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MELOXICAM-EXCIPIENT COMPATIBILITY STUDIES FOR ADVANCED DRUG DELIVERY SYSTEMS DEVELOPMENT

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ABSTRACT

Meloxicam emulgels are a topical formulation that contains the non-steroidal anti-inflammatory drug (NSAID) Meloxicam. It is used for the treatment of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis Emulgels are the result of combining the terms emulsion and gel. It has a number of features, including enhanced permeability and strong thermodynamic stability. These are either water in oil emulsion or oil in water emulsion, by combining it with a gelling agent, it became gelled Emulgels offers a dual control and a long-lasting release and patient compliance. It was concluded that the drug Meloxicam was found to be compatible with various excipients which were selected for the formulation development of the Meloxicam Emulgels. 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: Meloxicam, Compatibility, Excipients, Development, Preformulation, Emulgels.

INTRODUCTION

Preformulation studies[1-130]

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.

In the present study, it was proposed to Meloxicam-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 Meloxicam emulgels for topical application.

MATERIALS AND METHODS

Meloxicam and all excipients (Carbopol 974, Spearmint, Triethanolamine, Liquid paraffin, Tween 80, Propylene glycol, Methyl paraben Na, Purified water) as a gift from (Global Pharmaceutical Industry Company-Yemen).

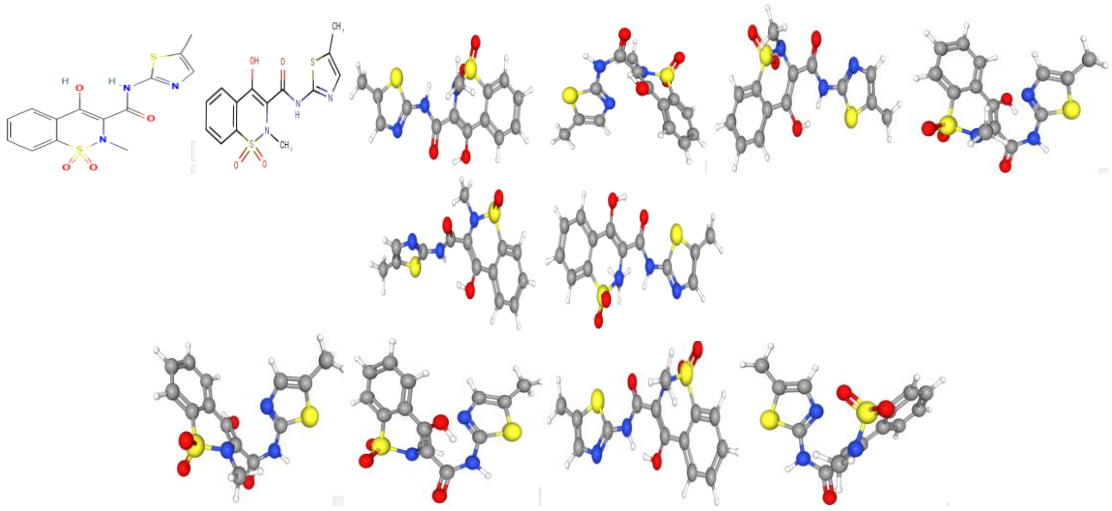
Equipment's

UV spectrophotometer (Model: V630), Infrared spectrometer (Model: Nicolet S10), Melting point tester (Model: SMP30), Viscometer (Model: VR3000), pH tester (Manufacture: ISOLAB), Balance (Model: ED224S).

Evaluation of Drug-Excipient Compatibility Studies Methods[40-273]

Table 1: Meloxicam data.

