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LORNOXICAM-EXCIPIENT COMPATIBILITY STUDIES FOR MICROSPONGE-BASED DRUG DELIVERY SYSTEMS DEVELOPMENT

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ABSTRACT

Multiparticulate drug delivery systems are important because they are simple to build and can control drug release in various ways, such as rate control, site control, or both. In the present study that the Lornoxicam was chosen to be the active pharmaceutical ingredient (API) in microsponge gel preformulation. Drug-entrapped microsponge can be used to make a variety of formulations, including tablets, gels, capsules, powders, lotions, and creams. This microsponge drug delivery technique provides enhanced drug entrapment and stability, allowing for greater formulation flexibility and a significant reduction in unwanted side effects. Lornoxicam (chlortenoxicam), a new nonsteroidal anti-inflammatory drug (NSAID) of the oxicam class with analgesic, anti-inflammatory and antipyretic properties, is available in oral and parenteral formulations. It differs from other oxicam compounds in its potent inhibition of prostaglandin biosynthesis, a property that explains the particularly pronounced efficacy of the drug. It is a strong analgesic and anti-inflammatory NSAID as compared to other NSAIDs. A total of four microsponge gel formulations of Lornoxicam with excipients like; Eudragit, Polyvinyl alcohol (PVA) in different ratios were prepared with a view to increase its effect by decreasing the time required for the drug to be released. Preformulation, formulation and evaluation of Lornoxicam to avoid problems associated with conventional delivery system such as limited permeation, low dissolution and bioavailability. Preformulation studies parameters were evaluated. It was concluded that the drug Lornoxicam was found to be compatible with various excipients which were selected for the formulation development of the Lornoxicam microsponge gel DDS. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process.

KEYWORDS: Lornoxicam, Compatibility, Microsponge Gel, Delivery System, Development.

INTRODUCTION

Preformulation Studies of Microsponge Delivery System[1-120]

Preformulation is essentials of pharmaceutical science that utilizes biopharmaceutical principles in the determination of physicochemical properties of the drug substance. Prior to the development of any dosage form new drug, it is essential that certain fundamental physical and chemical properties of drug powder are determined. This information may dictate many of subsequent event and approaches in formulation development. The safety, efficacy, quality and stability of a formulation are major concepts of any API development process. In API development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process.

One of the objectives of this study is to development of drug delivery systems by building scientific pharmaceutical research information depend on formulation scientists to join the knowledge and experience as well as experimental and practical results of this study with regard to information in previous studies, and approved references. It was found to be that the most important concepts and basics of preformulation studies such as definitions, methods, conclusion, idea, and types of pharmaceutical analysis techniques using in evaluation of preformulation studies parameters, in this study that we focused on developing drug delivery systems and linking the formulation development to establish the basics of pharmaceutical research in studying the drug-excipient compatibility, dug with various excipients, which is important for the safety, effectiveness, quality, formulation, stability,

bioavailability, and pharmacokinetics of the drug etc.

Determination of physical chemical properties of API substance with the goal of developing a new drug which is safe stable and efficacious, each API, has intrinsic chemical and physical properties that were considered prior to the development of pharmaceutical formulation, the purpose of preformulation study is to generate useful information for the formulator in the development of stable and bioavailable dosage form, inappropriate preformulation study results in poor stability of active ingredients increase the overall cost of development and increased development time, preformulation studies help to fortify the pharmaceutical scientific foundation of the guidance, provide regulatory relief and conserve resources in the drug development and evaluation process, enhance public safety standards, improve product quality, promote the implementation of new technologies, aids policy development and regulatory decision making and after compiling all data it is transferred to the development pharmacist and for the day work on formulation of dosage form.

Preformulation Study Objectives: To establish the Physico-chemical parameters of a new API entity, determine its kinetics and stability, establish its compatibility with common excipients, it provides insights into how drug products should be processed and stored to ensure their quality, estimate problem may arise during formulation that is stability problem poor *in-vivo* dissolution, poor bioavailability, to interpret BCS classification of drugs and its significance and develop optimal drug delivery system.

