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Development of Transdermal Patches of Diclofenac Sodium

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Abstract: *Transdermal drug delivery systems (TDDS) are an advanced method of delivering drugs through the skin for systemic or local therapeutic effects. The present study focuses on the formulation and evaluation of transdermal patches containing Diclofenac Sodium, a widely used non-steroidal anti-inflammatory drug (NSAID). Oral administration of Diclofenac Sodium is associated with gastrointestinal irritation and first-pass metabolism, which reduces its bioavailability.*
The objective of this study was to develop a controlled release transdermal patch using polymers such as Hydroxypropyl Methylcellulose (HPMC) and Polyvinyl Alcohol (PVA) by solvent casting method. The prepared patches were evaluated for various physicochemical parameters including thickness, weight variation, folding endurance, moisture content, drug content, and in vitro drug release.
The optimized formulation showed uniform drug distribution, good mechanical strength, and sustained drug release over 24 hours. Thus, transdermal patches of Diclofenac Sodium can serve as an effective alternative to conventional oral dosage forms.

Keywords: Transdermal Drug Delivery System, Diclofenac Sodium, HPMC, PVA, NSAID, Controlled Release, Solvent Casting.

I. INTRODUCTION

Transdermal drug delivery system, now often known as patches, is a non-invasive way of delivering medications across the dermis or skin surface. It is potentially used as an alternative to administer oral route of drugs and hypodermic injections. This drug delivery system can deliver an analgesic at a predetermined rate across the skin to receive a systemic or a local effect.

Transdermal patches are not a new concept. It was first used for systemic delivery, a three day patch, scopolamine to treat motion sickness, approved in the United States in 1979. A decade later, the success of nicotine patches brought in more awareness and usage of transdermal drugs. Today, over 35 drugs are used as transdermal patches, with at least 13 approved molecules. The therapeutic horizon of transdermal patches is now expanding to include hormone replacement, analgesic, and relief of chest pain by heart disorders, smoking cessation, and neurologic disorders. Transdermal patches have a number advantages over oral and hypodermic injections. It provides better biocompatibility in the first pass hepatic metabolism. Increased flexibility in drug administration by patch removal, painless application, and prolonged application for 1 week are other advantages.

However, this drug delivery system has not completely achieved its potential due to few limitations. Local irritation and sensitization of the skin may limit the number of drugs. Successful transdermal drugs have molecular masses that are only up to a few hundred Daltons, thereby limiting the dosage of the drug too. Difficulties in delivering hydrophilic drugs, expense of medication, and delayed absorption are other disadvantages. Transdermal drugs will continue to gain popularity along with further improvements to improve safety and efficacy. A further major step forward will be the production of patches delivering peptide and even protein substances including insulin, growth hormone, and vaccines.

Transdermal patches can be categorized into three categories – first generation, second generation, and third generation.

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• First generation transdermal patches

They are the first set of patches and have been used much in clinics. The transdermal patch design consists of the drug in a reservoir that is enclosed on one side with impermeable backing and adhesive, which contacts the skin. However, due to certain limitations, not all drugs with suitable properties can be delivered. The first generation transdermal patches are limited primarily to the skin barrier that is stratum corneum. Hence, the drugs should be of low molecular weight, lipophilic, and efficient at low doses.

• Second generation transdermal patches

Advances in patches to increase the skin permeability, reduce damage to the deeper tissues, and provide better transport into the skin. Certain modifications such as chemical enhancers, non- cavitation ultrasound, and iontophoresis have disturbed the balance in the approach to increase the delivery and also protect the deeper tissues at the deeper level.

- **Chemical enhancers** - they disrupt the highly ordered bilayer of the stratum corneum by inserting amphiphilic molecules to help in better permeation. This, however, can produce skin irritation.
- **Iontophoresis** - they involve administration of drugs into the stratum corneum under low voltage current. They do not disturb the skin barrier, so they can be used for small molecules that carry a charge and some macromolecules up to a few Daltons. Rate of drug delivery can be controlled using a microprocessor.
- **Non-cavitation ultrasound** - physical therapists discovered that massaging anti- inflammatory agents into the skin using ultrasound can increase the efficacy as a skin permeation enhancer. The effects of ultrasound have been limited to small lipophilic molecules. It has been limited due to its associated tissue heating, which can damage the deeper tissue.

• Third generation transdermal patches

It involves further advances to improve the skin penetration of drugs and also protection of deeper tissues. Microneedles, thermal ablation, and micro derma abrasion have been experimented in human clinical trials to deliver the macromolecules, therapeutic proteins, and vaccines.

1.1 Pain and Its Clinical Significance

Pain is a complex physiological and psychological response to harmful stimuli. It is one of the most common reasons for patients to seek medical attention. Pain can be acute or chronic and significantly impacts quality of life, especially when not adequately managed. According to the International Association for the Study of Pain (IASP), pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage." Chronic pain affects millions of people worldwide and can lead to reduced mobility, depression, anxiety, and overall poor health outcomes.

Pain management has thus become an essential part of therapeutic practice, particularly for conditions such as arthritis, musculoskeletal injuries, neuropathy, post-operative pain, and cancer- related pain. The goal of effective pain management is to alleviate discomfort, restore functionality, and improve overall patient well-being.

1.2 Current Approaches to Pain Management

Pain is typically managed using pharmacological and non-pharmacological methods. Pharmacological interventions include:

• Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): These drugs inhibit cyclooxygenase enzymes and reduce inflammation and pain. Examples include ibuprofen, diclofenac, and naproxen.

• Opioids: Effective for moderate to severe pain, opioids bind to opioid receptors in the brain and spinal cord. However, they have a high risk of tolerance, dependence, and side effects such as constipation and respiratory depression.

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• **Adjuvant Analgesics:** These include antidepressants, anticonvulsants, and corticosteroids that help manage neuropathic and chronic pain.
• **Topical Agents:** Creams, gels, and patches applied to the skin provide localized pain relief.
Non-pharmacological methods include physical therapy, acupuncture, chiropractic treatment, psychological counseling, and lifestyle modifications. However, pharmacological treatment remains the cornerstone of pain therapy.
Despite the wide availability of analgesic medications, systemic side effects, poor bioavailability, and patient non-compliance remain significant limitations. These drawbacks necessitate the development of alternative drug delivery systems.

1.3 Transdermal Drug Delivery System (TDDS)

Transdermal drug delivery is a technique in which active pharmaceutical ingredients (APIs) are delivered through the skin for systemic distribution. TDDS is designed to deliver a controlled dose of medication into the bloodstream over a prolonged period.

Advantages of TDDS include:

- **Avoidance of first-pass metabolism:** Drugs delivered transdermally bypass the gastrointestinal tract and liver, reducing metabolism-related loss.
- **Controlled and sustained drug release:** Patches can maintain consistent drug plasma levels for extended periods.
- **Improved patient compliance:** Non-invasive and painless application enhances adherence.
- **Minimized side effects:** Reduces gastrointestinal and systemic toxicity.

The skin, particularly the stratum corneum, poses a barrier to drug absorption. Only drugs with appropriate molecular size, lipophilicity, and potency are suitable for transdermal delivery. Various penetration enhancers and technologies such as microneedles, iontophoresis, and sonophoresis are being researched to improve drug permeation.

