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Formulation and evaluation of diclofenac hydrogel

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ABSTRACT:
Diclofenac is a commonly used non-steroidal anti-inflammatory drug (NSAID) for the management of pain and inflammation in musculoskeletal disorders. Oral administration of diclofenac is associated with gastrointestinal and systemic side effects, which can be minimized by topical drug delivery systems. The present study aimed to formulate and evaluate a diclofenac hydrogel for topical application to achieve effective localized drug delivery. Diclofenac hydrogel was prepared using hydroxypropyl methylcellulose (HPMC) and guar gum as gelling agents, glycerin as a humectant, methylparaben as a preservative, and triethanolamine for pH adjustment. Different formulations were developed by varying polymer concentrations. The prepared hydrogels were evaluated for organoleptic properties, pH, viscosity, spreadability, drug content uniformity, and in vitro drug release. All formulations exhibited acceptable pH suitable for skin application and uniform drug content. Viscosity and spreadability were found to be satisfactory. FTIR studies confirmed drug–excipient compatibility. The study concludes that diclofenac hydrogel is a promising topical formulation with improved patient compliance and reduced systemic side effects.

KEYWORDS: Diclofenac, hydrogel, topical drug delivery, HPMC, guar gum, NSAIDs, anti-inflammatory, polymer-based gel, localized drug delivery.

I. INTRODUCTION:

- Diclofenac hydrogel is a topical semi-solid dosage form containing diclofenac, a non-steroidal anti-inflammatory drug (NSAID), incorporated into a hydrogel base. It is widely used for the treatment of pain and inflammation associated with musculoskeletal disorders such as arthritis, sprains, strains, and joint injuries. Topical delivery of diclofenac provides localized therapeutic action while minimizing systemic absorption and gastrointestinal side effects commonly seen with oral NSAIDs.
- Hydrogels are three-dimensional networks of hydrophilic polymers capable of absorbing and retaining large amounts of water while maintaining structural integrity. Due to their high water content and soft, elastic nature, hydrogels closely resemble natural tissues, making them suitable for topical and biomedical applications. They can be prepared from natural polymers such as guar gum or synthetic polymers like hydroxypropyl methylcellulose (HPMC). These polymers form a cross-linked structure that allows swelling without dissolution, enabling controlled drug release.
- Topical hydrogels offer several advantages, including easy application, non-greasy texture, good spreadability, and enhanced patient compliance. They improve drug penetration by hydrating the stratum corneum and facilitate uniform drug distribution at the site of application. Diclofenac hydrogel acts by inhibiting cyclooxygenase (COX-1 and COX-2) enzymes, thereby reducing prostaglandin synthesis responsible for pain and inflammation.
- Compared to conventional topical formulations such as ointments and creams, hydrogels provide better aesthetic appeal, faster absorption, and improved drug release characteristics. Additionally, they reduce first-pass metabolism and systemic toxicity. Owing to these advantages, hydrogels are considered an effective and patient-friendly drug delivery system for topical NSAIDs.

II. MATERIALS AND METHODS:

Diclofenac, HPMC, guar gum, glycerin, methylparaben, and triethanolamine are used to prepare diclofenac hydrogel.

- Accurately weighed HPMC was slowly dispersed in a measured quantity of glycerin with continuous stirring until a uniform dispersion was obtained.
- The dispersion was allowed to stand to ensure proper swelling of HPMC.

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- Guar gum was gradually added to the above dispersion with continuous stirring to enhance viscosity and obtain a smooth gel base.
- Diclofenac was triturated with a small quantity of glycerin to form a smooth paste.
- Methylparaben was dissolved in a small quantity of warm glycerin and added to the drug mixture.
- The diclofenac mixture was slowly incorporated into the polymer gel base with gentle stirring until a homogeneous gel was formed.
- The pH of the formulation was adjusted to 6.8–7.2 using triethanolamine.
- The final weight was adjusted to 32 g using glycerin and mixed thoroughly to obtain a smooth, uniform hydrogel.

S. No.	Formulation	F1	F2	F3
1	Diclofenac	0.9g	0.9g	0.9g
2	HPMC	0.52g	0.50g	0.51g
3	Glycerin	5.73ml	5.66ml	5.70ml
4	Methyl paraben	0.060g	0.060g	0.070g
5	Guar gum	0.53g	0.60g	0.58g
6	Triethanolamine	0.26ml	0.28ml	0.24ml
	Total weight	8g	8g	8g

