application for generic can be filed. Generic drugs are equivalent to the brand-name product in almost all aspects and do not require huge investment for development hence, are cheaper but equally effective. But, the general population has the misconception that generic drugs are substandard, adulterated, less effective, and are of poor quality. The present study aimed to check the difference between the generic (Branded generic), which is cheaper, and branded (Costly) drugs.

Local market analysis was done to select the most frequently sold generic and branded tablets. All the selected drugs (Levocetirizine, Diclofenac, Cefixime, Amlodipine, Metformin) were passed through various tests like Weight variation, Hardness, Friability, Disintegration, Dissolution, and Cost analysis. After rigorous tests, we found that all the selected generic and branded tablets found to pass the tests and test values are within the standard acceptable limits. However generic is cheaper than branded and the cost difference between them per tablet was found to be significant. All the generic and branded tablets are pharmaceutically equivalent and there is no significant difference between them despite the cost of generic is lower than branded tablets. Hence, generic is the better option for the branded drug which may reduce the cost of the prescription, save huge public money annually, and increased patient survival at least in the low-income group.

Keywords: Pharmaceutical evaluation, Dissolution, Pain killer, Antacid, Cost analysis

Branded or Innovator Drug developed genuinely by Pharmaceutical companies after passing through rigorous evaluation tests, to be claimed as a safe and effective in the treatment of disease or disorders. Pharmaceutical companies invest ample amounts of money in new drug development, hence has the legal right to manufacture and distribute medicine for a specified period under brand name i.e. the patent period [1].

A generic drug is the same as a brand-name product in terms of dosage, strength, quality, bioavailability, efficacy, and intention, but may differ in colour, taste, and packaging, labelling, excipients, mechanism of delivery, and other factors [2-3]. The authorization from regulatory authority to manufacture generic drugs is legally obtained 180 days before the patent period expires.. The manufacture does not require to duplicate the original clinical trials data for safety and efficacy but has to prove the bioequivalence without undergoing tedious procedure. This reduces cost and makes generic drugs cheaper than branded [4].

70%, Over-the-counter (OTC) drugs, 21%, and patented brand name drugs, 9% account for market share revenues in India [5]. The Hatch Waxman Act allowed for the approval of generic copies of various drugs in the market because of less development cost. India is the world's largest producer of generic drugs, exporting them to over 200 countries and accounting for 20% of global exports. The majority of generic drugs in India are sold under their brand name (brand generics). India is a developing country, 70% of the Indian population spends money on health care from their own pockets, due to poor accessibility and affordability of people, generic drugs are the alternative to minimize the cost of treatment [6-8]. The Government of India's department of pharmaceuticals launched the 'Jan Aushadhi Campaign' in April 2008 to provide quality generic medicines at a lower cost than branded products.. In continuation to this in 2012, the West Bengal government health department implemented the policy of "mandatory generic drug use" in their government hospitals. Observing the success of the Bengal policy, the government of India promoted and supported pharmacists to open thousands of Jan Aushadhi stores under PradhanmantriBhartiyaJanaushadhiPariyojna, with the boom of generic markets, now battle for better drugs is going on. Recently A survey conducted in May-July 2015 by Government Medical College Hospital, Kolkata revealed that 90% of participants believed that generic drugs were as effective as their brand-name counterparts [9]. There is a lot of debate about encouraging people to use generic drugs



(REVIEW ARTICLE)



A review of approaches in computer-aided drug design in drug discovery

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Abstract

The process of discovering and developing a new medication is often seen as a lengthy and expensive endeavors. As a result, computer-aided drug design methods are now frequently utilized to improve the efficiency of the drug discovery and development process. Various CADD approaches are regarded as potential techniques based on their needs; nevertheless, structure-based drug design and ligand-based drug design approaches are well-known as highly efficient and powerful strategies in drug discovery and development. Both of these approaches may be used in conjunction with molecular docking to conduct virtual screening for the purpose of identifying and optimizing leads. In recent years, computational tools have become increasingly popular in the pharmaceutical industry and academic fields as a means of improving the efficiency and effectiveness of the drug discovery and development pipeline. In this post, we'll go over computational methods, which are a creative way of discovering new leads and assisting in drug discovery and development research.

Keywords: Computer Aided Drug Design (CADD); Structure-Based Drug Design; Ligand-Based Drug Design; Virtual Screening and Molecular Docking

1. Introduction

Computational methods to drug design, discovery, and development are being explored, implemented, and admired at a rapid pace. In terms of time, money, and people, introducing a new medication to the market is an extremely difficult, hazardous, and expensive procedure. In general, it is estimated that the medication research and development process takes 10-14 years and costs more than \$1 billion in total. As a result, computer assisted drug design (CADD) is extensively employed as a novel drug design methodology to reduce time, cost, and risk borne elements. It has been demonstrated that using CADD methods can cut drug research and development costs by up to 50%. Any software program-based approach for developing a standard to link activity to structure is referred to as CADD.

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2D-QSAR Modeling of Quinazolinone Derivatives as Angiotensin II Type 1a Receptor Blockers

Sapan K. Shah, Dinesh R. Chaple

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Abstract

Angiotensin receptor blockers (ARBs) are a group of drugs primarily used in the treatment of cardiovascular disease. Multiple quantitative structural activity relationship (QSAR) models established for prediction of angiotensin II type 1a (AT-1a) receptor blocking activity of quinazolinone derivatives to investigate the structural attributes that have significant correlation with biological activity. The genetic algorithm (GA) approach was used to generate a highly predictive models using easily interpretable Py, OEstate and Padel descriptors. OECD principles have been followed to develop statistically robust QSAR models ($R^2_{tr} = 0.8055 - 0.8625$) with good external predictivity ($CCC_{ex} = 0.7528 - 0.8450$). The multiple QSAR models successfully identified that increase in surface area of negatively charge carbon atom within four bonds from N atom, presence of tetrazole substituents and sp^3 N atoms governs the AT-1a receptor blocking activity. The validated QSAR models of present study might be helpful for evaluation AT-1a receptor blocking activity to identify novel hits.

Article Preview


Top

Introduction

Controlling hypertension is considered to be a prime objective in the management of cardiovascular diseases ("Principles of Treatment," 2009). Neurohormonal blockade of the renin-angiotensin system through inhibiting angiotensin-converting enzyme and angiotensin II has involved the pillar of treatment therapy of hypertension (Álvarez et al., 2004; Ma et al., 2010). Renin and angiotensin-converting enzyme (ACE) are two enzymes that work together to release the linear octapeptide angiotensin II, a potent vasoconstrictor that controls blood pressure homeostasis, fluid volume, and electrolyte balance (Pacurari et al., 2014; Piqueras & Sanz, 2020). Angiotensin II also activates the AT2-receptor subtype, which has been shown in experiments to mitigate the negative effects of AT1-receptor stimulation (Timmermans et al., 1992). Selective AT1 receptor blockade thus appears to be a viable therapeutic target in hypertension and cardiovascular disease. AT1-receptor blockers have an

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Phytophospholipid Complex of Caffeic Acid: Development, *In vitro* Characterization, and *In Vivo* Investigation of Antihyperlipidemic and Hepatoprotective Action in Rats

[Shubhada Mangrulkar](#) , [Pranav Shah](#), [Sonali Navnage](#), [Priyanka Mazumdar](#) & [Dinesh Chaple](#)[AAPS PharmSciTech](#) **22**, Article number: 28 (2021)**394** Accesses | **5** Citations | [Metrics](#)

Abstract

Caffeic acid (CA), a hydroxycinnamic acid possessing a variety of pharmacological activities, has caused a growing interest for the treatment of hyperlipidemia and associated conditions. This work endeavored to develop a novel formulation of CA-Phospholipon® 90H complex (CA-PC) using a solvent evaporation method. Scanning electron microscopy (SEM), differential scanning calorimetry (DSC), Fourier transform infrared spectrophotometry (FTIR), and powder X-ray powder diffraction (PXRD) was carried to confirm the formation of CA-PC. The CA-PC was functionally evaluated in terms of solubility, *in vitro* and *ex vivo* drug release, and *in vivo* bioavailability and efficacy studies. SEM, DSC, FTIR, and XRD studies indicated the physical interaction of CA with Phospholipon® 90H to form a complex. Dynamic light scattering (DLS) studies described particle size of $168 \pm$

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Review Article

Bioentrepreneurship: A venture for commercializing biotechnological knowledgeShailju G Gurunani¹, Shubhada V Mangrulkar^{1,*}, Dhanashri T Jawal¹,
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ABSTRACT

The term "biotechnology" is widely used and encompasses many different technologies. Consulting firms provide common definitions of modern biotechnology. The term "modern biotechnology" refers to all innovative methods, processes or products, including the use of living organisms or their cellular compartments, and the use of biochemistry, molecular biology, immunology, virology, microbiology, cell biology or environmental sciences and engineering. Biotechnology and entrepreneurship are intrinsically linked together, and are studied biotechnology at the regional, firm, and individual level of analysis. The concept of "bioentrepreneurship", is described as a wealth created by applying the life sciences to a business environment. Bioentrepreneurs seek business value in the technologies they use to conduct biotechnology research. Some well-known bio startups are based on multiple companies. Biotechnology and entrepreneurship are essentially linked. In recent years, a large number of articles in the business literature have studied biotechnology at the level of analysis of regions, companies and individuals. This review article will encourage stakeholders to address the research space which have been recognized and will help more progress in this captivating area of interest in the field of biotechnology and entrepreneurship.

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1. Introduction

In the current years, entire world is in the surge of innovation. Everyday new ideas lead to the development and reformation of any material which can be natural or synthetic. Biotechnology is one of those areas where wave of new ideas brought several products of agricultural, environmental, medical and pharmaceutical applications.

2. Definitions and Concepts

2.1. Biotechnology

The term "Biotechnology" was first used by "Karl Ereky" in 1919, meaning the production of products from raw materials with the aid of living organisms.¹The era of biotechnology-enhanced agriculture began in the 1990s with government approval for commercial deployment of biotech soybeans, corn, cotton, canola, and papaya. Because of their tremendous production advantages, biotech crops have become the most rapidly adopted technology in the history of agriculture.

The word "biotechnology" is extensively applied and covers a number of different technologies. A commonly used definition of modern biotechnology is provided by the

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Preparation And Evaluation of Herbal Tea Powder

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Abstract

Tea is a prevalent and focal point for cultural and social gathering. It is a preparation which boosts up immunity, keeps active, rejuvenates cells it relieves stress, fatigueness, tiredness and anxiety. The aim of present study is to prepare herbal tea with new combination of medicinal plants i.e. star anise, tulsi, black pepper, amla, stevia, lemon grass with the possibility to have maximum therapeutic benefits and suitable consumption. The medicinal plants selected here are reported for various activities such as anti-influenza, immunostimulant, anti-bacterial, bioavailability enhancer, vitamin C supplement, sweetner, flavorant and colorant respectively. The decoction of tea powder containing the above medicinal plants is evaluated for qualitative and quantitative estimations for carbohydrate, ascorbic acid, protein, tannins, and phenolic acid. The antioxidant activity has also been performed.

Keywords

Herbal tea, immunity, antioxidant, anti-anxiety.

INTRODUCTION:

Tea is a prevalent and focal point of cultural and social gathering. Tea is the most generally consumed beverage after water. It has cooling, slightly bitter, and astringent flavor that many people enjoy. Tea is one of the most popular beverages, consumed daily in all domestic, social and official meeting. It is a preparation which boosts up immunity, keeps active, rejuvenates cells, relieves stress, fatigueness, tiredness, anxiety and many more[1].

