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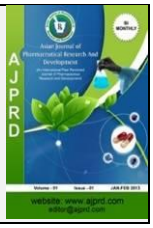

Open Access Research Article

Formulation Development and Evaluation of Transdermal Patches of Diclofenac sodium as a Analgesics

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ABSTRACT

Diclofenac is commonly prescribed for the treatment of pain, inflammation, and arthritic disorders. However, oral administration of diclofenac may lead to gastrointestinal side effects and extensive first-pass metabolism, which can reduce its therapeutic effectiveness. Transdermal drug delivery systems (TDDS) provide an alternative method of administration by delivering the drug through the skin in a controlled manner.

This research describes the formulation and evaluation of diclofenac transdermal patches prepared using different polymers, plasticizers, and permeation enhancers. Various preparation techniques, including solvent casting and solvent evaporation methods, are discussed. The review also summarizes important evaluation tests such as thickness, weight uniformity, folding endurance, drug content analysis, surface pH . In addition, the influence of permeation enhancers and release kinetics on drug delivery performance is highlighted.

Diclofenac transdermal patches have shown significant potential in improving patient compliance, reducing gastrointestinal complications, and providing sustained drug release. Hence, TDDS can be considered a suitable and promising approach for effective management of pain and inflammatory conditions.

KEYWORDS: Diclofenac, NSAID, Transdermal Drug Delivery Systems, Transdermal Patches

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INTRODUCTION

Transdermal drug delivery involves the application of therapeutic agents onto intact and healthy skin either to produce a local effect on tissues beneath the skin or to achieve systemic drug action. In transdermal systems, the main objective of dosage formulation is to enhance

the movement of the drug across the skin into systemic circulation while reducing drug accumulation and metabolic degradation within the skin layers.[1]

Transdermal drug delivery systems (TDDS), often called transdermal patches, are specially designed dosage forms used to administer therapeutic agents through the skin for systemic action. The effective development of these systems depends on understanding the structural, physical, and chemical properties of the skin. TDDS provides several benefits over conventional oral and injectable routes, including better patient convenience, painless administration, and elimination of first-pass hepatic metabolism. [2]

Advantages of Transdermal Drug Delivery System (TDDS) :

- Transdermal delivery bypasses hepatic first-pass metabolism, thereby improving drug availability.
- It helps maintain lower and more controlled plasma drug concentrations, which reduces the risk of side effects.
- TDDS minimizes fluctuations in plasma drug levels and is particularly useful for drugs with a short half-life or narrow therapeutic index.

- Drug administration can be stopped easily by removing the patch in case of toxicity or adverse reactions.
- It decreases the frequency of dosing and enhances patient adherence to therapy.
- Transdermal patches provide continuous and controlled release of medication over an extended duration, helping to avoid therapeutic failure or adverse effects associated with repeated dosing.
- This delivery system improves the therapeutic effectiveness of many drugs by overcoming problems such as gastrointestinal irritation, poor absorption, and degradation caused by first-pass metabolism.
- Because of improved bioavailability, the desired therapeutic response may often be achieved with a lower dose compared to oral administration.
- The simple and convenient dosage regimen improves patient compliance and reduces variatranbility between and within patients.[3]

Disadvantages of transdermal drug delivery system:

- Transdermal drug delivery systems are not suitable for delivering ionic drugs
- Drugs having a molecular weight greater than 500 Daltons are generally unsuitable for transdermal administration.
- This delivery system is unable to achieve high drug concentrations in the blood or plasma.
- Skin irritation, erythema, and itching may occur during therapy.
- Pulsatile delivery of drugs cannot be effectively achieved through transdermal systems.[10,11].

