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*Original Article*

# Formulation and Evalution of Diclofenac Gel

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## ABSTRACT

The present study focuses on the formulation and development of a topical gel containing diclofenac sodium for the treatment of localized musculoskeletal pain and inflammation. Diclofenac, a non-steroidal anti-inflammatory drug (NSAID), is widely used due to its potent analgesic and anti-inflammatory properties. The goal was to enhance the topical delivery of diclofenac through an effective gel formulation, thereby minimizing systemic side effects associated with oral administration. Various gel formulations were prepared using different concentrations of gelling agents such as Carbopol 934 and Hydroxypropyl Methylcellulose (HPMC). The prepared gels were evaluated for physicochemical properties including appearance, pH, viscosity, spreadability, drug content, and in vitro drug release. The optimized formulation exhibited suitable pH for skin application, satisfactory viscosity for topical use, uniform drug distribution, and sustained drug release over several hours. The findings demonstrate that a well-designed diclofenac gel can serve as an effective topical system for the management of inflammatory conditions with improved patient compliance.

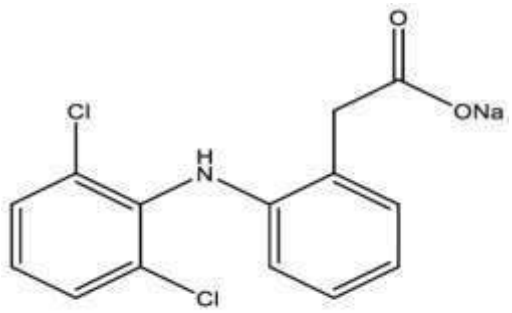
**Keywords:** Diclofenac sodium, NSAID, topical gel, formulation development, Carbopol 934

## INTRODUCTION

Pain and swelling are common problems that many people face, especially due to conditions like arthritis, muscle injuries, or joint issues. One of the most widely used medications to treat this pain is diclofenac, which helps reduce inflammation and discomfort. However, while diclofenac is effective, taking it in pill form can sometimes lead to stomach problems and other side effects, especially when used over long periods of time. This has led to the development of alternative methods to deliver the medication, such as through diclofenac gel[1]. Diclofenac gel is applied directly to the skin, allowing the medicine to target the painful area without affecting the whole body. This method is beneficial because it reduces the chance of side effects like stomach irritation, which can happen with oral forms of the drug. The gel works by being absorbed through the skin and penetrating deep into underlying tissues, such as muscles and joints, delivering the medicine right where it's needed. This transdermal absorption is enhanced by specific ingredients in the gel that help the active compound pass through the skin barrier more efficiently. Once absorbed, diclofenac works by blocking the production of prostaglandins—chemicals in the body responsible for pain and inflammation. This targeted delivery provides effective pain relief for conditions such as osteoarthritis, sports injuries, and tendinitis. The localized action of the gel allows for high concentrations of the drug at the site of pain with minimal levels in the bloodstream, reducing the risk of systemic side effects[2]. The first diclofenac gel products were introduced in the 1990s, and they quickly became a popular choice for people who needed pain relief but wanted to avoid the adverse effects of oral medications. Over time, the formulation of these gels has improved, with advances in pharmaceutical technology enabling better skin penetration, faster absorption, and longer-lasting effects. Newer versions of diclofenac gel are even more effective at delivering pain relief quickly and safely[3].

**Profile of Formulation Ingredients[4]:**

**Relevant conflicts of interest/financial disclosures**: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.




Structural formula of diclofenac sodium.

**1. Diclofenac Sodium[5]**

**Role:** Active Pharmaceutical Ingredient (API)

**Function:** The main ingredient responsible for the anti-inflammatory, analgesic, and antipyretic effects. It helps to reduce pain, swelling, and inflammation by inhibiting the enzymes (COX-1 and COX-2) involved in the production of prostaglandins, which mediate pain and inflammation.

