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FORMULATION AND EVALUATION OF GLYCEROGELATIN BASED MELOXICAM TRANSDERMAL PATCH

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ABSTRACT

The objective of the study was to develop and evaluate Glycerogelatin based Meloxicam (NSAIDS) Trandermal patch. The study aimed to create a monolithic transdermal therapeutic system for meloxicam using hydroxyl propyl methyl cellulose (HPMC) as a polymer rand gelatin, glycerin, and ethanol as plasticizer, penetration enhancer, and permeation enhancer, respectively, through solvent casting evaporation method. The transdermal patch was evaluated for various parameters, including physical appearance, folding endurance, moisture content, weight variation, drug content uniformity, and in-vitro drug release studies. The article also provides the methodology and experimental work that was done to prepare the transdermal patch, which involved heating gelatin with water, adding HPMC and glycerin, dissolving meloxicam in ethanol, and mixing and sonication of the solutions. The formulation chart of the glycerogelatin based meloxicam transdermal patch is also provided. The article discusses the advantages of transdermal patches over other routes of administration and highlights the potential of meloxicam transdermal patches to provide improved convenience, reduced side effects, consistent drug delivery.

KEYWORDS: *Meloxicam, Solvent Casting Evaporation Method, Evaluation*

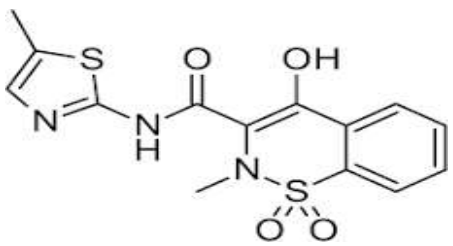
INTRODUCTION

Transdermal drug delivery systems (patches) are dosage forms designed to deliver a therapeutically effective amount of drug across a patient's skin also defined as Medicated adhesive patch that is placed on the skin to deliver a specific dose of Medication through the skin and into the blood stream. Several transdermal drug delivery systems (TDDS) have recently been developed with the aim of accomplishing the objective of systemic medication through the transdermal controlled delivery of pharmaceuticals. The potential of TDDS was first demonstrated by the successful development of a scopolamine releasing TDD system by Alza Corporation approved by FDA in 1981 (Transderm- Scop system, Ciba) for 72-hour prophylaxis or treatment of motion induced sickness and nausea.

Arthritis can be defined as inflammation of one or more joints, causing pain and stiffness that worsens with age. It is basically divided into two types 1. Rheumatoid arthritis 2. Osteoarthritis. It is mainly caused due to inflammation, neurological disorder, trauma, joint instability, genetic factors etc.

Meloxicam is a NSAID used to treat osteoarthritis in adults, rheumatoid arthritis in adults, and juvenile rheumatoid arthritis in pediatrics.

Fig 1: Meloxicam



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Meloxicam transdermal patch is formulated using Gelatin, Glycerin, HPMC-E15 and Ethanol.

Gelatin is a descriptive term for a material composed of a mixture of amino acids and short-chain peptides obtained either by acid hydrolysis (type A) or alkaline hydrolysis(type B) of animal collagen. It is used as coating agent, viscosity enhancer, penetration enhancer etc.

Glycerin is used as a solvent or co-solvent in creams and emulsions. Glycerin is additionally used in aqueous and non-aqueous gels and also as an additive in patch applications.

Ethanol structure enables for the dissolving into polar compounds such as water, non-polar and hydrophilic such as hexane and hydrophobic. Ethanol is also used as a medicinal solvent due to its low toxicity and non-polar capabilities.

HPMC is used as a thickening agent, coating polymer, bio-adhesive, solubility enhancer in solid dispersions, and binder in the process of granulation and in modified release formulations. It is a commonly used as a delivery component in oral pharmaceutical products that provides the release of a drug in a controlled fashion, effectively increasing the duration of release of a drug to prolong its therapeutic effect.

METHODOLOGY AND EXPERIMENTALWORK

Table 1: Formulation table of meloxicam transdermal patch

Sr no	Materials	Quantity
1	Meloxicam	7.5mg
2	Gelatin	5mg
3	Glycerin	0.5ml
4	HPMC	250mg
5	Ethanol	4ml
6	Distilled water	3ml

METHODOLOGY

1. Gelatin was first heated with water until it is dissolved.
2. HPMC in the required amount was added in the above solution followed by 2mlof water. Glycerin was then added when the temperature has decreased to some extent.
3. Meloxicam was separately dissolved in a minimum quantity of ethanol for forming a solution and was sonicated for 10min.
4. The above solution were then mixed and further sonicated for 10 min.
5. The final mixture formed in step4 was spread in petridish previously coated with a lubricant (Glycerin).
6. This petridish covered with a cut funnel and kept at room temp for 24hr away from sunlight.

Fig 2: Meloxicam transdermal patch

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EVALUATION OF DRUG LOADED PATCHES

Physical Appearance

Formulated patches were assessed for their physical attributes, homogeneity, lack of air bubbles, or drug precipitation, which in large part influences whether or not a patient will accept the patch and its therapeutic effectiveness.

Thickness

Using Mitutoyo Digimatic Micrometre, the thickness of the transdermal patch was measured. A rectangular patch's (2x2 cm) thickness was measured three times, and the average thickness was estimated. The same was done for the other patches as well. Each patch's thickness shouldn't vary considerably from the others.

Weight variation

Weighing 10 randomly chosen patches separately and calculating the average weight, weight fluctuation was explored. There shouldn't be a considerable difference between the individual weight and the average weight.