British introduced tea into India in an attempt to break the Chinese monopoly on tea [2]. Herbal tea or tisane is any beverage made with the infusion or decoction of herbs, spices, or other plant material in hot water, and usually does not contain caffeine[3]. These drinks are distinguished from caffeinated true teas which are prepared from the cured leaves of the tea plant, *Camellia sinensis*, as well as from decaffeinated tea, in which the caffeine

has been removed. In addition to serving as a beverage, many herbal teas are also consumed for their apparent medicinal benefits [4]. Herbal tea is in fact a catch all term used for any non-caffeinated beverages made from the infusion or decoction of herbs, spices, or other plant material, hence in some countries like in Europe, tisanes or herbal teas are also known as infusions.

Herbal Tea Varieties:

Depending on the plant used and on the method of preparation the beverage, there are many varieties of herbal tea. Many more herbal tea varieties can be found than tea varieties for one simple reason: tea is extracted from one plant, tisane is made from many. **Anise tea** is well-liked in the Mediterranean region and in the Southwest Asia where the anise plant is native. It is sweet and highly aromatic, notable by its characteristic flavor.

REVIEW

Open Access



Review on development of potential inhibitors of SARS-CoV-2 main protease (M^{Pro})

Soumya Gulab Katre^{*}, Alpana Jagdish Asnani, Kumar Pratyush, Nilima Gangadhar Sakharkar, Ashwini Gajanan Bhope, Kanchan Tekram Sawarkar and Vaibhav Santosh Nimbekar

Abstract

Background: The etiological agent for the coronavirus illness outbreak in 2019–2020 is a novel coronavirus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (COVID-19), whereas coronavirus disease pandemic of 2019 (COVID-19) has compelled the implementation of novel therapeutic options.

Main body of the abstract: There are currently no targeted therapeutic medicines for this condition, and effective treatment options are quite restricted; however, new therapeutic candidates targeting the viral replication cycle are being investigated. The primary protease of the severe acute respiratory syndrome coronavirus 2 virus is a major target for therapeutic development (M^{Pro}). Severe acute respiratory syndrome coronavirus 2, severe acute respiratory syndrome coronavirus, and Middle East respiratory syndrome coronavirus (MERS-CoV) all seem to have a structurally conserved substrate-binding domain that can be used to develop novel protease inhibitors.

Short conclusion: With the recent publication of the X-ray crystal structure of the severe acute respiratory syndrome coronavirus 2 M^{Pro}, virtual and in vitro screening investigations to find M^{Pro} inhibitors are fast progressing. The focus of this review is on recent advancements in the quest for small-molecule inhibitors of the severe acute respiratory syndrome coronavirus 2 main protease.

Keywords: SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), MERS-CoV (Middle East respiratory syndrome coronavirus), M^{Pro} inhibitor (main protease inhibitor), Virtual and in vitro screening

Background

SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) is a highly pathogenic beta coronavirus that surfaced in late December 2019 in Wuhan, Hubei Province. SARS-CoV-2 is the seventh human coronavirus (HCoV) to be identified, and it is the cause of COVID-19, which was declared a “Public Health Emergency of International Concern” by the World Health Organization (WHO) on January 30, 2020 [1]. COVID-19 symptoms are non-specific and encompass a wide clinical spectrum, making clinical diagnosis without a test difficult. Fever, cough, and anosmia are frequent symptoms; however, many

people remain asymptomatic. Asymptomatic patients, as well as those in the symptomatic and pre-symptomatic stages of the disease, can transmit the virus [2].

Many clinical and preclinical researches have been launched to explore feasible treatment options for COVID-19 patients as the number of new cases continues to rise significantly. Many of these possible therapeutic options are based on the repurposing of licensed medications or the evaluation of medications now in clinical trials. As a result, a wealth of information on the pharmacology and toxicity of any potential therapy already exists. In order to assess their efficacy and safety against COVID-19, all available data must be considered in this fast-paced and vital research sector. SARS-CoV-2 is a medium-sized, enveloped, positive-strand RNA virus (30 kb) of the genus Beta coronavirus that appears crown-shaped (corona) in electron

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A review on synthetic study and biological activities of tetrahydropyrimidinone derivatives

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ABSTRACT

The process of drug discovery involves the identification, synthesis, characterization, screening, assay and development of new chemical entities that are suitable for medical and pharmaceutical use. 2-thioxo-1, 2, 3, 4-tetrahydropyrimidine (THPM) are heterocyclic compound & represents are markable pharmacological efficient moieties and are with wide range of therapeutic properties. Synthetically they were synthesized using Multi-component reactions like Biginelli reaction or either microwave and conventional methods, having a multiple benefits of the time consuming and get high yield. In this review, we highlight recent developments on THPMs and recently developed as antimicrobial, anticancer, anti-inflammatory, analgesic, antifungal, antibacterial, anti-tubercular, antihypertensive, analgesic, anticonvulsant, antioxidant, etc. given a potent biological and pharmacological activity.

Keywords: Drug discovery; 2-thioxo-1, 2, 3, 4-tetrahydropyrimidine; Biginelli reaction; antioxidant activity; antihypertensive activity


INTRODUCTION

Pharmaceutical chemistry is the core branch of pharmacy education and research. It can be categorized as synthesis of new drug molecule, its analysis and pharmacological studies. The chemistry of heterocyclic compounds is important for the discovery of novel drug. The process of drug discovery involves the identification, synthesis, characterization, screening, assay and development of new chemical entities that are

suitable for medical and pharmaceutical use [1]. As a result of remarkable pharmacological efficiency of pyrimidine derivatives, intensive research has been focused on anti-inflammatory activity of pyrimidine nucleus. The present review highlights the synthesis & biological activity of pyrimidine derivatives [2]. During the last two decades, several pyrimidine derivatives have been developed as chemotherapeutic agents and have found wide clinical applications, which are anticancer, anti-inflammatory, antibacterial, antiviral, antimalarial,

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Ethnomedicinal and pharmacological potential of marine macroalgae for CNS disorders: An overview

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ABSTRACT

Marine macroalgae or seaweeds have created a favourable implication in the area of biomedical sciences, due to the present of potential bioactive substances. Extensive studies are reported on neuropharmacological effects of terrestrial plants and their constituents but there is inadequate information on the potential application of marine macroalgae for behavioural and neurological disorders. This review will emphasize on recent studies and/or updates on bioactive compounds or extracts from marine macroalgae and their potential toward CNS disorders.

KEYWORDS: Marine macroalgae, Seaweed, CNS disorders

INTRODUCTION

Most medicines are obtained from natural sources and researchers are still searching the tropical rainforest for potentially high-priced medicinal products. Many products of sea origin were used as food supplement since early 20th century, like cod liver and shark liver oil. It was only in early years of 1950s that researchers began to scientifically probe marine flora for medicines. Till now, around 10,000 bioactive compounds have been explored from marine sources. The quest still continues to discover new bioactive compounds from oceans (Colwell, 2002; Proksch *et al.*, 2002).

Marine plants involve marine algae, mangroves, sea grasses and sand dune plants. Almost 90 percent of marine plants are marine algae (Dhargalkar & Pereira, 2005). Marine algae are of two types, macroalgae (seaweeds) and microalgae. Marine macroalgae are found in the coastal area between high tide to low tide or in the subtidal region. Marine macroalgae are of three types: Green algae (Chlorophyta), Brown algae (Phaeophyta) and Red algae (Rhodophyta) (Garson, 1989; El Gamal, 2010). Green algae (Chlorophyta) found in the fresh as well as marine habitats. It contains chlorophyll a & b as photosynthetic pigments. The photosynthetic product of these algae is starch, with ulvan being the major polysaccharide component. Brown algae (Phaeophyta) are found only in marine habitat. Photosynthetic pigments of these algae are carotenoid, fucoxanthin (pigment responsible for brown colour), chlorophyll a & c, carotene and xanthophylls.

The cell walls are made of cellulose and alginic acid. The photosynthesis of brown algae produced Laminarian, fucane and Manitol. Red algae (Rhodophyta) are exclusively marine (except for few species). Red algae contain phycoerythrin and phycothyanin (pigment responsible for red colour), chlorophyll a and b-carotene. The primary polysaccharides of these algae are agars and carrageenans (Bold & Wynne, 1978).

The macroalgae are used for human consumption in China and Japan. The countries like Singapore, Malaysia, Thailand, Indonesia, Korea used marine macroalgae in soup, salad or jelly. Marine macroalgae are loaded with proteins, soluble dietary fibers, minerals, polyunsaturated fatty acids, vitamins, antioxidants and essential amino acids (Dhargalkar & Pereira, 2005). Extensive studies are reported on the therapeutic prospective of marine macroalgae toward various diseases. We have previously published a review paper on therapeutic potential of various *Sargassum* species and their health benefits (Yende *et al.*, 2014). In present review article, CNS potential of various marine macroalgae are explored.

CNS Potential of Marine Macroalgae

As per WHO report, out of approximately 450 million people suffering from a mental or behavioural disorder, small number of them receive basic treatment, this accounts for 12.3 percent of the global burden of disease and will increase to 15 percent by the year 2020 (Herrera-Ruiz *et al.*, 2006). From last few

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Identification of Bioactive Phytoconstituents from the Plant *Euphorbia hirta* as Potential Inhibitor of SARS-CoV-2: an *In-Silico* Approach

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Abstract: Currently, the entire globe is under the deadliest pandemic of Covid-19 caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). At present, no specific treatment is available to combat COVID-19 infection. *Euphorbia hirta* (Euphorbiaceae) have been reported for a variety of biological activities, including antiviral. The present investigation aimed to identify potential phytoconstituents of the plant *E. hirta* from the category flavonoids and coumarins against the SARS-CoV-2 using in silico approach. The molecular docking studies were performed using two different targets of SARS-CoV-2, namely Main protease (M^{Pro}; PDB ID: 6M2N) and RNA-dependent RNA polymerase (RdRp; PDB ID: 7BW4). Based on the molecular docking study in comparison with standard drug, four compounds, namely Euphorbianin, Quercetin, 3-o-alpha-rhamnoside, Isoquercitrin, and rutin, were screened against the target M^{Pro}. Three phytoconstituents, euphorbianin, myricetin, and rutin, were screened against the target RdRp. In the *in silico* toxicity studies of screened phytoconstituents, except myricetin all were predicted safe. Results of euphorbianin and rutin were found more interesting as both compounds had high binding affinity against both targets. Finally, we want to conclude that euphorbianin, quercetin 3-o-alpha-rhamnoside, isoquercitrin, and rutin could be further explored rapidly as they may have the potential to fight against COVID-19.

Keywords: in silico study; *Euphorbia hirta*; flavonoids; coumarins; M^{Pro}; RdRp.

