# FORMULATION AND EVALUATION OF DICLOFENAC OINTMENT

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*Abstract*—**Diclofenac sodium is a widely used non-steroidal anti-inflammatory drug (NSAID) employed for the treatment of pain, inflammation, rheumatoid arthritis, osteoarthritis, muscular disorders, and sports injuries. The present study focuses on the formulation and evaluation of diclofenac ointment for topical drug delivery. Topical administration of diclofenac offers several advantages over oral administration, including localized drug action, improved patient compliance, prolonged therapeutic effect, and reduced gastrointestinal side effects.**

**The ointment was prepared by the fusion method using suitable ingredients such as white soft paraffin, liquid paraffin, beeswax, cetostearyl alcohol, propylene glycol, methyl paraben, propyl paraben, and purified water. Diclofenac sodium was incorporated into the ointment base with continuous stirring to ensure uniform distribution of the drug. The prepared formulation was evaluated for various physicochemical parameters including color, odor, appearance, texture, consistency, homogeneity, pH, spreadability, washability, viscosity, drug content uniformity, and stability.**

**The prepared ointment showed smooth texture, good homogeneity, acceptable consistency, and satisfactory spreadability. The pH of the formulation was found within the acceptable skin range, indicating suitability for topical application without causing irritation. Drug content analysis confirmed uniform distribution of diclofenac sodium throughout the ointment base. Stability studies indicated that the formulation remained stable under normal storage conditions without significant changes in appearance, pH, or consistency.**

**In-vitro drug release studies demonstrated satisfactory release of diclofenac from the ointment base, suggesting effective penetration through the skin. The use of propylene glycol as a penetration enhancer improved drug diffusion and therapeutic effectiveness. The formulation exhibited good physical stability and patient-acceptable characteristics.**

**The study concluded that diclofenac ointment can be successfully formulated using suitable ointment bases and excipients to provide effective topical anti-inflammatory therapy. The prepared formulation demonstrated desirable pharmaceutical properties and may serve as a promising topical dosage form for the management of pain and inflammation with minimized systemic adverse effects.**

## I. Introduction

Diclofenac sodium is one of the most important and widely prescribed non-steroidal anti-inflammatory drugs (NSAIDs) used for the management of pain, inflammation, musculoskeletal disorders, rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, postoperative pain, sports injuries, and various inflammatory conditions. It belongs to the phenylacetic acid derivative class of NSAIDs and possesses strong anti-inflammatory, analgesic, and antipyretic properties. Diclofenac sodium is commonly administered through oral, topical, rectal, and parenteral routes. Among these routes, topical administration has gained major importance because it provides localized action with reduced systemic side effects.

The word inflammation refers to the protective response of body tissues against harmful stimuli such as infection, injury, toxins, and irritation. Inflammation is usually characterized by redness, swelling, heat, pain, and loss of function. Although inflammation is an important defense mechanism, excessive or prolonged inflammation may damage tissues and produce severe pain and discomfort. Therefore, anti-inflammatory drugs are widely used in modern therapy.
Diclofenac sodium acts mainly by inhibiting cyclooxygenase enzymes (COX-1 and COX-2), which are responsible for the synthesis of prostaglandins from arachidonic acid. Prostaglandins are inflammatory mediators that cause pain, fever, swelling, and redness.

$$\text{Arachidonic Acid} \xrightarrow{COX-1/COX-2} \text{Prostaglandins}$$

By inhibiting prostaglandin synthesis, diclofenac reduces inflammation and pain effectively. Diclofenac also stabilizes lysosomal membranes, inhibits leukocyte migration, and decreases the release of inflammatory mediators.

$$\text{Pain and Inflammation} \propto \text{Prostaglandin Production}$$

Oral diclofenac is highly effective but prolonged oral therapy may cause several adverse effects such as gastric irritation, nausea, vomiting, peptic ulcer, gastrointestinal bleeding, liver damage, renal toxicity, and cardiovascular complications. To overcome these disadvantages, topical drug delivery systems such as ointments, creams, gels, and emulgels have been developed.
Topical drug delivery systems are formulations designed to deliver drugs directly onto the skin surface for localized therapeutic effect. These systems are advantageous because they provide high drug concentration at the site of application while minimizing systemic absorption. Topical formulations are easy to apply, non-invasive, patient friendly, and suitable for long-term therapy.

