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Pharmacovigilance Process in India: An overview

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Abstract

Clinical trial study of drug generally detects common Adverse Drug Reaction (ADR) but, the reaction which occurs after long duration in a specific person or population remains undetected. Pharmacovigilance (PV) is a scientific activity which keeps constant watch on the drug throughout its life cycle. In India, Indian Pharmacopoeia Commission (IPC) and National Coordination Committee (NCC) through the Central Drug Standard Control Organization (CDSCO) cordially regulate the PV activity. To build a potential PV system in India, Pharmacovigilance Program of India (PvPI) have been proposed and implemented by the Indian government in 2010. The accurate detection and reporting of ADR is a heart of this system. Hence various regional, zonal and peripheral centres have been proposed for the smooth and effective reporting of ADR. Anyone can report ADR by filling the suspect ADR reporting form available online or offline to the nearest centre in suitable language. Considering Indian geographical distribution, huge population and mobile network connectivity, a toll free number and the mobile app is also provided for timely and effective reporting of ADR. The reported ADRs are collected and processed at the centres in Vigi-flow software. These centres detect signal which are reported to CDSCO and World Health Organisation (WHO) for the further regulatory action. CDSCO-WHO communicates their decision through a suitable media for the betterment of public health.

Keywords: Pharmacovigilance; Adverse drug reaction; Pharmacovigilance program of India; Vigi-flow; Central Drug Standard Control Organisation

Abbreviations: PV: Pharmacovigilance; ADR: Adverse Drug Reactions; AE: Adverse Event

Introduction

Clinical trial data should be able to potentially reflect the safety and effectiveness of a drug for the successful launching of product in the market. Generally the clinical trials are carried in limited number/controlled population and only the common adverse effects can be traced. But, the reaction which develops after long duration and occurs in a specific individual remains undetected. This may be due to the presence of individual genotype and specific physiological conditions. Any medicine is said to be safe only when its benefits are greater than associated risk. So to determine the complete safety profile of medicine/drug; a constant and continuous monitoring in a diverse population is essential which is possible in terms of Pharmacovigilance (PV). PV deals with the complete study of drug related adverse effects and other problems [1]. "Pharmakon" means "Drug" and "Vigilance" means "to keep watch or alert". Broadly speaking, all chemicals other than the food that can alter biological systems are called as drugs. A chemical which shows beneficial therapeutic effect on the body is called as a medicine. However, if it produces harmful or toxic effect then it is regarded as a poison. Thus every drug is poison depending on the dose and use. The noxious and unintended reactions occurring at normal therapeutic dose are named as Adverse Drug Reactions, (ADRs) [1]. While, the untoward events occurred during drug therapy having no relation with its use are called "adverse event" (AE) [2].

Evolution of PV

Before 1960s the health cautiousness and health care regulations were liberal and instead of drug safety, efficacy of drug was the first priority. In 1961, phocomelia due to the thalidomide tragedy forced to establish a system which ensures drug safety [3]. In 1968, World Health Organization (WHO) established the international drug monitoring program because of which the drug safety issues were globalized and

systematized. A French group of pharmacologists and toxicologists coined the term PV in mid-70s. Its primary aim was to find out the harms related with drug therapy [4]. Since 19th century few medicines have been developed as safe and effective out of many investigational drugs. It was well known that, almost all drugs possess beneficial and some adverse effects. ADRs are the very widespread problem. Hence, to minimize ADR, PV came in a picture for appropriate and effective monitoring of ADR which can safeguard the public health [5].

Chronological Development of PV

1747: James Ling reported clinical trial showing effectiveness of lemon juice in prevention of scurvy.

1937: Sulphanilamide disaster, where sulphonamide was dissolved in diethyleneglycol leading to death of more than 100 people because of renal failure.

1938: The preclinical toxicity and pre-marketing clinical studies made mandatory by FDA.

1950s: Aplastic anaemia caused due to use of chloramphenicol.

1960: The FDA started hospital based drug monitoring program.

1961: Thalidomide disaster.

1963: 16th world health assembly recognized importance to rapid action on ADR.

1968: Establishment of International Drug Monitoring Program by WHO.

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**SYNTHESIS AND EVALUATION OF MUTUAL PRODRUGS FROM CLOPIDOGREL
ANALOGUES AND SALICYLIC ACID**

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ABSTRACT

A series of 4,5,6,7- tetrahydrothieno[3,2-c]pyridine derivatives having structure analogs to clopidogrel was synthesized and prepared their mutual prodrug with salicylic acid and evaluated for anti-platelet and antithrombotic activity. The confirmation of structure was done by IR, NMR, and Mass fragmentation. All synthesized mutual prodrug were subjected to investigation for their anti-platelet and antithrombotic activity using clopidogrel and aspirin as the standard drugs alone or in combination, synthesized mutual prodrug of clopidogrel analogues and salicylic acid shows better activity as compared to standard drugs.

KEYWORDS: Clopidogrel, salicylic acid, anti-platelet activity and antithrombotic activity.