Table 1: Constituents of different formulations

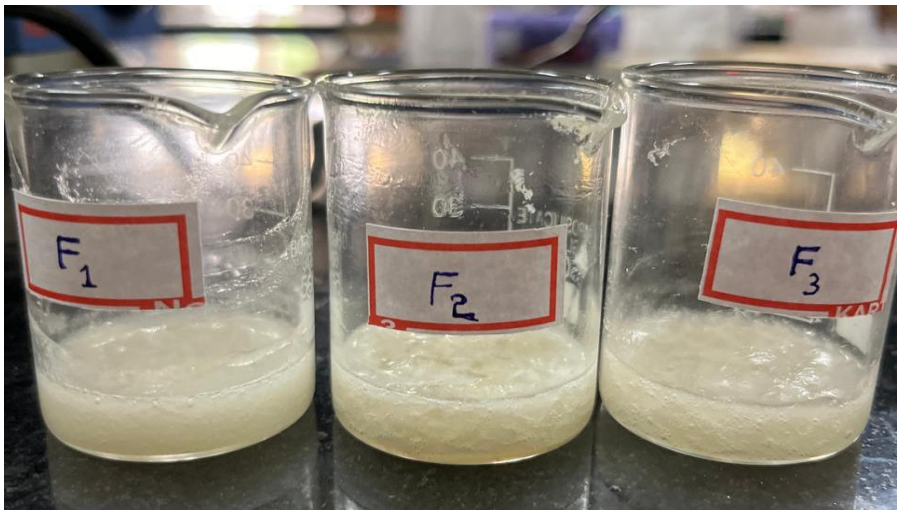

Fig 1: Hydrogel formulation (f1, f2, f3)

EVALUATION:

1. Organoleptic properties:

The desired organoleptic properties, such as color, odor, and taste, can be determined by visual inspection of the created hydrogel composition.

2. Drug content:

Weighed 1 g of each hydrogel formulation and transferred it into a 100 ml volumetric flask containing 50 ml of phosphate buffer at pH 6.8 and stirred for 30 minutes. The volume was made up to 100 ml and filtered. Take 1 ml of the above solution and dilute to 10 ml with solvent, and again 1 ml of the above solution was further diluted to 10 ml with alcohol. Measure the absorbance at 276 nm using a UV spectrophotometer.

3. Measurement of pH:

50 g of each gel formulation was weighed and transferred into a 1 ml beaker, and the pH was measured by using the digital pH meter.

4. Determination of viscosity:

The viscosity of the preparation was determined using a Brookfield digital viscometer (model DV-II,

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USA), and it was equipped with spindle S27. The gel sample (5 g) was placed in the sample holder of the viscometer and allowed to settle for 5 min, and the viscosity was measured at a rotating speed of 50 rpm at room temperature.

5. Irritability:

Diclofenac hydrogel (0.5 g) was applied on the shaved dorsal skin of rats/rabbits and observed for 72 hours. The treated area was examined for erythema and edema at 24, 48, and 72 hours. The irritation score was calculated and compared with the control gel. The formulation showed no irritation, indicating it is safe for topical use.

6. Spreadability:

The spreadability of the hydrogel was determined by placing 2 g of the hydrogel between horizontal plates. Above the plates, a standardized weight of 20 g was placed and left for 15 seconds.

Fig. 2: Spreadability

7. FTIR Spectral Analysis:

A Fourier Transform Infrared (FTIR) study was carried out to confirm the compatibility of diclofenac with excipients used in the hydrogel formulation and to ensure the absence of any chemical interaction. The preservation of characteristic diclofenac peaks in the formulated hydrogel indicates that diclofenac remained chemically stable and did not undergo any interaction with the excipients during formulation. Therefore, FTIR analysis confirms the compatibility of diclofenac with hydrogel components, supporting the suitability of the formulation for topical delivery.

III. RESULTS AND DISCUSSION OF PRE-FORMULATION STUDIES:

ANALYTICAL METHOD:

1. Determination of ƛmax by using in phosphate buffer:

The maximum absorption of diclofenac in phosphate buffer was 275 nm and it shows in following graph

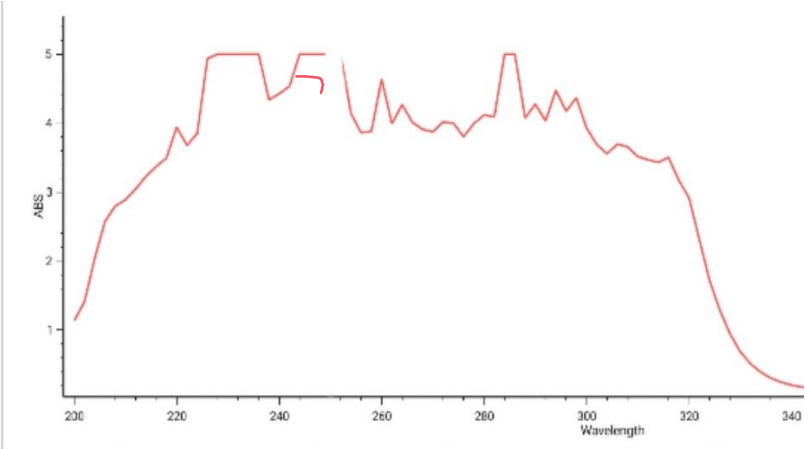

Fig. 3: ƛ max observation for diclofenac in phosphate buffer 7.4

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2. Preparation of standard curve of diclofenac in phosphate buffer:

The UV absorption spectrum of diclofenac in phosphate buffer in λ max is shown. Absorbance obtained for various concentrations of diclofenac in phosphate buffer is given below. The graph of absorbance vs concentration for diclofenac was found to be linear in the concentration and obeys Beer-Lambert's law.