Characterization of meloxicam



Meloxicam Structure and 3D Conformer

Chemical Structure	4-hydroxy-2-methyl-*N*-(5-methyl-1,3-thiazol-2-yl)-1,1-dioxo-1λ ,2-benzothiazine-3-carboxamide	**Appearance**	Meloxicam is a pastel yellow solid.
Chemical Formula	$C_{14}H_{13}N_3O_4S_2$	**Drug Solubility**	practically insoluble in water, with higher solubility observed in strong acids and bases. Very slightly soluble in methanol.
Molecular Weight	351.4 g/mol	**BCS**	Class- II Drug
Drug Action and Use	Meloxicam is an NSAID used to treat osteoarthritis in adults, rheumatoid arthritis in adults, and juvenile rheumatoid arthritis in pediatrics. Meloxicam is indicated for the symptomatic treatment of arthritis and osteoarthritis. In addition, it is indicated for the pauciarticular and polyarticular course of Juvenile Rheumatoid Arthritis (JRA) in patients aged 2 years old or above. Off-label uses include the treatment of dental or post-surgical pain. In addition to the above, meloxicam has also been studied in the		

<table>
<tr><td></td><td colspan="3">treatment of neuropathic pain.
Meloxicam inhibits prostaglandin synthetase (cylooxygenase 1 and 2) enzymes leading to a decreased synthesis of prostaglandins, which normally mediate painful inflammatory symptoms. As prostaglandins sensitize neuronal pain receptors, inhibition of their synthesis leads to analgesic and inflammatory effects. Meloxicam preferentially inhibits COX-2, but also exerts some activity against COX-1, causing gastrointestinal irritation.</td></tr>
<tr><td colspan="4">Meloxicam Pharmacokinetics</td></tr>
<tr><td>Drug Absorption</td><td>The absolute bioavailability oral capsules after a dose was 89% in one pharmacokinetic study. Cmax was reached 5–6 hours after administration of a single dose given after the first meal of the day. The Cmax doubled when the drug was administered in the fasting state. Despite this, meloxicam can be taken without regard to food, unlike many other NSAIDS.</td><td>Drug Distribution</td><td>The volume of distribution of meloxicam is 10-15L. Because of its high binding to albumin, it is likely to be distributed in highly perfused tissues, such as the liver and kidney. Meloxicam concentrations in synovial fluid, measured after an oral dose, is estimated at 40% to 50% of the concentrations measured in the plasma. This drug is known to cross the placenta in humans.
Meloxicam is about 99.4% protein bound, primarily to albumin.</td></tr>
<tr><td>Drug Metabolism</td><td>Meloxicam is almost completely metabolized. CYP2C9 is the main enzyme responsible for the metabolism of meloxicam with minor contributions from CYP3A4. Meloxicam has 4 major metabolites with no activity determined. About 60% of the ingested dose is metabolized to 5'-carboxy meloxicam from hepatic cytochrome enzyme oxidation of an intermediate metabolite, 5'-hydroxymethylmeloxicam. Two other metabolites are likely produced via peroxidation.</td><td>Drug Excretion</td><td>Meloxicam is mainly eliminated through metabolism. Its metabolites are cleared through renal and fecal elimination. Less than <0.25% of a dose is eliminated in the urine as unchanged drug. About 1.6% of the parent drug is excreted in the feces.
After an oral dose, the total clearance of meloxicam is 0.42–0.48 L/h. The FDA label indicates a plasma clearance from 7 to 9 mL/min. No dose changes are required in mild to moderate renal or hepatic impairment. The use of meloxicam in patients with severe renal or hepatic impairment has not been studied. FDA prescribing information advises against it.</td></tr>
<tr><td>The Elimination Half-Life (T1/2)</td><td>The half-life of meloxicam is approximately 20 hours, which is considerably longer than most other NSAIDS. It can therefore be dosed without the need for slow-release formulations.</td><td>Availability</td><td>Tablets - Injections</td></tr>
</table>

According to Meloxicam data as shown in Tables 1, it was selected that to preformulation study with Meloxicam in the present study.

UV-Visible Spectrophotometric Method
Determination of λ Max for Meloxicam
Weight amount of Meloxicam than dissolve in methanol (use methanol due to the sensitivity of the device) at lambda-max (400-200).

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 meloxicam
The most common and most basic method of determination is the capillary method. Melting point of

the Meloxicam 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.