INTRODUCTION

Several antiplatelet and antithrombotic agent are available in the market amongst them clopidogrel and aspirin are orally active inhibitor of platelet aggregation and antithrombotic agent. Clopidogrel is an adenosine diphosphate (ADP) receptor antagonist used for the reduction of myocardial infarction, ischemic heart disease, and vascular death.^[2] Where as, aspirin inhibits cyclooxygenase activity and affect the production of thromboxane TXA₂. Several antiplatelet agents with different mechanisms of action are currently available for secondary prevention of ischemic stroke.^[5,6] When used as a single agent, the efficacy of antiplatelet therapy is modest. Aspirin is the best-studied and most widely used antiplatelet agent for stroke prevention; however, it provides only an approximately 15% relative risk reduction for secondary prevention of stroke or other major vascular events. Combining two antiplatelet agents with different mechanisms of action was demonstrated to provide a substantial increase in efficacy.^[6,12] In recent years, there have been an increasing an interest in the design and development of mutual prodrugs, which involves combining of two different pharmacophores with similar pharmacological activities which may give synergistic action. Therefore an attempt has been made to adjoin their different derivatives through an ester linkage to form a series of mutual prodrugs which were further screened physiochemical and pharmacologically. This may improve acceptability of the compound by patient in the final stage along with their additive effect against platelet aggregation & thrombus formation. Clopidogrel contains 4,5,6,7-tetrahydrothieno[3,2-

c]pyridine as a basic ring. The structure of proposed derivatives was given in Fig: 1.

Compound	R ₁	R ₂
I	2-Cl	H
II	2-Cl	3-Br
III	2-Cl, 4-Cl	H
IV	2-Cl, 4-Cl	3-Br,5-Br

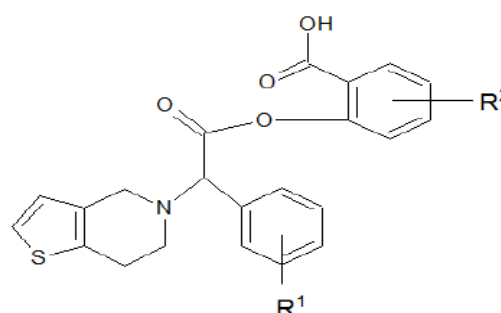


Fig. 1: Structure of proposed derivative.

MATERIALS AND METHODS

The chemicals used in the present work were AR grade and LR grade, purchased from Loba, Merck and Fisher scientific fine chemicals.

Mutual prodrugs of clopidogrel analogues and aspirin were synthesized as outline in Scheme1. The commercially available phenyl acetonitrile (1) serve as a convenient starting material in the synthesis on bromination gives 2-bromo-2-phenyl acetonitrile (2) which react with 4,5,6,7 tetrahydrothieno (3,2-c)pyridine

Herbal remedies for CNS disorders

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Abstract

Herbs, which have always been the principal form of medicine in developing countries, are once again becoming popular throughout the developing and developed world. The conventionally used drugs possess many side effects; the cost of modern drug is beyond the reach of most people with low income. Because of this, the need of alternatives that are effective, cheap, and safe is very common. Herbal remedies that have demonstrable psychotherapeutic activities have provided a potential to psychiatric pharmaceuticals and deserve increase attention in future studies. In this review article, the traditional herbal approaches for treatment of various CNS disorders are presented.

Introduction

The use of herbal remedies is widespread throughout the world and its use may be increasing. These are taken for a wide range of perceived benefits and treatment of specific conditions. A search for novel pharmacotherapy from medicinal plants for psychiatric illnesses has progressed significantly in the past decade. This is reflected in the large number of herbal preparations for which psychotherapeutic potential has been evaluated in a variety of animal models.⁽¹⁾ The disease is characterized by loss of memory and impairment of multiple cognitive and emotional functions. All critical analysis on commercial and other information available on traditionally known CNS active herbal remedies indicate that the most popular amongst such remedies are those which are clinically and preclinical the most well studied ones, and which are also recommended for therapeutic purposes by the health authorities of many Western and other countries outside the USA.⁽²⁾ Ancient pharmacopoeias from different regions of the world have recorded numerous herbal medicines purported to have psychotropic potential. These offer a vast repertory of potential substances that can be developed into modern psychiatric pharmaceuticals. Many of today's conventional drugs originated directly or indirectly from plants; many valuable psychoactive drugs, such as yohimbine, ephedrine, tubocurarine, and galanthamine, were discovered through the study of indigenous remedies. So there is a pressing need for development of herbal medicines which will be safe and having lesser side effects.

Anxiety

Anxiety is defined as a subjective emotional state of uneasiness, not pleasant and even fearful. When the anxiety reaches pathological levels the subject experiences conductal changes, apprehension, motor troubles, sweating, and hypertension.⁽³⁾ Phytotherapeutic interventions that may benefit anxiety disorders are classed as 'anxiolytics', and usually have

effects on the GABA system either via inducing ionic channel transmission by voltage-gated blockage, or through alteration of membrane structures, or less commonly via binding with benzodiazepine receptor sites (e.g., GABA-a).⁽⁴⁾

The roots of ashwagandha have been classified in Ayurvedic medicine as a 'Rasayana', a medicine used to enhance physical and mental performance. A preclinical study observed adaptogenic effects of ashwagandha given to rats over 21 days {25 or 50 mg/kg, orally (p.o.)} in a stress inducing procedure. A methanolic extract of ashwagandha root was found to inhibit the specific binding of GABA ligands and enhanced the binding of flunitrazepam to their receptor sites, displaying a GABA-mimetic activity. Many flavonoids were found to be ligands for the γ -aminobutyric acid type A (GABAA) receptors in the central nervous system (CNS); which led to the hypothesis that they act as benzodiazepine-like molecules. This is supported by their behavioral effects in animal models of anxiety, sedation and convulsion.⁽⁵⁾ Kava rhizome used for the treatment of the Anxiety.⁽⁶⁾