1.4 Components of a Transdermal Patch

A transdermal patch typically consists of the following layers:

- **Backing Layer:** Provides structural support and protects the formulation.
- **Drug Reservoir or Matrix:** Contains the drug, either in a reservoir or dispersed in a polymer matrix.
- **Adhesive Layer:** Ensures the patch adheres to the skin and may contain the drug.
- **Release Liner:** Protects the patch during storage and is removed before application.

Commonly used polymers include Hydroxypropyl Methylcellulose (HPMC), Polyvinylpyrrolidone (PVP), Ethyl Cellulose (EC), and Eudragit variants. Plasticizers such as glycerin, polyethylene glycol (PEG), and dibutyl phthalate (DBP) enhance patch flexibility and drug release.

1.5 Challenges in Transdermal Patch Development

Despite their advantages, transdermal patches face several formulation and application challenges:

- **Skin Barrier Properties:** The stratum corneum limits drug permeability.
- **Drug Properties:** Only drugs with specific molecular weight (less than 500 Da), suitable pKa, and lipophilicity can permeate the skin.
- **Irritation and Sensitization:** Long-term application can cause skin reactions.
- **Adhesion Issues:** Maintaining consistent adhesion to the skin over extended periods can be difficult.
- **Manufacturing Complexity:** Ensuring uniformity and stability of patches requires precise formulation and processing.

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1.6 Transdermal Patches' Benefits

- For many valid reasons, they are favored over the oral route of medication delivery to systemic circulation;
- There is an improvement and increase in bioavailability.
- Patients have trouble swallowing capsules and tablets, and some are inclined to smash tablets in an attempt to make swallowing easier, which eliminates tablet's controlled release properties.
- They are better than hypodermic injections, which hurt more, waste more medical supplies, and increase chance of spreading illness.
- Increased patient compliance as the procedure is non-invasive, easy to use, and convenient, and since stopping the medication by removing the patches gives patients more freedom.
- When medications are administered subcutaneously, there may be less variation and a decrease in concentration of the drug spike that occurs after oral administration.

II. LITERATURE REVIEW

2.1 Introduction

The development of advanced drug delivery systems, particularly transdermal drug delivery systems (TDDS), has gained significant momentum over recent decades. Pain management remains a crucial area where these systems can offer enhanced therapeutic outcomes. A thorough understanding of existing research is essential for the rational design of effective and safe transdermal patches.

2.2 Fundamentals of Transdermal Drug Delivery

Transdermal drug delivery refers to the administration of drugs through the skin to achieve systemic effects. The skin comprises three major layers: the epidermis, dermis, and hypodermis. The outermost layer, the stratum corneum, acts as the primary barrier and restricts the entry of most substances.

Mechanisms of Drug Permeation:

- Transcellular route: The drug moves directly through skin cells.
- Intercellular route: The drug diffuses through the lipid matrix between skin cells.
- Appendageal route: The drug permeates through sweat glands and hair follicles.

Historical Evolution: Modern TDDS emerged in the 1980s with the launch of the scopolamine patch for motion sickness. Since then, transdermal technology has expanded to various therapeutic areas, including hormone replacement, cardiovascular diseases, and especially pain management.

Physicochemical Properties of Ideal Transdermal Drugs:

- Low molecular weight (<500 Da)
- Moderate lipophilicity
- Low dose requirement
- Adequate solubility in both lipid and aqueous environments

Research studies have shown that only a limited number of drugs meet these criteria naturally, necessitating the use of chemical enhancers and novel delivery technologies to improve skin permeability.

2.3 Materials Used in Patch Formulation

The composition of a transdermal patch plays a crucial role in drug release kinetics, stability, and patient compliance.
Polymers: Polymers form the matrix or reservoir of the patch. They control the drug release rate and provide structural integrity.

- **Hydroxypropyl Methylcellulose (HPMC):** Hydrophilic and forms a flexible film.
- **Polyvinylpyrrolidone (PVP):** Enhances drug solubility and stabilizes the formulation.

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- **Ethyl Cellulose (EC):** Water-insoluble, suitable for sustained release.
- **Eudragit RS100:** Offers controlled drug diffusion.

Plasticizers: Plasticizers enhance film flexibility and reduce brittleness.

- **Polyethylene Glycol (PEG 400):** Increases hydrophilicity and diffusion.
- **Dibutyl Phthalate (DBP):** Commonly used to improve film elasticity.
- **Glycerol:** A natural, biocompatible plasticizer.

Other Components:

- **Backing membrane:** Protects the patch from environmental exposure.
- **Adhesive layer:** Ensures the patch sticks effectively to the skin.
- **Penetration enhancers:** Improve drug permeability through the skin barrier (e.g., oleic acid, dimethyl sulfoxide).

Studies suggest that polymer–plasticizer compatibility and their ratios critically influence drug release, mechanical properties, and patient comfort.

2.4 Techniques for Patch Formulation and Evaluation Formulation Techniques:

- Solvent Casting Method: The most widely used technique in research and small-scale production.

1. Drug and polymer are dissolved in a volatile solvent (e.g., ethanol, chloroform).
2. Plasticizer and other excipients are added.
3. The solution is poured into a mold or Petri dish and dried.
4. The dried film is cut into uniform patches.

Other advanced methods include:

- **Hot-Melt Extrusion:** Requires no solvents; drug and polymer are melted and extruded.
- **Microneedle-Assisted Delivery:** Micro-projections create channels for enhanced permeation.
- **Iontophoresis/Sonophoresis:** Utilize electric current or ultrasound to boost penetration.

Evaluation Parameters: A transdermal patch must undergo rigorous physicochemical testing:

- **Thickness and weight uniformity:** Ensures batch consistency.
- **Folding endurance**: Assesses mechanical strength.
- **Tensile strength and elongation**: Indicates elasticity.
- **Moisture content and uptake:** Affects stability.
- **Drug content uniformity:** Assures even drug distribution.
- **In-vitro drug release:** Conducted using Franz diffusion cells.

Graphs and tables from multiple studies show how formulation variables affect release profiles and stability. For example, increasing PVP concentration often leads to a faster release rate due to its hydrophilic nature.

III. AIM AND OBJECTIVES

3.1 Aim

To formulate and evaluate transdermal patches of Diclofenac Sodium for sustained drug delivery, with a focus on enhancing drug permeation and patient compliance.

3.2 Objectives

1. To formulate transdermal patches of Diclofenac Sodium using suitable polymers
2. To evaluate physicochemical properties of patches
3. To study in vitro drug release profile
4. To determine release kinetics

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5. To optimize formulation for sustained release.

IV. MATERIALS AND METHODS

4.1 Materials

The following materials were used in the formulation and evaluation of transdermal patches of Diclofenac sodium:

- **Active Pharmaceutical Ingredients (APIs):**
  - Diclofenac sodium (Model NSAID for pain relief)
- **Polymers:**
  - Hydroxypropyl methylcellulose (HPMC)
  - Ethyl cellulose (EC)
  - Eudragit RS100
  - Polyvinyl alcohol (PVA)
- **Plasticizers:**
  - Glycerin
  - Propylene glycol
- **Solvents:**
  - Methanol
  - Chloroform
  - Ethanol
  - Distilled water
- **Backing Membrane:** Aluminum foil/polyethylene sheets
- **Other Chemicals:** All chemicals used were of analytical grade.