**Concentration:** Typically, 1% or 2% in the gel formulation, depending on the product.

**2. Water (Aqua)[6]**

**Role:** Solvent and base

**Function:** Water acts as the primary solvent and base in the gel. It helps dissolve other ingredients and creates the gel-like consistency that makes the product easy to apply. It also helps in the absorption of diclofenac through the skin.

**Concentration:** Usually, a significant part of the formulation (often 60-80%).

**3. Carbomer**

**Role:** Gelling Agent

**Function:** Carbomer is a polymer used to create the gel structure. It is used to thicken the gel, giving it the right consistency, and helps to stabilize the formulation. Carbomer also improves the skin feel of the gel, making it less greasy.

**Concentration**: Typically, 0.5% - 1% depending on the desired gel consistency.

**4. Triethanolamine (TEA)[7]**

**Role:** pH Adjuster

**Function:** TEA is used to adjust the pH of the gel to ensure that it is in a suitable range for both the stability of the diclofenac and the skin's comfort. It neutralizes the carbomer to form the gel.

**Concentration**: Typically, low concentrations, depending on the pH of the formulation.

**5. Isopropyl Alcohol**

**Role:** Solvent and penetration enhancer

**Function:** Isopropyl alcohol is used as a solvent to help dissolve some ingredients and to enhance the penetration of diclofenac into the skin. It also aids in quick drying and evaporation after application.

**Concentration:** Around 2-5%, depending on the formulation.

**6. Propylene Glycol[8]**

**Role:** Humectant and skin conditioner

**Function:** Propylene glycol helps to maintain moisture in the gel and enhances the absorption of diclofenac through the skin. It can also improve the texture of the gel and reduce irritation.

**Concentration:** Typically, around 2-10%.

**7. Glycerin[9]**

**Role**: Humectant

**Function:** Glycerin attracts moisture, helping to keep the skin hydrated and improving the smooth application of the gel. It also contributes to the gel's texture.

**Concentration:** Typically, 3-5% in the formulation.

**Experimental Work:**

**A) Diclofenac Sodium Gel:**

**1. Name of The Preparation**

**Diclofenac Sodium Gel, 1% w/w**

**2. Category**

- Non-Steroidal Anti-Inflammatory Drug (NSAID)
- Topical Analgesic and Anti-inflammatory

**3. Active Ingredient**

- **Diclofenac Sodium** – 1% w/w (i.e., 0.3 g in 30 g formulation)

**4. Description**

A clear to slightly opaque, smooth, non-greasy gel intended for topical application. It is used for the relief of pain and inflammation associated with musculoskeletal and joint disorders.

## METHODOLOGY:

The chemical and reagents apply from Delight college of pharmacy Koregaon Bhima, Pune. Maharashtra, India-412216.

**Method for the Preparation of Diclofenac gel:**

| S. No. | Ingredients | Quantity (per 30 g) | Purpose |
|---|---|---|---|
| 1 | Diclofenac Sodium | 0.3 g | Active pharmaceutical ingredient (API); anti-inflammatory |
| 2 | Carbopol 934 | 0.15 g | Gelling agent |
| 3 | Propylene Glycol | 2.5 mL | Solvent; penetration enhancer |
| 4 | Ethanol (optional) | 2–3 mL | Co-solvent to aid dissolution |
| 5 | Methyl Paraben | 0.03 g | Preservative |
| 6 | Triethanolamine (TEA) | q.s. (to pH 6.5–7.0) | pH adjuster; neutralizer |
| 7 | Distilled Water | q.s. to 30 g | Vehicle; brings formulation to final weight |

**1. Prepare the Gel Base**

- Take 20 mL of distilled water in a clean beaker.
- Slowly sprinkle 0.15 g of Carbopol 934 while stirring.
- Allow it to swell for 2–3 hours (or overnight) to form a clear base.

**2. Prepare the Drug Solution**

- In another small beaker:
  - Dissolve 0.3 g of Diclofenac Sodium in 2.5 mL propylene glycol.
  - Add 2–3 mL ethanol to help it dissolve better (optional).
  - Add 0.03 g methyl paraben to this mixture and stir until fully dissolved.

