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Review Article

# Formulation and Evaluation of Transdermal Patches

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## ABSTRACT

Transdermal drug delivery (TDD) offers a compelling alternative to conventional drug administration routes, particularly for drugs with low oral bioavailability, short half-lives, or significant gastrointestinal side effects. This paper provides a detailed academic review of the formulation and evaluation of transdermal patches for diclofenac sodium (DS), a widely used non-steroidal anti-inflammatory drug (NSAID). The introduction highlights the rationale for transdermal delivery of DS, emphasizing the avoidance of first-pass metabolism and gastric irritation. The formulation section delves into the selection of polymers, plasticizers, penetration enhancers, and backing and release liner materials, outlining the common preparation methods such as solvent casting and hot melt extrusion. The evaluation section comprehensively covers various in-vitro, ex-vivo, and in-vivo assessment methodologies, including physical characterization (thickness, weight uniformity, folding endurance, tensile strength, drug content), in-vitro drug release, ex-vivo skin permeation studies using Franz diffusion cells, skin irritation potential, adhesion properties, and stability studies. Furthermore, the paper discusses the crucial role of penetration enhancers in overcoming the skin barrier and the challenges and future prospects in developing optimized DS transdermal delivery systems.

## INTRODUCTION

Pain and inflammation are significant global health concerns, impacting millions of lives. Non-steroidal anti-inflammatory drugs (NSAIDs) represent a cornerstone of pain management therapy. Among them, diclofenac sodium, a phenylacetic acid derivative, is a widely prescribed NSAID known for its potent analgesic and anti-inflammatory properties. It exerts its therapeutic effects by inhibiting cyclooxygenase (COX) enzymes, thereby reducing prostaglandin synthesis.

While oral diclofenac sodium is effective, its widespread use is hampered by a significant incidence of adverse gastrointestinal effects,

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including ulcers, bleeding, and perforation. Additionally, prolonged systemic exposure to NSAIDs has been linked to an increased risk of cardiovascular events. These limitations have spurred the development of alternative drug delivery systems that can provide localized and controlled release of diclofenac sodium, thereby enhancing therapeutic efficacy and minimizing systemic toxicity.

Transdermal drug delivery systems (TDDS), particularly transdermal patches, have emerged as a viable and attractive option for diclofenac sodium delivery. A transdermal patch is a medicated adhesive patch that is applied to the skin, delivering a specific dose of medication through the skin and into the bloodstream. This approach offers several advantages:

- **Sustained and Controlled Release:** TDDS allows for continuous drug release over an extended period, maintaining therapeutic drug concentrations and avoiding fluctuations associated with oral dosing.
- **Improved Patient Compliance:** Once-daily application of a patch can be more convenient than frequent oral administration, leading to better adherence to treatment regimens.
- **Reduced Gastrointestinal and Systemic Side Effects:** By bypassing first-pass metabolism in the liver and reducing overall systemic drug exposure for localized pain, TDDS can mitigate gastrointestinal issues and potentially lower cardiovascular risks.
- **Localized Delivery:** For conditions like localized musculoskeletal pain, the transdermal route can deliver higher concentrations of the drug directly to the affected area, maximizing therapeutic benefit while minimizing systemic exposure.

**Components of diclofenac sodium transdermal patch:**

**Table 1: Formulation Components of Diclofenac Sodium Transdermal Patches in different ratio:**

| Sr. No. | Ingredients | Activity | F1 | F2 | F3 |
|---|---|---|---|---|---|
| 1 | Diclofenac Sodium (mg) | Active ingredient (Drug) | 25 | 25 | 25 |
| 2 | Methyl Cellulose (mg) | Backing agent | 300 | 300 | 400 |
| 3 | PG, PEG-400 (ml) | Plasticizer | 1.2 | 1.2 | 1.2 |
| 4 | Dibutyl Phthalate (ml) | Penetration enhancer | 1.2 | 1.2 | 1.2 |
| 5 | Distilled water: Ethanol (ml) | Solvent | 1:4 | 1:4 | 1:4 |

**Preparation method for Diclofenac Sodium Transdermal Patch by Solvent Casting Method:**

1. Transdermal patches were fabricated using methyl cellulose as a polymers containing diclofenac sodium by solvent casting method[43] shown in Figure 1.
2. According to the formula methyl cellulose were accurately weighed and dissolved in mixture of ethanol: water (1:2) used as a solvent.
3. The drug was then dispersed in the polymeric solution and plasticizer of dibutyl phthalate was added with continuous stirring using a magnetic stirrer to obtain homogeneous mixture. Lastly, the bottom of petridish were covered with aluminium foil and the resulting solution was poured into levelled mercury surface in a petridish covered with a funnel in inverted position.
4. The solvent was allowed to evaporate and left undisturbed at room temperature for the next 24 hour.