Drug-Excipient Compatibility Study: The primary objective of this investigation was to identify a stable storage condition for API in solid state and identification of compatible excipients for its formulation. Incompatibilities are major concerns in formulation development. Selection of the proper excipient during preformulation studies is of prime importance.

Dosage Forms: DF contain API and pharmaceutical excipients, which are intended to generate an ideal formulation and manufacturability of pharmaceutical products, thereby enabling a much safer and more effective administration. Pharmaceutical excipients are ideally inactive and have no impact on the stability or therapeutic effect of the active ingredient. On the other hand, there are studies that have presented that some pharmaceutical excipients are just allegedly described as inactive ingredient. Some pharmaceutical excipients have the capacity to affect API, efficacy by affecting its pharmacokinetics. Excipients can affect the physical and chemical form of pharmaceuticals by several factors such as hydrogen bond interaction, polymorphic conversion, and others. Accordingly, drug-excipient compatibility should be conducted so as to determine any drug-excipient interactions that may obstruct the stability, bioavailability, and manufacturability of pharmaceutical dosage forms.

Importance of Drug-Excipient Compatibility

Studies of active pharmaceutical ingredient (API)-excipient compatibility represent an important study in the preformulation stage of the development of new dosage forms, stability of the dosage form can be maximized, any physical or chemical interaction between API, and excipient can affect bioavailability and stability of drug, it helps to avoid the surprise problem, by performing drug excipient compatibility studies (DECS) we can know the possible reaction before formulating final dosage form, DECS data is essential for IND (investigational new drug) submission, and now, USFDA has made it compulsory to submit DECS data for any new coming formulation before its approval.

The potential physical and chemical interactions between an API, and the excipients can affect the chemical nature, the stability and bioavailability of the former and, consequently, its therapeutic efficacy and safety, solid dosage forms are generally less stable than their API components and despite the importance of API-excipient compatibility testing, there is no universally accepted protocol to assess such interactions.

Pharmaceutical Excipients: Excipients are additive substances used to improve the bulkiness, disintegration, dissolution rate, and bioavailability of a formulation etc. Different dosage forms like powders, granules, capsules, tablets, oral liquids, injectable products, implants, eye products, nasal products, inhalers, topical creams, ointments, gels, transdermal patches and suppositories etc, contains different types of excipients. To make it acceptable and compatible various pharmaceutical excipients are added in pharmaceutical dosage form for their direct therapeutic action, manufacturing process, to protect, support or enhance stability, for bioavailability or patient compliance. These must be physiologically and chemically stable, must not have any incompatibility with the API, and must meet the standards of regulatory requirements.

Evaluation of Drug-Excipient Compatibility

The compatibility study of API and excipients is important to predict the stability of the API, in the final pharmaceutical product. It's the first time that API was compatible with excipients promoted physical and chemical compatibility studies was achieved by thermal and non-thermal methods. As a part of preformulation study, a compatibility study of API with the other excipients was carried out using physical blends in analytical techniques for the evaluation of drug-excipient interactions. The most commonly used pharmaceutical analytical techniques include, thermal techniques such as Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), Isothermal Microcalorimetry (IMC) and Hot stage microscopy (HSM) etc, and non-thermal techniques such as UV-Visible Spectrophotometric (UV), Infrared, Near-

Infrared and Raman Spectroscopy (FT-IR), (NIR), Powder *X*-Ray Diffraction (PXRD), Solid-State Nuclear Magnetic Resonance Spectroscopy (ssNMR), Microscopic techniques: Scanning Electron Microscopy (SEM), Chromatographic techniques: Thin Layer Chromatography (TLC), and High-Performance Liquid Chromatography (HPLC) etc.

Preformulation Parameters: According to dosage form of API, mainly solid state, particle size, shape, pKa, pH determination, common ion effect, temperature, partition coefficient, solubility studies, dissolution rate, melting point, powder flow properties, crystallinity, polymorphism, hygroscopicity, stability study and drug-excipient compatibility etc. While other dosage forms according to important of preformulation parameters used in study before start in development of formulation.