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1. Introduction

At the beginning of 2020, the emergence of a global public health emergency was noted due to novel coronavirus disease 2019 (COVID-19). Later, it was determined that Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is the primary cause of COVID-19 [1,2]. As of 10th May 2021, the virus has caused 3 288 455 deaths and 157 973 438 confirmed cases globally [3]. SARS-CoV-2 is a single-stranded RNA virus that belongs to the genus Beta coronavirus. This group also contains SARS-CoV and MERS-CoV, responsible for triggering the pneumonia epidemic in 2003 and 2012, respectively [4,5]. COVID-19 infection can lead to numerous respiratory, hepatic, enteric, and neurological conditions. The SARS-CoV-2 is primarily transmitted through respiratory droplets, aerosol particles, and personal contact [6]. It can enter into respiratory cells by coupling its spike protein to the angiotensin-converting enzyme 2 (ACE-2) receptors present over the pneumocytes in the lungs, which then induces



Exploring the active constituents of *Oroxylum indicum* in intervention of novel coronavirus (COVID-19) based on molecular docking method

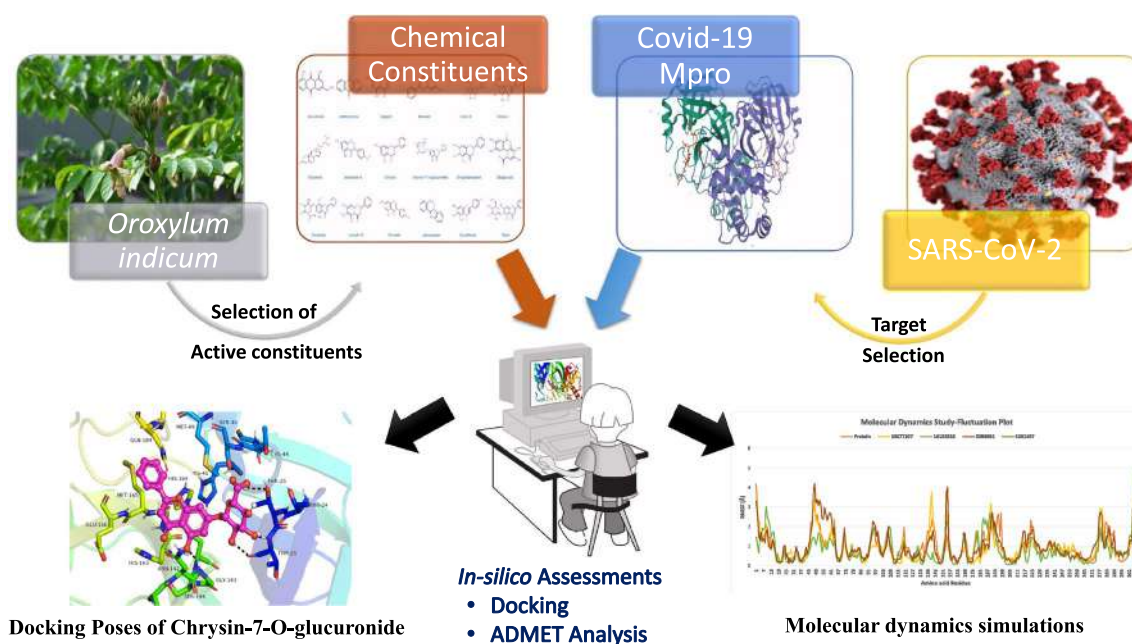
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Abstract

The severe acute respiratory syndrome COVID-19 declared a global pandemic by WHO has become the present wellbeing worry to the whole world. There is an emergent need to search for possible medications. We report in this study a molecular docking study of eighteen *Oroxylum indicum* molecules with the main protease (M^{pro}) responsible for the replication of SARS-CoV-2 virus. The outcome of their molecular simulation and ADMET properties reveal four potential inhibitors of the enzyme (Baicalein-7-*O*-diglucoside, Chrysin-7-*O*-glucuronide, Oroxindin and Scutellarein) with preference of ligand Chrysin-7-*O*-glucuronide that has the second highest binding energy (− 8.6 kcal/mol) and fully obeys the Lipinski's rule of five.

Graphical abstract



Keywords COVID-19 · *Oroxylum indicum* · Molecular docking · Molecular dynamics · ADMET study

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Review Article

Novel Drug Delivery System of Phytopharmaceuticals: A Review

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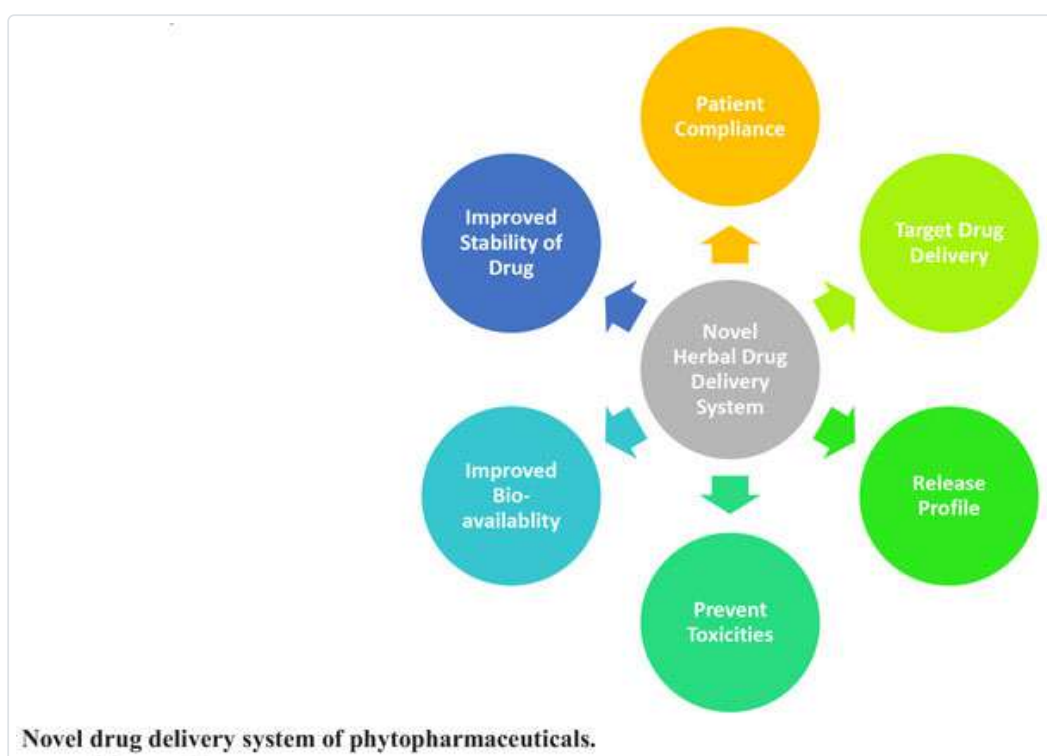


Abstract

Herbal extracts and isolated bioactives from plants have proven their therapeutic activities, as evidenced by preclinical and clinical research. However, there seems some disconnect in their clinical utility as marked by a lack of proper delivery mechanism at desired sites of action. This glitch nowadays is a task for global research activity and being addressed in novel drug delivery systems. Steady progress is observed in integrating novel techniques of drug delivery with successful incorporation of phytochemicals marked by scores of advantages. Limitations of conventional drug delivery systems have overcome to a considerable extent by innovative drug delivery methods which show improvement in targeted drug delivery, drug distribution, protection of active substance, prolonged action, and stability. The perspective of this review thus focuses on the progress in novel drug delivery systems with a spotlight on nanocarriers for active herbal agents, their preparation methods with types, examples of active ingredients incorporated, and biomedical applications.

Keywords: [Herbal bioactives](#), [novel drug delivery systems](#), [phytopharmaceuticals](#), [plant extract](#).

Graphical Abstract



Novel drug delivery system of phytopharmaceuticals.

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In silico prediction of phytoconstituents from *Ehretia laevis* targeting TNF- α in arthritis

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ABSTRACT

Objective Rheumatoid arthritis (RA) is an autoimmune disease involving the synovial lining of the major joints. Current therapies have noteworthy side effects. Our study involved *in silico* evaluation of *Ehretia laevis* (*E. laevis*) phytoconstituents targeting tumor necrosis factor- α (TNF- α).

Methods Molecular docking studies performed to investigate the binding pattern of the plant *E. laevis* phytoconstituents along with the crystal structure of TNF- α (PDB ID: 2AZ5) using AutoDock Vina followed by a study of interacting amino acid residues and their influence on the inhibitory potentials of the active constituents. Further the pharmacokinetic profile and toxicity screening carried out using SwissADME and pkCSM.

Results The docked results suggest that lupeol (– 9.4 kcal/mol) and α -amyrin (– 9.4 kcal/mol) has best affinity towards TNF- α compared to standard drug thalidomide (– 7.4 kcal/mol). The active chemical constituents represents better interaction with the conserved catalytic residues, leading to the inhibition/blockade of the TNF- α -associated signaling pathway in RA. Furthermore, pharmacokinetics and toxicity parameters of these phytochemicals were within acceptable limits according to ADMET studies.

Conclusion The binding potential of phytoconstituents targeting TNF- α showed promising results. Nonetheless, it encourages the traditional use of *E. laevis* and provides vital information on drug development and clinical treatment.

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**DEVELOPMENT AND VALIDATION OF STABILITY INDICATING
RP-HPLC ANALYTICAL METHODS FOR METFORMIN
HYDROCHLORIDE, GLIMEPIRIDE AND ATORVASTATIN CALCIUM
IN BULK AND COMBINED DOSAGE FORM**

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ABSTRACT

A simple, rapid and precise RP-HPLC method for simultaneous analysis of metformin hydrochloride, glimepiride and atorvastatin calcium in bulk and combined dosage form has been developed and validated. These drug were separated by using C-18 column (250×4.6mm, 5µm) with a mobile phase consisting of acetonitrile: water (70:30) at flow rate 1 ml/min and detection of analytes was carried out at 234nm. Metformin hydrochloride, glimepiride and atorvastatin calcium were eluted with retention time of 2.13 min, 6.91min and 3.46min, respectively. The method was validated for accuracy, precision, linearity, specificity and sensitivity in accordance

with ICH (Q2B) guidelines. The result of all validation parameters were found to be within the acceptable limits. Linearity was observed over the concentration range of 10-120µg/ml, 2- 50µg/ml and 2-50µg/ml for metformin hydrochloride, glimepiride and atorvastatin calcium respectively. Square of correlation coefficients was found to be > 0.999. The percentage recoveries of metformin hydrochloride, glimepiride and atorvastatin calcium was found to be 99.74, 98.33 and 99.47 respectively. The drugs were subjected to stress conditions including acidic, alkaline, oxidation and photolysis, heat degradation.

INTRODUCTION

Metformin hydrochloride is a medication for the treatment of type 2 Diabetes mellitus particularly in patient who are overweight and chemically it is N, N-dimethylimidodicarbonimide **Figure 1(a)**. Metformin hydrochloride (MET HCl) is an orally

DEVELOPMENT OF STABILITY INDICATING REVERSED PHASE-HPLC METHOD AND ITS VALIDATION FOR THE ANALYSIS OF BOTULINUM TOXIN IN API AND STERILE FORMULATION**Sonal Bhale*, Alpana Asnani and Dinesh Chaple**

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Corresponding Author*Sonal Bhale**Priyadarshini J. L. College of
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A rapid, simple, reliable and accurate reversed phase HPLC analytical method was developed for the evaluation of Botulinum toxin and the developed method was then validated as per ICH guidelines in sterile dosage form for stability studies. A C18 column was selected with a flow rate of 2 ml/min. The selected mobile phase consists of sodium phosphate buffer (0.05 M) at pH value of 2.8 and acetonitrile at the ratio of 30:70 respectively at 214 nm. Botulinum toxin peak was eluted at retention time of 2.1 min at 214 nm with total run time of 10min. Linearity and range was observed for concentration of 1µg/ml-10µg/ml. The developed method was linear with of 0.99 as the

correlation coefficient. The validation of method was done as per ICH guidelines for linearity, range, accuracy, precision, specificity, detection limit, quantitation limit, and forced degradation study.

