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Formulation And Evaluation Of Topical Hydrogel Of Diclofenac Sodium As Improved Therapy

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Abstract

Hydrogels are gaining popularity in recent times, especially when compared to other semisolid dosage forms such as ointments, creams, lotions, and pastes. This increased preference is largely due to their enhanced stability and ability to offer controlled release. The objective of this research was to formulate and evaluate a 2% & 1% of different polymer-based gel containing Diclofenac Sodium. The gel was assessed for various parameters, including pH, spreadability, consistency, homogeneity, drug content, skin irritation, and in vitro diffusion study. The percentage of drug release achieved was 99.94%. It can be concluded that the Diclofenac Sodium gel, formulated with 2% Carbopol 934P, exhibited promising characteristics for transdermal drug delivery.

Key Words: Hydrogel, Sodium CMC, Carbopol 934, Diclofenac sodium

Introduction

Diclofenac sodium (DS) is a widely used nonsteroidal anti-inflammatory drug (NSAID) that effectively reduces inflammation and alleviates pain in conditions such as rheumatoid arthritis, osteoarthritis, dysmenorrhea (menstrual pain), fever, and acute injuries. Despite its clinical benefits, diclofenac sodium has a relatively short plasma half-life of approximately 2 hours, with only about 50% of the oral dose reaching the bloodstream.

When taken orally, diclofenac potassium can increase the risk of serious gastrointestinal side effects, including bleeding, ulceration, and perforation of the stomach or intestines, which can potentially be fatal.

Transdermal delivery of diclofenac offers a promising alternative, as it may enhance the drug's bioactivity, reduce systemic side effects, and improve therapeutic efficacy by directly targeting the affected area.

Topical drug delivery can be effectively achieved by incorporating the drug into a gel matrix. This approach not only facilitates the direct delivery of the drug to the targeted site but also avoids the first-pass metabolism that occurs with oral administration. It ensures the drug's efficacy in providing local action, particularly for skin diseases and pain management. By using gels, the drug can be released gradually, improving both therapeutic outcomes and patient compliance.

Materials and Methods:

Diclofenac sodium, Carbopol 934 and Triethanolamine were received from RESEARCH-LAB FINE CHEM INDUSTRIES Mumbai, Propylene glycol was received from VISHAL CHEM Mumbai. All other ingredients were of analytical grade.

Table 1-

Sr. No	Name of the ingredient	Quantity Taken
1	Diclofenac sodium	1g
2	Carbopol 934	2g
3	Sodium CMC	1g
4	Methyl paraben	0.1g
5	Triethanolamine	1ml
6	Glycerine	10ml
7	Propylene Glycol	15ml
8	Ethanol	20ml
9	Distilled Water	upto 100ml

Formulation of Diclofenac sodium topical hydrogel:

Diclofenac sodium hydrogel was formulated using a selected concentration of 1% Sodium CMC and 2% Carbopol 934 polymer, which was chosen to optimize the formulation and achieve better results.

The process involves preparing two separate solutions (Solution A and Solution B) and then combining them. Here's a breakdown of the procedure you're outlining:

1. **Preparation of Solution A (Active Ingredient in Ethanol and Propylene Glycol):**
    - Weigh 1g of diclofenac sodium.
    - Dissolve it in 30 ml of ethanol (95%).
    - Add a specified amount of propylene glycol and mix to dissolve completely.

2. **Preparation of Solution B (Polymer Base in Water with Triethanolamine):**
    - Weigh a specified quantity of Carbopol 934P and Sodium CMC (a gelling agent).
    - Add Carbopol and Sodium CMC to sufficient water and mix uniformly using a magnetic stirrer to form a homogeneous solution. Dissolved methyl paraben in sufficient water added.
    - While continuing to stir, add triethanolamine to neutralize the Carbopol and initiate gel formation.

3. **Combination of Solution A and Solution B:**
    - Mix Solution A and Solution B thoroughly.
    - Adjust the final weight of the mixture to 100g by adding additional solvent (likely water or ethanol, depending on the formulation).

Hydrogel

Evaluation Parameters

The formulated gel was subjected to follow evaluation parameters

pH: The pH of the gel formulations was determined by using digital pH meter by placing the glass electrode completely into the gel system and measure pH of gel.

Physical appearance: The physical appearance and homogeneity of the prepared gels were tested by visual observations. The marketed formulation was considered as reference.

Spread ability test: Spread ability can be determined by applying the gel over an even surface and observed for the gritty nature of the hydrogel if present.

Skin irritation test: Test for irritation was performed on human volunteers. For each gel, 5 volunteer were selected and 1g of formulated gel was applied on the area of 2 square inch to the back of hand. The volunteers were observed for lesions or irritation.

Drug content: A quantity (100mg) of the prepared gel and marketed gel was dissolved in 100 ml of Phosphate buffer of PH 6.8. The volumetric flask containing gel solution was shaken for 2h on a mechanical shaker to allow the drug to dissolve completely. The solution was filtered and drug content was determined spectrophotometrically at 276 nm using Phosphate buffer (PH 6.8) as blank.