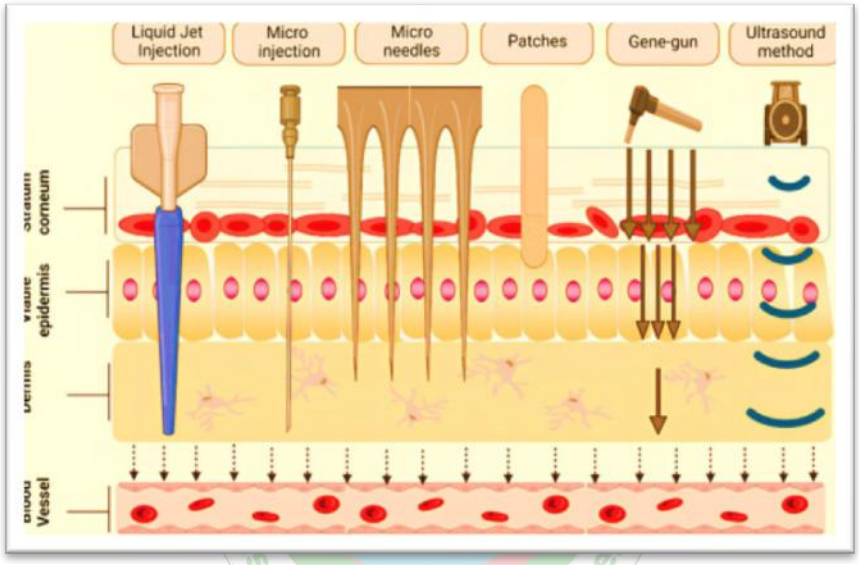


Figure: 2 1L;P

Figure 2: illustrates the commonly used transdermal drug delivery devices arranged from left to right, each offering distinct features and advantages. These devices include liquid jet injectors, microinjection systems, microneedles, transdermal patches, gene guns, and ultrasound-based delivery techniques. [4]

Types of Transdermal Patches:

Transdermal patches are mainly classified into four categories according to their design and method of preparation: drug-in-adhesive, reservoir, matrix, and micro-reservoir systems.

A. Drug-in-Adhesive (DIA) System :

In this type of patch, the drug is incorporated directly into the adhesive layer. When the patch is applied to the skin, the adhesive sticks to the skin surface and slowly releases the medication over a specific period.

B. Reservoir System :

The reservoir system contains the drug in a separate liquid compartment away from the adhesive layer. The drug is delivered through a microporous membrane that controls therelease rate after the patch is attached to the skin.

C. **Matrix System :**

This system consists of a drug dispersed within a semi-solid polymer matrix, which may contain the drug in dissolved or suspended form. The drug-containing matrix remains in direct contact with the skin, while the adhesive layer surrounds the matrix and helps maintain patch adhesion

D. Micro-Reservoir System :

The micro-reservoir system combines the characteristics of both reservoir and matrix systems. In this design, the drug is first suspended in an aqueous solution of a water-soluble polymer and then uniformly distributed within a lipophilic polymer, forming numerous tiny non-leaking drug reservoirs throughout the patch.[5].

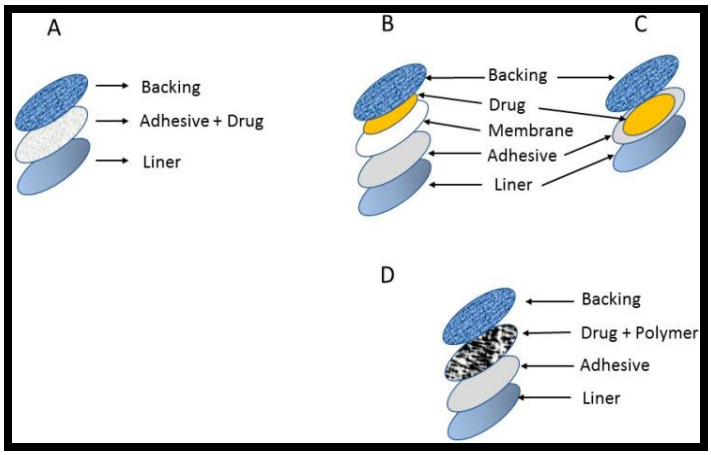


Figure 3: Types of transdermal patches

DICLOFENAC SODIUM AS CANDIDATE FOR TDDS :

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) widely prescribed for the management of pain and inflammation. Since the pure acid form has limited water solubility, it is commonly converted into salt forms such as diclofenac sodium or diclofenac potassium to enhance its solubility, absorption, and therapeutic effectiveness.[13, 14].

MATERIALS AND METHODS :

Materials used for formulation of transdermal patches :

("All materials and chemicals used for the formulation study were obtained from the college Laboratory.")