Drug-excipient compatibility studies

A physical mixture including Meloxicam and excipient was created in a 1:1 ratio, and it was subjected to analytical techniques such as FTIR spectroscopy. FTIR, of both pure drug and physical mixes were obtained, and the spectra of the both drug and mixture of excipient with drug were compared to look for any incompatibilities.

FTIR Spectroscopy Study

FTIR study KBr-disc method was used to record the FTIR spectra and KBr pellets were made in 1:100 ratio of sample and KBr. FTIR spectra was recorded using FTIR spectrum in a range of 4000-400cm^{-1}. Different functional groups of test compound for distinctive vibrational frequencies are identified using FTIR spectroscopy. FTIR spectra were used for the investigation of interaction in the physical mixture of API and excipient through shifting of peaks to lower or higher wavenumbers and appearance or disappearance of characteristic peaks of functional groups for pure API in physical mixture. FTIR spectroscopic study was performed to check the compatibility between API, and different excipients in amount (5mg:5mg) as ratio (1:1) as shown in Table 2. The FTIR spectra of a API alone and API with excipients were obtained by KBr method and compared with the standard FTIR spectrum of the pure API. Infrared spectrophotometer is not only used for determining the compatibility of excipients with the APIs, but also for API identification.

Preparation of IR Samples

The sample was determined by the disc method. Triturate 5mg of the substance to be examined with 300-400 mg of finely powdered and dried potassium bromide R or potassium chloride R. Each excipient was mix with Meloxicam equally then of potassium bromide is added to the mixture. Carefully grind the mixture, spread it uniformly in a suitable die, and submit it to a pressure of about 800 MPa (8 t·cm^{-2}). Then the tablets were inserted to the device and the Infrared spectra was recorded at mild-infrared light in wavenumber range of 4000 cm^{-1} to 400 cm^{-1}. After that the spectra were compared with the reference.

Infrared Spectral Study of Samples in Room Condition

Compatibility studies were performed by preparing blend of different excipients with Meloxicam in room condition as shown in Table 2.

Table 2: The Drug and Excipients Compatibility Studies.

NO	Materials	Excipient: Drug
1	Meloxicam	1
2	Carbopol 974 + Meloxicam	1:1
3	Spearmint+ Meloxicam	1:1
4	Triethanolamine+ Meloxicam	1:1
5	Liquid paraffin+ Meloxicam	1:1
6	Tween 80+ Meloxicam	1:1
7	Propylene glycol + Meloxicam	1:1
8	Methyl paraben Na+ Meloxicam	1:1
9	Purified Water + Meloxicam	1:1

RESULTS AND DISCUSSION

Preformulation studies

Characterization of Meloxicam by UV Spectroscopy

UV of Meloxicam analysis

Wavelength of Meloxicam in methanol by UV Scanning show in Figures (1-8), at 258.3nm.

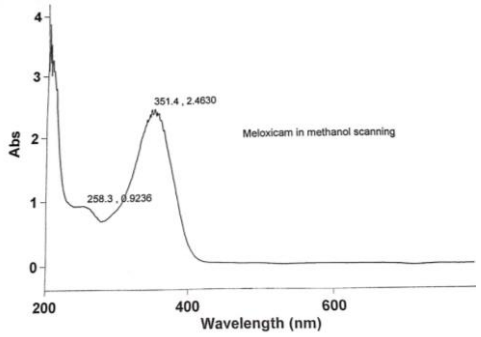


Fig. 1: Wavelength of Meloxicam in UV Spectrophotometer.

Excipient and Drug Compatibility (UV)

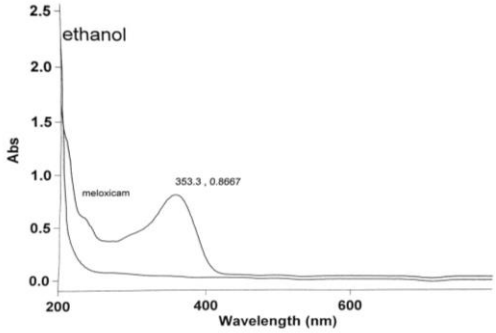


Fig. 2: UV of Ethanol with Meloxicam.