Table 2: Data of absorbance vs concentration

S.NO.	CONCENTRATION (ml)	ABSORBANCE (µg)
1	0.5	0.0980
2	1.0	0.1964
3	1.5	0.2938
4	2.0	0.3798
5	2.5	0.4875

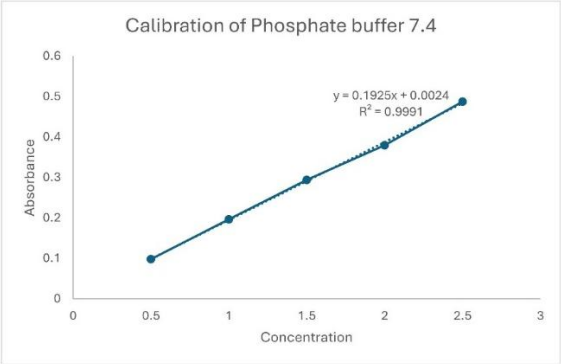

Fig. 4: Calibration curve of diclofenac

3. FTIR spectral analysis:

IDENTIFICATION OF DICLOFENAC BY FTIR SPECTROSCOPY

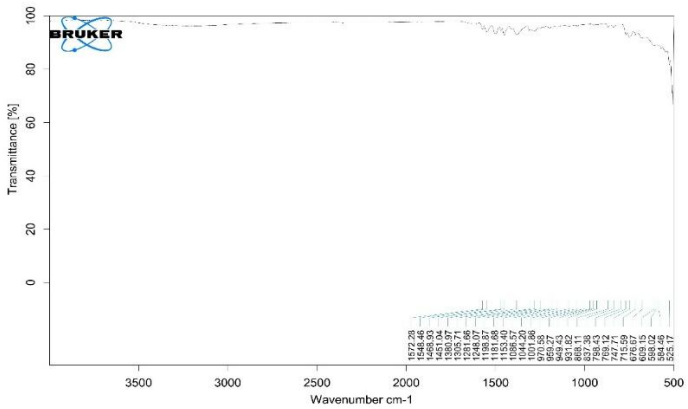

Fig 5: FTIR Spectrum of pure drug diclofenac

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DRUG EXCIPIENT COMPATIBILITY STUDIES

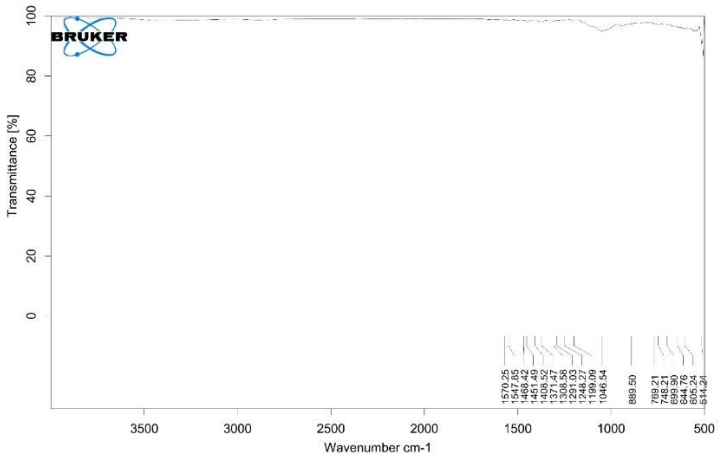

Fig. 6: FTIR Spectrum of drug diclofenac and HPMC

4. Organoleptic properties:

Colour : White to slightly off-white powder
Odour : Odorless
Taste : Bitter

5. Determination of melting point:

According to IP melting point of Diclofenac

S.NO.	MELTING POINT	CONCORDANT VALUE
1	280˚C	283˚C
2	285˚C	
3	283˚C	

Table 3: Determination of melting point

6. Determination of solubility:

S.NO.	SOLVENT	SOLUBILITY
1	Water	Insoluble
2	Ethanol	Poorly soluble
3	Methanol	Very soluble
4	Acetone	Very soluble

Table 4: Determination of solubility

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7. Drug content:

Drug content = (Absorbance/slope)×Dilution factor×(1/1000)

Formulation code	Drug content
F1	9.7
F2	9.8
F2	9.85

Table 5: Determination drug content

8. Determination of pH:

Commonly, the pH of the diclofenac hydrogel formulation should be between 6.5 and 7.5.

Formulation code	pH
F1	6.9
F2	7.0
F3	7.2

Table 6: Determination of Ph

9. Determination of viscosity:

The measurement of all formulation batches of hydrogel was taken by using a Brookfield viscometer.

Formulation code	Viscosity (cps)
F1	5700
F2	7700
F3	10,100

Table 7: Determination of viscosity

IV. CONCLUSION:

The diclofenac hydrogel was prepared and evaluated for its physicochemical parameters. The results confirm that the hydrogel base provides an efficient medium for the topical delivery of diclofenac. With superior patient compliance compared to traditional ointments and a steady release profile, this formulation successfully meets the requirements for a topic.

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