Table 1: Materials used In formulation

Sr no	Drug name	Role
1	Hydroxypropyl methylcellulose	Film forming polymer
2	Propylene glycol	Permeation enhancer
3	Methyl cellulose	Thickening agent
4	Glycerine	Plasticizer
5	Menthol	Soothing effecter
6	Ethanol	Solvent
7	Distilled water	Solvent

Drug profile : Diclofenac sodium

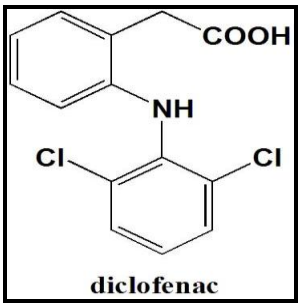


Figure 4 Structure Of Diclofenac

Chemical Formula: $C_{14}H_{11}Cl_2No_3$ (pure acid form)

Molecular Weight: 296.15 gm/ mol

Melting Point: 283 to 285°c (pure acid form) [6]

PREFORMULATION STUDY OF DICLOFENAC SODIUM :

Preformulation studies of diclofenac transdermal patches help determine the fundamental physicochemical characteristics of diclofenac acid or its salts and evaluate

their compatibility with selected polymers. These studies are essential for achieving uniform drug release, effective skin adhesion, and efficient systemic absorption while avoiding hepatic first-pass metabolism.[17]

1. **Determination of melting point of diclofenac sodium:**

Melting point of diclofenac sodium wasDetermined by digital melting point apparatus. In this method the capillary tube was sealed with gentle heating from one end, then the small quantity of pure drug diclofenac sodium was filled into the sealed capillary then capillary tube was placed in the melting point apparatus and temperature range at which the drug starts melting was noted [18]

Drug excipient compatibility study :

1. **Differential Scanning Calorimetry (DSC):**

DSC analysis was carried out to evaluate the thermal behavior and melting characteristics of the drug. The study was performed using a DSC Shimadzu-60 instrument. Samples were accurately placed in aluminum pans, sealed properly, and heated under a continuous nitrogen flow at a scanning rate of 10°C/min over a temperature range of 50°C to 200°C. An empty aluminum pan was used as the reference, and the heat flow corresponding to temperature changes was recorded.[18]

2. **Fourier Transform Infrared (FT-IR) Spectroscopy:**

Drug–excipient interaction studies were performed to evaluate any possible physical or chemical incompatibility among the materials used in the formulation. The interactions were analyzed using FT-IR spectroscopy (Shimadzu FT-IR) by the KBr pellet method. For sample preparation, the drug sample and potassium bromide (KBr) were mixed in a 1:100 ratio and finely triturated in a mortar to ensure uniform distribution. The mixture was then compressed into a disc-shaped pellet by applying a pressure of 5 tons for 5 minutes using a hydraulic press. The prepared pellet was subjected to FT-IR analysis over a wavenumber range of 4000–400 cm^{-1}. [19]

Formulation & Matrix Evaluation :

The formulation of transdermal patches consists of active pharmaceutical ingredients (APIs) along with various excipients that collectively help in achieving controlled and efficient drug delivery through the skin. The important components include:

Active Pharmaceutical Ingredients (APIs) :

The choice of APIs for transdermal drug delivery is very important. Suitable drug candidates generally possess:

Low molecular weight (<500 Da)

Adequate lipophilicity (Log P between 1 and 3)

High potency, as only small amounts can permeate the skin [20]

Adhesives :

Adhesives are essential for maintaining proper contact between the patch and the skin surface. Commonly used adhesives include:

- Acrylate-based adhesives
- Silicone-based adhesives
- Polyisobutylene-based adhesives [21]

Backing Layer :

The backing layer offers mechanical strength and shields the patch from external environmental conditions. Materials commonly used for backing layers include:

- Polyester films
- Aluminium foil laminates [22]

Release Liners :

Release liners are designed to protect the adhesive portion of the patch before application and are removed prior to use. These are generally prepared from: Silicone-coated paper [23]

In Vitro Permeation and Release :

Drug Permeation Studies (In-vitro Release Studies) :

In-vitro drug release studies were carried out using a Franz diffusion cell fitted with a cellophane membrane. Prior to the experiment, the cellophane membrane was soaked in 100 mL of phosphate buffer solution for 24 hours and then cut into pieces of 6 cm^2 area. The membrane was mounted on the diffusion cell and allowed to equilibrate with the receptor fluid for 15 minutes.

