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# FORMULATION AND EVALUATION OF DICLOFENAC SODIUM TOPICAL GEL

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## ABSTRACT

Topical drug delivery systems have gained increasing attention due to their ability to deliver drugs locally at the site of action while minimizing systemic side effects. Diclofenac sodium is a widely used non-steroidal anti-inflammatory drug (NSAID) that exhibits potent analgesic and anti-inflammatory activity. The present study was aimed at formulating and evaluating diclofenac sodium topical gel using Hydroxypropyl Methylcellulose (HPMC) and Carbopol 940 as gelling agents. The gel formulation was prepared using ethanol as solvent, propylene glycol and glycerine as humectants and penetration enhancers, and triethanolamine as neutralizing agent. Methyl paraben and propyl paraben were incorporated as preservatives. The prepared formulations were evaluated for physical appearance, pH, viscosity, spread ability, extrudability and stability at room temperature. The results demonstrated that the prepared gel was homogeneous, smooth and exhibited acceptable physicochemical properties suitable for topical application. Stability studies indicated that the formulation remained stable without significant changes in pH, viscosity or appearance. Therefore, the developed diclofenac sodium gel can be considered suitable for topical treatment of inflammation and pain.

**KEYWORDS**: Diclofenac sodium, topical gel, Carbopol 940, HPMC, NSAID, formulation, evaluation.

## 1. INTRODUCTION

Topical drug delivery systems have become an important area in pharmaceutical research due to their advantages over conventional oral dosage forms. These systems allow the drug to be delivered directly to the site of action, thereby reducing systemic side effects and improving therapeutic efficacy.

Diclofenac sodium is a widely used NSAID belonging to the phenylacetic acid class. It exhibits anti-inflammatory, analgesic, and antipyretic activities by inhibiting cyclooxygenase (COX) enzymes responsible for prostaglandin synthesis. Prostaglandins play an important role in inflammation, pain, and fever.

However, oral administration of diclofenac sodium may cause gastrointestinal irritation, ulceration, and systemic side effects. Topical formulations such as gels provide localized drug delivery and reduce the risk of systemic adverse effects.

Gels are semisolid preparations consisting of a three-dimensional polymeric network capable of retaining large amounts of water or solvent. They are widely used in topical drug delivery because they provide a cooling effect, improved drug penetration, ease of application, and better patient compliance.

Carbopol 940 is a cross-linked polyacrylic acid polymer commonly used as a gelling agent due to its high viscosity and excellent clarity at low concentration. Hydroxypropyl methylcellulose (HPMC) is a semi-synthetic polymer derived from cellulose and widely used in pharmaceutical formulations because of its stability, non-toxicity, and good film-forming properties.

The present study focuses on the formulation and evaluation of diclofenac sodium topical gel using HPMC and Carbopol 940 as gelling agents.

## 2. Drug Profile

1) Drug Name: Diclofenac Sodium
2) Category: Non-steroidal anti-inflammatory drug (NSAID)
3) Mechanism of Action: Diclofenac sodium inhibits cyclooxygenase enzymes (COX-1 and COX-2), thereby reducing the synthesis of prostaglandins responsible for inflammation and pain.

**4) Uses**

- Treatment of arthritis
- Musculoskeletal pain
- Sprains and strains
- Inflammatory conditions

Molecular Formula: $C_{14}H_{10}C_{l2}NaO_2$

## 3. Excipient Profile

| Ingredient | Function |
|---|---|
| Carbopol 840 | Gelling agent |
| HPMC | Gelling agent |
| Ethanol (95%) | Drug-solvent |
| Propylene glycol | Co-solvent |
| Glycerine | Humectant |
| Triethanolamine | Neutralizer |
| Methyl paraben | Preservative |
| Propyl paraben | Preservative |
| Water | Vehicle |

## 4. MATERIALS AND METHODS

### Materials

Diclofenac sodium, Carbopol 840, HPMC, ethanol, propylene glycol, glycerine, triethanolamine, methyl paraben, propyl paraben, and purified water were used in the formulation.

## 5. Formulation Design

| Ingredient | F1 | F2 | F3 | Role |
|---|---|---|---|---|
| Diclofenac sodium | 0.25g | 0.25g | 0.25g | Anti-inflammatory activity |
| Carbopol 840 | 0.50g | | 0.5g | Gelling agent |
| HPMC | -- | 1.25g | 1.0g | Gelling agent |
| Ethanol (95%) | 3ml | 3ml | 3ml | Drug-solvent |
| Propylene glycol | 5ml | 5ml | 5ml | Co-solvent |
| Glycerin | 2.5ml | 2.5ml | 2.5ml | Humectant |
| Triethanolamine | QS | QS | QS | Neutralizer |
| Methyl paraben | 0.05g | 0.05g | 0.05g | Preservative |
| Propyl paraben | 0.025g | 0.025g | 0.025 | Preservative |
| Olic Acid | | 0.5ml | | Penetration Enhancer |
| Isopropyl Alcohol | | | 5ml | Penetration Enhancer |
| Water | QS | QS | QS | Vehicle |

**Preparation Method**

**Step 1: Preparation of Polymer Base**

- A measured quantity of purified water was heated to approximately 60–70°C.
- The required quantity (q.s. to 100 mL) of purified water was taken, and the gelling agent (HPMC/Carbopol) was slowly added with continuous stirring to avoid lump formation.
- The dispersion was allowed to hydrate completely until a uniform polymeric solution was formed.