Folding Endurance

The folding capacity of the patches must be determined in order to evaluate folding endurance. Folding endurance is assessed by folding the patch ten times in a row at the same location. Folding endurance value is the number of times a patch can be folded in the same location without breaking.

Moisture Uptake

Patch was kept in desiccators at room temperature for 24hrs. The patch was then taken out and exposed to 84% relative humidity using saturated solution of Potassium chloride in a desiccators until a constant weight is achieved.

Moisture Content

The prepared patches were weighed individually and kept in a desiccators containing calcium chloride at room temperature for 24hrs. The patches were weighed again after a specified interval until they show a constant weight. The percent moisture content was calculated using following formula.

In-Vitro Permeation Studies

Studies of drug permeation are conducted to assess how a drug moves from a patch to the skin's microcirculation. In this investigation, the donor and receptor compartments of Franz diffusion cell12, 13, were separated by a synthetic membrane made of cellulose nitrate. In the receptor compartment, phosphate buffer with a pH of 7.4 was present. On the cellulose nitrate membrane, a transdermal patch was positioned with the donor compartment facing outward. The phosphate buffer-containing receptor compartment was on the other side of the cellulose nitrate membrane. The receiver compartment was maintained at room temperature and was continuously stirred with the help of magnetic stirrer. Samples were withdrawn at specific time interval and equal amount of phosphate buffer was replaced each time to maintain volume of receptor compartment at a constant level. Samples withdrawn were then analyzed for their absorbance and concentration was then calculated.

RESULTS AND DISCUSSION

1. Physical appearance:

Table 2: Physical Appearance of Meloxicam Transdermal Patch

Characteristics	Result
Appearance	Congealed preparation
Color	Slightly yellow
Clarity	Transparent
Flexibility	Good
Smoothness	Good
Presence of air bubble	None

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2. Thickness, Weight variation and folding endurance

Table 3: Result of Thickness, Weight Variation and Folding Endurance

	Thickness (mm)	Weight variation (mg)	Folding endurance
MXP1	0.25 ±0.02	498±4	295±7
MXP2	0.28±0.01	508±6	311±9
MXP3	0.29±0.02	496±6	298±4
MXP4	0.26±0.01	502±0	302±0
MXP5	0.28±0.01	506±4	304±2

3. Moisture Content and Moisture Uptake

Table 4: Result of Moisture Content and Moisture Uptake

	Moisture content (%)	Moisture uptake (%)
MXP1	3.12±0.01	3.35±0.09
MXP2	2.27±0.05	2.65±0.18
MXP3	3.24±0.12	3.54±0.14
MXP4	2.95±0.23	3.12±0.05
MXP5	2.55±0.01	2.99±0.28

4. Drug Content Uniformity

Table 5: Result of Drug Content Uniformity

	Drug Content Uniformity (%)
MXP1	95±8.2
MXP2	87±0.2
MXP3	85±1.8
MXP4	82±4.8
MXP5	85±1.8

5. In-Vitro Drug Release

Table 6: In-Vitro Drug Release Studies

Time	Concentration of drug release(%)
0	0
1	3.52
2	6.92
3	12.48
4	20.85
5	26.46
6	32.86
7	41.42
8	50.63
9	59.43
10	64.83
11	75.43
12	84.23

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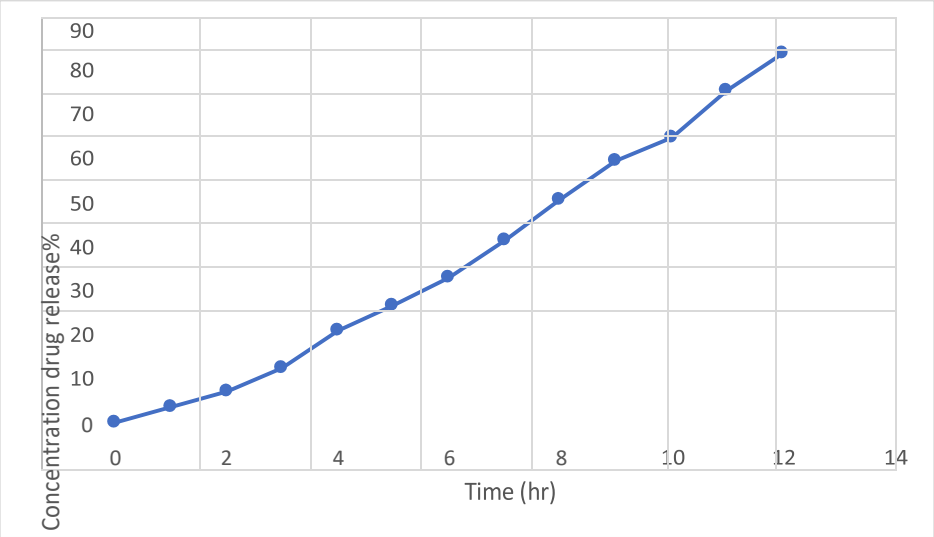

CONCLUSION

It was concluded that suitable Meloxicam transdermal patch was formulated using (HPMC-E15) and Glycerin as a plasticizer, ethanol as skin permeation enhancer using solvent casting method.

The formulated patches were evaluated for the physical parameters and in-vitro drug release studies.

Developed transdermal patch possessed the required physicochemical properties such as folding endurance, thickness of the patch, percentage moisture content, percentage moisture uptake, drug content uniformity.

The thicknesses of the patches were found to be appropriate.

From the result of drug content determination, it was found that there was uniform distribution of drug in patch and deviation was within acceptable limits. All the patches showed uniform drug content.

The formulation showed good in-vitro drug release, attributed to the nature of polymer, permeation enhancer and plasticizers.

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