



Preparation and Evaluation of Diclofenac Sodium Transdermal Patch

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Received: 27 December 2025

Revised: 10 January 2026

Accepted: 29 January 2026

ABSTRACT:

The present study focuses on the formulation and evaluation of diclofenac sodium transdermal patches aimed at achieving sustained drug release, improved patient compliance, and minimized gastrointestinal side effects associated with oral administration. Patches were prepared using the solvent casting technique employing ethyl cellulose as the film-forming polymer and PEG-400 as the plasticizer and permeation enhancer. The prepared formulations were evaluated for physical appearance, thickness, weight uniformity, folding endurance, and moisture content. Among all the formulations, F4 exhibited optimal physical and mechanical properties, indicating its potential as a suitable transdermal delivery system for diclofenac sodium.

Keywords: Diclofenac sodium, transdermal patch, sustained release, PEG-400, ethyl cellulose, solvent casting method, Analgesic effect.

1. INTRODUCTION

Transdermal drug delivery systems (TDDS) offer an alternative route for systemic drug administration that avoids first-pass metabolism and improves bioavailability. They deliver drugs through the skin into the bloodstream, maintaining constant plasma concentrations and reducing side effects compared to oral routes. Diclofenac sodium, a non-steroidal anti-inflammatory drug (NSAID), is commonly used for pain and inflammation but is associated with plays a significant role in patch flexibility and stability. The comparison with conventional oral dosage forms revealed that transdermal patches provide improved patient compliance, reduced gastrointestinal side effects, and sustained analgesic effects.

ADVANTAGE OF DICLOFENAC SODIUM TRANSDERMAL PATCHES:

Avoids first-pass metabolism: The drug directly enters the systemic circulation through the skin, bypassing the liver. → Results in better bioavailability.

Sustained drug release: Provides controlled and prolonged release of diclofenac, maintaining a steady plasma concentration for longer periods.

Reduced dosing frequency: Patients need to apply the patch once a day or once every few days, improving convenience and compliance.

Minimized gastrointestinal side effects: Unlike oral diclofenac, transdermal delivery reduces gastric irritation, ulceration, and nausea.

Non-invasive and painless: No needles or swallowing required — suitable for patients with difficulty in taking oral medication.

DISADVANTAGE OF DICLOFENAC SODIUM TRANSDERMAL PATCHES:

Limited drug absorption: The drug penetration through the skin may be low, especially in thick or dry skin.

Skin irritation: Prolonged use may cause redness, itching, or rash at the site of application.

Slow onset of action: Compared to oral or injectable forms, drug action begins more slowly.

Dose limitation: Only a limited amount of diclofenac can be delivered through the skin; not suitable for severe pain or inflammation.

Adhesion problems: The patch may not stick properly if the skin is oily, sweaty, or hairy.

Routes of drug permeation through skin

| Route main class | Route sub class | Description |
|----------------------------|---|--|
| A. Transepidermal | 1. Transcellular (minor route) (intracellular) 2. Paracellular (major route) (intercellular) | Through the cell EX: lipophilic drugs. Between the cells EX: hydrophilic drugs |
| B. Transappendageal | 3. Via sweat glands (major route) 4. Via hair follicle (major route) (sebaceous gland) | Through the sweat glands Through the channels, presents besides the hair follicles |

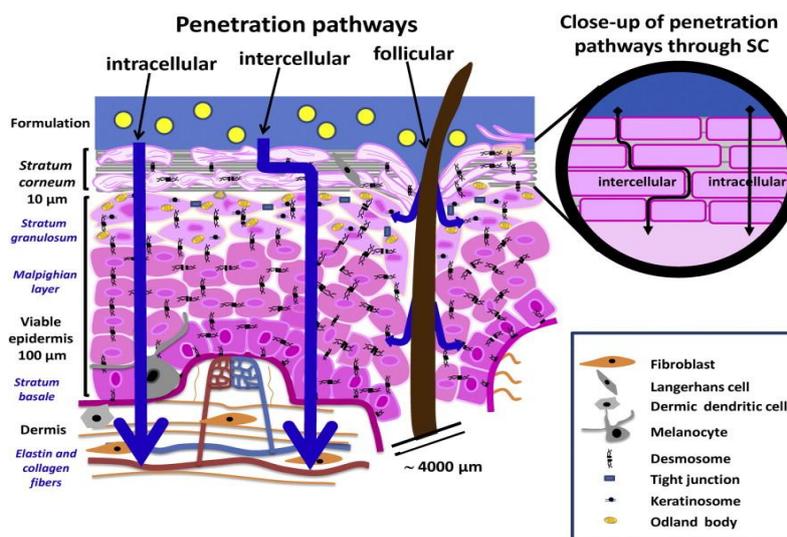


Figure 1: Routes of drug permeation through the skin

DRUG PROFILE: DICLOFENAC SODIUM

Generic Name: Diclofenac Sodium

Brand Names: Voltaren, Cataflam, Voveran, Zipsor, Zorvolex, etc.

Drug Class: Non-Steroidal Anti-Inflammatory Drug (NSAID)

Chemical Name: 2-[(2,6-Dichlorophenyl)amino]benzeneacetic acid sodium salt

Molecular Formula: C₁₄H₁₀Cl₂NNaO₂

Molecular Weight: 318.13 g/mol

Mechanism of Action : Inhibits cyclooxygenase enzymes (COX-1 and COX2). This reduces the synthesis of prostaglandins, which are mediators of inflammation, pain, and fever.