**3. Combine the Two**

- Slowly add the drug solution into the Carbopol gel base.
- Stir gently until mixed well.

**4. Adjust the Ph And Form the Gel**

- Add Triethanolamine (TEA) drop by drop while stirring.
- Continue adding until the pH reaches 6.5 to 7.0 and the gel forms (you'll notice the mixture becomes thicker and gel-like).

**5. Make Up To 30 G**

- Add distilled water slowly to bring the total weight up to 30 grams.
- Stir gently to mix everything well and remove air bubbles.

**6. Final Packing**

- Transfer the gel into a clean, labeled container.
- Store in a cool, dry place away from sunlight.

## OBSERVATION:

**1. Colour:** The appearance of the gel should be aesthetically acceptable. The colour may vary from slightly cloudy to clear depending on the presence and concentration of ethanol in the formulation.

**Procedure:** Visually inspect a small amount of gel against a white background under natural or white light to observe its clarity and colour.

**2. Odor**: The gel should possess a mild and pleasant odor. If ethanol is used, an alcohol-like odor may be present, which is acceptable.

**Procedure:** Take a small quantity of the gel on a spatula and gently smell it to evaluate the presence of any characteristic or unpleasant odor.

**3. Consistency**: A good gel should have a uniform and semi-solid consistency that is easy to apply and spread over the skin surface.

**Procedure**: Check the gel manually by pressing a small quantity between the fingers to assess its smoothness, uniformity, and feel.

**4. PH**: The pH of the gel should be compatible with the skin (between 6.5 to 7.0) to avoid irritation upon application.

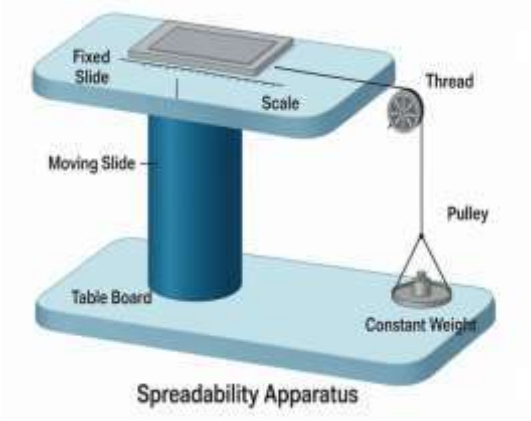

**Figure 1: PH Meter**

**Procedure:**

1. Dissolve 1g of the gel in 10 ml of distilled water.
2. Measure the pH using a calibrated digital pH meter.

**Theory**: This test ensures how easily the gel spreads on the skin, which affects patient compliance and drug delivery.

**5. Spreadability**




**Spread ability (gm./s**) = M×L/T

Where:

M = Weight in grams
L = Length the slide moved (in cm)
T = Time in seconds

**Procedure**:

1. Place a small quantity of gel between two glass slides.
2.Apply a weight (usually 500g) on the top slide for 1 minute.
3. Measure the diameter of the spread gel area or note the time taken for the top slide to slip off.

**6. Drug Solubility:** The active ingredient (Diclofenac Sodium) must be fully dissolved in the gel base to ensure uniform distribution and efficacy.

**Procedure**:

1. Visually inspect for any undissolved particles.
Optionally, analyze using UV spectrophotometry to confirm drug solubility in the formulation.

**7. Viscosity:** Viscosity determines the flow properties and stability of the gel. An ideal gel should have adequate viscosity for proper application and retention.


**Figure 3: Brookfield Viscometer**

**Procedure**:

1. **Prepare the Sample**:

- Ensure the **diclofenac gel** is homogenous and at room temperature (25°C) or body temperature (37°C).

2. **Setup**:

- Attach the appropriate spindle (e.g., **RV Spindle 64**) to the **Brookfield Viscometer**.
- Place the gel in a **250 mL beaker** (about 100-200 mL) and immerse the spindle, ensuring it doesn't touch the sides or bottom.

3. **Set Speed**:

- Set the viscometer to **12 RPM** (or 10/50 RPM for different shear rates).