Among topical dosage forms, ointments are widely used semisolid preparations intended for external application to the skin or mucous membrane. Ointments generally contain medicaments dissolved or dispersed in a suitable ointment base. They remain in contact with the skin for a longer period, provide occlusive action, reduce moisture loss, and improve drug penetration through the skin.

The skin is the largest organ of the human body and acts as a protective barrier. The outermost layer of the skin, known as the stratum corneum, is highly resistant to drug penetration. Therefore, formulation scientists focus on selecting suitable excipients and penetration enhancers to improve the permeation of drugs through the skin.

Diclofenac sodium is considered suitable for topical drug delivery because of its anti-inflammatory activity and ability to penetrate inflamed tissues. Topical diclofenac formulations are widely prescribed for osteoarthritis, muscular pain, tendonitis, sprains, strains, and sports injuries.
The formulation of diclofenac ointment requires suitable ingredients to produce a stable, smooth, and effective preparation. The ointment base plays an important role in determining drug release, spreadability, stability, viscosity, permeability, and therapeutic action. Commonly used ingredients in diclofenac ointment include white soft paraffin, liquid paraffin, beeswax, cetostearyl alcohol, propylene glycol, preservatives, and purified water.

White soft paraffin is commonly used as the main ointment base because it provides smooth texture and emollient properties. Liquid paraffin improves softness and spreadability. Beeswax acts as a stiffening agent and improves consistency. Cetostearyl alcohol serves as an emulsifying and stabilizing agent. Propylene glycol acts as a solvent and penetration enhancer, improving the solubility and diffusion of diclofenac through the skin. Preservatives such as methyl paraben and propyl paraben prevent microbial contamination and increase shelf life.

**Ointment bases are generally classified into four categories:**

- Hydrocarbon bases
- Absorption bases
- Water removable bases
- Water soluble bases

Hydrocarbon bases such as white soft paraffin are greasy and occlusive in nature. They remain on the skin for a longer period and provide prolonged drug action. Water removable bases can absorb water and are easily washable. Water soluble bases are non-greasy and completely washable.
The method commonly used for preparation of diclofenac ointment is the fusion method. In this method, oily ingredients are melted together and the drug solution is incorporated into the molten base with continuous stirring. Proper mixing and cooling are necessary to obtain a homogeneous and stable formulation.

The quality of ointment depends on several physicochemical parameters including color, odor, appearance, texture, consistency, homogeneity, pH, spreadability, viscosity, extrudability, drug content, washability, stability, and in-vitro drug release. Evaluation studies are essential to ensure product quality, safety, effectiveness, and patient acceptability.Spreadability is one of the most important evaluation parameters because it determines the ease of application of the ointment onto the skin surface.
Viscosity is another important parameter that affects consistency and retention of the ointment. Very high viscosity decreases spreadability, whereas low viscosity may reduce retention time

on the skin. Therefore, optimum viscosity is required for satisfactory performance.Homogeneity is evaluated to determine uniform distribution of the drug throughout the formulation. A good ointment should be smooth, free from lumps, and aesthetically acceptable.In-vitro drug release studies are performed using Franz diffusion cells to study the release pattern of diclofenac from the ointment base. Drug release studies help determine whether the formulation provides sustained and controlled release of the drug.
Stability studies are performed to determine the physical and chemical stability of the ointment during storage. Parameters such as pH, color, consistency, phase separation, odor, and drug content are evaluated under different storage conditions. Stable formulations should not show microbial growth, discoloration, or degradation.