Alzheimer disease

Alzheimer Disease (AD) is a progressive brain disease affecting greater than 5.0 million Americans with approximately 11 to 16 million people projected to be afflicted with AD by the year 2050.⁽⁷⁾ Alzheimer's disease (AD) is a progressive and complex neurodegenerative disease, characterized by progressive decline in memory, language and other cognitive functions. It is associated with impairment of the basal forebrain cholinergic system, especially in the elderly.⁽⁸⁾ Neuroinflammatory processes in the brain are believed to play a crucial role in the development of Alzheimer's and Parkinson's disease as well as injury associated with stroke.⁽⁹⁾

There is a growing body of evidence to suggest that flavonoids and other polyphenols may be able to counteract this neuronal injury, thereby delaying the. For example, a Ginkgo biloba extract has been shown



DOCKING STUDY OF CHLOROGENIC ACID ON PPAR – γ FOR SCREENING OF ANTI-OBESITY ACTIVITY

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ABSTRACT

Objective: Screening of chlorogenic acid for anti obesity action by molecular docking on PPAR – γ receptor. The different conformations were critically studied. **Methods:** Molecular docking studies were carried out by the help of software *AUTODOCK*. Conformations were studied using *PyMol* software. **Results:** Conformations were studied and the numbers of hydrogen bonds formed were analyzed and tabulated. **Conclusion:** Best 10 conformations were selected by *AUTODOCK* software that showed that 9 such conformations formed hydrogen bonds. Formation of these hydrogen bonds justifies that chlorogenic acid shows better binding towards PPAR- γ receptor which shows anti obesity activity.

KEYWORDS: Chlorogenic acid, PPAR- γ , Anti obesity, Autodock, Pymol.

INTRODUCTION

Peroxisomes are subcellular organelles found in most plant and animal cells that perform diverse metabolic functions including H_2O_2 -based respiration, β -oxidation of fatty acids (FAs), and cholesterol metabolism. Peroxisome proliferator- activated receptors (PPARs) proteins belong to superfamily of phylogenetically related protein termed nuclear hormone factor.^[1] PPARs were identified in rodents in 1990 and these belong to a nuclear hormone receptor superfamily containing 48 members. But, these agents are associated with no proliferation in the human beings. Structurally, PPARs are similar to steroid or thyroid hormone receptor and are stimulated in response to small lipophilic ligands. In rodents, a large class of structurally related chemicals including herbicides, industrial solvents, and hypolipidemic drugs lead to significant increase in the number and size of peroxisomes in the liver and may cause liver hypertrophy, liver hyperplasia, hepatocarcinogenesis, and transcription of genes encoding proximal enzymes. PPARs mainly exist in three subtypes; α , β/δ , and γ , each of which mediates the physiological actions of a large variety of FAs and FA-derived molecules. Activated PPARs are also capable of transcriptional repression through DNA-independent protein-protein interactions with other transcription factors such as NF κ B signal activators and transducers of transcription STAT-1 and AP-1 signaling.^[2]

Isoforms of peroxisome proliferator- activated receptors

PPARs are transcription factors that belong to

the Superfamily of nuclear receptors. Other members of this family include retinoic acid, estrogen, thyroid, vitamin D and glucocorticoid receptors and several other proteins involved in xenobiotic metabolism. PPARs act on DNA response elements as heterodimers with the retinoid X receptor (RXR). Their natural activating ligands are lipid- derived substrates. The family of PPARs is represented by the following three members: PPAR- α , PPAR- δ and PPAR- γ . They play an essential role in energy metabolism; however, they differ in the spectrum of their activity— PPAR- γ regulates energy storage, whereas PPAR- α is expressed predominantly in the liver, and to a lesser extent, in muscle, in the heart and in bone and PPAR- δ present ubiquitously expressed in whole body regulate energy expenditure; expression of PPAR- γ in endothelial cells, vascular smooth muscle cells. PPAR- γ is further subdivided in four isoforms.^[3]

- $\gamma 1$ - expressed in virtually all tissues, including heart, muscle, colon, kidney, pancreas, and spleen.
- $\gamma 2$ - expressed mainly in adipose tissue (30 amino acids longer).
- $\gamma 3$ - expressed in macrophages, large intestine, and white adipose tissue.
- $\gamma 4$ - expressed in endothelial cells.

Mechanism of action of PPAR- γ

Thiazolidinediones (TZDs) are the most widely studied PPAR- γ ligands. Troglitazone was the first drug approved for this use, followed by rosiglitazone and pioglitazone. The mechanism of action of TZDs was



**SYNTHESIS AND EVALUATION OF 2-PHENYL 4-(2H-BENZIMIDAZOLYL) THIO
QUINAZOLINE DERIVATIVE AS A ANALGESIC AND ANTIINFLAMMATORY
AGENT**

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ABSTRACT

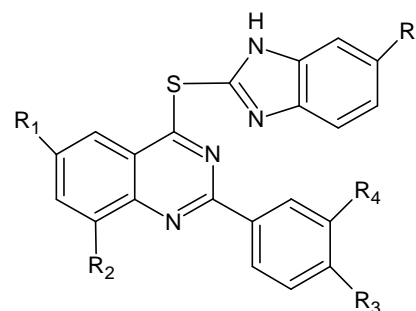
Objective: A new series of substituted 2-phenyl 4-(2H-benzimidazolyl)thione quinazoline were synthesized by condensation of various quinazolines and benzimidazoles in order to study their *in vivo* analgesic and anti-inflammatory effect. **Methods:** The structure of the synthesized derivative was confirmed by spectral (IR, NMR, MS) and elemental (C, H, N) analysis. **Results:** These synthesized compounds screened for its analgesic and anti-inflammatory activity using hot plate method and rat paw edema method respectively. **Conclusion:** Compound QB1, QB4, QB5 and QB9 possess good analgesic activity and QB5, QB7, QB8, QB13 possess good anti-inflammatory activity when compared with tramadol and indomethacin respectively as standard.