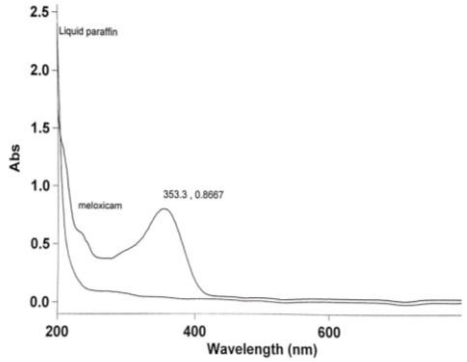


Fig. 3: UV Liquid Paraffin with Meloxicam.

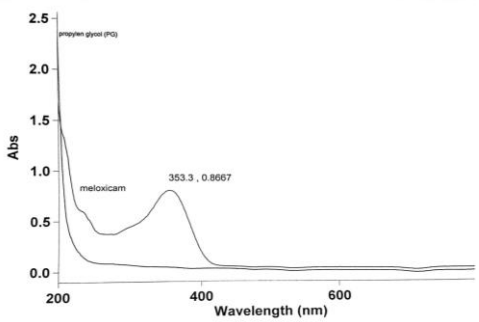


Fig. 4: UV of Propylene Glycol with Meloxicam.

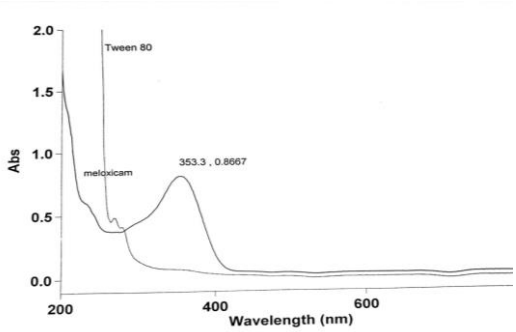


Fig. 5: UV of Tween 80 with Meloxicam.

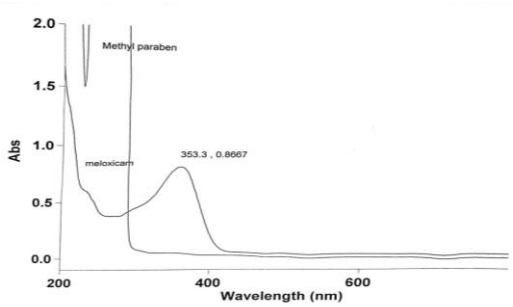


Fig. 6: UV of Methyl Paraben with Meloxicam.

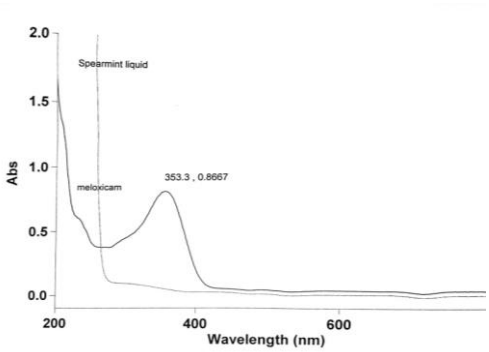


Fig. 7: UV of Spearmint with Meloxicam.

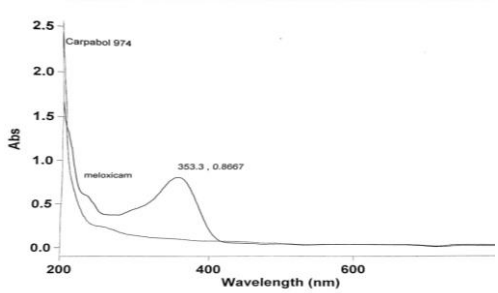


Fig. 8: UV of Carbopol 974 with Meloxicam.