KEYWORDS: RP-HPLC, Botulinum toxin, method development, method validation, degradation study etc.

INTRODUCTION

In 2010, the Food and Drug Administration (FDA) approved Botox as a prescription medication treatment for people with chronic migraines. Using Botox for migraine treatment has proved beneficial for patients who experience 15 or more migraines a month, but using Botox doesn't come without risk. Read more about using Botox for migraine treatment, including its benefits, and risks, from this overview.

ONE POT SYNTHESIS OF PYRANO[2,3-C]PYRAZOLE: A REVIEW

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The synthesis of pyranopyrazole bioactive heterocycles has caught the interest of medicinal and organic chemists due to their biological and therapeutic capabilities. This review summarizes the One Pot Synthetic pathways of pyranopyrazoles. Green approaches, nanoparticulate catalysts, microwave irradiation, ultrasonic irradiations, and other catalysts are among the reaction conditions that can be varied. The present review describes the literature reports for the period 2010 to 2021.

KEYWORDS: One pot synthesis, Microwave irradiation, Pyranopyrazole, Green approach, Ultrasonic irradiation.

INTRODUCTION

Heterocyclic compounds are widely employed because they have a wide range of applications in pharmaceuticals. The ability to develop diverse structures that are required to fulfil specific significant functions is the primary reason for their versatile application.

In the antibacterial, pharmaceutical, and medicinal sectors, pyran-based heterocyclic chemicals have been extensively used. "Multicomponent Reactions" (MCRs) have recently emerged as an alternative to traditional ways for creating a variety of complex organic compounds by combining three or more initial substrates. Many organic chemists have been drawn to one-pot multicomponent reactions because of their streamlined operation, simplified purification, decreased waste, lowered safety criteria, and reduced duration.^[1]

Pyranopyrazoles are a fascinating class of heterocycles due to their synthetic versatility and effective biological activities. Isomer (**1**) is the most studied of the four probable isomeric forms: pyrano[2,3-c]pyrazole (**1**), pyrano[4,3-c]pyrazole (**2**), pyrano[3,2-c]pyrazole (**3**), and

**A REVIEW: USE OF THE HERBAL MEDICINAL PLANTS AS AN IMMUNOMODULATOR FOR COVID 19**

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❖ ABSTRACT

The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is a highly infectious virus that spreads quickly from person to person and has never been seen in humans before. The World Health Organization (WHO) designated the infection COVID-19 (coronavirus disease-2019) on February 11, 2020, and declared the outbreak pandemic on March 11, 2020. It impacts everyone, without exception. The elderly and those with impaired immune systems, on the other hand, are more vulnerable. Coughing, sneezing, or touching infected hands to eyes, nose, or mouth spread the virus mostly through droplet infection from an infected person to a healthy person. The infection's symptoms range from moderate to severe. Fever of high grade (104°F),

dyspnea, pneumonia, and severe acute respiratory syndrome may emerge in severe cases (about 14% of cases). There is currently no particular therapy or vaccine available for new coronavirus-2019. We know from past and recent experiences that herbal remedies are effective against a variety of severe viral illnesses. This study's findings on immune-boosting herbs could be extremely beneficial to the body's fight against COVID-19 infection.

KEYWORDS: SARS-CoV-2, Antiviral, Herbal medicine, Immunomodulator drug.

❖ INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or 2019 novel coronavirus (2019-nCoV) is rapidly spreaded from its origin in Wuhan, Hubei Province, China, to the rest of the world. Till 7 /8/ 2021 around 202,693,744 cases of coronavirus disease 19 and 4,295,952 death have been reported. India has reported 31,913,083 cases till date.^[1,2] The first case of COVID-19 in India was an imported case from Wuhan, China on

SYNTHETIC STUDY OF INDOLE AND IT'S DERIVATIVES; AS POTENT ANTINEOPLASTIC AGENTS

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1. ABSTRACT

Cancer is a disease that entails a loss of genomic stability and seems to have a high global mortality rate. Since its revealed, several people have been searching for an effective treatment, evaluating numerous compounds for their anticancer properties. Whereas, indoles are natural compounds with antineoplastic activities due to their propensity to trigger cell death in a variety of cancer cell lines. An indole is an aromatic heterocyclic composite which has its heterobicyclic configuration as a six-membered ring fused to a five-membered pyrrole ring. 'Indole' is the name given to all indole derivatives which have an indole ring system. Indole derivatives possess various biological activities, i.e. antiviral, anti-inflammatory, anti-cancer, anti-HIV, antioxidant, antimicrobial, anti-tubercular, antidiabetic,

anticholinesterase, antimalarial activities, etc., prompting researchers to explore variety of indole derivatives. This review addresses the synthesis of indole and its various derivatives, facilitated induction and recent studies with indoles as showing potential chemotherapeutic activity.

KEYWORDS: Indoles, heterobicyclic configuration, indole derivatives, biological activities, anti-cancer agents.

2. INTRODUCTION

According to several discoveries, cancer has become one of the most difficult diseases to treat, and according to World Health Organization figures, it has now surpassed heart disease as the second leading cause of death worldwide. Nearly 10 million people died from cancer

AN OVERVIEW ON COVID 19 TREATMENT BY HERBAL MEDICINES

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ABSTRACT

Herbal-based traditional medicines or phytomedicines play a significant role in disease management in Africa and are widely used as alternative medicines. Therefore, it is important to evaluate both the safety and efficacy of these indigenous botanical assets in medicine prior to endorsing their use by the medical community and the public. There have been several declarations by institutions in Member States on the use of herbal-based traditional medicine for the prevention of SARS-CoV-2 transmission or treating people with a presumptive or definitive diagnosis of corona virus disease 2019 (COVID-19). Many of the claims are difficult to verify because of the lack of documented evidence showing that these remedies prevent or clear SARS-CoV-2 infection and/or improve clinical outcomes of those suffering from COVID-19. As the pandemic continues to spread in Africa, there are increasing messages promoting the use of herbal-based traditional medicines for COVID-19. Currently, no herbal remedy has been validated for use to prevent or treat COVID19. Herbal remedies or medicines are naturally occurring, plant-derived substances that are developed mostly through a process with minimal or no respect for good clinical practice (GCP). The current pandemic of COVID-19 that is spreading across countries originated in Wuhan, China. The single cause of this highly communicable disease is a novel corona virus, called severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), which is the seventh known virus of the Corona viridae family capable of infecting humans. The latest report from the World Health Organization cited that there are now over 19 million confirmed cases and over 700,000 deaths worldwide caused by this virus. The United States of America now has the highest number of COVID19 cases (over 4 million cases), followed by Brazil (almost 3 million cases) and India (over 2 million cases). The fast propagation of this disease is mainly through close contact with infected individuals via respiratory droplets from either sneezing or coughing. Furthermore, there are two other ways of transmitting the virus, including contact and aerosol transmission.

Keywords: Phytomedicines, Herbal Remedies , Covid Treatment ,Respiratory syndrome

INTRODUCTION

The disease is typically confirmed by reversetranscription polymerase chain reaction (RT-PCR) reverse Real-Time PCR assay (RRT-PCR), which can be carried out using a variety of clinical specimens, including Bronchoalveolar lavage fluid, fibro bronchoscope

UV SPECTROSCOPIC METHOD FOR THE ESTIMATION OF AZELNIDIPINE - A REVIEW

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ABSTRACT

Azelnidipine is a calcium channel antagonist that blocks lipophilic dihydropyridine calcium channels. Calcium channel blockers called dihydropyridine (DHP) are generated from the chemical dihydropyridine and are commonly used to lower systemic vascular resistance and arterial pressure. The focus of this review is on the azelnidipine uv spectroscopic analytical approach. The correlation coefficient of the calibration curve was found to be between 0.98 and 0.99, indicating that methanol is extensively utilised as a solvent solution in UV spectroscopy.

KEYWORDS: Lipophilic, Calcium channel blocker, Azelnidipine, and UV-spectroscopy.

INTRODUCTION

Chemically, azelnidipine (AZEL) is 3-*o*-(1-benzhydrylazetid-3-yl)5-*o*-propan-2-yl 2-amino-6-methyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate. It is a calcium channel blocker (CCB) of the dihydropyridine (DHP) class used to treat hypertension. Due to an asymmetric structure, AZEL contains two enantiomers.^[1]

The DHP ring's 4-position contains carbon. The drug's pharmacological effect The (R)-enantiomer of AZEL is the active form. This contrasts sharply with additional CCBs where the (S)-enantiomer is the active ingredient biological function The three-dimensional structure of the object is unusual. The active enantiomer of AZEL might be linked to its one-of-a-kind structure. pharmacological characteristics that other DHPs don't have, such as a

AN OVERVIEW OF REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRIES

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Abstract: Pharmaceutical drug regulatory affairs cover extraordinary registration parameter of pharmaceutical product. As it's miles the new career which changed into developed from the favored of everywhere in the international to protect the general public fitness through providing correct excellent of drugs such as safety and efficacy within the region of now not handiest pharmacy however also inside the area of the veterinary medicinal drug, scientific tool, pesticides, agrochemical, beauty and complementary medication. It also made the interface among the pharmaceutical company and the regulatory organizations. It is also liable for keeping the appropriateness and accuracy of the product data. And its principal role to behave as a liaison with regulatory groups, supplying information and regulatory intelligence in translating regulatory requirement into sensible practicable plan, advising the corporation on regulatory aspects and climate that might affect their proposed activities. Regulatory affairs in the pharmaceutical industry play an essential position because the Pharmaceutical area is rising very hastily and there's a need of regulatory affairs specialists to provide the current desires of industries for the worldwide opposition. A regulatory affair is a profession which acts as the interface among pharmaceutical industries and authorities internationally. The goal of the regulatory affairs professional is the protection of human health, ensuring safety, efficacy, and quality of drugs, making sure appropriateness and accuracy of product facts. This gift article discusses the evolution of Regulatory Affairs, its role inside the pharmaceutical enterprise and its involvement for the implementation of regulatory suggestions which improve the increase of the industry.

Keywords: Regulatory Affairs, Pharmaceutical industries, regulatory bodies.

Introduction: The modern Pharmaceutical enterprise is well prepared, systematic and compliant to international regulatory standards for manufacturing of Chemical and biological tablets for human and veterinary intake in addition to scientific gadgets, conventional herbal merchandise and cosmetics. Stringent GMPs are being accompanied for blood and its by-product in addition to controlled production for classic herbal drug treatments, Cosmetics, food and dietary products which became in any other case otherwise a century before. Each regulatory gadget had confronted certain occasions which brought about modern-day well-defined managed regulatory framework. This has resulted into systematic manufacturing and advertising of secure, efficacious and qualitative pills. With the boom of enterprise, the legislation from each area have come to be increasingly complex and created a need for regulatory specialists.¹

Regulatory Affairs (RA), also known as Government Affairs, is a profession inside regulated industries, including pharmaceuticals, clinical gadgets and so on. RA profession at its heart is all about gathering, studying and speaking the dangers and advantages of health care products to regulatory organizations and public all around the international.