MATERIAL AND METHODS:

| INGREDIENTS | USES |
|--------------------------------|--------------------------------------|
| Diclofenac sodium | API |
| Ethyl cellulose | Film forming polymer |
| PEG-400 | Plasticizers and permeation enhancer |
| Ethanol and chloroform solvent | solvent |



METHODS: SOLVENT CASTING METHOD

Step 1: Preparation of Polymer Solution: Dissolve the polymer(s) in a suitable solvent or solvent mixture. Stir until a clear, homogeneous solution is obtained.

Step 2: Incorporation of Plasticizer: Add a plasticizer to the polymer solution to impart flexibility and elasticity to the patch.

Step 3: Drug Loading : Dissolve or disperse the drug in the polymeric solution. Mix thoroughly to ensure uniform distribution of the drug.

Step 4: Casting the Solution : Pour the resulting solution onto a leveled glass plate, petri dish or casting surface. Use a mercury substrate or Teflon mold if required for smooth removal. Spread evenly using a film applicator or adjustable casting knife.

Step 5: Drying : Allow the solvent to evaporate at controlled temperature (e.g., 30–50°C) and humidity. This forms a uniform, dry film.

Step 6: Cutting and Storage : Cut the dried film into desired size patches (usually 2–4 cm²). Store in airtight containers or between release liners until use.

EVALUATION

Physical appearance

The general appearance of TDDs its visual identity and all over elegance – **shape, colour, surface textures**. These all parameters are essential for consumer acceptance.

Thickness of the patch

The thickness of the drug loaded patch is measured in different points by using a digital micrometer and the average thickness and standard deviation is determined to ensure the thickness of the prepared patch. The thickness of transdermal film is determined by travelling microscope dial gauge, screw gauge or micrometer at different points of the film.

Weight uniformity

The prepared patches are dried at 60°C for 4hrs before testing. A specified area of patch is to be cut in different parts of the patch and weigh in digital balance. The average weight and standard deviation values are to be calculated from the individual weights.

Folding endurance

A strip of specific area is to be cut evenly and repeatedly folded at the same place till it breaks. The number of times the film could be folded at the same place without breaking gives the value of the folding endurance.

Percentage moisture content

The prepared films are to be weighed individually and to be kept in a desiccators containing fused calcium chloride at room temperature for 24 hrs. After 24 hrs the films are to be reweighed and determine the percentage moisture content from the below mentioned.

RESULT AND DISCUSSION

PHYSICAL APPEARANCE

| S.NO | PHYSICAL APPEARANCE | RESULT |
|------|---------------------|-----------|
| 1 | colour | Off white |
| 2 | Surface texture | smooth |
| 3 | shape | cube |



Figure 2: Transdermal patch.

Thickness of the patch

| S.NO | FORMULATION | THICKNESS |
|------|-------------|-----------|
| 1 | F1 | 0.245 |
| 2 | F2 | 0.252 |
| 3 | F3 | 0.259 |
| 4 | F4 | 0.272 |

Weight uniformity

| S.NO | FORMULATION | WEIGHT UNIFORMITY |
|------|-------------|-------------------|
| 1 | F1 | 590 |
| 2 | F2 | 593 |
| 3 | F3 | 594 |
| 4 | F4 | 598 |

Folding endurance:

| S.NO | FORMULATION | FOLDING ENDURANCE |
|------|-------------|-------------------|
| 1 | F1 | 25 |
| 2 | F2 | 24 |
| 3 | F3 | 26 |
| 4 | F4 | 30 |

% of moisture content

| S.NO | FORMULATION | Percentage of moisture content |
|------|-------------|--------------------------------|
| 1 | F1 | 5.2% |
| 2 | F2 | 5.03% |
| 3 | F3 | 5.12% |
| 4 | F4 | 3.77% |

Comparison study of diclofenac patch with Conventional dosage form

| S.NO | FEATURE | ORAL DICLOFENAC TABLET | TRANSDERMAL DICLOFENAC PATCH |
|------|--------------------------------|------------------------|------------------------------|
| 1 | Analgesic Efficiency | Effective | Effective less high |
| 2 | Gastrointestinal side -effects | Higher risk | Lower risk |
| 3 | Patient compliance | Moderate | Higher |
| 4 | Onset of action | Moderate | Faster |
| 5 | Overall Tolerability | Moderate | Higher |



DISCUSSION :

The present study aimed to formulate and evaluate transdermal patches of diclofenac sodium to provide sustained drug release and enhance patient compliance by avoiding gastrointestinal side effects associated with oral administration.

CONCLUSION :

The present study evaluated various formulations of diclofenac sodium transdermal patches based on physical appearance, folding endurance, percentage of moisture content, weight uniformity, and other relevant parameters. Among all the formulations, Formulation F4 exhibited superior characteristics demonstrating optimal drug release, acceptable mechanical strength, and stability.

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How to cite this article:

S.Divya et al. Ijppr.Human, 2026; Vol. 32 (2): 159-163.

Conflict of Interest Statement: All authors have nothing else to disclose.

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