Melting point determination of meloxicam

Melting point of pure Meloxicam was determined by open capillary method. The capillary tube was closed at one end by fusion and was filled with Meloxicam 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 melting was recorded. The melting point range of Meloxicam was identical to reference melting point stated in MP (239-241.5°C). The sample started to melt at 241°C, and turned into liquid at 241.5°C, indicating that the sample used is pure. That reading has stated in melting point tester.as shown in Table 3.

Table 3: Results of Melting Point of Meloxicam.

Test	Temp Rang Analyzed (Melting)	Results
Test I Meloxicam	(239-241.5°C)	241.5°C
Test II Meloxicam	(240 -241.5°C)	241.5 °C

Characterization of Meloxicam by FTIR

FTIR spectrum studies indicated that major functional groups present in Meloxicam show characteristic peaks in IR spectrum. Figures (9) to (17) show peaks observed at different wave numbers and the functional group associated with these peaks for drug and drug with different excipients. The major peaks are identical to functional group of Meloxicam. Hence, it was confirmed that there was compatibility between drug and various excipients, thus conforming that no interaction of drug occurred with the components of the formulation excipients.

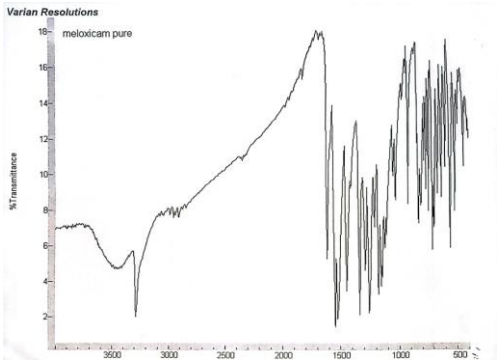


Fig. 9:IR of Meloxicam.

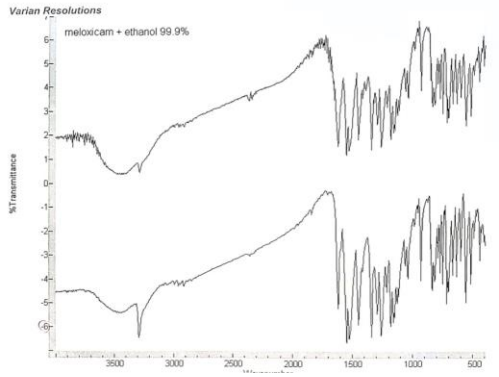


Fig. 10: IR of Ethanol with Meloxicam.

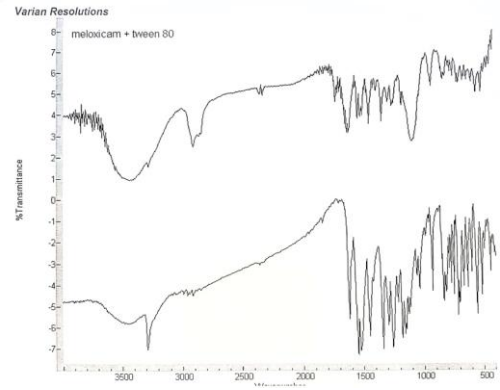


Fig. 11: IR of Tween 80 with Meloxicam.

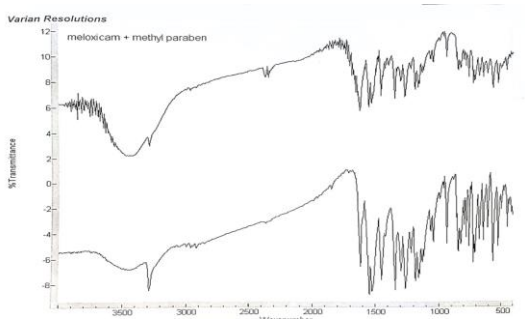


Fig. 12: IR of Methyl Paraben with Meloxicam.