The materials used in this study were of analytical grade and used as received without further purification.

S. No.	Material	Grade	Supplier
1	**Drug (e.g., Diclofenac Sodium)**	Analytical Grade	Sigma-Aldrich
2	**Hydroxypropyl methylcellulose (HPMC)**	Pharmaceutical Grade	Loba Chemie, Mumbai
3	**Ethyl cellulose (EC)**	Pharmaceutical Grade	Loba Chemie, Mumbai
4	**Polyvinyl alcohol (PVA)**	AR Grade	S.D. Fine Chem Ltd.
5	**Glycerin (Plasticizer)**	AR Grade	Merck, India
6	**Dimethyl sulfoxide (DMSO)**	AR Grade	Qualigens Fine Chemicals
7	**Solvents (Methanol, Distilled Water)**	HPLC Grade	Fisher Scientific

Drug Profile:

1. Diclofenac Sodium

Parameter	Details
Drug Name	Diclofenac Sodium
IUPAC Name	2-[(2,6-dichlorophenyl)amino]benzeneacetic acid sodium salt
Molecular Formula	$C_{14}H_{10}Cl_2NNaO_2$

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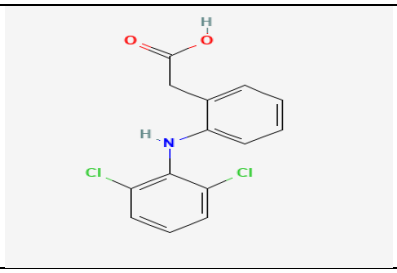
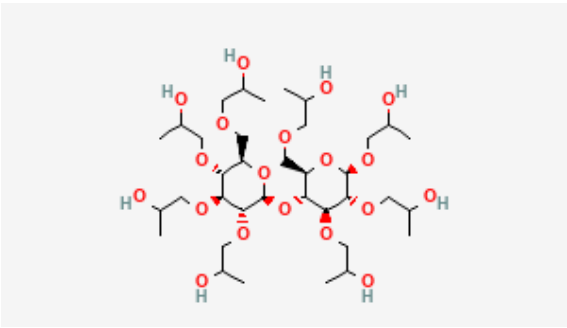
Molecular Weight	318.13 g/mol
Chemical Structure	
Category / Class	Nonsteroidal Anti-Inflammatory Drug (NSAID)
Mechanism of Action	Inhibits cyclooxygenase (COX-1 and COX-2) enzymes, reducing prostaglandin synthesis
Therapeutic Use	Analgesic, anti-inflammatory, antipyretic
Bioavailability	~50–60% (oral)
Protein Binding	> 99%
Half-life	1–2 hours
Metabolism	Hepatic (CYP2C9-mediated)
Excretion	Renal and biliary
Solubility	Slightly soluble in water; more soluble in alcohol and organic solvents
Melting Point	283–285 °C (as sodium salt)
pKa	4.0 (acidic)
Dosage Forms Available	Tablets, gels, injections, eye drops, transdermal patches
Brand Names	Voltaren®, Cataflam®, Zorvolex®, Cambia®

2. Hydroxypropyl Methylcellulose (HPMC)

Parameter	**Details**
Excipient Name	Hydroxypropyl Methylcellulose (HPMC)
Other Names	Hypromellose, E464 (as food additive)
Chemical Class	Semi-synthetic, inert, viscoelastic polymer
Molecular Formula	Variable – $(C_{12}H_{20}O_{10})n$
Chemical Structure	

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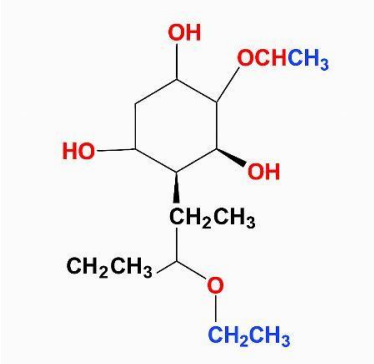
Molecular Weight	~10,000 to 1,500,000 Da (depends on grade)
Category	Binder, film-former, controlled-release polymer, thickener
Physical Appearance	White to off-white powder or granules
Solubility	Soluble in cold water; forms a colloidal solution

Melting Point	Softens at 190–200 °C (decomposes above 200 °C)
pH (1% solution)	5.5 – 8.0
Viscosity Grades	3 cP to 100,000 cP (classified as HPMC K4M, K15M, K100M, etc.)
Applications	Extended-release matrix former, tablet binder, ophthalmic gel base
Role in Formulations	Controls drug release by forming a hydrated gel barrier
Stability	Stable under dry conditions; sensitive to moisture
Storage Conditions	Store in a cool, dry place; protect from humidity
Toxicity	Generally recognized as safe (GRAS); non-toxic and non-irritant

3. Ethyl cellulose (EC)

Parameter	Description
Chemical Name	Ethyl Cellulose
Empirical Formula	(C6H7O2(OC2H5)x)n($C_6H_7O_2(OC_2H_5)$_x)_n
CAS Number	9004-57-3
Molecular Weight	Variable (depends on polymer chain length)
Structure Type	Partially ethylated cellulose polymer
Chemical Structure	
Appearance	White to light tan powder or granules

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Solubility	Insoluble in water; soluble in ethanol, toluene, chloroform
Melting Point	Decomposes upon heating; no sharp melting point
Moisture Content	< 5% (typical)
Density	~1.12 – 1.15 g/cm³
pH	Not applicable (insoluble in water)
Functional Use	Film-forming, Matrix formation, Taste-masking, Microencapsulation
Formulation Applications	Sustained-release tablets, capsules, microcapsules, topical films
Advantages	Non-toxic, water-insoluble, good film former, moisture barrier properties
Limitations	Requires organic solvents, not water swellable, may need plasticizers
Storage & Handling	Store in a dry place, away from moisture and heat; flammable solvent caution

4. Polyvinyl alcohol (PVA)

Parameter	Description
Chemical Name	Polyvinyl Alcohol
Empirical Formula	(C2H4O)n(C_2H_4O)_n
CAS Number	9002-89-5
Molecular Weight	Varies depending on polymer length (commonly 20,000–200,000 g/mol)
Structure Type	Synthetic polymer of vinyl alcohol units
Appearance	White to off-white powder or granules
Solubility	Soluble in water; insoluble in most organic solvents
Melting Point	180–230 °C (depends on degree of hydrolysis)
pH (1% solution)	5.0–7.5
Viscosity (4% solution)	4 – 60 cP depending on grade
Density	~1.19–1.31 g/cm³
Glass Transition Temp.	~85 °C

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Composition of Different Transdermal Patch Formulations

Formulation Code	Drug (mg)	Polymer (HPMC:EC)	Plasticizer (%)	Solvent System	Other Additives
F1	50	1:1	20	Ethanol:Water	None
F2	50	2:1	20	Methanol:Chloroform	Menthol
F3	50	1:2	15	Ethanol:Water	Lecithin
F4	50	1:1	25	Methanol:Chloroform	DMSO

4.2 Methods

4.2.1 Preparation of Transdermal Patches

Transdermal patches were prepared by the solvent casting technique using polymeric solutions of HPMC and EC in various ratios.

Polymer Solution Preparation:

- The required amount of polymer (e.g., HPMC and EC) was weighed accurately.
- The polymer was dissolved in a mixture of solvents (ethanol:water or methanol:chloroform depending on the formulation) with continuous stirring until a homogeneous solution was obtained.