The diffusion cell consisted of two compartments: a donor compartment and a receptor compartment. The donor compartment was exposed to the external environment, while the receptor medium was continuously stirred using a magnetic stirrer to maintain uniform mixing. Samples were withdrawn from the receptor compartment at predetermined time intervals of 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 hours. Each withdrawn sample was. replaced with an equal volume of fresh phosphate buffer (pH 7.4-it accurately mimics the physiological pH of human blood and tissue fluids)[25]to maintain sink conditions. The collected samples were suitably diluted with phosphate buffer , and the drug content was analyzed using a UV-visible spectrophotometer[24]

Diclofenac uses:

Diclofenac Sodium is an NSAID commonly employed for relieving pain associated with therapeutic dental extractions.

Nonsteroidal anti-inflammatory drugs are frequently prescribed for the management of post-extraction pain because of their effective analgesic and anti-inflammatory effects.

Transdermal administration of NSAIDs provides multiple benefits, such as enhanced bioavailability, prolonged therapeutic action, decreased gastrointestinal irritation,

and better patient convenience when compared with oral formulations.[17]

Diclofenac Sodium patches and intramuscular diclofenac for postoperative pain management in orthognathic surgery patients [18]

Limitation of Conventional diclofenac therapy:

Conventional diclofenac therapy, usually administered through oral tablets or capsules, has several limitations due to its narrow therapeutic safety margin.

It is associated with serious adverse effects such as **gastrointestinal ulceration, cardiovascular complications** including **heart attack and stroke, as well as renal and hepatic toxicity**

In addition, repeated dosing and inadequate localized drug delivery can lead to variations in plasma drug concentration and reduced patient compliance.[7]

Method of Preparation of Patch:

(Solvent evaporation method)

The solvent evaporation method is a common technique used in pharmaceutical formulation to

prepare various drug delivery systems, including transdermal patches. This method involves

the dissolution of the active pharmaceutical ingredient (API) and other excipients in a volatile solvent, followed by the removal of the solvent to form a solid dosage form

1. **Prepare Polymer Solution:**

   Dissolve selected polymers in ethanol or a suitable solvent. Add plasticizers for flexibility.

2. **Incorporate Drug Extract:**

   Mix the extract into the polymer solution for the desired dosage.

3. **Cast the Patch:**

   Pour the solution onto a flat surface to form a uniform film.

4. **Evaporate Solvent:**

   Allow the solvent to evaporate, forming a solid patch structure.

5. **Dry and Cure:**

   Remove residual moisture and optionally cure the patches for improved properties.

6. **Cut and Package**:

   Cut patches to desired sizes, place them on backing membranes, and seal them in packaging [8 , 9]

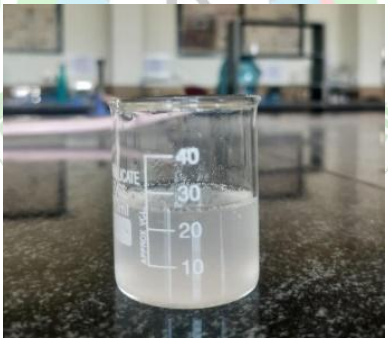


Figure 5: Preparation of polymer solution

Table 2: Formulation of Transdermal Patches

Sr no	Ingredients	Qty F1	Qty F2	Qty F3	Qty F4	Qty F5	Qty F6	Qty F7
1	Diclofenac Sodium (mg)	100	100	100	100	100	100	100
2	HPMC (mg)	300	200	400	300	500	600	700
3	Methyl cellulose (mg)	100	300	400	200	300	200	100
4	Glycerine (ml)	0.5	0.6	0.2	0.3	0.3	0.4	0.5
5	Propylene glycol (ml)	0.3	0.5	0.4	0.6	0.5	0.6	0.7
6	Menthol (%)	1	3	4	5	2	3	4
7	Ethanol (ml)	3	2	5	6	5	6	7
8	Distilled water (ml)	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s

RESULT AND DISCUSSION

Differential Scanning Calorimetry (DSC):