AN OVERVIEW ON ANTIDIABETICS BY VARIOUS ANALYTICAL TECHNIQUES

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ABSTRACT

Its a meglitinide simple is an oral indication intended to regular hour aldohexose outings. Through not an antidiabetic, it acts in A comparable to way by restricting to antidiabetic receptor moreover on elective one particular receptor-» conclusion of adenosine triphosphate subordinate K⁺ channel-» of depolarization-» inner discharge unharnesses. Repaglinide prompts quick beginning short-enduring inner emission released. It is directed antero each fundamental supper to balance out postprandial hyperglycemia; the portion should be radiated if a food material is inconceivable. In light of less perpetual activity, it maybe had a lower hazard of the reality of hypoglycemia. Repaglinide is shown exclusively in type-II DM as another to sulfonylureas, or to enhance metformin/long inside discharge. It should be kept away from in sickness. This audit conveys a detail portrayal very surprising of different scientific ways were printed for the assessment of repaglinide and its mix medication in physician recommended drugs and natural grids. This appraisal incorporates distinctive logical ways like compound examination ways, forceful fluid movement (HPLC), predominant slender layer action (HPTLC), fluid chromatography-mass spectroscopic investigation (LC-MS), and ultra-execution fluid action (UPLC), GC-MS, [LC-ESI-MS-MS], slim action (CE), titrimetric and synthetic science strategy, and assignment concentrate for the assessment of repaglinide and along with a combination

Keywords: Biological frameworks, Chromatography, Repaglinide, Analytical strategies, Type-II diabetic medications Presentation

INTRODUCTION

Repaglinide is another carboxymethyl benzoic corrosive subordinate, otherwise called 2-ethoxy - 4-[2-[[3-methyl-1-[2-(1-piperidinyl) phenyl] butyl] amino]-2-oxoethyl] (Fig. 1). It is a novel prandial glucose controller for the treatment of type-II diabetes mellitus [1]. It diminishes fasting glucose focuses in patients with type-II diabetes mellitus. It assists with controlling the glucose levels by pancreas builds insulin levels. Repaglinide is an oral enemy of hyperglycaemia specialist utilized for the treatment of non-insulin-subordinate diabetes mellitus (NIDDM). It has a place with the meglitinide is an enemy of Diabetic sort II class drug with of short-acting insulin secretagogues, which act by restricting to the β cells of the pancreas, and it animates and delivers the insulin discharge levels [2]. Repaglinide actuates an insulin reaction to early suppers decreasing the postprandial blood glucose levels. May be multi month of a course is required for a lessening in fasting blood glucose levels is seen. Meglitinides may commonly affect slight development in weight. The complete normal weight acquire brought about by meglitinides seems, by all accounts, to be lower than that is brought about by sulfonylureas. Because of their own instrument of activity, meglitinides it might in light of the fact that hypoglycemia [3]. The danger is believed to be lower than that of sulfonyl urea's since their activity is presence on glucose-subordinate. As well as diminishing postprandial and fasting glucose, meglitinides are appeared to diminish glycosylated hemoglobin (HbA1c) levels, which are intelligent of the last 8–10 weeks of glucose control. Repaglinide is altogether used in the liver and discharged in bile salts. Roughly 90% of a solitary orally controlled portion is disposed of in the face and 8% in pee. The substance equation of C₂₇H₃₆N₂O₄ and it is solvent in methanol and methylene chloride. However, for all intents and purposes insoluble in water-dissolvability of around 20

“COMPUTER-AIDED DRUG DESIGN (CADD) & MOLECULAR MODELLING IMPORTANCE IN PHARMACEUTICAL SCIENCES.”

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Abstract

Computer-aided drug design (CADD) depends on the extent of structure and other information available regarding the target (enzyme/receptor/protein) and the ligands. The theoretical basis of CADD involves molecular mechanics, quantum mechanics, molecular dynamics, structure-based drug design (SBDD), ligand-based drug design (LBDD), homology modeling, ligplot analysis, molecular docking, de novo drug design, pharmacophore modeling and mapping, virtual screening (VS), quantitative structure-activity relationships (QSARs), In silico ADMET (absorption, distribution, metabolism, excretion and toxicity) prediction etc. CADD centre was created to foster collaborative research between biologist, biophysicists, structural biologists and computational scientists. The major goal of the CADD centre is to initiate these collaborations leading to the establishment of research projects to discover novel chemical entities with the potential to be developed into novel therapeutic agents.

Keywords: Bioinformatics, Softwares, Homology modeling, Ligplot analysis, Molecular docking, De novo drug design, Pharmacophore modeling, Virtual screening (VS), Quantitative structure-activity relationships (QSARs), Lipinski's rule.

❖ INTRODUCTION

Advances in the field of biochemistry, molecular biology and mobile biology, facilitated by using traits in genomics and proteomics, are producing a massive wide variety of novel organic goals that may be exploited for therapeutic intervention. To facilitate the discovery of novel healing marketers, rational drug design methods in mixture with structural biology provide wonderful capability. The trendy technological advances are (QSAR/QSPR, shape-based totally layout and bioinformatics). Drug discovery and developing a brand new medicine is an extended, complicated, high-priced and exceptionally unstable procedure that has few friends in the commercial global. This is why laptop-aided drug design (CADD) tactics are being widely used inside the pharmaceutical industry to accelerate the method. The value benefit of using computational equipment within the lead optimization section of drug improvement is full-size. On an average, it takes 10-15 years and US \$500-800 million to introduce a drug into the marketplace, with synthesis and trying out of lead analogues being a large contributor to that sum. Therefore, it's far beneficial to apply computational equipment in hit-to-lead optimization to cowl a wider chemical space at the same time as reducing the quantity of compounds that should be synthesized and examined in vitro.

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Review Article

Cancer cachexia: Current strategies and future perspectives

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ABSTRACT

Cancer cachexia is complex, and can often occur in the presence of malnutrition, age-related changes in anabolism, physical deconditioning and comorbidity. These factors can also form potentially reversible components of the overall 'cachexia burden'. Separating cancer cachexia from the effects and complications after cancer therapy is often difficult. This review aims to briefly describe cancer cachexia and these novel biological agents currently under investigation for the treatment of cancer –related cachexia. Treatment that can be reduces the muscle wasting which is resulting into cancer cachexia. The main aim of review is to the potential treatment for cancer cachexia, which include Pharmacological, non-pharmacological, neutraceutical and investigational new treatments.

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1. Introduction

Cachexia is a multifactorial infection portrayed by weight reduction through skeletal muscle and fat tissue misfortune, awkwardness in metabolic guideline, and decreased food consumption. It is brought about by components of catabolism delivered by tumours in the fundamental course as well as physiological factors, for example, the imbalanced fiery initiation, proteolysis, autophagy, and lipolysis that may happen with gastric, pancreatic, oesophageal, cellular breakdown in the lungs, liver, and entrails malignant growth. Disease cachexia not just adversely influences the personal satisfaction of patients with malignant growth yet additionally lessens the viability of hostile to disease chemotherapy and builds its poisonousness, prompting expanded malignancy related mortality and consumption of clinical assets. Right now, there are no powerful clinical intercessions to totally turn around cachexia and no endorsed drugs. Sufficient

wholesome help is the principle strategy of cachexia treatment, while drugs that focus on the restraint of catabolism, cell harm, and extreme enactment of irritation are under examination.¹

Cancer cachexia is an insidious syndrome that not only has a dramatic impact on patient quality of life, but is also associated with poor responses to chemotherapy and survival. Indeed, cachexia occurs in the majority of terminal cancer patients and, according to Warren, is responsible for the death of 22% of cancer patients.^{1,2} Current therapies focus on palliation of symptoms and the reduction of distress of patients and families rather than cure.³ In many cases, cachexia remains a largely underestimated and untreated condition. Approximately half of all patients with cancer experience cachexia, with the prevalence rising as high as 86% in the last 1-2 week of life, and with 45% of patients losing more than 10% of their original body weight over the course of their disease progression. Death usually occurs when there is 30% weight loss.⁴ The best management strategy of cancer cachexia is to treat the underlying cancer as this will completely reverse the cachexia syndrome. Unfortunately, this remains an

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**PHARMACEUTICAL CO-CRYSTAL: A TECHNIQUE FOR ENHANCEMENT OF
PHYSICOCHEMICAL PROPERTIES OF DRUGS**

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ABSTRACT

In development of new product major constraints are poor aqueous solubility and low oral bioavailability. Crystallization emerge as potential technique for enhancement of solubility of poorly aqueous soluble drugs also helps to improve physicochemical with preserving the pharmacological properties of the API. Cocrystals are solids that are crystalline single-phase materials composed of two or more different molecular and/or ionic compounds generally in a stoichiometric ratio which are neither solvates/hydrates nor simple salts. It is multicomponent system in which one component is API and another is called coformer. Coformer selection is the main challenging step during cocrystal synthesis, so various screening methods for the selection of cofomers were explained. This article also summarizes differences between cocrystals with salts, solvates and hydrates along with the implications and limitations of cocrystals. It also provides a brief review on different methods of cocrystal formation and characterization technique of cocrystals.

KEYWORDS: Pharmaceutical cocrystals, Cocrystallization, Cofomers, Solubility, Stability, Bioavailability, Dissolution, Grinding, Supramolecular synthons.

INTRODUCTION

Pharmaceutical cocrystals are solids crystalline single-phase materials composed of two or more different molecular and/or ionic compounds generally in a stoichiometric ratio which are neither solvates nor simple salts. Thus, it is a multiple component crystal modified by intermolecular interaction such as hydrogen bonding, van der Waals force, π - π interactions, and halogen bond between an active pharmaceutical ingredients (drug) and coformer.^[1,2]

As a promising formulation, pharmaceutical cocrystals can improve some of the physicochemical properties of APIs, such as the solubility, dissolution rate, bioavailability, and stability, without altering their inherent chemical structures.^[3,4,5] Meanwhile, the guidance for industry regulatory classification of pharmaceutical cocrystals announced by the U.S. Food and Drug Administration (FDA) claims that cocrystals, as a drug product intermediate or a fixed-dose combination product, should substantially dissociate before reaching the site of pharmacological activity.^[6,7]

Actually, cocrystals are metastable solids because of their weak intermolecular interaction and easily dissociate into their respective components in solution.^[8,9]

It is essential to explore the detailed behaviours of pharmaceutical cocrystals between their dissolved and

dissociated processes, which will be beneficial to advance the development and application of pharmaceutical cocrystals.