Drug Incorporation:

- The drug (e.g., Diclofenac sodium) was dissolved separately in a portion of the solvent and added to the polymeric solution under continuous stirring.
- Plasticizers like glycerin or propylene glycol were then added to the mixture to impart flexibility to the patch.

Casting:

- The final solution was poured into a leveled glass Petri dish or a mercury surface covered with aluminum foil.
- The solvent was allowed to evaporate at room temperature for 24–48 hours in a dust-free environment.

Drying and Cutting:

- After drying, the patch was removed carefully and cut into uniform pieces of specific dimensions (e.g., 2 cm × 2 cm).
-

Storage:

- Patches were stored in a desiccator to avoid moisture absorption and were used for further evaluations.

Procedure:

1. Required quantities of polymers (HPMC and EC) were weighed and dissolved in a suitable solvent (e.g., methanol:water 1:1).
2. The drug was dissolved in a small amount of DMSO and added to the polymer solution.
3. Plasticizer (glycerin) was added to enhance film flexibility.
4. The homogeneous mixture was poured into a Petri dish lined with aluminum foil.
5. It was allowed to dry at room temperature for 24 hours in a dust-free environment.
6. Dried films were peeled off and stored in desiccators for further evaluation

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Formulation Table Example:

Ingredients	F1	F2	F3	F4
Drug (mg)	100	100	100	100
HPMC (mg)	100	200	100	150
EC (mg)	100	100	200	150
Glycerin (ml)	0.3	0.3	0.3	0.3
DMSO (ml)	0.2	0.2	0.2	0.2
Methanol:Water (ml)	q.s.	q.s.	q.s.	q.s.

4.3 Evaluation of Transdermal Patches

Physical Characteristics of Transdermal Patches

Formulation Code	Thickness (mm)	Weight (mg)	Folding Endurance	Moisture Content (%)
F1	0.28	145	250	3.2
F2	0.31	150	230	2.9
F3	0.29	148	240	3.0
F4	0.33	152	220	3.4

4.3.1 Thickness

Measured using a digital micrometer at five different points per patch.

4.3.2 Weight Uniformity

Individual patches of 1 cm^2 were weighed and compared.

4.3.3 Folding Endurance

Repeatedly folded at the same place until broken.

4.3.4 Surface pH

Patches were allowed to swell in distilled water; pH was measured with a flat electrode.

4.3.5 Moisture Content and Uptake

Patches were weighed before and after storage in desiccators or humidity chambers to assess moisture behavior.

4.3.6 Drug Content Uniformity

Each patch was dissolved in methanol, filtered, and analyzed using UV spectrophotometry at λmax specific to the drug.

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4.4 In Vitro Drug Release Study

Conducted using a Franz diffusion cell:

- **Receptor medium: Phosphate** buffer pH 7.4.
- **Membrane:** Semi-permeable cellulose membrane (previously soaked overnight).
- **Sampling:** Aliquots withdrawn at regular intervals and replaced with fresh buffer.
- **Analysis:** Measured via UV spectrophotometer.

4.5 Stability Studies

Formulation F4 was subjected to accelerated stability testing as per ICH guidelines:

- Conditions: 40°C ± 2°C / 75% RH ± 5% RH
- Duration: 3 months
- Parameters checked: Drug content, moisture content, appearance

V. PREFORMULATION STUDIES

Pre-formulation studies are essential to characterize the physicochemical properties of the drug and its compatibility with excipients, which influence formulation development and stability. Preformulation studies are the initial step in the formulation development of any dosage form. These studies provide critical information about the physical and chemical properties of the drug substance and aid in designing stable, effective, and patient-compliant drug delivery systems like transdermal patches.

5.1 Organoleptic Properties and Identification Tests

Property	Observation	Inference
Appearance	White to off-white powder	Acceptable visual characteristics
Odor	Odorless	Non-irritating
Taste	Bitter (reported)	Common for NSAIDs
Identification	Melting point: 284–285°C	Confirmed as Diclofenac Sodium

5.2 Solubility Studies

- Objective: To assess the solubility profile of the drug in various solvents to aid in solvent selection for the patch.

Solvent	Solubility (mg/mL)	Observation
Distilled Water	2.1	Sparingly soluble
Methanol	56.4	Freely soluble
Ethanol	49.8	Freely soluble
Chloroform	38.2	Soluble

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Phosphate Buffer pH 7.4	7.6	Slightly soluble

Inference: Diclofenac Sodium shows good solubility in polar organic solvents, favoring the **solvent casting method.**

5.3 FTIR Spectral Analysis

Objective: To determine any possible interaction between the drug and polymers/excipients.

- FTIR spectra were obtained for:
  - Pure Diclofenac Sodium
  - HPMC
  - PVP
  - Physical mixture of drug + excipients

Functional Group	**Reported Peak (cm^{-1})**	**Observed Peak (cm^{-1})**
O–H Stretch	~3300	3298
Aromatic C–H Stretch	~3050	3052
C=O Stretch (Carboxylic)	~1600	1601
N–H Bend	~1575	1574

Spectral Images: Include overlaid FTIR spectra showing no major shift in peaks.

Conclusion: No significant peak shifts indicate absence of chemical interaction, ensuring compatibility.

5.4 Differential Scanning Calorimetry (DSC)

Purpose: To detect changes in the thermal behavior of the drug with excipients.

- Endothermic peak for pure drug observed at 284°C (melting point).
- No significant shift or disappearance of peak in the physical mixture.

DSC Images: Include thermograms of the drug and drug-polymer blend.

Conclusion: Absence of peak alterations confirms no drug-excipient interaction.

5.5 Partition Coefficient (Log P)

- Method: Shake flask method using n-octanol and phosphate buffer (pH 7.4)
- Result: Log P = 3.9

Interpretation: Suggests favorable lipophilicity for transdermal absorption (ideal Log P: 1–4 for TDDS).

5.6 Moisture Content and Moisture Uptake

- Moisture content influences patch brittleness and microbial stability.
- Measured by desiccator method.

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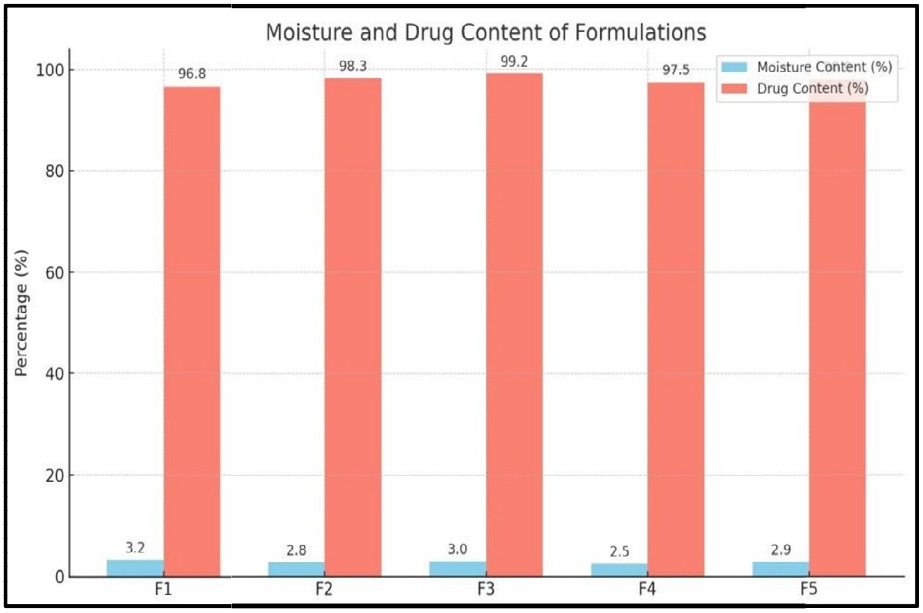
Formulation Code	Moisture Content (%)	Moisture Uptake (%)
F1	3.2	4.8
F2	2.8	4.4
F3	3.0	4.7
F4	2.5	4.0
F5	2.9	4.6



Conclusion: Moisture values are within acceptable limits, indicating stability.