4. **Measure Viscosity**:

- Allow the spindle to rotate for **30-60 seconds**.
- Record the **viscosity in cP** (centipoise) from the digital display.

5. **Repeat (Optional)**:

- Measure viscosity at **different speeds** (10, 20, 50 RPM) to assess shear-thinning behavior.

6. **Clean Up**: Clean the spindle and container thoroughly after use.

**8. Simple Diffusion Test for Diclofenac Gel**

**MATERIALS:**

1. Diclofenac gel
2. Franz diffusion cell (or small glass setup)
3.Dialysis membrane or cling film
4. Warm water (37°C)
5. Phosphate-buffered saline (PBS)

**Figure 4: Franz Cell Diffusion Apparatus**

**Steps**:

**1. Prepare Membrane:** Soak membrane in warm PBS for 10 minutes.

**2. Set Up Cell:** Place membrane between two compartments:

1. Top (Donor): Apply 1g diclofenac gel
2. Bottom (Receptor): Fill with PBS

**3. Keep Warm & Stir:** Keep setup at 37°C and stir the PBS.

**4. Sample at Times:** Every 30 mins, take a few drops from PBS below.

## RESULT:

The formulation of the Diclofenac Sodium gel (1%) was successful, and the final product met the expected characteristics. The gel appeared smooth, clear, and had a good consistency, making it easy to apply on the skin. The pH of the gel was found to be around 6.6, which is ideal for skin use. The gel was neither too thick nor too runny, with a viscosity that allowed it to stay on the skin without dripping. The Diclofenac Sodium was completely dissolved in the solvent mixture, and there were no lumps or separation in the final product. The gel was stable and did not show any signs of instability, such as changes in color, texture, or odor, after preparation.


**Figure 5: Diclofenac Gel**

## SUMMARY AND CONCLUSION:

## SUMMARY:

Diclofenac gel is a topical NSAID designed to provide localized relief from pain and inflammation associated with conditions such as osteoarthritis, muscle injuries, and tendonitis. Unlike oral forms, the gel offers targeted delivery with fewer systemic side effects. The formulation typically includes Diclofenac Sodium as the active ingredient, along with excipients like Carbopol, Propylene Glycol, Triethanolamine, and preservatives to ensure stability, spreadability, and effectiveness. The experimental formulation involved the preparation of a 1% Diclofenac Sodium gel, followed by evaluation based on parameters like pH, color, consistency, viscosity, and spreadability.

The results showed a stable, smooth, and effective gel with ideal properties for topical use. Observations confirmed good solubility of the drug and compatibility with skin ph.

## CONCLUSION:

The formulated Diclofenac Sodium gel (1%) met all the key pharmaceutical requirements for a topical analgesic. It exhibited good consistency, pH compatibility, spreadability, and stability, making it a suitable and effective alternative to oral NSAIDs. By minimizing systemic exposure, the gel reduces the risk of gastrointestinal and renal side effects. This study confirms the potential of topical Diclofenac as a safe and effective treatment for localized pain and inflammation, with scope for further enhancement through improved formulations and clinical testing.

## FUTURE SCOPE:

**1. Improving Effectiveness:** Future studies could focus on enhancing the drug absorption by adding new penetration enhancers (like menthol or alcohol) to make the gel work faster and deeper into the skin.

**2. Testing Different Concentrations:** The formulation could be tested with different concentrations of Diclofenac Sodiumto see how the strength of the gel affects its pain-relieving properties.

**3. Formulating for Other Uses:** The gel could be developed for other conditions, like muscle pain or arthritis by adding other active ingredients alongside Diclofenac.

**4. Clinical Testing:** Human trials or animal studies could be done to test the gel's safety and effectiveness over a longer period of time.

**5. Long-Term Stability:** Stability testing can be done to ensure the gel maintains its quality over long periods, especially in different temperature and humidity conditions.

**6. Eco-Friendly Packaging:** Future work can focus on using environmentally friendly packaging to make the product more sustainable.

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