International Journal of Pharmaceutical research and Applications
Volume 11, Issue 1, Jan - Feb 2026, pp:210-215 www.ijprajournal.com ISSN: 2456-4494

"Formulation And Evaluation of Diclofenac Sodium Gel for Treatment of Rheumatoid Arthritis"

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Date of Submission: 08-01-2026 Date of Acceptance: 20-01-2026

I. BRIEF RESUME OF THE INTENDED WORK

1.1 NEED FOR THE STUDY

Topical drug delivery systems offer localized therapeutic action with minimal systemic exposure. Among these, topical gels are preferred due to their ease of application, non-greasy nature, uniform drug distribution, and good patient compliance. Diclofenac sodium gel is commonly used for the treatment of arthritis, muscle pain, sprains, and soft tissue injuries.

The formulation of an effective topical gel largely depends on the selection of an appropriate gelling agent. Carbopol 934 and Carbopol 940 are widely utilized polymers owing to their excellent gelling properties, stability, viscosity control, and skin compatibility. Previous research studies have demonstrated that diclofenac sodium gels formulated using Carbopol exhibit satisfactory physicochemical properties and enhanced drug release. Therefore, the present study aims to formulate and evaluate a diclofenac sodium gel using Carbopol as a gelling agent to develop a stable, effective, and patient-friendly topical preparation.

Pain and inflammation are major clinical symptoms observed in several disease conditions, particularly arthritis, musculoskeletal disorders, sports injuries, and post-surgical conditions. Arthritis is a chronic inflammatory disorder characterized by joint pain, swelling, stiffness, and reduced mobility, which can significantly impair daily functioning and quality of life. Effective management of inflammation and pain is essential to improve patient comfort and prevent disease progression.

Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly prescribed for the management of pain and inflammation. Diclofenac sodium is a widely used NSAID due to its potent analgesic, anti-inflammatory, and antipyretic activities. The drug exerts its therapeutic effect by inhibiting cyclooxygenase enzymes, thereby decreasing prostaglandin synthesis involved in inflammatory responses. Despite its effectiveness, prolonged oral administration of diclofenac sodium is associated with adverse effects such as gastrointestinal irritation, renal toxicity, and cardiovascular complications, which necessitates the development of safer delivery approaches.

1.2 REVIEW OF LITERATURE:

1. Ahuja *et al.* (2008) developed a diclofenac sodium topical gel using natural polymers as gelling agents. The formulations were evaluated for parameters such as pH, viscosity, spreadability, uniformity, and drug content, and were found to be suitable for skin application. In-vitro release studies demonstrated controlled and adequate drug diffusion. The study concluded that natural polymers can effectively be used in the formulation of diclofenac sodium gel as a safe alternative to synthetic polymers.
2. Abrar *et al.* (2012) formulated and evaluated topical gel preparations of NSAIDs to study their in-vitro performance. The developed gels were assessed for physicochemical parameters such as pH, viscosity, spreadability, homogeneity, and drug content, which were found to be within acceptable limits. In-vitro drug release studies demonstrated satisfactory diffusion, indicating that NSAID gels are suitable for effective topical delivery.
3. Bhanja *et al.* (2013) developed and evaluated a diclofenac transdermal gel to enhance topical drug delivery. The formulation was assessed for physicochemical parameters such as pH,

viscosity, spreadability, homogeneity, and drug content, which showed acceptable results. In-vitro diffusion studies demonstrated effective drug release, concluding that diclofenac transdermal gel is a promising system for localized anti-inflammatory therapy.

4. Goci *et al.* (2014) formulated and evaluated a topical diclofenac sodium gel to study its in-vitro performance. The prepared formulations were assessed for physicochemical properties such as pH, viscosity, spreadability, homogeneity, and drug content, which were found to be appropriate for topical application. In-vitro drug release studies showed satisfactory diffusion of diclofenac sodium from the gel. The study concluded that diclofenac sodium gel is a suitable and effective topical dosage form for localized anti-inflammatory action.
5. Shamira *et al.* (2018) formulated and evaluated diclofenac sodium gel using Carbopol as a gelling agent. The developed formulation was evaluated for physicochemical parameters such as pH, viscosity, spreadability, homogeneity, and drug content, which were found to be within acceptable limits. In-vitro drug release studies showed satisfactory diffusion, indicating that Carbopol-based diclofenac sodium gel is effective and suitable for topical application.
6. Rajalakshmi *et al.* (2022) formulated and evaluated diclofenac sodium gel using Carbopol 934 and Carbopol 940 as gelling agents. The prepared gels were assessed for physicochemical properties such as pH, viscosity, spreadability, homogeneity, and drug content, which were found to be within acceptable limits. In-vitro drug release studies demonstrated satisfactory diffusion, concluding that both Carbopol grades are suitable for developing effective topical diclofenac sodium gel formulations.
7. Zinjad *et al.* (2022) formulated and evaluated diclofenac sodium gel using Carbopol 934 as a gelling agent. The gel was assessed for physicochemical parameters including pH, viscosity, spreadability, homogeneity, and drug content, all of which were within acceptable limits. In-vitro drug release studies demonstrated effective diffusion, indicating that Carbopol 934 is a suitable polymer for stable and efficient topical diclofenac gel formulations.
8. Manian *et al.* (2022) formulated and evaluated topical dermatological products containing diclofenac sodium to study their in-vitro performance. The formulations were assessed for physicochemical characteristics and in-vitro drug release behavior. The study reported that formulation composition significantly affects drug release and performance, concluding that optimized topical formulations can enhance the efficacy of diclofenac sodium for dermatological applications.
9. Kasparaviciene *et al.* (2024) developed and evaluated two-phase gel formulations containing sodium diclofenac and camphor to enhance topical delivery. The gels were assessed for physicochemical properties and in-vitro drug release, which showed improved diffusion and effectiveness. The study concluded that two-phase gels can be an efficient system for delivering active ingredients like diclofenac through the skin.
10. Ekka *et al.* (2024) prepared and evaluated a pain-relieving gel containing diclofenac and aceclofenac for topical application. The formulations were assessed for physicochemical properties such as pH, viscosity, spreadability, homogeneity, and drug content, which were found to be within acceptable limits. In-vitro drug release studies demonstrated effective diffusion of both drugs, indicating that the combined gel formulation is suitable for topical pain management.
11. Todmal *et.al* conducted research on the formulation and evaluation of diclofenac sodium gel using Carbopol 940 as a gelling agent. The prepared gel was evaluated for parameters such as pH, viscosity, spreadability, homogeneity, and drug content and showed acceptable results. In-vitro drug release studies indicated satisfactory diffusion, concluding that Carbopol 940 is a suitable polymer for developing stable and effective diclofenac sodium topical gel formulations.
12. Kokare and Shinde (2025) developed and evaluated a topical diclofenac gel to assess its physicochemical characteristics and in-vitro performance. The formulation was examined for parameters such as pH,