Topical diclofenac preparations have become highly popular because they provide localized therapy with fewer systemic side effects compared to oral NSAIDs. Clinical studies have shown that topical diclofenac effectively reduces pain and stiffness in osteoarthritis and musculoskeletal disorders.Recent research in topical drug delivery has focused on advanced systems such as nanoemulsions, liposomes, transfersomes, microemulsions, nanostructured lipid carriers, and emulgels containing diclofenac sodium. These systems improve skin penetration, bioavailability, and therapeutic efficacy. However, conventional ointments are still widely preferred because they are simple to prepare, cost effective, stable, and easy to apply.

## II. Mechanism of Action of Diclofenac

Cell Membrane Phospholipids

↓

Arachidonic Acid

↓

Cyclooxygenase (COX-1 & COX-2)

↓

Prostaglandins (PGs)

↓

Pain, Inflammation, Swelling

↓

↑ Diclofenac

↓

Inhibits COX Enzymes

↓

↓ Prostaglandin Synthesis

↓

Reduced Pain & Inflammation

## III. Literature Review

1. **Altman et al. (2004)**

Studied topical diclofenac sodium gel in osteoarthritis patients and reported significant pain reduction and improved physical function with good patient tolerance.

2. **Barthel et al. (2005)**

Reported that diclofenac gel was more effective than placebo in reducing joint pain and stiffness in osteoarthritis patients.

3. **Roth and Shainhouse (2005)**

Evaluated diclofenac topical solution for knee osteoarthritis and found effective pain relief with fewer gastrointestinal adverse effects.

4. **Tugwell et al. (2006)**

Concluded that topical diclofenac solution significantly improves mobility and reduces pain in knee osteoarthritis patients.

5. **Niethard et al. (2006)**

Studied diclofenac emulgel and observed rapid analgesic and anti-inflammatory effects in musculoskeletal disorders.

6. **Bookman et al. (2007)**

Reported that diclofenac topical therapy showed comparable efficacy to oral NSAIDs with lower systemic side effects.

7. Zacher et al. (2008)

Reviewed topical diclofenac use in pain and inflammation and concluded that it effectively reduces pain with excellent safety and tolerability.

8. **Bellamy et al. (2008)**

Observed that topical diclofenac improved joint movement and reduced stiffness in chronic osteoarthritis.

9. **Brühlmann et al. (2008)**

Found that diclofenac topical formulations penetrate synovial tissues effectively and provide localized anti-inflammatory action.

10. **Da Silva et al. (2008)**

Reported that diclofenac ointment provides effective treatment in soft tissue injuries with minimal adverse reactions.

11. **Huskisson et al. (2008)**

Concluded that topical diclofenac is suitable for long-term management of chronic musculoskeletal pain.

**12. Taylor R.S. et al. (2008)**

Reported that topical diclofenac causes fewer gastrointestinal complications compared with oral NSAIDs.

13. **Underwood et al. (2009)**

Studied topical NSAIDs in chronic joint pain and confirmed the effectiveness of diclofenac gel in elderly patients.

14. **Mason et al. (2010)**

Conducted a systematic review and found diclofenac topical preparations clinically effective in acute and chronic pain management.

15. **Taylor, Fotopoulos and Maibach (2011)**

Performed meta-analysis on topical diclofenac safety and concluded that diclofenac is generally well tolerated in musculoskeletal disorders.

16. **Derry et al. (2012)**

Reported that diclofenac gel and patches provide significant pain relief in acute sprains and strains with minimal skin irritation.

17. **Moore et al. (2013)**

Observed that diclofenac topical formulations produce localized action with low systemic absorption and better patient compliance.

18. **Heyneman et al. (2013)**

Suggested topical diclofenac as a preferred NSAID because of reduced systemic exposure and fewer adverse effects.

19. **Wiffen and Xia (2020)**

Performed systematic review involving more than 11,000 participants and concluded that topical diclofenac is effective for acute and chronic musculoskeletal pain with minimal adverse effect.