Pharmaceutical cocrystal solubility commonly comprises a dissolution-dissociation process, and its evaluation is based on kinetic solubility, thermodynamic solubility, and the intrinsic dissolution rate. Kinetic solubility usually indicates a dynamic process such that the concentration fluctuations vary with time during cocrystal dissolution and depends on parameters such as the surface area, particle size and distribution, fluid dynamics, and experimental apparatus.^[10] However, thermodynamic solubility focuses on the dissolved extent of the cocrystal when all the cocrystal components achieve dynamic equilibrium in the solution phase entirely.^[11] The intrinsic dissolution rate concentrates on how the powder compacts affect the drug dissolution under a constant temperature and surface condition, which will contribute to approximately simulating the *In-vivo* behaviours of drug formulation.^[12]

The process of solvation is a vital factor for the cocrystal dissolution-dissociation process in the human gastrointestinal tract that is related to coformer solubility, the type and concentration of surfactants, and the ion concentration in dissolution media. In addition, cocrystal solubility is influenced by the strength of the crystal lattice that is associated with the crystal stacked form and intermolecular distances of API and CCF.^[13]



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Safety and Efficacy of the Pfizer-BioNTech COVID-19 Vaccine

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Abstract- COVID-19 vaccine development is moving quickly, with the possibility of a vaccine being ready in as little as six months. So, when there is insufficient supply to fulfil demand in the first instance, who should be prioritized for vaccination? There's little doubt that health-care personnel in all contexts should be vaccinated first, but who comes next will be a difficult decision depending on local epidemiology, societal values, and the vaccines' capacity to prevent both severe disease and transmission, eliciting herd protection. The decision on who to vaccinate should be fair, contextualized, and based on each vaccine's properties. The elderly may be prioritized in some contexts, while the populace may be prioritized in others. COVID-19 has had a disastrous effect, and efforts are underway to accelerate vaccines. The rising problem of vaccination apprehension may have an impact on COVID-19 vaccine uptake. Individual, communicative, and societal variables of vaccination uptake were investigated. SARS coronavirus infection (SARS) affects approximately 240.6 million people around the world, and as a result, they become infected with coronavirus illness (covid 19). As a result, a safe and effective vaccine is required. COVID-19 can be severe in pregnant women due to prenatal maternal physiological changes. The Pfizer-BioNTech COVID-19 vaccine (BNT162b2 mRNA) has been found to be highly effective, and it is recommended for those aged 16 and up, including pregnant women.

The two messenger RNA (mRNA) vaccines BNT162b2 and mRNA-1273 were recently approved by the Food and Drug Administration (FDA) for emergency use against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes the COVID-19 coronavirus disease. Pfizer-BioNTech and Moderna, respectively, produced BNT162b2 and mRNA-1273 vaccines in 2020. The BNT162b2 vaccine was first used in the United Kingdom, Bahrain, Canada, Mexico, the United States, Singapore, Oman, Saudi Arabia, Kuwait, and the European Union, while the mRNA-1273 vaccine was first used in the United States and Canada in mid-December 2020. Studies reported on the 28th of December 2020. People who received the BNT162b2 vaccine had severe allergic reactions, while just a few people who received the mRNA-1273 vaccine had mild symptoms. As a result, the authors of the letter aim to investigate possible reasons of anaphylaxis after COVID-19.

Keywords – COVID-19 vaccines; high-risk; epidemiology; transmission; vaccine development; clinical trials. Anaphylaxis · Antibody · BNT162b2 · COVID-19 · IgE · MRNA-1273 · MRNA vaccine · SARS-CoV-2 · PEG

1. INTRODUCTION

On 8 December 2020 the UK became the first country to implement a covid-19 vaccination program after the approval of the Pfizer-BioNTech messenger RNA (mRNA) vaccine, BNT162b2, for emergency use vaccinated. ^[1] The burden of covid-19 in the UK remains high, and early evidence on the effectiveness of vaccines is essential for informing policy decisions on the ongoing delivery of the program and the use of other non-drug interventions.^[2] During the first few weeks of the program, the priority groups for vaccination included older residents of care homes and their carers, those aged 80 years and older, and frontline health and social care workers.^[3] From 18 January, vaccine delivery was extended to those aged 70 years and older and those in clinically extremely vulnerable groups. Delivery was initially through hospital trusts and care homes, when possible, then subsequently also through primary care providers and mass vaccination centers. Interim results from phase III clinical trials have found the BNT162b2 and ChAdOx1-S vaccines to be highly effective when using a two dose schedule with a target interval of three and four weeks, respectively, between doses.^[4, 5] Data from the ChAdOx1-S trial suggests that protection might be greater with a longer dosing interval.^[5] A reanalysis of the BNT162b2 trial data suggests that a single dose of this vaccine has an efficacy of 92.6% in the early post-vaccination period.^[6] Furthermore, with other vaccines an extended interval between the prime and booster doses typically provides a better immune response to the booster dose.^[7, 8] Based on this evidence, the increasing incidence of covid-19 in the UK and the need to rapidly vaccinate as many vulnerable people as possible, on 20 December 2020 the Joint Committee on Vaccination and Immunisation advised that the dose interval for both vaccines could be extended to up to 12 weeks.

BNT162b2 is a lipid nanoparticle-based, nucleoside-modified RNA vaccine that encodes a perfusion-stable, membrane-anchored SARS-COV-2 full-length spike protein. BNT162b2 is a highly effective anti-covid -19 drug that is now being used in emergency situations. Everyone who was freshly vaccinated between December 20, 2020 and February 1, 2021. The vaccine received emergency use permission (EUA) ² from the Food and Drug Administration (FDA) in December 2020, as well as an interim

**DEVELOPMENT AND VALIDATION OF STABILITY INDICATING
RP-HPLC ANALYTICAL METHODS FOR METFORMIN
HYDROCHLORIDE, GLIMEPIRIDE AND ATORVASTATIN CALCIUM
IN BULK AND COMBINED DOSAGE FORM**

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ABSTRACT

A simple, rapid and precise RP-HPLC method for simultaneous analysis of metformin hydrochloride, glimepiride and atorvastatin calcium in bulk and combined dosage form has been developed and validated. These drug were separated by using C-18 column (250×4.6mm, 5µm) with a mobile phase consisting of acetonitrile: water (70:30) at flow rate 1 ml/min and detection of analytes was carried out at 234nm. Metformin hydrochloride, glimepiride and atorvastatin calcium were eluted with retention time of 2.13 min, 6.91min and 3.46min, respectively. The method was validated for accuracy, precision, linearity, specificity and sensitivity in accordance

with ICH (Q2B) guidelines. The result of all validation parameters were found to be within the acceptable limits. Linearity was observed over the concentration range of 10-120µg/ml, 2- 50µg/ml and 2-50µg/ml for metformin hydrochloride, glimepiride and atorvastatin calcium respectively. Square of correlation coefficients was found to be > 0.999. The percentage recoveries of metformin hydrochloride, glimepiride and atorvastatin calcium was found to be 99.74, 98.33 and 99.47 respectively. The drugs were subjected to stress conditions including acidic, alkaline, oxidation and photolysis, heat degradation.

INTRODUCTION

Metformin hydrochloride is a medication for the treatment of type 2 Diabetes mellitus particularly in patient who are overweight and chemically it is N, N-dimethylimidodicarbonimide **Figure 1(a)**. Metformin hydrochloride (MET HCl) is an orally

DEVELOPMENT OF STABILITY INDICATING REVERSED PHASE-HPLC METHOD AND ITS VALIDATION FOR THE ANALYSIS OF BOTULINUM TOXIN IN API AND STERILE FORMULATION**Sonal Bhale*, Alpana Asnani and Dinesh Chaple**

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A rapid, simple, reliable and accurate reversed phase HPLC analytical method was developed for the evaluation of Botulinum toxin and the developed method was then validated as per ICH guidelines in sterile dosage form for stability studies. A C18 column was selected with a flow rate of 2 ml/min. The selected mobile phase consists of sodium phosphate buffer (0.05 M) at pH value of 2.8 and acetonitrile at the ratio of 30:70 respectively at 214 nm. Botulinum toxin peak was eluted at retention time of 2.1 min at 214 nm with total run time of 10min. Linearity and range was observed for concentration of 1µg/ml-10µg/ml. The developed method was linear with of 0.99 as the

correlation coefficient. The validation of method was done as per ICH guidelines for linearity, range, accuracy, precision, specificity, detection limit, quantitation limit, and forced degradation study.

KEYWORDS: RP-HPLC, Botulinum toxin, method development, method validation, degradation study etc.

INTRODUCTION

In 2010, the Food and Drug Administration (FDA) approved Botox as a prescription medication treatment for people with chronic migraines. Using Botox for migraine treatment has proved beneficial for patients who experience 15 or more migraines a month, but using Botox doesn't come without risk. Read more about using Botox for migraine treatment, including its benefits, and risks, from this overview.

ONE POT SYNTHESIS OF PYRANO[2,3-C]PYRAZOLE: A REVIEW

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The synthesis of pyranopyrazole bioactive heterocycles has caught the interest of medicinal and organic chemists due to their biological and therapeutic capabilities. This review summarizes the One Pot Synthetic pathways of pyranopyrazoles. Green approaches, nanoparticulate catalysts, microwave irradiation, ultrasonic irradiations, and other catalysts are among the reaction conditions that can be varied. The present review describes the literature reports for the period 2010 to 2021.

KEYWORDS: One pot synthesis, Microwave irradiation, Pyranopyrazole, Green approach, Ultrasonic irradiation.

INTRODUCTION

Heterocyclic compounds are widely employed because they have a wide range of applications in pharmaceuticals. The ability to develop diverse structures that are required to fulfil specific significant functions is the primary reason for their versatile application.

In the antibacterial, pharmaceutical, and medicinal sectors, pyran-based heterocyclic chemicals have been extensively used. "Multicomponent Reactions" (MCRs) have recently emerged as an alternative to traditional ways for creating a variety of complex organic compounds by combining three or more initial substrates. Many organic chemists have been drawn to one-pot multicomponent reactions because of their streamlined operation, simplified purification, decreased waste, lowered safety criteria, and reduced duration.^[1]

Pyranopyrazoles are a fascinating class of heterocycles due to their synthetic versatility and effective biological activities. Isomer (**1**) is the most studied of the four probable isomeric forms: pyrano[2,3-c]pyrazole (**1**), pyrano[4,3-c]pyrazole (**2**), pyrano[3,2-c]pyrazole (**3**), and

**A REVIEW: USE OF THE HERBAL MEDICINAL PLANTS AS AN IMMUNOMODULATOR FOR COVID-19**

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❖ ABSTRACT

The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is a highly infectious virus that spreads quickly from person to person and has never been seen in humans before. The World Health Organization (WHO) designated the infection COVID-19 (coronavirus disease-2019) on February 11, 2020, and declared the outbreak pandemic on March 11, 2020. It impacts everyone, without exception. The elderly and those with impaired immune systems, on the other hand, are more vulnerable. Coughing, sneezing, or touching infected hands to eyes, nose, or mouth spread the virus mostly through droplet infection from an infected person to a healthy person. The infection's symptoms range from moderate to severe. Fever of high grade (104°F),

dyspnea, pneumonia, and severe acute respiratory syndrome may emerge in severe cases (about 14% of cases). There is currently no particular therapy or vaccine available for new coronavirus-2019. We know from past and recent experiences that herbal remedies are effective against a variety of severe viral illnesses. This study's findings on immune-boosting herbs could be extremely beneficial to the body's fight against COVID-19 infection.

KEYWORDS: SARS-CoV-2, Antiviral, Herbal medicine, Immunomodulator drug.

❖ INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or 2019 novel coronavirus (2019-nCoV) is rapidly spreaded from its origin in Wuhan, Hubei Province, China, to the rest of the world. Till 7 /8/ 2021 around 202,693,744 cases of coronavirus disease 19 and 4,295,952 death have been reported. India has reported 31,913,083 cases till date.^[1,2] The first case of COVID-19 in India was an imported case from Wuhan, China on

SYNTHETIC STUDY OF INDOLE AND IT'S DERIVATIVES; AS POTENT ANTINEOPLASTIC AGENTS

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1. ABSTRACT

Cancer is a disease that entails a loss of genomic stability and seems to have a high global mortality rate. Since its revealed, several people have been searching for an effective treatment, evaluating numerous compounds for their anticancer properties. Whereas, indoles are natural compounds with antineoplastic activities due to their propensity to trigger cell death in a variety of cancer cell lines. An indole is an aromatic heterocyclic composite which has its heterobicyclic configuration as a six-membered ring fused to a five-membered pyrrole ring. 'Indole' is the name given to all indole derivatives which have an indole ring system. Indole derivatives possess various biological activities, i.e. antiviral, anti-inflammatory, anti-cancer, anti-HIV, antioxidant, antimicrobial, anti-tubercular, antidiabetic,

anticholinesterase, antimalarial activities, etc., prompting researchers to explore variety of indole derivatives. This review addresses the synthesis of indole and its various derivatives, facilitated induction and recent studies with indoles as showing potential chemotherapeutic activity.