homogeneity, spreadability, viscosity, drug content, and skin irritation, all of which were found to be within acceptable limits. In-vitro diffusion studies showed a high percentage of drug release, indicating the effectiveness of the gel for topical anti-inflammatory therapy.

13. Adamiak-Giera *et al.* (2025) evaluated the in-vitro skin permeation of diclofenac sodium from Pentravan® transdermal formulations and Celugel hydrogel using human skin. The study assessed permeation parameters and drug diffusion behavior, showing effective penetration of diclofenac sodium through the skin. The findings confirmed that advanced transdermal bases and hydrogels can significantly influence drug permeation and enhance topical delivery of diclofenac sodium.

1.3 OBJECTIVES OF STUDY:

1. To formulate a topical gel dosage form of diclofenac sodium using suitable gelling agents.
2. For selecting and optimizing a certain concentration of gelation polymers such as Carbopol 934 or Carbopol 940 for proper gel formation.
3. To add appropriate excipients such as penetration enhancers and preservatives in the gel to enhance its efficiency and shelf life.
4. For assessing the pH value of the prepared gel to make sure that it is safe and skin-friendly.
5. In order to determine the viscosity and spreadability of the gel in relation to its application on the skin.
6. To evaluate the uniformity and consistency of diclofenac sodium in the gel formulation.

1.4 AREA OF STUDY: This project is mainly related to the subject of Pharmaceutics. It focuses on the development of a topical gel formulation of diclofenac sodium for the treatment of pain and inflammation. The study involves the preparation of a semi-solid dosage form and its evaluation for quality and performance.

The work comes under topical drug delivery systems, where the drug is applied directly to the skin to provide localized therapeutic effect. The project also includes the use of pharmaceutical polymers like Carbopol and the evaluation of important parameters such as pH, viscosity, spreadability, and drug content. Overall, this study combines formulation development and evaluation techniques to create a safe, effective, and easy-to-use topical gel, which can reduce the side effects associated with oral drug therapy.

1.5 MATERIALS AND METHODS:

Ingredients Used in Diclofenac Sodium Gel

1. Active Pharmaceutical Ingredient (API): Diclofenac Sodium (1% w/w)

Used for analgesic and anti-inflammatory activity.

2. Polymers (Gelling Agents): These polymers provide gel structure, viscosity, and stability:

- Carbopol 934 – Commonly used; provides good viscosity and clarity
- Carbopol 940 – Produces clear, smooth gels with high viscosity
- Hydroxypropyl Methylcellulose (HPMC) – Provides smooth texture and controlled release
- Sodium Carboxymethyl Cellulose (Na-CMC) – Improves viscosity and spreadability
- Natural Polymers (e.g., guar gum, xanthan gum) – Biocompatible and eco-friendly alternatives

3. Solvents / Vehicles

- Purified Water – Primary vehicle
- Ethanol / Isopropyl Alcohol – Enhances drug solubility and penetration

4. Neutralizing Agents

- Triethanolamine (TEA) – Adjusts pH and activates Carbopol gel formation
- Sodium Hydroxide (NaOH) – Alternative pH adjuster

5. Penetration Enhancers

- Propylene Glycol – Improves skin penetration and acts as humectant
- Glycerin – Enhances moisturization and drug diffusion

6. Preservatives

- Methyl Paraben
- Propyl Paraben
- Prevent microbial growth in the gel.

7. Other Excipients (Optional)

- Menthol / Camphor – Provides cooling effect and improves patient acceptability
- Perfume / Fragrance – Improves aesthetic appeal.

Equipment:

- Analytical balance
- Beakers
- Measuring cylinders
- Glass rod
- Magnetic stirrer
- pH meter
- Thermometer
- Spatula
- Clean airtight containers

Evaluation Tests:

- Physical appearance
- pH determination
- Homogeneity
- Viscosity
- Spreadability
- Drug content
- In-vitro drug release
- Skin irritation test

Strengths and Concerns:

- The formulation process is simple and easy to carry out
- Economical and non-toxic excipients were used
- The gel provides effective localized action
- Convenient topical application improves patient acceptance
- The study was restricted to in-vitro evaluation
- In-vivo and clinical assessments were not conducted
- Long-term stability testing was not performed

II. SOURCE OF DATA:

JOURNALS

• International Journal of Research and Reviews in Pharmacy and Applied science
• World Journal of Pharmaceutical Research
• International Journal of Pharmaceutics
• European Journal of Pharmaceutics and Biopharmaceutics
• Asian Journal of Pharmaceutical Education and Research
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