Drug-excipient compatibility and formulation stability is not depended on API only but also its affected by excipient. Excipient play important role in dosage form but side by side it also increases compatibility problem so proper selection of excipient is very important in development of formulation. Incompatibility can be result mainly in any of following changes: Changes in organoleptic properties, changes in dissolution performance, decrease in potency, and increase in degradation rate etc.

Drug excipient physicochemical characterization is a systematic approach towards design of therapeutically active and stable dosage forms. The rapid advancements in novel drug delivery systems development have led to an interest by formulation scientists in the role and functionality of the excipients.

Multiparticulate drug delivery systems are important because they are simple to build and can control drug release in various ways, such as rate control, site control, or both. Multiparticulate drug delivery systems are expected to improve drug absorption because they are more likely to be distributed uniformly throughout the absorption site. Microspheres, microbeads, or microcapsules, microballoons, and microsponges are some of the microparticulate systems developed and explored for this purpose.

Drug-entrapped microsponge can be used to make a variety of formulations, including tablets, gels, capsules, powders, lotions, and creams. This microsponge drug delivery technique provides enhanced drug entrapment and stability, allowing for greater formulation flexibility and a significant reduction in unwanted side effects.

In the present study, it was proposed to Lornoxicam-excipient compatibility studies of the safety, efficacy, quality and stability of a formulation are major concepts of any API development process. In API development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage, with commonly different excipients using for formulation development of microsponge gel DDS.

MATERIALS AND METHODS

As shown in Table 1.

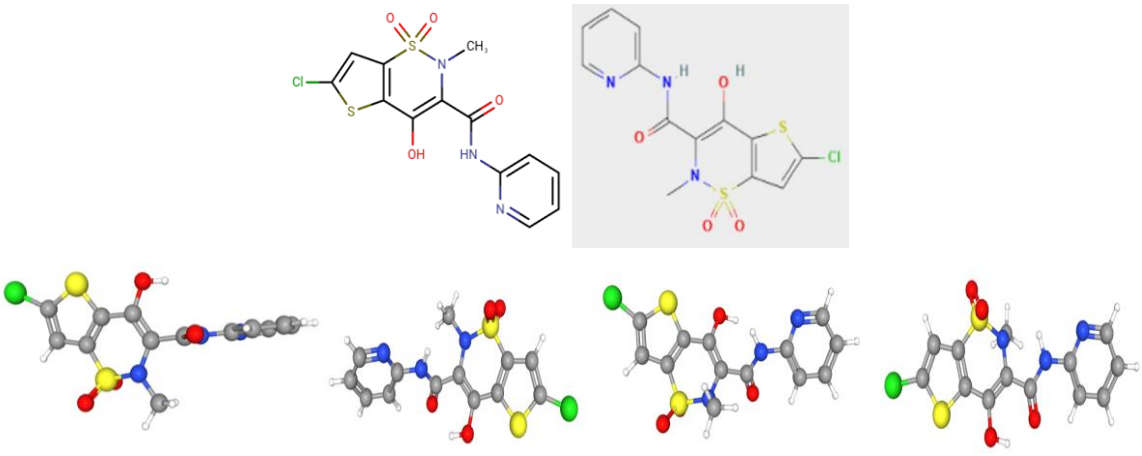
Table 1: List of Materials Used.

