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FORMULATION AND EVALUATION OF MELOXICAM EMULGEL DELIVERY SYSTEM FOR TOPICAL APPLICATIONS

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ABSTRACT

Meloxicam emulgel is 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 Emulgel offers a dual control and a long-lasting release and patient compliance. Five formulas were prepared and the evaluation of Meloxicam emulgel involves assessing its physicochemical properties, drug release characteristics and potential therapeutic effects. **It was concluded** that, **F1** is the best formula for formulation of Meloxicam Emulgel when compared to other formulations.

KEYWORDS: Meloxicam, Formulation, Emulgels.

INTRODUCTION

Meloxicam is one of non-steroidal anti-inflammatory drug (NSAID) and commonly used in treatment of pain and inflammations associated with rheumatic diseases such as rheumatoid arthritis (RA), osteoarthritis (OA), ankylosing spondylitis (AS) and juvenile rheumatoid arthritis (JRA) among others.

An emulgel is a combined dosage form of both an emulsion and a gel. It is a better formulation with numerous advantages of both a gel and an emulsion. They include ability to

incorporate both hydrophilic and hydrophobic drugs, enable controlled release of drugs, improved formulation stability, reduced cost of production and they are more aesthetically appealing since.[1-2]

Emulgels

Emulgel is a new field for topical medication administration, with few commercialized products to date, therefore focusing on it is both exciting and demanding. Although gels have many advantages, they have a limitation in the delivery of hydrophobic medications. To overcome this limitation and enjoy delivery of hydrophobic drugs in the form of gel, the concept of emulgel was developed, in which hydrophobic drugs are integrated in an emulsion and then gelled.[1-3]

The advantages include, avoiding the first-pass metabolic process, patient compliance has improved, convenient and simple to use[3-5] while the disadvantages include, contact dermatitis causes skin irritation, allergic reactions possibility and formation of a bubble during the emulgel formulation process.[6-8] 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. [9-77]

In the present study, it was proposed to Formulation and evaluation study 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), Viscometer (Model: VR3000), pH tester (Manufacture: ISOLAB), Balance (Model: ED224S).

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).

Preparation of gel formulations[8]

Distilled water was added to the Carbopol 974 and mixed mechanically by high-speed mixer. To this mixture, Liquid paraffin 15% was added vigorously. In water bath with a temperature not exceeding 50 °C, the Meloxicam in a concentration of 0.5 was added to prepare five formulations, F1, F2, F3, F4 and F5, respectively. Separately dissolved Spearmint, Tween 80, methyl paraben in propylene glycol, were also added to this gel. The remaining quantity of Triethanolamine and purified water was added, and the pH was drop wise adjusted the final weight was adjusted with water as shown in Table 1.

Table 1: Composition of meloxicam emulgels formulations.

Materials	F1	F2	F3	F4	F5
Meloxicam	0.5	0.5	0.5	0.5	0.5
Carbopol 974	0.5	1	1	1.5	1.5
Spearmint	5	7	7	9	9
Triethanolamine	Qs	Qs	Qs	Qs	Qs
Liquid paraffin	15	15	15	15	15
Tween 80	1	-	1	1	-
Propylene glycol	10	15	15	30	30
Methyl paraben Na	0.5	0.5	0.5	0.5	0.5
Purified water	67.5	61	60	42.5	43.5
Total	100	100	100	100	100

Evaluation parameters of meloxicam emulgels formulations[9-87]

General appearance

Physical appearance of drug was examined by various organoleptic properties. The general appearance of emulgel, its visual identity and overall elegance' is essential for consumer acceptance. The control of general appearance involves color, presence or absence of odor Homogeneity, Phase separation.

pH Test of Emulgels

The optimal pH value of skin on most of our face and body lies between 4.7 and 5.75 to avoid skin irritant. All formulas pH were measured by pH tester.

Rheological study[8]

The viscosity of the developed emulgel formulations is determined by using viscometer apparatus with different spindle size, and at different r.p.m, The formulation whose viscosity was to be determined was added to the beaker and record the results.

Skin irritant test[8]

Skin irritation test for emulgel formulation was conducted over skin of human volunteers. The prepared emulgel formulation was applied on the skin of hand, face, nick and observed for any type of undesirable effect.

Spreadability test

Two optimized formula tests for Spreadability on volunteers' skin and saw if spread smooth and easily the results evaluated in terms: good, very good, excellent.

Microbial test

10 g weight from prepared formula and put it in peptone buffer (pH =7). The sample was transferred to Petri dishes contain Sabouraud Dextrose agar (for Fungi microorganisms' growth test) at 22.5°C and to Petri dishes contain Trypto Soya agar (for bacterial growth test) at 32.5°C and then, these plates incubated for 7 days. After 7 days, dishes were observed for the growth of the Fungi microorganisms /bacteria.

RESULTS AND DISCUSSION

Solubility analysis

Solubility profile of Meloxicam indicted that the drug is practically insoluble in water, soluble in methanol conc. 96%.

pH Test of Meloxicam emulgels

The pH of all formula was measured by pH tester, and the results was shown in the Table 2.

Table 2: pH of Meloxicam Emulgels.

Formulation Code	F1	F2	F3	F4	F5
PH Value	5.51	5.61	5.2	5.19	5.1

Rheological study

The viscosity of all formulation was measured by viscometer, and the results were within the acceptable limit as shown in the Table 3.

Tablet 3: Viscosity of meloxicam emulgels.

Formulation Code	R.P.M	Cp	Temp.	Time
F1	200	6800	23.6	00.02:34
F2	-	-	-	-
F3	200	10920	23.3	00.23:50
F4	100	29480	23.9	00.03:13
F5	-	-	-	-

Skin irritation test

All the gel formulations were found to be safe while being applied on the skin and there was no irritation or sensitivity to the skin.

Spreadability test

Ther results as shown in Table 4, the formulations F1, F3, F4 were the best according to spreadability.

Table 4: Spreadability of meloxicam emulgels.

Formulation Code	Spreadability
F1	Excellent
F2	--
F3	Very good
F4	Good
F5	--

Microbial test of meloxicam

All results in **Table 5,** are comfort with USP specification.

Table 5: Microbial test of meloxicam emulgels.

Tests	Formulation code		
	F1	F3	F4
T.A.M.C	L.T10	L.T10	L.T10
T.Y.M.C	L.T10	L.T10	L.T10
Pathogen Tests	---	---	---

The work was undertaken to formulate and evaluate Meloxicam emulgel by the simple method used for the preparation of emulgel includes three main steps. The first two steps are the formulation of emulsion and gel base separately followed by incorporation of an emulsion into gel base that leads to the formulation of emulgel.[88-90] Through the work it become clear that the F2 and F5 out of the limit while F1, F3, F4 were the best according to pH value, spreadability... etc. In comparison to other research work.[8] The present study shows better result in terms of pH value and viscosity.

CONCLUSION

It was concluded that, formulation and evaluation of Meloxicam emulgel, show that, all excipients are compatible according to pervious study UV and IR with Meloxicam. The best preparation was **F1** as compared to the other formulations, based on the excellent results of spreadability, viscosity and appearance, and absents of microbial growth.

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