In vitro diffusion Study: Phosphate buffer of pH 6.8 was used for in vitro release as a receptor medium. The membrane filter paper was used in Franz diffusion cell. The gel sample was applied on the membrane and then fixed in between donor and receptor compartment of diffusion cell. The receptor compartment content phosphate buffer (50ml) of pH 6.8. The temperature of diffusion medium was thermostatically controlled at 37± 1˚ by surrounding water in jacket and the medium was stirred by magnetic stirrer at 500 rpm. The sample at predetermined intervals were withdrawn and replaced by equal volume of fresh fluid. The samples withdrawn and replaced by equal volume of fresh fluid. The samples withdrawn were spectrophotometrically estimated at 276 nm against their respective blank.

Viscosity: Viscosity measures the flow characteristics of gel formulation. Change in viscosity of the product is indicative of change in stability and effectiveness of product. The viscosity of gel was determined by using Brook field viscometer (Brookfield DV-E-LV model)

Table 2- Values of evaluation parameter of developed hydrogel and marketed gel

	Physical appearance	pH	Spreadability (g.cm/sec)	Viscosity (cp)	Skin irritation test	Homogeneity	Drug content (%)
Formulated hydrogel	Slightly opaque	6.8	6.0	99	Nil	Good	99.94
Marketed gel	Clear	6.8	5.5	99	Nil	Good	99.90

Table 3- In vitro diffusion studies of Formulated and marketed gel

Sr. N o.	Time (min)	Medium pH	% drug release of formulated gel	% drug release of marketed gel
1	30	6.8	48.75	49.87
2	60	6.8	64.39	68.24
3	90	6.8	80.01	80.88
4	120	6.8	97.12	98.65

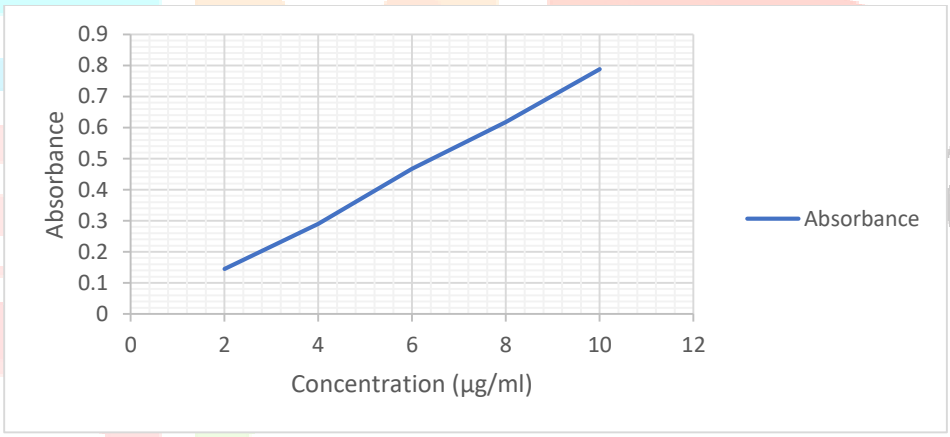

Fig- Calibration curve of Diclofenac sodium

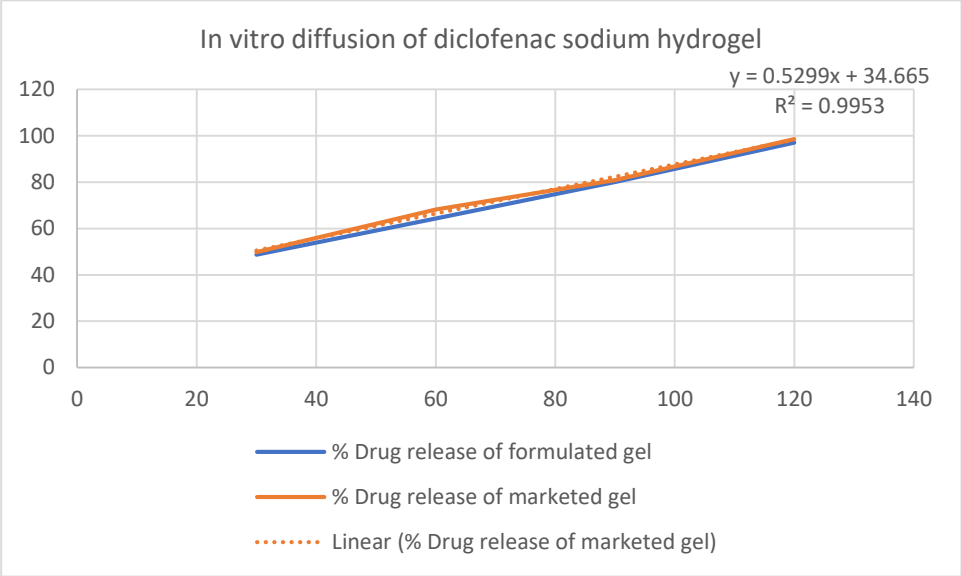

Fig- In vitro diffusion of diclofenac sodium hydrogel

Conclusion: Diclofenac Sodium is commonly recommended for the long-term management of rheumatoid arthritis and osteoarthritis. To address the limitations associated with the oral administration route, Diclofenac has been formulated as a hydrogel. This topical formulation offers a targeted approach, providing relief at the site of pain with potentially fewer systemic side effects. Diclofenac Sodium is recommended in long term use of rheumatoid arthritis and osteoarthritis. To overcome the disadvantage in oral route the Diclofenac was formulated as gel. The formulated Gels are evaluated for pH, homogeneity, grittiness, drug content, viscosity, spreadability, extrudability, skin irritation studies.

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