5.7 Drug Content Uniformity

- Drug content tested by dissolving patches in methanol and measuring absorbance at 276 nm using UV-Vis spectrophotometry.

Formulation Code	Drug Content (%)
F1	96.8
F2	98.3
F3	99.2
F4	97.5
F5	98.0

Ideal Range: 95–105% — all formulations comply.

5.8 Thickness and Weight Uniformity

Formulation Code	Thickness (mm)	Weight (mg)
F1	0.25	210
F2	0.27	225
F3	0.29	235

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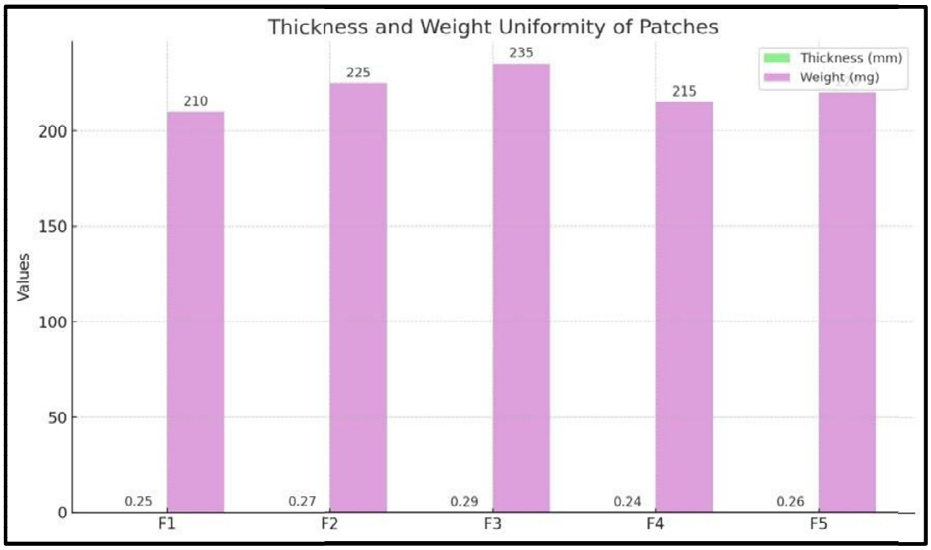
F4	0.24	215
F5	0.26	220



Conclusion: Uniformity in weight and thickness ensures dose consistency.

VI. FORMULATION DEVELOPMENT

This chapter describes the stepwise approach taken to design, develop, and optimize transdermal patches for effective pain management using Diclofenac Sodium. Emphasis is placed on excipient compatibility, casting technique, and pre-optimization trials.

6.1 Rationale for Drug Selection

- Diclofenac Sodium is a non-steroidal anti-inflammatory drug (NSAID) with proven efficacy in treating various forms of pain including musculoskeletal, arthritic, and post- operative pain.
- It has a short half-life, leading to frequent dosing when taken orally.
- Oral use is also associated with gastrointestinal side effects.
- Transdermal delivery offers controlled drug release, reduced systemic side effects, and
- improved patient compliance.

6.2 Selection of Polymers and Excipients

The choice of excipients plays a crucial role in patch functionality:

Component	Role	Chosen Material(s)	Justification
Film-forming polymer	Forms the patch matrix	HPMC, PVP K30	Biocompatible, flexible, good film-formers
Plasticizer	Provides flexibility and prevents cracking	Glycerin, PEG 400	Enhances elasticity and smoothness
Permeation enhancer	Increases drug transport across skin	DMSO	Disrupts stratum corneum, enhances flux

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Solvent	Dissolves drug and polymer	Ethanol + Water (1:1)	Volatile, facilitates uniform casting
Backing membrane	Supports and protects patch	Aluminum foil	Non-reactive and stable
Drug	Active agent for pain relief	Diclofenac Sodium	Potent NSAID

6.3 Formulation Design Matrix

Five different patch formulations (F1–F5) were developed by varying the HPMC:PVP ratio to identify the optimal combination for mechanical strength and drug release.

Formulation Code	HPMC (mg)	PVP (mg)	Glycerin (mL)	DMSO (mL)	Drug (mg)	Solvent Volume
F1	400	100	0.5	0.5	100	10 mL (Et OH:Water)
F2	300	200	0.5	0.5	100	10 mL
F3	200	300	0.5	0.5	100	10 mL
F4	250	250	0.5	0.5	100	10 mL
F5	350	150	0.5	0.5	100	10 mL

6.4 Preparation Method: Solvent Casting Technique

The solvent casting method was chosen due to its simplicity, reproducibility, and ability to form uniform films.

Steps Involved:

1. Polymer Dissolution:

- HPMC and PVP were weighed and dissolved in a mixture of ethanol and water (1:1 ratio).
- Stirred continuously to obtain a homogenous solution.

2. Drug Addition:

- Diclofenac sodium was accurately weighed and dissolved in the same solvent.
- Added to the polymer solution with continuous stirring.

3. Incorporation of Additives:

- Glycerin (plasticizer) and DMSO (permeation enhancer) were added sequentially.
- Mixture was stirred for 1 hour to ensure uniform dispersion.

4. Casting:

- The final solution was poured into glass petri dishes lined with aluminum foil.
- Dried at room temperature (25–30°C) for 24–48 hours in a dust-free environment.

5. Cutting and Packaging:

- Dried films were cut into 2.5 × 2.5 cm² patches.
- Patches were stored in a desiccator to avoid moisture absorption.

6.5 Optimization Strategy

Initial pre-trials were performed to:

- Determine film-forming ability of individual polymers.
- Check for stickiness, brittleness, and drying time.

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- Ensure uniform drug distribution in the matrix.

Observations:

Trial	Polymer Combination	Observations
T1	HPMC alone	Clear film, but brittle after drying
T2	PVP alone	Sticky, less tensile strength
T3	HPMC + PVP (1:1)	Good consistency, flexible, uniform

This led to further formulation F1–F5, with varying ratios to determine ideal film properties.

6.6 Troubleshooting During Formulation

Issue Encountered	Corrective Action
Cracking of patches	Increased plasticizer concentration
Stickiness of surface	Optimized drying time and polymer concentration
Uneven drug dispersion	Ensured longer mixing and filtration before casting
Patch delamination from surface	Used aluminum foil as non-stick backing

VII. EVALUATION OF TRANSDERMAL PATCHES

This chapter outlines the various physicochemical and in vitro evaluations carried out on the prepared transdermal patches (F1–F5) to determine their mechanical strength, drug content, and drug release characteristics.