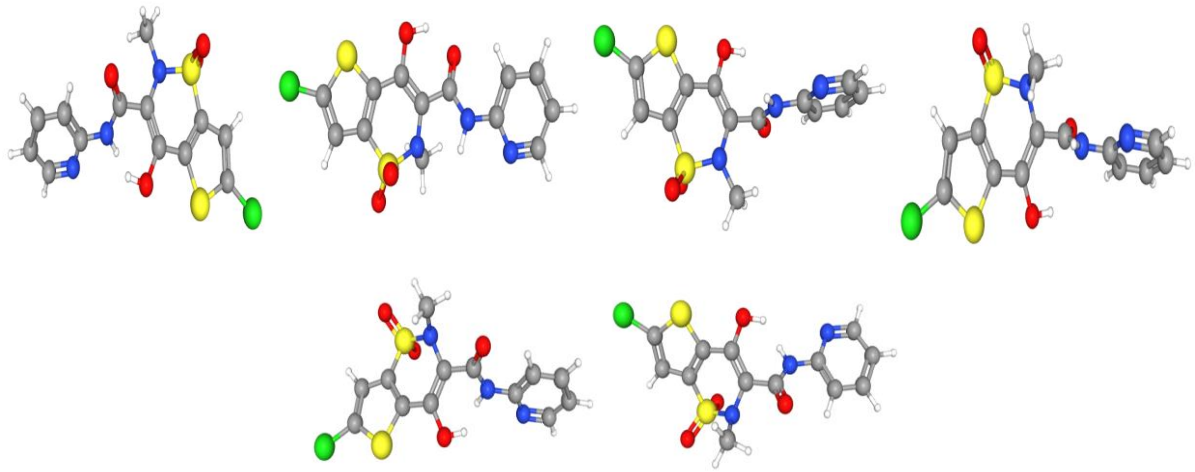
NO	Materials
1	Lornoxicam
2	Eudragit® (RS 100, S100, L100, E100)
3	Polyvinyl alcohol (PVA)
4	Glycerol
5	Methyl Paraben
6	Carbopol 940
7	Phosphate buffer
8	Triethanolamine
9	Dichloromethane
All materials were purchase from the local market and China market.	

Evaluation of Drug-Excipient Compatibility Studies Methods[20-152]

Table 2: Lornoxicam Data.

Characterization of Lornoxicam





Lornoxicam Structure and 3D Conformer

Chemical Structure	6-chloro-4-hydroxy-2- methyl-N-2-pyridyl-2H-thieno-[2,3-e]-1,2-thiazine-3- carboxamide-1,1-dioxide	**Appearance**	A yellow crystalline powder
Molecular Formula	C13H10ClN3O4S2	**Drug Solubility**	Slightly soluble in chloroform and 0.1mol/L NaOH and very slightly soluble in methanol and acetonitrile and hardly soluble in water.
Molecular Weight	371.8 g/mol	**BCS**	Class-II Drug
Drug Action and Use	Analgesic, antipyretic and anti-inflammatory agent. Lornoxicam is like all NSAIDs, it acts by inhibiting the metabolites of COX branch of arachidonic acid pathway. It inhibits both isoforms in the same concentration range i.e. COX-1/ COX-2 = 1. It differs from other oxicam compounds in its potent inhibition of prostaglandin biosynthesis, a property that explains the particularly pronounced efficacy of the drug. Lornoxicam is an active substance from the group of acidic anti-pyretic analgesics. The accumulation of acidic analgesics in the inflamed tissue is considered to be a significant aspect of their anti-inflammatory effect. Lornoxicam has been shown to produce dose related analgesia. 16 mg and 32 mg were significantly superior to 4 mg with respect to pain relief. Lornoxicam is found effective in acute sciatica, lumbosciatica and chronic low back pain. Lornoxicam can decrease the opioid requirement when used as an adjunctive analgesic in patients with cancer pain. Lornoxicam decreases the number of headache episodes and also reduces the analgesic intake in migraine attacks.		
Lornoxicam Pharmacokinetics			
Drug Absorption	Bioavailability: 90-100%	**Drug Distribution**	**Proteins binding**: Lornoxicam is 99% bound to plasma proteins
Drug Metabolism	Lornoxicam is metabolized by cytochrome 450 2C9 (CYP2C9).	**Drug Excretion**	Approximately 70% of the drug is eliminated via the liver and 30% via the kidneys. Clearance: no significant change
The Elimination Half-Life (T1/2)	The elimination half-life (3 to 5 hours).	**Availability**	Tablets, Injections, Gel.

The Lornoxicam was chosen to be the active pharmaceutical ingredient (API) in microsponge gel delivery system according to Lornoxicam data as shown in Table 2.

Preformulation Studies

Preformulation studies are initiated to define the physical and chemical properties of the agent. The key goals of preformulation studies are to ensure the delivery of drug product with acceptable stability, bioavailability, and manufacturability.