5. The patch was obtained intact by slowly lifting from the Petri dish and transdermal patches were cut into radius of 2cm2.[44-46] Ingredients to be used are shown in Table 2.

**Evaluation and Characterization**

1. **Physical Appearance**

World Journal of Pharmaceutical Research All the transdermal film were organoleptically inspected and all over elegance for colour, transparency, shape, texture of the surface, homogeneity of thickness, film formation (no collapse or shrinkage)upon drying.

2. **Thickness of Patch:**

The thickness of the drug loaded patch is determined by screw gauge and micrometer at different point and average of readings were calculated.

3. **Uniformity of Weight:**

Weight variation is determined by weighing 5 randomly selected patches and calculating the average weight. The individual weight should not digress significantly from the average weight.

4. **Folding Endurance:**

This test is performed to determine the elasticity and fragility of transdermal patches.[50] The test was conducted by folding the patch at the same point n number of times till the patch is broken. The number of folds is considered to be the value of resistance to folding.

5. **Surface pH:**

Each film was allowed to swell by adding 0.5mL of distilled water on the film surface for 1hr at room temperature. Then, pH was noted by bringing the electrode into contact to the surface of the film and allowing it to equilibrate for 1 min.

6. **Swelling Index:**

The film were weighed (WF) immersed in a beaker containing 25mL phosphate buffer pH 7.4.The beaker were kept at 25℃ using thermo stated water bath. At specific intervals up to 2 hour, the swollen film were weighed (WS) after removal of excess surface water by light blotting with a filter paper. The experiment was discontinued when the film begins to dissolve.

The swelling index was calculated by.

$$\text{Swelling index} = \frac{WS - WF}{WF} \times 100$$

Where, WF = weight of the dried polymer film.

WS = weight after swelling.

7. **Moisture Uptake:**

World Journal of Pharmaceutical Research The films were placed in a desiccator containing activated silica gel for 24 hr. Then, they were weighed (WD) and then transfer to another desiccator containing saturated sodium chloride (75%). The films were weighed daily until they showed constant weight (WU).

The percentage of moisture uptake was calculated by.

$$\text{Moisture uptake capacity\%} = \frac{WU - WP}{WD} \times 100$$

8. **Moisture Loss:**

The film were weighed (WF), kept in a desiccator containing silica gel at 25℃ and weighed daily until they showed constant weight (WD).

The percentage moisture loss was calculated by.

$$\text{Moisture loss \%} = \frac{WF-WD}{WD} \times 100$$

**9. Content Uniformity Test:**

Randomly patches are selected and content in each patch is determined individually. If 9 out of 10 patches have content between 85% to115% of the specified value and one has content not less than 75% to 125% of the specified value, then transdermal patches passes the test of content uniformity. But if 3 patches have content in the range of 75% to 125%, then additional 20 patches are tested for drug content. If these 20 patches have range from 85% to 115%, then the transdermal patches passes the test.

**10. Drug Content:**

A specified area of patch is to be dissolved in phosphate buffer solution (pH 7.4). The content was allowed to dissolve in solution. Then the solution is to be filtered through a filter medium and absorbance were measured with the help of UV at wavelength 320nm. Each value represents average of three different samples.

**11. Stability Study:**

The developed transdermal patch were sealed in polyethylene coated aluminium foils and kept at 40±0.5°C and 75±5%RH for 6 months. The samples are withdrawn at different interval of 0, 30, 60, 90 and 180 days and analysed suitably for the drug content and any physical changes brought about on storage.

**RESULT AND DISCUSSION:**

**Standard Graph of Diclofenac Sodium:**

The lambda max of the Diclofenac sodium was found to be 320nm. After the determination of lambda max the calibration curve and absorption are to be evaluated by the UV spectroscopy. The results of the absorption and concentration were given below in the Table 2. Standard graph of diclofenac sodium are shown in Figure 2.