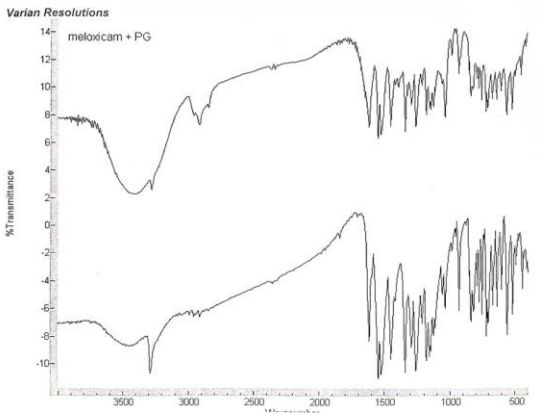


Fig. 13: IR of Propylene Glycol with Meloxicam.

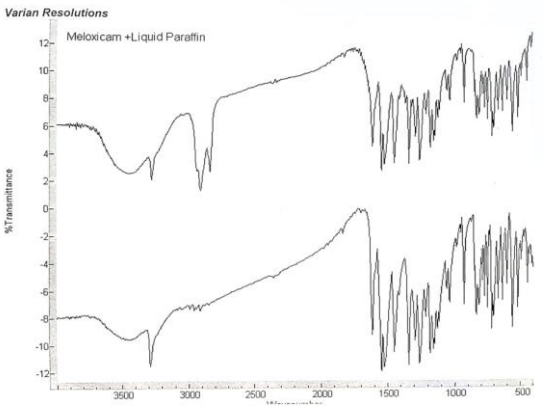


Fig. 14: IR of Liquid Paraffin with Meloxicam.

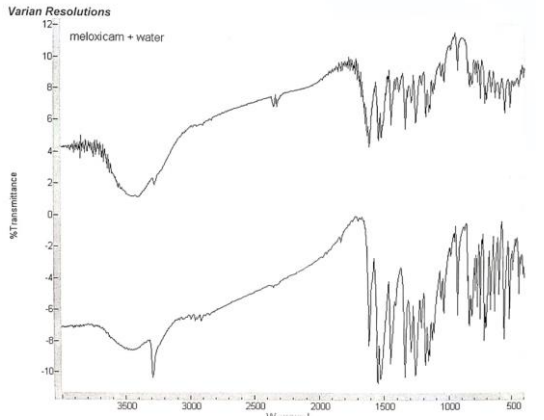


Fig. 15: IR of Purified Water with Meloxicam.

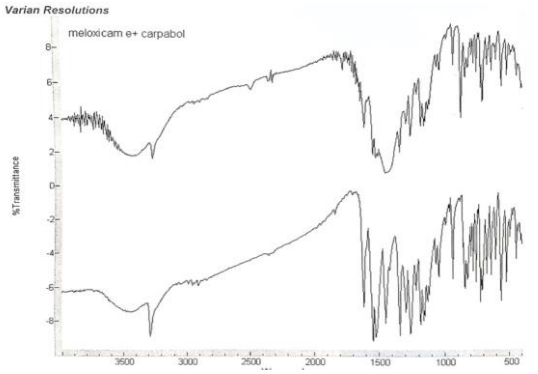


Fig. 16: IR of Carbopol 974 with Meloxicam.

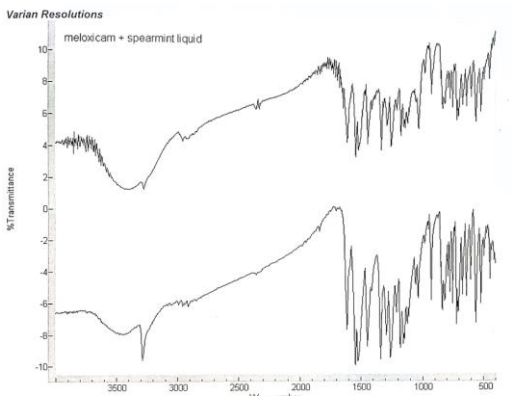


Fig. 17: IR of Spearmint with Meloxicam.

CONCLUSION

It was concluded that the drug Meloxicam was found to be compatible with various excipients which were selected for the formulation development of the Meloxicam emulgels, show that, all excipients are compatible according to UV and IR with Meloxicam. 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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