Melting Point Determination of Lornoxicam

The most common and most basic method of determination is the capillary method. Melting point of the Lornoxicam was determined by capillary method; one sided closed capillary filled with drug and put into the Melting Point Apparatus. Temperature was noted at which solid drug changed into liquid.

Determination of the Production Yield

The production yield of the microsponge was determined by calculating accurately the initial weight of the raw materials and the last weight of the microsponges obtained.

$$\text{Production yield} = \frac{\text{Practical mass of microsponges}}{\text{Theoritical mass (Polymer+Drug)}} \times 100 \quad \ldots\ldots\text{equation}$$

Particle Size Analysis and Surface Morphology of Lornoxicam Microsponge Gel Delivery System

Determination of the average particle size of Lornoxicam loaded microsponges was determined with an optical microscope using a calibrated ocular and stage micrometer under a regular polarized light. A minute quantity of microsponges was spread on a clean glass slide and the particle size was calculated.

Melting Point Determination of Lornoxicam

Melting point of pure Lornoxicam was determined by open capillary method. The capillary tube was closed at one end by fusion and was filled with Lornoxicam by repeated tapings. The capillary tube was placed in a digital melting point apparatus. The instrument was set to automatically increase the temperature of the heating bath. The rise in temperature was viewed through screen. The temperature at which the drug started d melting was recorded. The melting point range of Lornoxicam was identical to reference melting point stated in MP (225-230°C). The sample started to melt at 226°C, and turned into liquid at 227°C, indicating that the sample used is pure. That reading has stated in melting point tester.as shown in Table 3.

RESULTS AND DISCUSSION

Table 3: Results of Melting Point of Lornoxicam.

Test	Temp Rang Analyzed (Melting)	Results
Test I Lornoxicam	(225-230°C)	227°C
Test II Lornoxicam	(225-230°C)	227°C

Determination of the Production Yield

According to the results as shown in Table 3, the production yield appears less in F4.

Table 4: Percentage Yield of Lornoxicam Microsponge Gel Delivery System.

Formulation Code	Production Yield %
F1	71%
F2	60.5%
F3	55.2%
F4	47.7%

Particle Size Analysis and Surface Morphology of Lornoxicam Microsponge Gel Delivery System

As shown in Table 5, the F2 is less size in compression with other formulations.

Table 5: Mean Particle Size of Lornoxicam Microsponge Gel Delivery System.

Formulation Code	Mean Particle Size (µm)
F1	63.1
F2	57.9
F3	64.4
F4	65.8

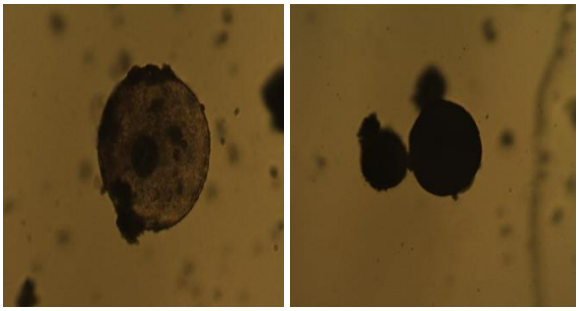


Fig. 1: Surface Morphology of Lornoxicam Microsponge Gel Delivery System (F1&F2).

As shown in Figure 1, the results of F1 illustrate the drug/polymer ratio increases in compare with F2 while the particle size is decreased. This is probably due to the fact that at higher relative drug content, the amount of polymer available per microsponge to encapsulate the drug becomes less, thus reducing the thickness of the polymer wall and hence, smaller microsponges. The microsponge delivery system is easy to build and may regulate drug release through rate, location, or both.

CONCLUSION

The compatibility studies of physical mixtures of Lornoxicam with different used excipients such as Eudragit, Polyvinyl alcohol (PVA) were investigated. The Lornoxicam formulations prepared were evaluated for preformulation study parameters of Lornoxicam microsponge gel DDS. It was concluded that the drug Lornoxicam was found to be compatible with various excipients which were selected for the formulation development of the Lornoxicam microsponge gel DDS. Multiparticulate drug delivery systems are important because they are simple to build and can control drug release in various ways, such as rate control, site control, or both. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process.

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