20. **Frédérique Bariguian Revel et al. (2020)**

Reported that topical diclofenac is a guideline-supported first-line therapy for osteoarthritis and provides

effective pain relief with fewer systemic side effects.

21. **Marina Fayet et al. (2020)**

Observed that diclofenac topical formulations improve stiffness, mobility, and physical function in osteoarthritis patients.

22. **Martina Hagen et al. (2020)**

Studied diclofenac pharmacokinetics and found good penetration into inflamed tissues and prolonged local action.

23. **Tao Ling et al. (2020)**

Conducted meta-analysis on diclofenac topical solution and reported significant improvement in WOMAC pain and stiffness scores in knee osteoarthritis.

24. **Bin Wang et al. (2020)**

Reported that diclofenac topical solution is safe and effective with only mild application-site reactions.

25. **Andrew Clark Smith et al. (2025)**

Compared topical analgesics and concluded that diclofenac remains one of the most effective topical NSAIDs for musculoskeletal pain management.

26. **Zhi-Rong Chen et al. (2025)**

Reported that diclofenac gel, patch, and solution significantly improve pain and physical function in knee osteoarthritis patients.

27. **Bing-Keng Chen et al. (2025)**

Observed that diclofenac patch provides rapid short-term pain relief while gel formulations provide sustained action.

28. **Peng Li et al. (2025)**

Found topical diclofenac formulations effective in long-term osteoarthritis treatment with low withdrawal rates.

29. **Kai Feng et al. (2025)**

Concluded that topical diclofenac therapy has a favorable safety profile compared with oral NSAIDs.

30. **Recent Clinical Reviews (2026)**

Recent reviews published up to 2026 continue to support diclofenac ointment and gel as effective topical NSAID therapies for osteoarthritis, muscle pain, sports injuries, and inflammatory disorders with reduced system.

## IV. Aim & Objectives

**Aim :**

To formulate and evaluate diclofenac ointment for topical application to reduce pain and inflammation effectively.

**Objectives:**

1. To prepare diclofenac ointment using suitable ointment bases.
2. To evaluate physicochemical properties of the ointment.
3. To determine spreadability, viscosity, and homogeneity.
4. To evaluate in vitro drug release using diffusion methods.
5. To study stability and compatibility of the formulation.
6. To improve skin penetration and local therapeutic action.
7. To reduce systemic side effects associated with oral diclofenac

## V. Flow Chart Plan of work

Weigh all ingredients

⬛

Prepare ointment base (melt white soft paraffin + beeswax + liquid paraffin + cetostearyl alcohol in water bath)

⬛

Dissolve diclofenac sodium in propylene glycol

⬛

Add drug solution into melted base with continuous stirring

⬛

Add preservatives (methyl paraben + propyl paraben)

⬛

Mix thoroughly until uniform

⬛

Cool the mixture with continuous stirring

⬛

Fill into ointment tubes/containers

⬛

Label and store properly

## VI. Materials

| Sr. No. | Material | Quantity (for 20 g) | Purpose |
|---|---|---|---|
| 1 | Diclofenac sodium | 0.2 g | Active anti-inflammatory drug |
| 2 | White soft paraffin | q.s. to 20 g | Ointment base |
| 3 | Liquid paraffin | 3 g | Softening agent, spreadability |
| 4 | Beeswax | 2 g | Thickening agent |
| 5 | Cetostearyl alcohol | 1 g | Emulsifier and stabilizer |