KEYWORDS: Anti-inflammatory, Quinazoline, Benzimidazole, Analgesic, Hot plate method.

INTRODUCTION

Inflammation is part of the complex biological response of vascular tissues to harmful stimuli, such as pathogens, damaged cells, or irritants (L.F.Miliani, 2007). It is a protective attempt by the organism to remove the injurious stimuli and to initiate the healing process (C.G. Wermuth). The search of new anti-inflammatory and analgesic agent with reduced toxicity is still a challenging task.^[1-3] One of the most frequently reported heterocyclic compound in medicinal chemistry is quinazoline, which possesses diverse biological activities like antimicrobial, analgesic and anti-inflammatory and anticonvulsant, anti-malarial, anticancer, antitubercular, antiviral, anthelmintic activities.^[4-8] Benzimidazole is also widely explored for the same set of activities such as antimicrobial, analgesic, anti-inflammatory and anticonvulsant activity while quinazoline with substitution at 2 and 4 positions has been reported to be associated with anti-inflammatory property.^[9-14] As

quinazoline and benzimidazole possess good anti-inflammatory activity, therefore it has been planned to fuse both these moieties sequentially for getting better activity (**Title Compound, Table 1**).



Title Compound: 2-Phenyl-4-(2H-benzimidazolyl) thiol quinazoline

Table 1. 2-Phenyl-4-(2H-benzimidazolyl) thiol quinazoline derivatives

Sr. No.	Comp. Code	R ₁	R ₂	R ₃	R ₄	R ₅
1.	QB1	H	H	H	H	H
2.	QB2	H	H	H	Cl	Cl
3.	QB3	H	H	Cl	H	Br
4.	QB4	Br	Br	Cl	H	CH ₃
5.	QB5	Br	Br	H	Cl	NO ₂
6.	QB6	Br	Br	H	H	H
7.	QB7	Br	H	H	Cl	H
8.	QB8	Br	H	Cl	H	H



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Behavioral effect of phosphatidylcholine isolated from soy lecithin in streptozotocin induced experimental alzheimers model

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Abstract

Background: Phospholipids are lipids containing a phosphoric acid residue; they are nature's principal surface-active agents. They are found in all living cells. Neurodegenerative disorders are characterized by progressive irreversible loss of neuron from specific region of brain.

Objectives: The present research work was designed to investigate the effects of different fractions of Phosphatidylcholine (PC), its antioxidant property in streptozotocin induced Alzheimer's disease in mice.

Methods: Intracerebroventricular administration of Streptozotocin to induce cognitive dysfunction & oxidative stress as an Alzheimer's disease in Swiss albino mice. Morris water maze, Elevated plus Maze were used to study cognitive behavior.

Results: Treatment of ICV STZ produced a significant decrease in MWM and EPM performance of mice hence reflecting loss of learning and memory. The study of the memory in Alzheimer's disease was found that PC 95 and 55 (200 and 300mg/kg) treated STZ-injected mice showed significant results. The time spent with target quadrant in MWM and retention latency in EPM was increases with PC as compared to STZ group.

Conclusion: Phosphatidylcholine showed improvement in cognitive impairment & it is a good promising candidate for increasing memory in Alzheimer's disease. The study demonstrates the effectiveness of PC in preventing the cognitive deficits as well as the oxidative stress caused by ICV STZ in mice and suggests its potential in age neurodegenerative disorders. In STZ induced memory deficit, there is a decreased activity of glycolytic enzymes resulting in a reduction in acetylcholine level which is intricately associated with cognition. PC showed memory improvement by its potent antioxidant action, is enhancement in CBF and energy metabolism.

Keywords: Soy lecithin, phosphatidylcholine, antioxidant, STZ, CBF

Introduction

The Alzheimer's disease (AD) was first described in 1907 by Alois Alzheimer Neuropath logically it is a progressive neurodegenerative disorder set to become the developed world's largest socioeconomic healthcare burden over the coming decades^[1]. AD is thought to affect 4–8% of the population over 65 years of age, with the incidence continuing to increase with increasing age. AD can occur at any age, even as young as 40 years. The rate of occurrence of the disease increases exponentially with age, which means that it occurs very rarely among those 40-50 years old, increases between 60 and 65 years, and is very common over 80 years^[2]. Lecithin is mixtures or fractions of phospholipids obtained by physical procedures from animal or vegetable food stuffs; they also include the hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzymatic activity. Lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides. Phosphatidylcholine (once given the trivial name 'lecithin') is usually the most abundant phospholipid in animal and plants, often amounting to almost 50% of the total, and as such it is obviously the key building block of membrane bilayers. In particular, it makes up a very high proportion of the outer leaflet of the plasma membrane. Phosphatidylcholine is the major Phospholipid of the brain, liver, plasma and most other tissues^[3]. PC is a polar lipid molecule that is a naturally occurring, integral component of the cellular membrane, adding fluidity and strength to cells. PC serves as a source of choline, an important nutrient for liver function and a precursor of the neurotransmitter acetylcholine. Choline is required for the synthesis of Acetylcholine in neurons: treatment that increase brain choline levels also increase the synthesis and release of Acetylcholine^[4]. Phosphatidylcholine is important for normal cellular composition and repair. It is the major delivery form of choline, which is a precursor to the synthesis of acetylcholine and other phospholipids.