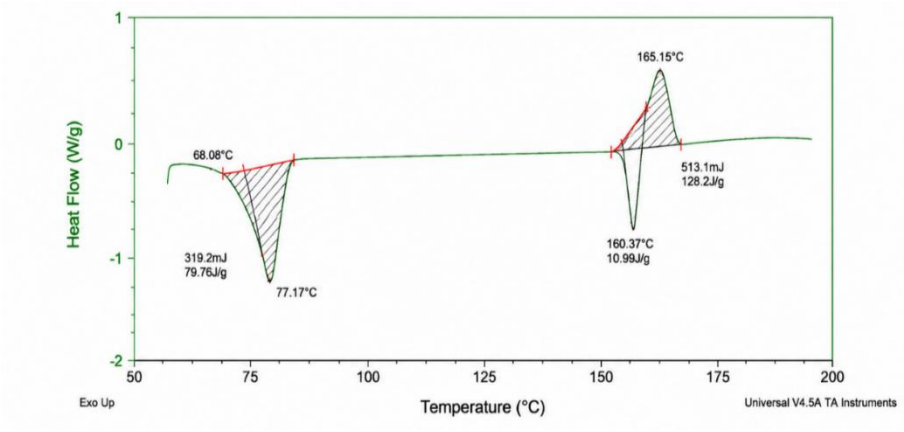
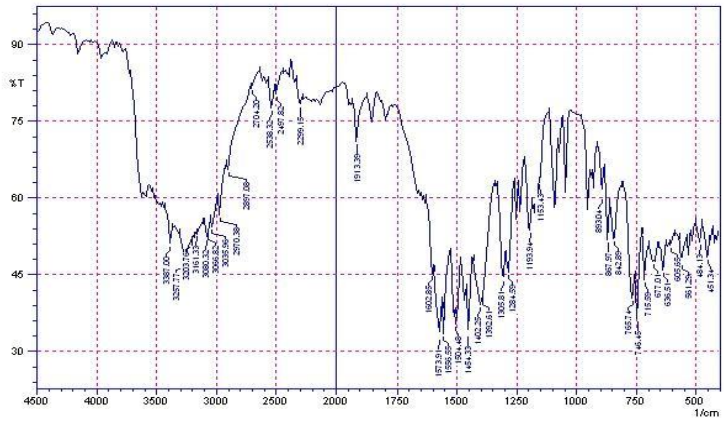


Figure 6: DSC Thermogram of pure diclofenac sodium

The DSC thermogram of pure Diclofenac Sodium exhibited a characteristic endothermic peak corresponding to its melting temperature. The thermogram of the drug-excipient mixture showed no significant shift or disappearance of the characteristic peak, indicating the absence of any major interaction between the drug and formulation excipients. These findings suggest that the drug remained stable throughout the formulation process.



Fourier Transform Infrared (FT-IR) Spectroscopy:

Figure 7: FTIR spectrum of diclofenac sodium

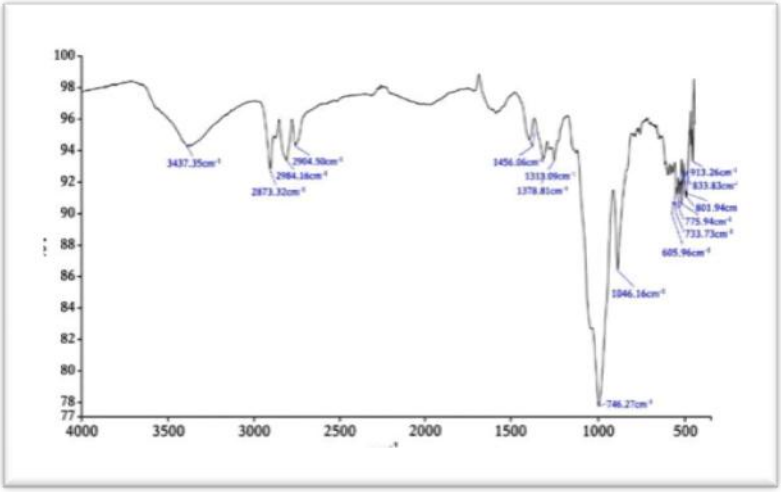


Figure 8: FTIR Spectra of Diclofenac sodium + Excipients

FT-IR spectroscopy was employed to investigate possible drug-excipient interactions. The FT-IR spectrum of pure Diclofenac Sodium displayed all characteristic absorption peaks corresponding to its functional groups. Similar peaks COOH (1574) , NH (3334), Cl (765) were observed in the spectra of the drug-polymer mixtures without any significant changes in peak position or intensity. The results confirmed the compatibility of Diclofenac Sodium with the selected polymers and other excipients used in the formulation

In – vitro permeation study:

The in-vitro permeation study was carried out using a Franz diffusion cell with phosphate buffer as the receptor medium. All formulations exhibited a sustained drug release pattern over the study period. Among the prepared formulations, F6 showed the highest cumulative percentage drug release and permeation through the membrane. The enhanced release observed in F6 may be attributed to the optimum polymer composition, which facilitated effective drug diffusion while maintaining the structural integrity of the patch.