**Step 2: Preparation of Drug Solution**

- Diclofenac sodium was accurately weighed and dissolved in a sufficient quantity of ethanol with continuous stirring until completely dissolved.
- After complete dissolution of the drug, propylene glycol and glycerin were added gradually with continuous mixing.
- Methyl paraben and propyl paraben (previously dissolved in a small quantity of ethanol) were then added to the above solution to form a uniform drug solution.

**Step 3: Mixing of Both Phases**

The prepared drug solution was slowly added to the hydrated polymer solution under continuous stirring to ensure uniform mixing and prevent air entrapment.The mixture was stirred continuously until a homogeneous system was obtained.

**Step 4: Gel Formation**

Finally, the volume was adjusted using water(q.s.). Then add triethanolamine for suitable Ph (q.s.). The mixture was stirred gently until a smooth, uniform gel was formed.

❖ **Evaluation Parameters**

- **Physical Appearance**-The gel was visually examined for colour, homogeneity, and texture.
- **pH Determination**-The pH of the gel was determined using pH paper after dilution with distilled water.
- **Viscosity**-Viscosity was measured using a Brookfield viscometer.
- **Spread ability**- Spread ability was measured using the glass slide method.
- **Extrudability**-Extrudability was evaluated by measuring the force required to extrude the gel from a collapsible tube.

- **Stability Study**-The prepared gel was stored at room temperature (25°C) for 30 days and evaluated periodically.

## 6. RESULTS

Three gel formulations were prepared using different polymers: HPMC (F1), Carbopol 940 (F2), and a combination of HPMC + Carbopol 940 (F3). The prepared formulations were evaluated for various physicochemical parameters including physical appearance, pH, viscosity, spreadability, extrudability and stability.

❖ **Physical appearance**

| | |
|---|---|
| Colour | Transparent |
| Clarity | Clear |
| Homogeneity | Uniform |
| Texture | Soft & smooth |
| Air bubbles | Minimal |
| Odor | Characteristic |

❖ **pH of diclofenac gel**

- Use pH appears to measure the pH of diclofenace.
- The pH of diclofenac gel is 6.8.

**A. Viscosity**-Viscosity of diclofenac gel (The standard range of viscocity is 30,000-600,000cp) The viscosity of the prepared diclofenac sodium gelis determine using a Brookfield viscometer

| Formulation | Viscosity (in centipoise) cP |
|---|---|
| F1 | 4300 |
| F2 | 77800 |
| F3 | 3800 |

**B. Extrudability test:** In this we determine the gel can be extruded from a collapsible tube under applied pressure.

**C. Spreadability** of Gel.

Method (Glass Slide Method)

$$S= M*L/T$$

Where:

S = Spreadability

M = Weight applied (g)

L = Length moved by slide (cm)

T = Time taken

Stability Study of Gel at Room Temperature

The physical and chemical stability of the prepared gel formulation at room temperature. Storage Condition.

**Procedure**

Step 1: Fill the prepared gel into Aluminum collapsible tube ORWide mouth container then Seal properly to avoid contamination

Step 2: Store the sample at room temperature (25°C) away from direct sunlight. Keep in a clean, dry place.

Step 3: Evaluation Schedule

Evaluate the formulation at:

Day 0 (Initial)stable

7 days Stable

15 days- Stable

30 days- Upper layer Dry

60 days – Phase separate

## 7. DISCUSSION

The prepared diclofenac sodium gel showed desirable physicochemical properties. The pH of the formulation was within the acceptable range for topical preparations, indicating good compatibility with the skin. The viscosity values suggested that the gel had appropriate consistency for topical application. Spreadability studies indicated that the gel spreads easily on the skin surface and forms a uniform film. Extrudability studies demonstrated that the gel could be easily removed from the container, which is important for patient convenience. Stability studies indicated that the formulation remained stable under room temperature conditions.

## CONCLUSION

The present study successfully formulated diclofenac sodium topical gel using three different polymer systems: HPMC, Carbopol 940, and a combination of HPMC and Carbopol. Among the tested formulations, the gel prepared using a combination of HPMC and Carbopol 940 demonstrated the most desirable characteristics, including appropriate viscosity, good

spreadability, satisfactory extrudability, and acceptable stability. Therefore, the HPMC–Carbopol combination gel formulation may be considered the most suitable formulation for topical delivery of diclofenac sodium for the treatment of inflammation and pain.

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