TASTE MASKING BY CO-CRYSTALLIZATION: A REVIEW

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ABSTRACT

Acceptability of any dosage form mainly depends on its taste i.e. mouth feel. Dosage form interacts with taste receptor on the tongue to give bitter, sweet or salty taste sensation, when it dissolves in saliva. In market, there are numbers of pharmaceutical preparations available in which actives are bitter in taste. Pediatric patients frequently fail to take medications properly because of unpleasant taste of medication. Thus bitterness of preparation leads to patient incompliance. So masking of bitterness becomes essential. To overcome this problem, many technique has been developed to mask the bitter taste of drugs. Co-crystallization involves alteration in molecular assemblies and composition of pharmaceutical substance and which ultimately results in enhancing physical properties. Co-crystals contains API and pharmaceutically acceptable co-formers. Co-crystals are molecular

complexes, bringing about changes in solubility, bioavailability, stability and taste masking of bitter drug in pharmaceutical designing without interacting with therapeutic utility. The main objective of this review is discuss co-crystallization as a technique for masking the bitter taste of the drug.

KEYWORDS: Taste, Taste buds, Bitter drug, Taste masking, Co-crystallization, Sweetener.

INTRODUCTION

There are numerous pharmaceuticals that contain actives, which are bitter in taste. With respect to oral preparations, the bitterness of the preparation leads to lack of patient compliance. The problem of bitter and obnoxious taste of drug in pediatric formulations is a

**LUBRICANTS IN PHARMACEUTICAL SOLID DOSAGE FORMS
WITH SPECIAL EMPHASIS ON MAGNESIUM STEARATE**

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ABSTRACT

Lubrication plays a key role in successful manufacturing of pharmaceutical solid dosage form; lubricants are essential ingredients in robust formulation to achieve this. Although many failures in pharmaceutical manufacturing operations are caused by issues related to lubrication, in general, lubricants do not gain adequate attention in the development of pharmaceutical formulations. The addition of lubricants also affect tablet properties and can affect the behaviour of the powder mixture. In this review, the fundamental background on lubrication is introduced, in which the relationships between lubrication and friction/adhesion forces are discussed. The application of lubrication in the development of pharmaceutical products and manufacturing processes is discussed with an emphasis on magnesium stearate. In particular, the effect of hydration state (anhydrate,

monohydrate, dihydrate, and trihydrate) of a lubricant like Magnesium stearate and its powder characteristics on lubricant efficiency, as well as product and process performance is summarized.

KEYWORD: lubricant, magnesium stearate, effect of lubricant on tablet properties.

INTRODUCTION

The most important drug delivery route is undoubtedly the oral route. Despite the phenomenal advances in the inhalable, injectable, transdermal, nasal and other routes of administration the unavoidable truth is that oral drug delivery remains well ahead of the pack as the preferred delivery route.^[1] Oral drug delivery is the most desirable and preferred

COCRYSTALLIZATION TECHNIQUES FOR ENHANCEMENT OF SOLUBILITY

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ABSTRACT

The aim of this review is focused on the improvement of the solubility and bioavailability of poorly soluble drugs by using Crystal engineering approaches. Therapeutic effectiveness of a drug depends upon the bioavailability and ultimately upon the solubility of drug molecules especially in oral formulation. So many times it becomes challenging to formulate poorly water soluble drugs. Therefore it is necessary to improve solubility of drug by methods like co-solvency, salt formation, addition of solubilizing agent, micronization complexation, solid dispersion etc. A pharmaceutical co-crystal is a novel approach where single crystalline solid incorporates two neutral molecules, one being an active pharmaceutical ingredient (API) and the other a co-crystal former. Pharmaceutical co-crystals are nonionic supramolecular complexes and can be used to address physical

property issues such as solubility, taste masking. This review cover the co-crystallization, techniques, properties and application in pharmaceutics.

KEYWORDS: Bioavailability, BCS-II Cocystal, Conformer, Solubility, Salt formation.

INTRODUCTION

The oral route of drug administration is the most important method for administering drugs for systemic effects. Almost more than 90% drugs are orally administered. Drug absorption, sufficient and reproducible bioavailability, pharmacokinetic profile of orally administered drug substances is highly dependent on solubility of that compound in aqueous medium.