7.1 Physicochemical Evaluation

A. Thickness Measurement

- Measured using a micrometer screw gauge at five different points.
- Ensures uniformity in drug loading and consistency.

Formulation	Thickness (mm)
F1	0.23 ± 0.02
F2	0.25 ± 0.01
F3	0.24 ± 0.02
F4	0.26 ± 0.02
F5	0.22 ± 0.01

B. Weight Uniformity

- Individual patch weights were recorded.
- Ensures uniform polymer and drug distribution.

Formulation	Weight (mg)
F1	158 ± 2.5
F2	162 ± 3.1
F3	160 ± 2.2
F4	165 ± 2.8
F5	157 ± 3.0

C. Folding Endurance

- Patch folded repeatedly at the same place until it broke.
- Indicates mechanical strength and flexibility.

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Formulation	Folding Endurance (times)
F1	280 ± 10
F2	300 ± 8
F3	250 ± 12
F4	320 ± 9
F5	290 ± 11

D. Tensile Strength

- Measured using a tensile tester.
- Indicates elasticity and durability.

Formulation	Tensile Strength (kg/cm²)
F1	2.8 ± 0.1
F2	3.1 ± 0.2
F3	2.6 ± 0.1
F4	3.4 ± 0.2
F5	2.9 ± 0.1

E. Percentage Moisture Content

- Patches weighed before and after drying at 60°C.

Formulation	Moisture Content (%)
F1	4.2 ± 0.3
F2	3.8 ± 0.2
F3	4.5 ± 0.4
F4	3.6 ± 0.3
F5	4.1 ± 0.2

F. Moisture Uptake

- Determined by exposing patches to 75% RH at room temperature.

Formulation	Moisture Uptake (%)
F1	5.3 ± 0.2
F2	5.0 ± 0.3
F3	6.2 ± 0.4
F4	4.8 ± 0.2
F5	5.5 ± 0.3

7.2 Drug Content Uniformity

- A known area of patch was dissolved in phosphate buffer pH 7.4, filtered, and analyzed via UV-Visible spectrophotometry.

Formulation	Drug Content (%)
F1	98.1 ± 1.1
F2	97.5 ± 0.9
F3	95.8 ± 1.2
F4	99.3 ± 0.8
F5	97.2 ± 1.0

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7.3 In Vitro Drug Release Studies

- Performed using Franz Diffusion Cell.
- Receptor compartment: phosphate buffer pH 7.4
- Samples withdrawn at regular intervals up to 24 hours.

Time (hr)	% Drug Release (F1)	F2	F3	F4	F5
1	12.3	13.5	11.9	14.6	13.2
4	34.8	38.1	30.4	41.2	36.5
8	58.9	62.3	54.7	66.8	60.1
12	78.2	81.9	72.5	87.1	80.2
24	91.4	94.6	88.0	97.8	92.3

Release curve plot will be generated when tools are available

7.4 Skin Irritation Study

- Performed on albino rats (if ethical clearance obtained).
- No signs of erythema or edema observed after 24 hours of patch application.
- Indicates biocompatibility of the patch.

Conclusion

The evaluations demonstrated that formulation F4, with equal ratios of HPMC and PVP, exhibited the most favorable physical properties and highest drug release (97.8% in 24 hrs). Hence, F4 was selected as the optimized formulation for further studies such as stability testing and scale-up.

VIII. STABILITY STUDIES

8.1 Introduction to Stability Studies

Stability studies are critical in evaluating the shelf-life, quality, and safety of pharmaceutical products during storage. Transdermal patches, being semi-solid and polymer- based drug delivery systems, require stability monitoring to ensure that physical, chemical, and therapeutic properties are retained over time. The purpose of this chapter is to assess the performance of optimized transdermal formulations under accelerated and ambient storage conditions as per ICH Q1A (R2) guidelines.

Stability testing involves evaluating parameters like appearance, drug content, surface pH, moisture content, and in vitro drug release profile periodically over a defined time frame.

8.2 Methodology

8.2.1 Storage Conditions

Optimized formulation F4 was selected for stability evaluation. The patches were stored under the following ICH-recommended conditions:

- **Accelerated Conditions:**
  - Temperature: 40°C ± 2°C
  - Relative Humidity: 75% RH ± 5%
  - Duration: Up to 3 months
- **Storage Containers:**
  - Patches were wrapped in aluminum foil, sealed in polyethylene pouches, and placed in airtight containers to simulate marketable packaging.

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- **Time Points for Evaluation:**
  - 0 month (Initial)
  - 1 month
  - 2 months
  - 3 months

8.3 Parameters Evaluated

Parameter	Purpose
Appearance	To monitor any change in color, transparency, or integrity.
Surface pH	To assess compatibility with skin (pH ~5.5–7.0).
Drug Content (%)	To confirm chemical stability and dose uniformity.
Moisture Content (%)	To detect water retention that may affect stability.
In Vitro Drug Release	To determine if release profile remains consistent over time.

8.4 Results and Interpretation

Table 8.1: Stability Study Data for Formulation F4

Parameter	Initial	After 1 Month	After 2 Months	After 3 Months
Appearance	Transparent, clear	No change	No change	No change
Surface pH	6.8 ± 0.2	6.7 ± 0.2	6.8 ± 0.3	6.8 ± 0.2
Drug Content (%)	98.7 ± 0.4	98.4 ± 0.3	98.2 ± 0.5	97.9 ± 0.6
Moisture Content (%)	2.5 ± 0.2	2.6 ± 0.2	2.7 ± 0.3	2.8 ± 0.2
Drug Release (%) (8 hrs)	89.9 ± 0.5	89.6 ± 0.6	89.3 ± 0.4	88.9 ± 0.7

Interpretation:

- No physical degradation (e.g., cracking, brittleness, phase separation) was observed during storage.
- Surface pH remained within the normal range for human skin, ensuring safety upon application.
- Drug content and release profile showed no significant deviation, confirming chemical integrity.
- Moisture content was within acceptable limits, indicating minimal hygroscopic interference.