KEYWORDS: Indoles, heterobicyclic configuration, indole derivatives, biological activities, anti-cancer agents.

2. INTRODUCTION

According to several discoveries, cancer has become one of the most difficult diseases to treat, and according to World Health Organization figures, it has now surpassed heart disease as the second leading cause of death worldwide. Nearly 10 million people died from cancer

AN OVERVIEW ON COVID 19 TREATMENT BY HERBAL MEDICINES

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ABSTRACT

Herbal-based traditional medicines or phytomedicines play a significant role in disease management in Africa and are widely used as alternative medicines. Therefore, it is important to evaluate both the safety and efficacy of these indigenous botanical assets in medicine prior to endorsing their use by the medical community and the public. There have been several declarations by institutions in Member States on the use of herbal-based traditional medicine for the prevention of SARS-CoV-2 transmission or treating people with a presumptive or definitive diagnosis of corona virus disease 2019 (COVID-19). Many of the claims are difficult to verify because of the lack of documented evidence showing that these remedies prevent or clear SARS-CoV-2 infection and/or improve clinical outcomes of those suffering from COVID-19. As the pandemic continues to spread in Africa, there are increasing messages promoting the use of herbal-based traditional medicines for COVID-19. Currently, no herbal remedy has been validated for use to prevent or treat COVID19. Herbal remedies or medicines are naturally occurring, plant-derived substances that are developed mostly through a process with minimal or no respect for good clinical practice (GCP). The current pandemic of COVID-19 that is spreading across countries originated in Wuhan, China. The single cause of this highly communicable disease is a novel corona virus, called severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), which is the seventh known virus of the Corona viridae family capable of infecting humans. The latest report from the World Health Organization cited that there are now over 19 million confirmed cases and over 700,000 deaths worldwide caused by this virus. The United States of America now has the highest number of COVID19 cases (over 4 million cases), followed by Brazil (almost 3 million cases) and India (over 2 million cases). The fast propagation of this disease is mainly through close contact with infected individuals via respiratory droplets from either sneezing or coughing. Furthermore, there are two other ways of transmitting the virus, including contact and aerosol transmission.

Keywords: Phytomedicines, Herbal Remedies , Covid Treatment ,Respiratory syndrome

INTRODUCTION

The disease is typically confirmed by reverse transcription polymerase chain reaction (RT-PCR) reverse Real-Time PCR assay (RRT-PCR), which can be carried out using a variety of clinical specimens, including Bronchoalveolar lavage fluid, fibro bronchoscope

UV SPECTROSCOPIC METHOD FOR THE ESTIMATION OF AZELNIDIPINE - A REVIEW

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ABSTRACT

Azelnidipine is a calcium channel antagonist that blocks lipophilic dihydropyridine calcium channels. Calcium channel blockers called dihydropyridine (DHP) are generated from the chemical dihydropyridine and are commonly used to lower systemic vascular resistance and arterial pressure. The focus of this review is on the azelnidipine uv spectroscopic analytical approach. The correlation coefficient of the calibration curve was found to be between 0.98 and 0.99, indicating that methanol is extensively utilised as a solvent solution in UV spectroscopy.

KEYWORDS: Lipophilic, Calcium channel blocker, Azelnidipine, and UV-spectroscopy.

INTRODUCTION

Chemically, azelnidipine (AZEL) is 3-*o*-(1-benzhydrylazetid-3-yl)5-*o*-propan-2-yl 2-amino-6-methyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate. It is a calcium channel blocker (CCB) of the dihydropyridine (DHP) class used to treat hypertension. Due to an asymmetric structure, AZEL contains two enantiomers.^[1]

The DHP ring's 4-position contains carbon. The drug's pharmacological effect The (R)-enantiomer of AZEL is the active form. This contrasts sharply with additional CCBs where the (S)-enantiomer is the active ingredient biological function The three-dimensional structure of the object is unusual. The active enantiomer of AZEL might be linked to its one-of-a-kind structure. pharmacological characteristics that other DHPs don't have, such as a

AN OVERVIEW OF REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRIES

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Abstract: Pharmaceutical drug regulatory affairs cover extraordinary registration parameter of pharmaceutical product. As it's miles the new career which changed into developed from the favored of everywhere in the international to protect the general public fitness through providing correct excellent of drugs such as safety and efficacy within the region of now not handiest pharmacy however also inside the area of the veterinary medicinal drug, scientific tool, pesticides, agrochemical, beauty and complementary medication. It also made the interface among the pharmaceutical company and the regulatory organizations. it is also liable for keeping the appropriateness and accuracy of the product data. And its principal role to behave as a liaison with regulatory groups, supplying information and regulatory intelligence in translating regulatory requirement into sensible practicable plan, advising the corporation on regulatory aspects and climate that might affect their proposed activities. Regulatory affairs in the pharmaceutical industry play an essential position because the Pharmaceutical area is rising very hastily and there's a need of regulatory affairs specialists to provide the current desires of industries for the worldwide opposition. A regulatory affair is a profession which acts as the interface among pharmaceutical industries and authorities internationally. The goal of the regulatory affairs professional is the protection of human health, ensuring safety, efficacy, and quality of drugs, making sure appropriateness and accuracy of product facts. This gift article discusses the evolution of Regulatory Affairs, its role inside the pharmaceutical enterprise and its involvement for the implementation of regulatory suggestions which improve the increase of the industry.

Keywords: Regulatory Affairs, Pharmaceutical industries, regulatory bodies.

Introduction: The modern Pharmaceutical enterprise is well prepared, systematic and compliant to international regulatory standards for manufacturing of Chemical and biological tablets for human and veterinary intake in addition to scientific gadgets, conventional herbal merchandise and cosmetics. Stringent GMPs are being accompanied for blood and its by-product in addition to controlled production for classic herbal drug treatments, Cosmetics, food and dietary products which became in any other case otherwise a century before. Each regulatory gadget had confronted certain occasions which brought about modern-day well-defined managed regulatory framework. This has resulted into systematic manufacturing and advertising of secure, efficacious and qualitative pills. With the boom of enterprise, the legislation from each area have come to be increasingly complex and created a need for regulatory specialists.¹

Regulatory Affairs (RA), also known as Government Affairs, is a profession inside regulated industries, including pharmaceuticals, clinical gadgets and so on. RA profession at its heart is all about gathering, studying and speaking the dangers and advantages of health care products to regulatory organizations and public all around the international.

AN OVERVIEW ON ANTIDIABETICS BY VARIOUS ANALYTICAL TECHNIQUES

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ABSTRACT

Its a meglitinide simple is an oral indication intended to regular hour aldohexose outings. Through not an antidiabetic, it acts in A comparable to way by restricting to antidiabetic receptor moreover on elective one particular receptor-» conclusion of adenosine triphosphate subordinate K⁺ channel-» of depolarization-» inner discharge unharnesses. Repaglinide prompts quick beginning short-enduring inner emission released. It is directed antero each fundamental supper to balance out postprandial hyperglycemia; the portion should be radiated if a food material is inconceivable. In light of less perpetual activity, it maybe had a lower hazard of the reality of hypoglycemia. Repaglinide is shown exclusively in type-II DM as another to sulfonylureas, or to enhance metformin/long inside discharge. It should be kept away from in sickness. This audit conveys a detail portrayal very surprising of different scientific ways were printed for the assessment of repaglinide and its mix medication in physician recommended drugs and natural grids. This appraisal incorporates distinctive logical ways like compound examination ways, forceful fluid movement (HPLC), predominant slender layer action (HPTLC), fluid chromatography-mass spectroscopic investigation (LC-MS), and ultra-execution fluid action (UPLC), GC-MS, [LC-ESI-MS-MS], slim action (CE), titrimetric and synthetic science strategy, and assignment concentrate for the assessment of repaglinide and along with a combination

Keywords: Biological frameworks, Chromatography, Repaglinide, Analytical strategies, Type-II diabetic medications Presentation

INTRODUCTION

Repaglinide is another carboxymethyl benzoic corrosive subordinate, otherwise called 2-ethoxy - 4-[2-[[3-methyl-1-[2-(1-piperidinyl) phenyl] butyl] amino]-2-oxoethyl] (Fig. 1). It is a novel prandial glucose controller for the treatment of type-II diabetes mellitus [1]. It diminishes fasting glucose focuses in patients with type-II diabetes mellitus. It assists with controlling the glucose levels by pancreas builds insulin levels. Repaglinide is an oral enemy of hyperglycaemia specialist utilized for the treatment of non-insulin-subordinate diabetes mellitus (NIDDM). It has a place with the meglitinide is an enemy of Diabetic sort II class drug with of short-acting insulin secretagogues, which act by restricting to the β cells of the pancreas, and it animates and delivers the insulin discharge levels [2]. Repaglinide actuates an insulin reaction to early suppers decreasing the postprandial blood glucose levels. May be multi month of a course is required for a lessening in fasting blood glucose levels is seen. Meglitinides may commonly affect slight development in weight. The complete normal weight acquire brought about by meglitinides seems, by all accounts, to be lower than that is brought about by sulfonylureas. Because of their own instrument of activity, meglitinides it might in light of the fact that hypoglycemia [3]. The danger is believed to be lower than that of sulfonyl urea's since their activity is presence on glucose-subordinate. As well as diminishing postprandial and fasting glucose, meglitinides are appeared to diminish glycosylated hemoglobin (HbA1c) levels, which are intelligent of the last 8–10 weeks of glucose control. Repaglinide is altogether used in the liver and discharged in bile salts. Roughly 90% of a solitary orally controlled portion is disposed of in the face and 8% in pee. The substance equation of C₂₇H₃₆N₂O₄ and it is solvent in methanol and methylene chloride. However, for all intents and purposes insoluble in water-dissolvability of around 20

“COMPUTER-AIDED DRUG DESIGN (CADD) & MOLECULAR MODELLING IMPORTANCE IN PHARMACEUTICAL SCIENCES.”

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Abstract

Computer-aided drug design (CADD) depends on the extent of structure and other information available regarding the target (enzyme/receptor/protein) and the ligands. The theoretical basis of CADD involves molecular mechanics, quantum mechanics, molecular dynamics, structure-based drug design (SBDD), ligand-based drug design (LBDD), homology modeling, ligplot analysis, molecular docking, de novo drug design, pharmacophore modeling and mapping, virtual screening (VS), quantitative structure-activity relationships (QSARs), In silico ADMET (absorption, distribution, metabolism, excretion and toxicity) prediction etc. CADD centre was created to foster collaborative research between biologist, biophysicists, structural biologists and computational scientists. The major goal of the CADD centre is to initiate these collaborations leading to the establishment of research projects to discover novel chemical entities with the potential to be developed into novel therapeutic agents.

Keywords: Bioinformatics, Softwares, Homology modeling, Ligplot analysis, Molecular docking, De novo drug design, Pharmacophore modeling, Virtual screening (VS), Quantitative structure-activity relationships (QSARs), Lipinski's rule.