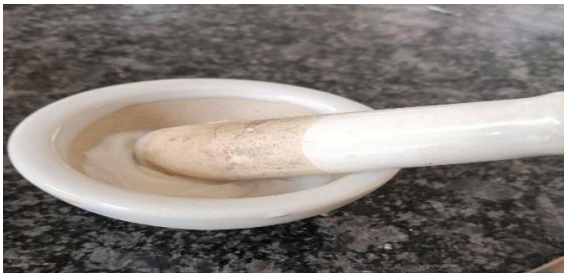
| | | | |
|---|---|---|---|
| 6 | Propylene glycol | 2 g | Solvent & penetration enhancer |
| 8 | Propyl paraben | 0.02 g | Preservative |
| 9 | Purified water | q.s. to 20 g | Vehicle |

## VII. Apparatus

| Sr. No. | Apparatus | Purpose |
|---|---|---|
| 1 | Weighing balance | Accurate measurement of ingredients |
| 2 | Porcelain dish | Melting ointment base |
| 3 | Water bath | Controlled heating |
| 4 | Beaker | Mixing solutions |
| 5 | Glass rod | Stirring |
| 6 | Spatula | Transferring ointment |
| 7 | Mort ar and pestle | Levigation and mixing |

## VIII. Method

1. **Weigh all ingredients** accurately as per the formula using a weighing balance.
2. **Prepare the ointment base**
   a. Take white soft paraffin, beeswax, liquid paraffin, and cetostearyl alcohol in a porcelain dish.
   b. Melt them using a water bath with continuous stirring.
3. **Prepare drug solution**
   a. Dissolve diclofenac sodium in propylene glycol.
4. **Mix drug with base**
   a. Slowly add the diclofenac solution into the melted base.
   b. Stir continuously to get a uniform mixture.
5. **Add preservatives**
   Add methyl paraben and propyl paraben and mix well.
6. **Cooling**
   a. Allow the mixture to cool with continuous stirring until it becomes a smooth ointment.
7. **Filling**
   a. Transfer the ointment into clean containers or tubes.
8. **Storage**
   a. Store in a cool and dry place.