Table 3: Cumulative Drug Release (%) at Different Time Intervals

Time (Hr)	F1	F2	F3	F4	F5	F6	F7
0	0	0	0	0	0	0	0
1	10.2	11.5	12.1	13.4	14.2	15.8	16.5
2	18.9	21.2	23.5	25.1	27.3	30.4	32.6
3	27.6	31.8	34.5	37.9	40.7	45.3	48.2
4	36.8	42.5	46.2	50.4	54.6	60.2	63.7
5	45.7	52.8	57.6	62.1	66.5	72.9	76.8
6	54.9	62.3	68.1	73.5	77.4	83.5	87.2

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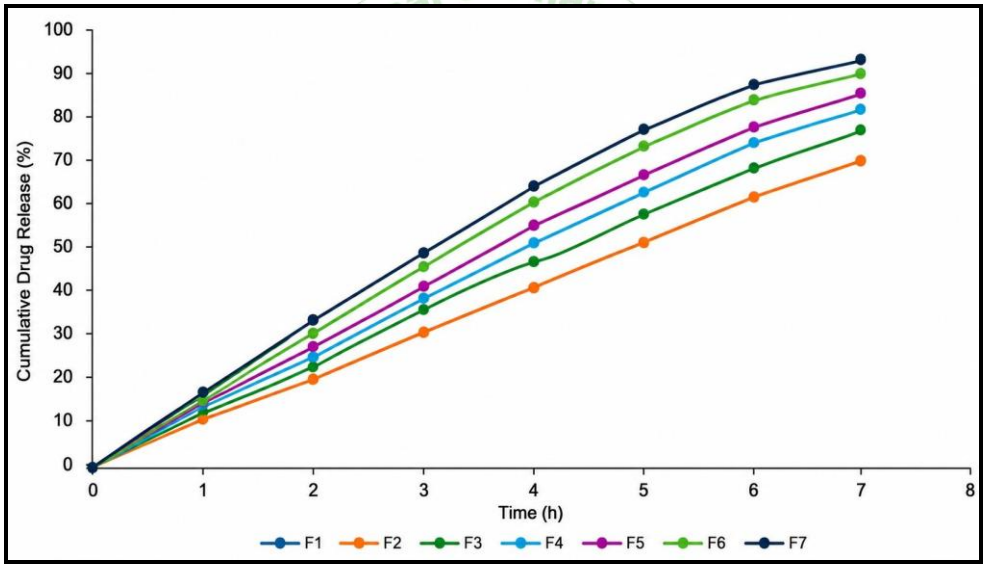

Graph: Cumulative Drug Release (%) at Different Time Intervals

The thickness of Transdermal Patches, weight Uniformity, folding endurance percentage moisture content was given in table :

Table 4: Result including thickness weight Uniformity, folding endurance, % moisture content Justification:

Sr No	Sample	Thickness (mm)	Weight Uniformity (Mg)	Folding ndurance	Percentage moisture content (%)
1	F1	0.21	498	18	1.82
2	F2	0.23	512	20	1.96
3	F3	0.26	534	22	2.08
4	F4	0.28	548	24	2.12
5	F5	0.31	590	26	2.15
6	F6	0.34	598	30	2.84
7	F7	0.37	593	27	3.42

Table 5: Comparative Evaluation of Formulations

Formulation	Observation	Interpretation
F1	Moderate drug release and permeation (54.9%)	Lower concentration of permeation enhancer and balanced polymer ratio resulted in controlled drug diffusion
F2	Good drug release with improved permeation (62.3%)	Increased methyl cellulose concentration enhanced hydration and drug diffusion through the membrane.
F3	Lower drug release than F2 (68.1%)	Higher total polymer content increased matrix density, reducing drug diffusion.
F4	Improved drug release compared to F1 and F3 (73.5%)	Optimum balance of HPMC and methyl cellulose facilitated better drug permeation.
F5	Moderate drug release (77.4 %)	Drug diffusion restricted by polymer matrix
F6	**Highest drug release** (83.3 %)	**Optimum polymer ratio (1:1) and better drug permeation**
F7	Lower drug release than F6 (87.2%)	Increased matrix density reduced drug diffusion