**FORMULATION AND EVALUATION OF *IN SITU* OCULAR GEL
FOR DRY EYE SYNDROME****Dr. Rahul Kasliwal***, Abhilasha Narad, Shambhavi Tiwari, Mamta Behune and **Anup
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Zone Building, MIDC,
Hingna Road, Nagpur-
440016, India.**ABSTRACT**

Ophthalmic drug delivery must be able to sustained the drug release and to remain in the vicinity in front of the eye for prolong period of time. The topical application of drugs is the method of choice under most circumstance because of its convenience and safety for ophthalmic chemotherapy. To develop the in situ ocular gel of a polymixin B sulphate which release the drug in sustained manner by using high esterified pure pectin, guar gum and hydroxyl propyl methylcellulose. Ocular in situ gel was prepared by dispersion method. In the present research work it can be shown that polymixin B sulphate, an antibacterial agent used in the treatment of dry eye syndrome was successfully formulated as an ion-activated in situ forming ophthalmic solution using pectin, guar gum in combination

with HPMC as a viscosity enhancer. The in situ gel was subjected to content uniformity and was found to be between 97% to 98%. The developed formulation is a viable alternative of conventional eye drop due its ability to enhance bioavailability through its longer precorneal residence time and ability to sustain release drug.

KEYWORDS: Ophthalmic drug, Antibacterial agent, Bioavailability, Polymixin B.**INTRODUCTION**

Eye is most interesting organ due to its drug deposition characteristics. Generally, topical application of drug is the method of choice under most circumstances because of it's or convenience and safety for ophthalmic chemotherapy.^[1] A significant challenge to the formulator is to circumvent (by pass) the protective barrier of the eye without causing

**DEVLEOPMENT, EVALUATION AND VALIDATION PARAMETER
OF MEMORY ENHANCER SYRUP****Dr. Rahul Kasliwal***, Mamta Behune, Tejaswini Tonde, **Anup Thakre** and Abhilasha
NaradDepartment of Pharmacy, Priyadarshini J. L. College of Pharmacy, Electronic Zone Building,
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440016, India.**ABSTRACT**

In psychology, memory is the process in which information is encoded, stored and retrieved. Encoding allows information that is from the outside world to reach our senses in the forms of chemical and physical stimuli. Memory it's an unconscious faculty in which mental impression are retained and reproduced in mind. Memory consist of four process such as learning, retention, recall and recognition. From an information processing perspective there are three main stages such as Encoding, Storage and Retrieval of memory. Loss of memory may develop dementia. The number of phytoconstituents remains present in polyherbal syrup, it is much tedious to establish the quality control and standardization parameters for polyherbal preparations. The present study shows validation parameters and techniques of quality assurance

for its quality, efficacy, stability and purity. A different modem analytical technique like HPLC and GC can also be used for the method development of active constituents present in herbal memory enhancer syrup. The method developed with HPTLC for bacoside A.

KEYWORDS: Syrup, HPLC, HPTLC, GC, bacoside A, dementia.**INTRODUCTION**

In psychology, memory is the process in which information is encoded, stored, and retrieved. Encoding allows information that is from the outside world to reach our senses in the forms of chemical and physical stimuli. Memory its a unconscious faculty in which mental impressions are retained and reproduced in mind. In this first stage we must change the information so that we may put the memory into the encoding process. Storage is the second



Evaluation of Commercial Vitamin B9 Supplements with Modified Dissolution Test and Validation of HPLC Method

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Women who are at high risk of having babies with neural tube defects should take 5 mg/day of vitamin B9 commonly known as folic acid (FA). The purpose of this study was to evaluate number of brands of FA (5 mg), available commercially for compliance with IP dissolution test and validate HPLC method. Ten tablets from each of the six brands were tested by dissolution test apparatus and further analysis was continued in concentrated dissolution medium by applying chromatography method to validate in terms of specificity, linearity and accuracy for the dissolution of FA in formulations. The results indicated that four brands failed to release 60% of nominal drug content and thus did not comply with the test. Two of the six brands that passed the dissolution test went on to content. However, dissolution test followed by HPLC was found to be linear in range of 0.02 to 1 mg/ml of FA with a correlation coefficient of 0.999. These results highlight the problems of dose uniformity and potential health risk of slow dissolution and under-dosing in commercially available FA dosage form. Hence, dissolution studies of FA obtained by the modified method are in good agreement with liquid chromatography method and provide an accurate quality analysis on FA supplements.

KEYWORDS: Evolution, Folic Acid, Neural Tube Defect, Dissolution, HPLC.

INTRODUCTION

Neural tube defects (NTDs) are common complex multifactorial disorders in the neurulation of brain and spinal cord that occurs between 21 and 28 days after conception in women (Pitkin, 2007). Maternal exposure to dietary factors during pregnancy can influence embryonic development and may modulate phenotype of offspring through epigenetic programming. Folate is critical for nucleotide synthesis, and preconceptional intake of folic acid (FA) is credited with reduced incidences of NTD in infants (Barua et al., 2014). Women who are at high risk of having babies with NTD such women should take 5 mg/day of vitamin B9 commonly known as FA for 2 months before conception and during the first trimester (Kennedy and Koren, 2012). Over the years, numerous studies including community-based trials often suggested NTDs as vitamin deficiency disorders and have shown that the exogenous or preconceptional supplementation of maternal FA can reduce the risk of NTDs in offspring (De Regil, 2010).

This is not surprising, as inter subject variability in many factors associated with FA metabolism and response has been clarified during past decade, suggesting that higher daily doses of vitamin B9 might be needed to maximize its protective effect on fetus.

Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare, Government of India. IPC is created to set standards of drugs in the country. It publishes official documents for improving quality of medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). The IP is an official document meant for overall quality control and assurance of pharmaceutical and biotechnology products marketed in India by way of contributing on their safety, efficacy and affordability and it prescribes standards for identity, purity and strength of drugs essentially required from health care perspective of human beings and animals (Birdi et al., 2014).