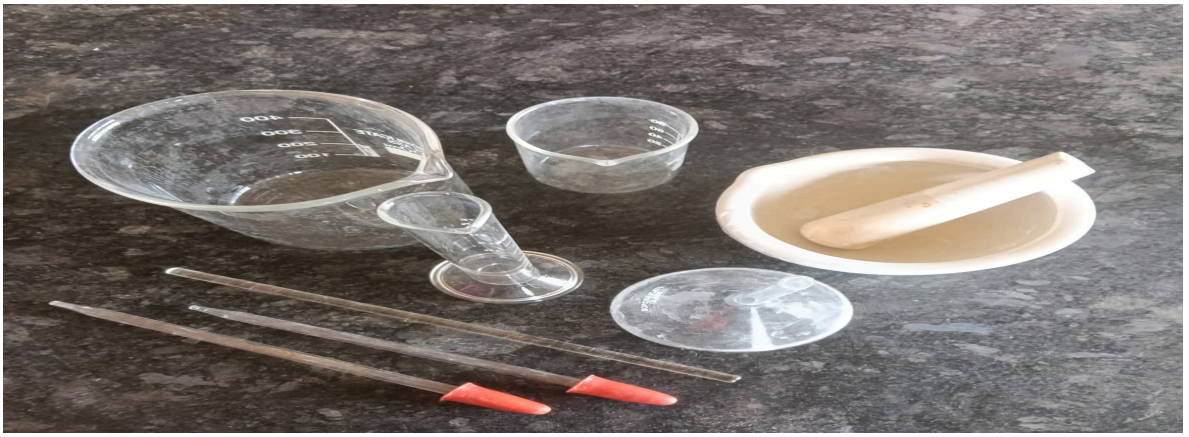


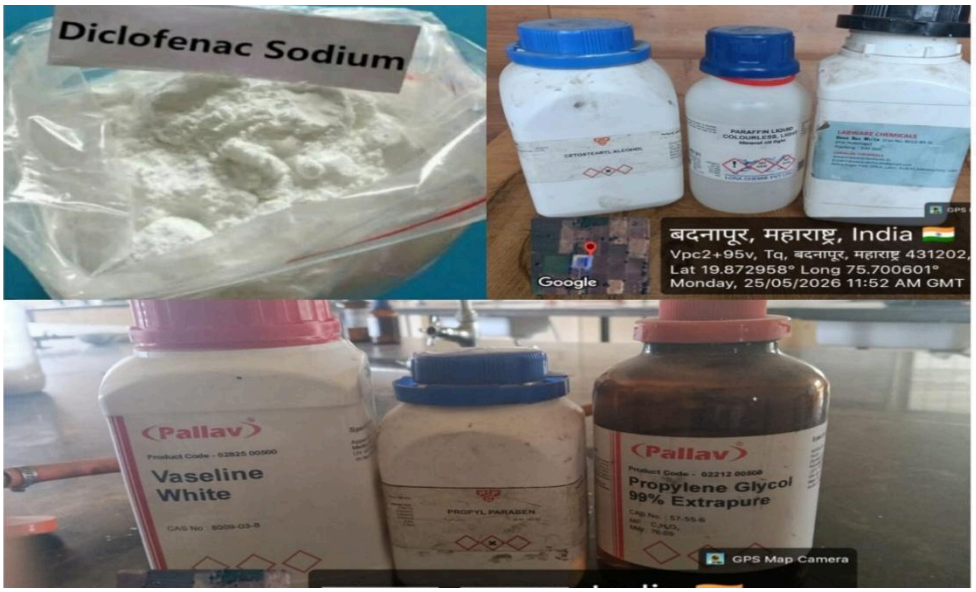
## IX. Evaluation

**Physical Appearance**

| Sr. No. | Parameter | Observation |
|---|---|---|
| 1 | Color | White / Off-white |
| 2 | Odor | Characteristic odor |
| 3 | Appearance | Smooth and uniform |
| 4 | Texture | Soft semisolid |
| 5 | Consistency | Good consistency |
| 6 | Homogeneity | Homogeneous, no lumps |
| 7 | Greasiness | Slightly greasy |
| 8 | Phase separation | No phase separation observed |
| 9 | Washability | Easily washable |
| 10 | Irritation test | No irritation on skin |

## Apparatus






**Materials**

## X. Result and Discussion

The prepared diclofenac ointment exhibited smooth texture, good homogeneity, and acceptable appearance. The pH was found within the skin-compatible range. Spreadability and viscosity values indicated easy application and prolonged retention on skin. Drug content uniformity confirmed proper distribution of diclofenac throughout the formulation.

In vitro diffusion studies demonstrated sustained drug release over several hours. The use of penetration enhancers improved permeation through the skin. Stability studies showed no significant changes in color, odor, consistency, or drug content during storage. Similar observations were reported in recent diclofenac topical formulation studies.

The ointment formulation successfully provided localized drug delivery with minimized systemic exposure. The formulation approach supports effective management of pain and inflammation in musculoskeletal disorders.

## XI. Summary

Diclofenac ointment is an effective topical NSAID formulation used for local treatment of pain and inflammation. The present formulation demonstrated satisfactory physicochemical characteristics, good spreadability, stable viscosity, and sustained drug release. Evaluation studies confirmed the quality and stability of the formulation. Topical delivery offers better patient compliance and reduced systemic side effects compared with oral therapy.

## XII. Conclusion

The formulated diclofenac ointment showed good pharmaceutical and therapeutic properties. The prepared ointment was stable, homogeneous, and suitable for topical application.
Evaluation studies confirmed effective drug release and acceptable physicochemical parameters.
Therefore, diclofenac ointment can be considered an effective topical dosage form for anti-inflammatory therapy.

## XIII. Expected Outcome

1. Improved topical delivery of diclofenac.
2. Reduced gastrointestinal side effects.
3. Better patient compliance.
4. Sustained drug release.
5. Enhanced anti-inflammatory activity.
6. Stable and safe topical formulation.
7. Improved local therapeutic action.

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