The formulation F6 was selected as the optimized formulation because:

It exhibited the highest cumulative percentage drug release and permeation among all formulations. The combination of HPMC (600 mg) and methyl cellulose (200 mg) provided an optimum balance between patch integrity and drug diffusion. The presence of propylene glycol (0.6 mL), glycerine (0.4 mL), and menthol (3%) enhanced flexibility and permeation characteristics. F6 showed sustained and controlled drug release throughout the study period, indicating its suitability for transdermal delivery of diclofenac sodium. Therefore, F6 was considered the optimized formulation with superior physicochemical and drug release properties compared to the other formulations.

DISCUSSION:

The present work was undertaken to develop and assess transdermal patches of diclofenac sodium aimed at achieving sustained and controlled drug release via the skin. Transdermal drug delivery systems (TDDS) are regarded as a valuable alternative to conventional oral dosage forms, as they bypass first-pass hepatic metabolism, minimize gastrointestinal adverse effects, and enhance patient adherence to therapy. Diclofenac sodium was chosen as the model drug because it is widely used for the management of pain and inflammation, and its oral administration is often linked with gastric irritation and variable bioavailability.

Various types of transdermal systems, including drug-in-adhesive, reservoir, matrix, and micro-reservoir patches, have been explored. Among these, matrix systems are commonly favored due to their ease of formulation, uniform drug dispersion, and ability to provide controlled and consistent drug release. In the preparation of diclofenac sodium patches, polymers such as HPMC and methyl cellulose were utilized along with plasticizers and permeation enhancers to improve mechanical strength, flexibility, and drug permeation through the skin.

Overall, the study indicates that diclofenac sodium transdermal patches can offer extended therapeutic effects with reduced dosing frequency and lower systemic side effects compared to oral administration. These results highlight the increasing relevance of TDDS as a convenient and patient-friendly strategy for the treatment of pain and inflammatory condition

SUMMARY AND CONCLUSION:

Summary:

This review focuses on the formulation and evaluation of diclofenac sodium transdermal patches as an alternative to conventional oral therapy for pain and inflammation management. Diclofenac, a widely used NSAID, often causes gastrointestinal irritation, first-pass metabolism, and fluctuating plasma drug levels when administered orally. Transdermal drug delivery systems (TDDS) overcome these limitations by delivering the drug through the skin in a controlled and sustained manner.

The review discusses various types of transdermal patches, including drug-in-adhesive, reservoir, matrix, and micro-reservoir systems. Different formulation components such as HPMC, methyl cellulose, plasticizers, permeation enhancers, solvents, and adhesives play an important role in determining the effectiveness and stability of the patch. The solvent evaporation method was used for patch preparation, followed by evaluation tests such as thickness, weight uniformity, folding endurance, moisture content, and drug content analysis.

The prepared patches showed satisfactory physical appearance, uniform thickness, acceptable weight variation, good flexibility, and controlled moisture content. Overall, diclofenac transdermal patches demonstrated the potential to provide sustained drug release, improved patient compliance, reduced dosing frequency, and minimized systemic side effects compared to oral dosage forms.

CONCLUSION:

Diclofenac sodium transdermal patches represent a promising and effective drug delivery system for the treatment of pain and inflammatory conditions. The developed patches showed suitable physicochemical properties, satisfactory mechanical strength, and controlled drug release characteristics. By bypassing first-pass metabolism and reducing gastrointestinal adverse effects, TDDS improves the therapeutic efficiency and patient compliance associated with diclofenac therapy.

The study also confirms that polymers such as HPMC and methyl cellulose, along with plasticizers and permeation enhancers, significantly contribute to patch stability, flexibility, and drug permeation through the skin. Among different formulations, the prepared transdermal patches exhibited acceptable evaluation parameters such as thickness uniformity, folding endurance, and moisture content. Therefore, diclofenac transdermal patches can be considered a safe, convenient, and patient-friendly alternative to conventional oral formulations for prolonged and controlled drug delivery

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