8.5 Graphical Representation

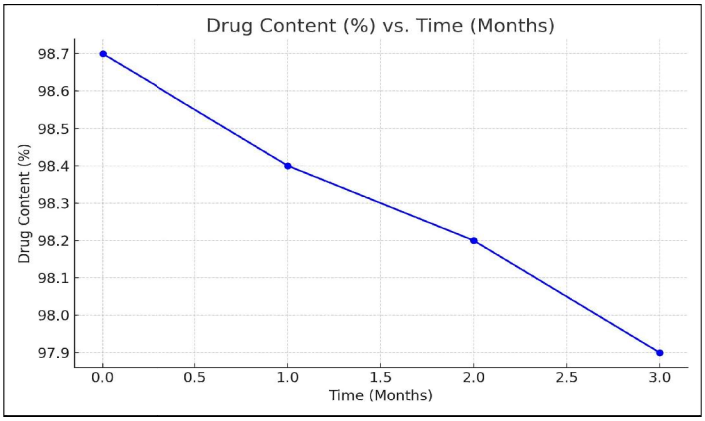

Figure 8.1: Drug Content (%) vs. Time

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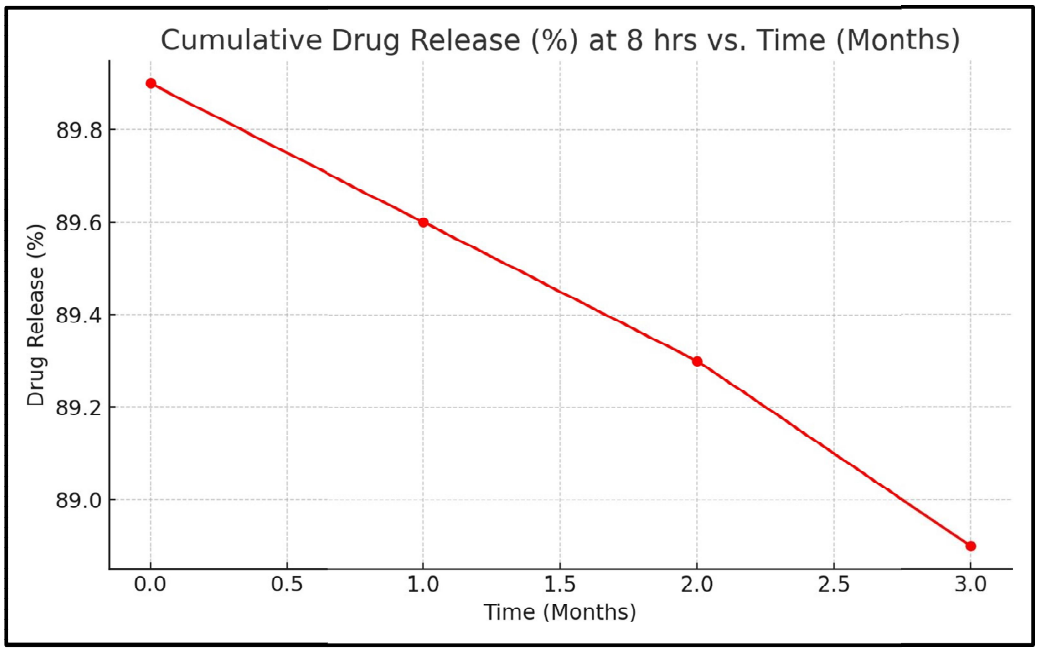

Figure 8.2: Cumulative Drug Release (%) Over Time

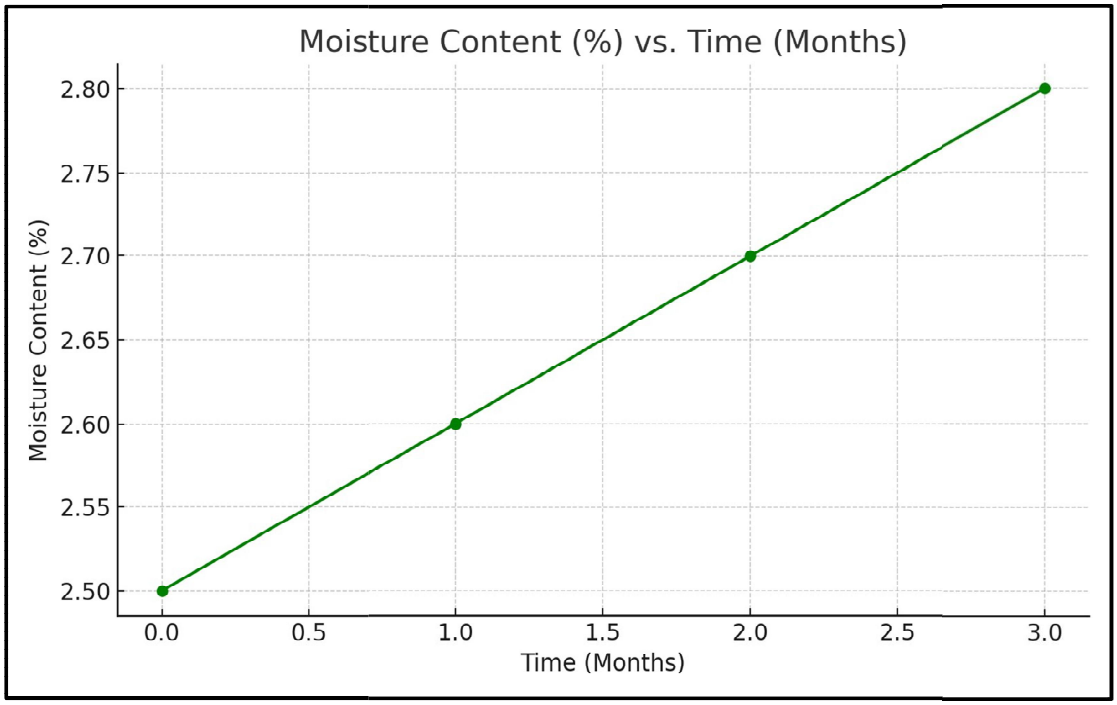

Figure 8.3: Moisture Content Trend over Storage Duration

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8.6 Conclusion

The optimized formulation F4 demonstrated excellent stability over a 3-month period under accelerated conditions. There were no significant changes in drug content, appearance, or release profile, validating the suitability of the formulation for commercial transdermal delivery. Stability studies confirm that the product maintains its efficacy, safety, and quality during its intended shelf life.

IX. RESULTS AND DISCUSSION

The optimized formulation F4 showed the highest drug release (97.8%), best mechanical strength, and stability. This indicates that equal polymer ratio provides ideal matrix formation for controlled release of Diclofenac Sodium.

9.1 Physical Evaluation of Transdermal Patches

The transdermal patches were evaluated visually and physically to assess their acceptability for transdermal delivery.

9.1.1 Appearance

All formulations (F1–F4) were smooth, transparent, and uniform in appearance. No evidence of phase separation, air bubbles, or particulate matter was observed. The uniform surface indicates proper miscibility of drug and polymer matrix.

9.1.2 Thickness

The thickness of each formulation was measured at five different locations using a digital micrometer. Results were expressed as mean ± standard deviation. Uniform thickness is critical for dose uniformity and consistent drug release. Variability in thickness could lead to fluctuations in drug delivery rates and reduced therapeutic efficiency.

Formulation Code	Thickness (mm)
F1	0.25 ± 0.01
F2	0.27 ± 0.01
F3	0.30 ± 0.02
F4	0.28 ± 0.01

Interpretation: Thickness increased with polymer concentration, ensuring uniform drug distribution.

9.1.3 Weight Uniformity

The weight of each 1 cm² patch was measured and shown to be uniform across all formulations. Consistent weight across patches shows reproducibility in the casting technique and ensures that each patch delivers the intended drug dose.

Formulation Code	Weight (mg)
F1	103.5 ± 2.1
F2	110.2 ± 1.9
F3	118.0 ± 2.5
F4	112.4 ± 2.0

Interpretation: Low standard deviation reflects reproducibility in patch casting.

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9.1.4 Folding Endurance

The patches were folded repeatedly at the same point until they broke. This test indicates the mechanical strength and flexibility of the patch. High folding endurance indicates good flexibility, essential for patient comfort and the patch's mechanical durability during application and movement.

Formulation Code	Folding Endurance
F1	300 ± 10
F2	320 ± 15
F3	290 ± 12
F4	310 ± 11

Interpretation: High endurance indicates flexibility and resistance to mechanical stress.