❖ INTRODUCTION

Advances in the field of biochemistry, molecular biology and mobile biology, facilitated by using traits in genomics and proteomics, are producing a massive wide variety of novel organic goals that may be exploited for therapeutic intervention. To facilitate the discovery of novel healing marketers, rational drug design methods in mixture with structural biology provide wonderful capability. The trendy technological advances are (QSAR/QSPR, shape-based totally layout and bioinformatics). Drug discovery and developing a brand new medicine is an extended, complicated, high-priced and exceptionally unstable procedure that has few friends in the commercial global. This is why laptop-aided drug design (CADD) tactics are being widely used inside the pharmaceutical industry to accelerate the method. The value benefit of using computational equipment within the lead optimization section of drug improvement is full-size. On an average, it takes 10-15 years and US \$500-800 million to introduce a drug into the marketplace, with synthesis and trying out of lead analogues being a large contributor to that sum. Therefore, it's far beneficial to apply computational equipment in hit-to-lead optimization to cowl a wider chemical space at the same time as reducing the quantity of compounds that should be synthesized and examined in vitro.

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Review Article

Cancer cachexia: Current strategies and future perspectives

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ABSTRACT

Cancer cachexia is complex, and can often occur in the presence of malnutrition, age-related changes in anabolism, physical deconditioning and comorbidity. These factors can also form potentially reversible components of the overall 'cachexia burden'. Separating cancer cachexia from the effects and complications after cancer therapy is often difficult. This review aims to briefly describe cancer cachexia and these novel biological agents currently under investigation for the treatment of cancer –related cachexia. Treatment that can be reduces the muscle wasting which is resulting into cancer cachexia. The main aim of review is to the potential treatment for cancer cachexia, which include Pharmacological, non-pharmacological, neutraceutical and investigational new treatments.

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1. Introduction

Cachexia is a multifactorial infection portrayed by weight reduction through skeletal muscle and fat tissue misfortune, awkwardness in metabolic guideline, and decreased food consumption. It is brought about by components of catabolism delivered by tumours in the fundamental course as well as physiological factors, for example, the imbalanced fiery initiation, proteolysis, autophagy, and lipolysis that may happen with gastric, pancreatic, oesophageal, cellular breakdown in the lungs, liver, and entrails malignant growth. Disease cachexia not just adversely influences the personal satisfaction of patients with malignant growth yet additionally lessens the viability of hostile to disease chemotherapy and builds its poisonousness, prompting expanded malignancy related mortality and consumption of clinical assets. Right now, there are no powerful clinical intercessions to totally turn around cachexia and no endorsed drugs. Sufficient

wholesome help is the principle strategy of cachexia treatment, while drugs that focus on the restraint of catabolism, cell harm, and extreme enactment of irritation are under examination.¹

Cancer cachexia is an insidious syndrome that not only has a dramatic impact on patient quality of life, but is also associated with poor responses to chemotherapy and survival. Indeed, cachexia occurs in the majority of terminal cancer patients and, according to Warren, is responsible for the death of 22% of cancer patients.^{1,2} Current therapies focus on palliation of symptoms and the reduction of distress of patients and families rather than cure.³ In many cases, cachexia remains a largely underestimated and untreated condition. Approximately half of all patients with cancer experience cachexia, with the prevalence rising as high as 86% in the last 1-2 week of life, and with 45% of patients losing more than 10% of their original body weight over the course of their disease progression. Death usually occurs when there is 30% weight loss.⁴ The best management strategy of cancer cachexia is to treat the underlying cancer as this will completely reverse the cachexia syndrome. Unfortunately, this remains an

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PHARMACEUTICAL CO-CRYSTAL: A TECHNIQUE FOR ENHANCEMENT OF PHYSICOCHEMICAL PROPERTIES OF DRUGS

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ABSTRACT

In development of new product major constraints are poor aqueous solubility and low oral bioavailability. Crystallization emerge as potential technique for enhancement of solubility of poorly aqueous soluble drugs also helps to improve physicochemical with preserving the pharmacological properties of the API. Cocrystals are solids that are crystalline single-phase materials composed of two or more different molecular and/or ionic compounds generally in a stoichiometric ratio which are neither solvates/hydrates nor simple salts. It is multicomponent system in which one component is API and another is called coformer. Coformer selection is the main challenging step during cocrystal synthesis, so various screening methods for the selection of cofomers were explained. This article also summarizes differences between cocrystals with salts, solvates and hydrates along with the implications and limitations of cocrystals. It also provides a brief review on different methods of cocrystal formation and characterization technique of cocrystals.

KEYWORDS: Pharmaceutical cocrystals, Cocrystallization, Cofomers, Solubility, Stability, Bioavailability, Dissolution, Grinding, Supramolecular synthons.

INTRODUCTION

Pharmaceutical cocrystals are solids crystalline single-phase materials composed of two or more different molecular and/or ionic compounds generally in a stoichiometric ratio which are neither solvates nor simple salts. Thus, it is a multiple component crystal modified by intermolecular interaction such as hydrogen bonding, van der Waals force, π - π interactions, and halogen bond between an active pharmaceutical ingredients (drug) and coformer.^[1,2]

As a promising formulation, pharmaceutical cocrystals can improve some of the physicochemical properties of APIs, such as the solubility, dissolution rate, bioavailability, and stability, without altering their inherent chemical structures.^[3,4,5] Meanwhile, the guidance for industry regulatory classification of pharmaceutical cocrystals announced by the U.S. Food and Drug Administration (FDA) claims that cocrystals, as a drug product intermediate or a fixed-dose combination product, should substantially dissociate before reaching the site of pharmacological activity.^[6,7]

Actually, cocrystals are metastable solids because of their weak intermolecular interaction and easily dissociate into their respective components in solution.^[8,9]

It is essential to explore the detailed behaviours of pharmaceutical cocrystals between their dissolved and

dissociated processes, which will be beneficial to advance the development and application of pharmaceutical cocrystals.

Pharmaceutical cocrystal solubility commonly comprises a dissolution-dissociation process, and its evaluation is based on kinetic solubility, thermodynamic solubility, and the intrinsic dissolution rate. Kinetic solubility usually indicates a dynamic process such that the concentration fluctuations vary with time during cocrystal dissolution and depends on parameters such as the surface area, particle size and distribution, fluid dynamics, and experimental apparatus.^[10] However, thermodynamic solubility focuses on the dissolved extent of the cocrystal when all the cocrystal components achieve dynamic equilibrium in the solution phase entirely.^[11] The intrinsic dissolution rate concentrates on how the powder compacts affect the drug dissolution under a constant temperature and surface condition, which will contribute to approximately simulating the *In-vivo* behaviours of drug formulation.^[12]

The process of solvation is a vital factor for the cocrystal dissolution-dissociation process in the human gastrointestinal tract that is related to coformer solubility, the type and concentration of surfactants, and the ion concentration in dissolution media. In addition, cocrystal solubility is influenced by the strength of the crystal lattice that is associated with the crystal stacked form and intermolecular distances of API and CCF.^[13]



Safety and Efficacy of the Pfizer-BioNTech COVID-19 Vaccine

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Abstract- COVID-19 vaccine development is moving quickly, with the possibility of a vaccine being ready in as little as six months. So, when there is insufficient supply to fulfil demand in the first instance, who should be prioritized for vaccination? There's little doubt that health-care personnel in all contexts should be vaccinated first, but who comes next will be a difficult decision depending on local epidemiology, societal values, and the vaccines' capacity to prevent both severe disease and transmission, eliciting herd protection. The decision on who to vaccinate should be fair, contextualized, and based on each vaccine's properties. The elderly may be prioritized in some contexts, while the populace may be prioritized in others. COVID-19 has had a disastrous effect, and efforts are underway to accelerate vaccines. The rising problem of vaccination apprehension may have an impact on COVID-19 vaccine uptake. Individual, communicative, and societal variables of vaccination uptake were investigated. SARS coronavirus infection (SARS) affects approximately 240.6 million people around the world, and as a result, they become infected with coronavirus illness (covid 19). As a result, a safe and effective vaccine is required. COVID-19 can be severe in pregnant women due to prenatal maternal physiological changes. The Pfizer-BioNTech COVID-19 vaccine (BNT162b2 mRNA) has been found to be highly effective, and it is recommended for those aged 16 and up, including pregnant women.

The two messenger RNA (mRNA) vaccines BNT162b2 and mRNA-1273 were recently approved by the Food and Drug Administration (FDA) for emergency use against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes the COVID-19 coronavirus disease. Pfizer-BioNTech and Moderna, respectively, produced BNT162b2 and mRNA-1273 vaccines in 2020. The BNT162b2 vaccine was first used in the United Kingdom, Bahrain, Canada, Mexico, the United States, Singapore, Oman, Saudi Arabia, Kuwait, and the European Union, while the mRNA-1273 vaccine was first used in the United States and Canada in mid-December 2020. Studies reported on the 28th of December 2020. People who received the BNT162b2 vaccine had severe allergic reactions, while just a few people who received the mRNA-1273 vaccine had mild symptoms. As a result, the authors of the letter aim to investigate possible reasons of anaphylaxis after COVID-19.

Keywords – COVID-19 vaccines; high-risk; epidemiology; transmission; vaccine development; clinical trials. Anaphylaxis · Antibody · BNT162b2 · COVID-19 · IgE · MRNA-1273 · MRNA vaccine · SARS-CoV-2 · PEG

1. INTRODUCTION

On 8 December 2020 the UK became the first country to implement a covid-19 vaccination program after the approval of the Pfizer-BioNTech messenger RNA (mRNA) vaccine, BNT162b2, for emergency use vaccinated. ^[1] The burden of covid-19 in the UK remains high, and early evidence on the effectiveness of vaccines is essential for informing policy decisions on the ongoing delivery of the program and the use of other non-drug interventions. ^[2] During the first few weeks of the program, the priority groups for vaccination included older residents of care homes and their carers, those aged 80 years and older, and frontline health and social care workers. ^[3] From 18 January, vaccine delivery was extended to those aged 70 years and older and those in clinically extremely vulnerable groups. Delivery was initially through hospital trusts and care homes, when possible, then subsequently also through primary care providers and mass vaccination centers. Interim results from phase III clinical trials have found the BNT162b2 and ChAdOx1-S vaccines to be highly effective when using a two dose schedule with a target interval of three and four weeks, respectively, between doses. ^[4, 5] Data from the ChAdOx1-S trial suggests that protection might be greater with a longer dosing interval. ^[5] A reanalysis of the BNT162b2 trial data suggests that a single dose of this vaccine has an efficacy of 92.6% in the early post-vaccination period. ^[6] Furthermore, with other vaccines an extended interval between the prime and booster doses typically provides a better immune response to the booster dose. ^[7, 8] Based on this evidence, the increasing incidence of covid-19 in the UK and the need to rapidly vaccinate as many vulnerable people as possible, on 20 December 2020 the Joint Committee on Vaccination and Immunisation advised that the dose interval for both vaccines could be extended to up to 12 weeks.

BNT162b2 is a lipid nanoparticle-based, nucleoside-modified RNA vaccine that encodes a perfusion-stable, membrane-anchored SARS-COV-2 full-length spike protein. BNT162b2 is a highly effective anti-covid -19 drug that is now being used in emergency situations. Everyone who was freshly vaccinated between December 20, 2020 and February 1, 2021. The vaccine received emergency use permission (EUA) ² from the Food and Drug Administration (FDA) in December 2020, as well as an interim