The World Health Organization (WHO) has continuously advocated the use of generic brands in order to make the cost of medicines affordable especially for developing countries like India (WHO, 2007). However, this approach has not provided sufficient evidence for substitution of one

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Retrospective pharmacoeconomic evaluation of two types of cataract surgeries in a private hospital: cost effectiveness analysis

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Abstract

Objective: Cataract surgery is performed by two methods; small incision cataract surgery (SICS) and topical phacoemulsification (TPE) with intraocular lens (IOL) implantation. SICS is a widely used method but technological advances have led to increasing use of TPE. Both procedures require different capital investment. Pharmacoeconomic evaluation tends to investigate the selection and use of treatment program to make the patient medication efficient, safe and economical. The objective of the present study was to evaluate the economics and effectiveness of SICS and TPE.

Materials and Method: Records of 800 patients in a private hospital over last 5 years were retrospectively analyzed. Patients were selected with inclusion and exclusion criteria and divided into two groups; SICS (n= 350) and TPE (n=450). Follow up was done after day 1; 1, 4, 8 weeks and 2 years. The cost was calculated including direct and indirect medical and non-medical costs. Outcomes were determined according to economical benefit, surgical benefits and humanistic outcomes as per SF-36 questionnaire with slight modifications. The cost effectiveness ratio (CER) was calculated with the help of QALY and utility values.

Results: Average cost of SICS and TPE over the period of 5 years was approximately Rs. 21220 and Rs. 30670 respectively. The QALY scores of patients in TPE group were significantly higher as compared to SICS group. CER was found to be lesser with TPE.

Conclusion: Retrospective pharmacoeconomic study revealed that TPE, although having higher cost, was clinically superior and cost effective than SICS as indicated from the analysis of consequences and CER.

Keywords: Pharmacoeconomic evaluation, small incision cataract surgery, topical phacoemulsification, cost effectiveness analysis.

Introduction

Cataracts are the major cause of blindness and of severe visual impairment leading to bilateral blindness.⁽¹⁾ Modern cataract surgery aims to achieve a better unaided visual acuity with rapid post surgical recovery and minimal surgery related complications. Early visual rehabilitation, better unaided visual acuity and surgical safety can be achieved in a great measure by reducing the incision size. Incision size depends on the mode of nucleus delivery and the type of intraocular lens used. It is a leading cause of unilateral and more often bilateral blindness. The only effective means of its treatment is surgery – extraction of diseased lens and its replacement by an artificial intraocular lens (IOL).⁽²⁾

Small incision cataract surgery with IOL implantation (SICS) involves the expression of entire lens out of the eye through a self-sealing scleral tunnel wound. Phacoemulsification with IOL implantation (TPE) is a modern cataract surgery in which the eye's natural crystalline lens is emulsified with ultrasound energy and aspirated from the eye. Aspirated fluids are replaced with irrigation of balanced salt solution, thus maintaining the anterior chamber, as well as cooling the handpiece.^(2,3,4)

The two types of surgeries have different capital investment although the outcomes are almost similar with few exceptions. Hence the objective of the present study was to analyse the cost and consequences of these

cataract procedures and to evaluate cost effectiveness by pharmacoeconomic evaluation methods.

Materials and Method

The patients who have been operated for cataract in a private hospital in Nagpur were included in the study. They were selected on the basis of inclusion and exclusion criteria⁽⁵⁾ as shown in Table 1. The selected patients were divided in two groups according to the surgical procedure; SICS group and TPE group.

Table 1: Inclusion and exclusion criteria for selection of patients

Criterion	Parameters
Inclusion	Visual acuity less than 6/60
Exclusion	Traumatic cataract, Preexisting ocular conditions like pterygium, corneal opacities, glaucoma, diabetic retinopathy, retinal detachment

Estimation of cost: The cost of each type of surgery was calculated including direct medical, direct non-medical and indirect non-medical cost.

The direct medical cost included preoperative consultation and investigations, intraoperative



Development and validation of a simple UV spectrophotometric method for the determination of antihyperlipidemic drugs both in bulk and marketed dosage formulations

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Abstract

A rapid, specific and economic UV spectrophotometric method has been developed using Methanol as a solvent to determine the simvastatin and ezetimibe content in bulk and pharmaceutical dosage formulations at a pre-determined λ_{\max} of Simvastatin and Ezetimibe 249 nm and 228 nm respectively, it was proved linear in the range of 2.0–10.0 $\mu\text{g/mL}$, and exhibited good correlation coefficient ($R^2=0.999$ for Simvastatin and $R^2=0.998$ for Ezetimibe) and excellent mean recovery (99.65–99.98 % for Simvastatin and 98.23–99.11 % for ezetimibe). This method was successfully applied to the determination of simvastatin and ezetimibe content in marketed brands and the results were in good agreement with the label claims. The method was validated statistically and by recovery studies for linearity, precision, repeatability, and reproducibility. The obtained results proved that the method can be employed for the routine analysis of simvastatin and ezetimibe in bulks as well as in the commercial formulations.