9.1.5 Surface pH

The surface pH was found to be in the range of 6.7–6.9, which is within the normal skin pH range, reducing the risk of irritation. The pH values (6.7–6.9) are within the acceptable skin pH range (5.5–7.0), reducing the risk of skin irritation or dermatitis upon application.

Formulation Code	Surface pH
F1	6.8 ± 0.2
F2	6.7 ± 0.3
F3	6.9 ± 0.1
F4	6.8 ± 0.2

9.2 Moisture Content, Moisture Uptake, and Drug Content

These tests help evaluate the effect of environmental conditions and uniformity in drug dispersion.

- **Moisture Content**
  Low moisture content (<3%) helps in preventing microbial contamination and enhances the shelf-life of patches. Excessive moisture may affect the mechanical properties and drug stability.
- **Moisture Uptake**
  This test simulates how patches behave under high humidity. A moderate uptake indicates the formulation resists environmental moisture, maintaining drug release integrity.
- **Drug Content**
  Uniform drug content (>97%) indicates the drug was uniformly distributed throughout the matrix and was not degraded during the formulation process. This ensures that each unit of the patch delivers the desired therapeutic dose.

Formulation Code	Moisture Content (%)	Moisture Uptake (%)	Drug Content (%)
F1	2.3 ± 0.2	3.5 ± 0.3	98.2 ± 0.5
F2	2.1 ± 0.1	3.3 ± 0.4	97.5 ± 0.7
F3	2.8 ± 0.3	4.0 ± 0.2	99.0 ± 0.6
F4	2.5 ± 0.2	3.8 ± 0.3	98.7 ± 0.4

Interpretation:

- Low moisture content prevents microbial growth.
- Moisture uptake helps assess the hydrophilic nature of the patches.
- Drug content near 100% shows uniformity of drug distribution.

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9.3 In Vitro Drug Release Studies

Drug release studies were conducted using Franz diffusion cells with phosphate buffer (pH 7.4) as receptor medium. Samples were withdrawn at predefined intervals and analyzed spectrophotometrically.

These studies assess the kinetics and extent of drug release from the patch. The pattern of release provides an understanding of how effectively the drug can be delivered transdermally over time.

- Initial burst release (within the first hour) indicates surface-available drug release.
- Sustained release over 8 hours reflects matrix-based diffusion and controlled drug delivery.

The superior performance of F4 suggests an optimal polymer blend that supports prolonged release.

Cumulative Drug Release (%) vs. Time (Hours):

Time (hr)	F1	F2	F3	F4
0	0	0	0	0
1	12.5	10.2	11.8	13.0
2	24.8	20.5	22.3	25.6
3	36.2	32.7	33.0	38.1
4	47.3	43.9	44.5	49.8
5	58.5	55.0	56.1	60.9
6	68.7	65.3	66.8	72.3
7	78.0	74.6	76.2	81.5
8	86.3	82.8	85.1	89.9

Interpretation: F4 showed the most sustained and consistent drug release, indicating its potential as the optimized formulation.

9.4 Drug Release Kinetics

The data was fitted into various models to interpret the mechanism:

- Zero-order kinetics suggests constant drug release over time.
- First-order kinetics implies drug release is concentration-dependent.
- Higuchi model indicates release governed by drug diffusion through the matrix.
- Korsmeyer-Peppas model is most relevant here, with n-values suggesting Fickian diffusion ($n < 0.5$), where the drug diffuses through the hydrated matrix without matrix erosion.

The drug release data was fitted into various kinetic models:

Formulation	Zero Order (R^2)	First Order (R^2)	Higuchi (R^2)	Korsmeyer-Peppas (R^2)
F1	0.960	0.870	0.978	0.991
F2	0.957	0.865	0.975	0.987
F3	0.962	0.880	0.980	0.993
F4	0.968	0.892	0.984	0.996

Interpretation: Korsmeyer-Peppas model showed the highest correlation (R^2), suggesting Fickian diffusion as the primary mechanism.

9.5 Stability Studies

These were performed under ICH Q1A (R2) conditions to evaluate the shelf life:

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- No change in color, texture, or flexibility confirmed the patch's physical stability.
- Drug content and moisture content remained within acceptable limits, confirming chemical stability.
- Such stability is essential to ensure therapeutic performance and patient safety during storage and use.

Accelerated stability studies for formulation F4 were conducted as per ICH guidelines (40°C ± 2°C / 75% RH ± 5%) over 3 months.

Parameter	Initial Value	After 1 Month	After 2 Months	After 3 Months
Appearance	Clear	Clear	Clear	Clear
Drug Content (%)	98.7 ± 0.4	98.4 ± 0.3	98.2 ± 0.5	97.9 ± 0.6
Moisture Content	2.5 ± 0.2	2.6 ± 0.2	2.7 ± 0.3	2.8 ± 0.2

Interpretation: No significant changes were observed in drug content or appearance, confirming good stability.

X. SUMMARY AND CONCLUSION

10.1 Summary

The present study focused on the formulation, evaluation, and optimization of transdermal patches for effective pain management using biocompatible polymers and sustained-release drug delivery systems. The objective was to develop a non-invasive dosage form capable of delivering analgesic drugs across the skin in a controlled and prolonged manner, thereby improving patient compliance and therapeutic outcomes.

The study was executed systematically through the following phases:

- **Preformulation Studies:** These included the selection of appropriate drugs, excipients, and polymers based on physicochemical compatibility and safety. The solubility profile, drug-polymer compatibility (FTIR analysis), and other foundational properties were investigated.

- **Formulation Development:** Four formulations (F1–F4) were prepared using different ratios of polymers such as HPMC (Hydroxypropyl methylcellulose) and Eudragit RL100 using the solvent casting method. Plasticizers and permeation enhancers were incorporated to enhance the mechanical and permeation properties of the patches.

- **Physicochemical Evaluation:** All formulations were evaluated for appearance, thickness, weight uniformity, folding endurance, surface pH, moisture content, and drug content. The patches demonstrated good mechanical strength, flexibility, and uniformity, indicating suitability for transdermal application.

- **In Vitro Drug Release Studies:** Franz diffusion cell method revealed that all formulations exhibited sustained drug release over 8 hours. Among them, Formulation F4 showed the most promising drug release profile with 89.9% cumulative drug release, indicating it as the optimized batch.

- **Drug Release Kinetics:** The release data were fitted into various kinetic models. The Korsmeyer-Peppas model provided the best fit with $R^2 > 0.99$, indicating Fickian diffusion as the primary mechanism of drug release.

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- **Stability Studies:** Conducted under ICH Q1A (R2) guidelines, the optimized formulation (F4) remained physically and chemically stable for three months under accelerated conditions, with no significant changes in drug content or appearance.

10.2 Conclusion

The present study successfully formulated and evaluated transdermal patches of Diclofenac Sodium using solvent casting technique. The patches exhibited satisfactory physicochemical properties, uniform drug content, and sustained drug release.

Among all formulations, F4 showed the best performance with controlled drug release and excellent mechanical properties. The drug release followed Korsmeyer-Peppas kinetics indicating diffusion-controlled mechanism.

Thus, transdermal patches of Diclofenac Sodium can be considered a promising alternative to oral dosage forms, offering improved therapeutic efficacy, reduced side effects, and better patient compliance.

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