Keywords: simvastatin, ezetimibe, UV spectrophotometric method

1. Introduction

Simvastatin chemically known as butanoic acid, 2, 2-dimethyl-1, 2, 3, 7, 8, 8a-hexahydro-3, 7-dimethyl-8-[2(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)-ethyl]-1-naphthalenyl ester (Figure 1), is an anti-lipidemic drug which is derived synthesized from fermentation products of *Aspergillus terreus* [1]. Simvastatin mainly used for the treatment and management of dyslipidemia and the prevention of cardiovascular disease.[2]It is instructed to use only after other measures such as diet, exercise, and weight reduction have not improved cholesterol levels [3]. General adverse reactions may include abdominal pain, diarrhoea, indigestion, and a general feeling of weakness. Rare side effects include joint pain, memory loss, and muscle cramps [4]. Cholestatic hepatitis, hepatic cirrhosis, rhabdomyolysis and myositis have been reported in patients receiving the drug chronically [5]. Ezetimibe (Figure 2) is a drug that decreases cholesterol. It decreases absorption of cholesterol in the intestine. It may be used alone (marketed as Zetia or Ezetrol), when other cholesterol lowering medications are not tolerated, or simultaneously with statins (ex-simvastatin/ezetimibe marketed as vytorin) when statins alone don't suppress cholesterol. Although ezetimibe controls cholesterol, the outcomes of two clinical trials (2008 and 2009) proved that it was not having any improvement, like major coronary events, and shown some outcomes, like thickening of artery wall, worse. Eventually, a panel of experts concluded in 2008 that it should "can be the last resort" [6].

Simvastatin was estimated by several methods including liquid chromatography with UV detection (LC–UV) [7, 9], gas

chromatography-mass spectrometry (GC-MS) [10]. Ezetimibe was estimated alone or without combination of several drugs by high performance liquid chromatography and spectrophotometrically [11, 12].

Literature investigations reveal some HPLC methods have been reported for the estimation of these two drugs in combined dosage forms. Preliminary separation enforces pursuing of present research work.

2. Materials and methods

2.1 Apparatus

- Shimadzu UV–visible spectrophotometer (UVmini-1601, Shimadzu Corporation, Kyoto, Japan) was used for all absorbance measurements with matched quartz cells.
- Precision balance model Citizen Cy 220 having sensitivity 0.1 mg was used for weighing the substances.
- pH meter model Electronic India was used for measuring pH of solvents.

2.2 All reagents and chemicals used were of HPLC and analytical grade

All HPLC solvents and solution were filtered through membrane filter (ultipore'n86', Nylon 66, 0.45 μm pore size) and degassed before use. The pure drugs Simvastatin (100.07 %) and Ezetimibe (99.75 %) were gifted by Zim Lab, Kalmeshwar, Nagpur and Blue Cross Lab Nashik were used as reference standard, respectively.

The tablets formulation was purchased from local market, its details are given in Table 1.



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PHYTOCHEMICAL SCREENING AND EVALUATION OF PHARMACOLOGICAL ACTIVITIES OF *EULOPHIA NUDA* LIND. TUBER EXTRACTS

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Keywords:

Eulophia nuda,
Antibacterial activity, Antifungal
activity, Hepatoprotective activity

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ABSTRACT: *Eulophia nuda* Lind. belongs to family Orchidaceae and is a rare and endangered orchid. Present research work was carried out on tuber extracts of *Eulophia nuda* for the evaluation of antimicrobial activities and hepatoprotective. Preliminary phytochemical screening revealed presence of phytochemical constituents like alkaloids, flavonoids, steroids, glycosides (cardiac), tannins, saponins, carbohydrates in three tuber extracts prepared by using solvents (chloroform, acetone and ethanol). Antibacterial activity was carried out with Disc Diffusion method against *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Acetone extract was more effective against *Staphylococcus aureus* with maximum zone of inhibition 18 mm compared to standard antibiotic Ampicillin with zone of inhibition 20 mm. Antifungal studies was carried out using well diffusion method against *Candida albicans*, *Aspergillus niger* and *Aspergillus flavus*. Chloroform extract was more effective against *Aspergillus niger* having zone of inhibition 17 mm compared with standard antifungal Fluconazole (20mm). Acetone extract shown the zone of inhibition of 16 mm against *Aspergillus flavus* compared to standard Fluconazole (22mm). Hepatoprotective activity was carried out as per OECD guidelines 425 using Wistar albino rats. Effect of these extracts on CCl₄ induced hepatotoxic rats was studied by SGOT, SGPT and ALP parameters compared with standard LIV 52. From the research work, it was concluded that *Eulophia nuda* tuber extracts are active as antibacterial, antifungal and hepatoprotective which could be used for the development of some promising formulations, furthermore, structural elucidation of isolated components from the extracts of *Eulophia nuda* can be carried out using studies like IR and NMR.

INTRODUCTION: Traditional herbal medicines are naturally occurring; plant derived substances with minimal or no industrial processing that have been used to treat illness with local or regional healing practices.

Herbal medicines also known as botanical / phyto-medicine refers to using a plant, seeds, berries, roots, leaves, barks, tubers or flowers for their medicinal purposes¹. The family Orchidaceae to which orchid belongs is the largest family amongst monocotyledons contains almost 600 - 800 genera / species.

The genus *Eulophia* is terrestrial with almost round pseudo bulbs enveloped by a few sheath carrying 3 - 4 lanceolate, plicate, acuminate, long plicate, long grooved stalks which have several leaf like bracts. The plants blooms in springs with tall thick fleshy

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