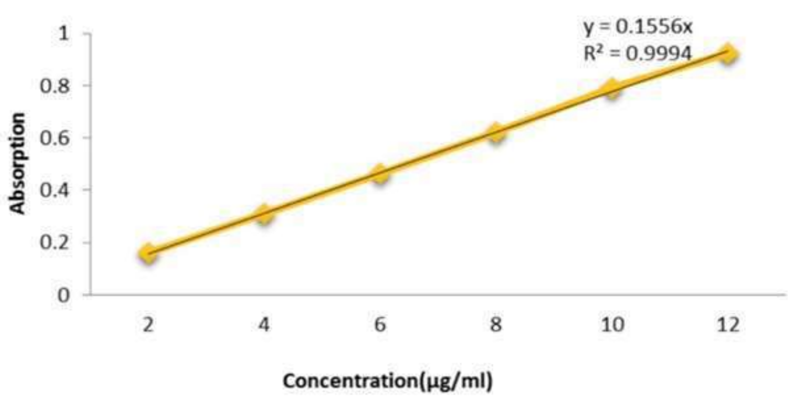



**Figure 2: Standard Graph of Diclofenac Sodium.**

**Table 2: Concentration and Absorption of Diclofenac Sodium.**

| Sr. No | Concentration(μg/ml) | Absorption |
|---|---|---|
| 1 | 2 | 0.160 |
| 2 | 4 | 0.310 |
| 3 | 6 | 0.463 |
| 4 | 8 | 0.623 |
| 5 | 10 | 0.790 |
| 6 | 12 | 0.925 |

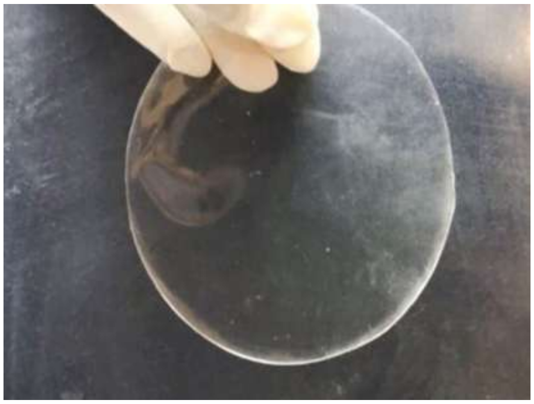
**Result of Evaluation Studies**

**1. Physical Appearance:**

The patch was visually inspected for colour, surface texture, shape. Figure 3 and Table 3. Helps to explain the physical appearance of patch. Transdermal patch cut in 2cm2.

**Table 3: Physical Appearance of Patch.**

| Sr. No | Physical appearance | Result |
|---|---|---|
| 1 | Color | Transparent |
| 2 | Surface texture | Smooth |
| 3 | Shape | Round |



**2. Thickness of Patch:**

The thickness of the prepared patch was measured by Vernier Calliper. The mean thickness was measured at different point of the film were given in Table 4.

**Table 4: Determination of Thickness of Patch.**

| Sr. No | Sample | Thickness (mm) |
|---|---|---|
| 1 | F1 | 0.295±0.012 |
| 2 | F2 | 0.245±0.09 |
| 3 | F3 | 0.259±0.011 |

The thickness of patch was determined. It was found that F2 (0.2452mm) show less thickness whereas F1 (0.295mm) shows more thickness.

**3. Uniformity of Weight:**

The quantified area of 2cm2 radius is to be cut at different parts of the patch and weigh in digital balance. The average weight calculated from individual weight are shown in Table 5.

**Table 5: Determination of Uniformity of Weight.**

| Sr. No | Sample | Weight variation (mg) |
|---|---|---|
| 1 | F1 | 590±0.025 |
| 2 | F2 | 598±0.016 |
| 3 | F3 | 593±0.017 |

Uniformity of weight was measured. It was found that F2 (598mg) shows more weight whereas F3(587mg) shows less weight.

**4. Folding Endurance:**

The folding endurance of the Patches are given below in the Table 6.

**Table 6: Determination of Folding Endurance.**

| Sr. No | Sample | Folding Endurance |
|---|---|---|
| 1 | F1 | 26±8 |
| 2 | F2 | **30±7** |
| 3 | F3 | 27±4 |

Folding endurance of prepared transdermal patches were noted. It was found that more folding endurance value is seen in F2 (30) and less folding endurance value in F3 (27).

**5. Surface pH:**

Surface pH of F1 to F3 were determined. The results were tabulated in Table 7.

**Table 7: Determination of Surface pH.**

| Sr. No | Sample | pH |
|---|---|---|
| 1 | F1 | 6.6±1 |
| 2 | F2 | 6.8±1 |
| 3 | F3 | 5.9±2 |

Surface pH was determined and found to be that F2 (6.8) has more pH as compare to other samples.

**6. Swelling Index:**

The swelling index at different time interval are given in Table 8 and Table 9.

**Table 8: Determination of Swelling Index after 1 hour.**

| Sr. No | Sample | Swelling Index (%) |
|---|---|---|
| 1 | F1 | 1.86±0.046 |
| 2 | F2 | **2.85±0.032** |
| 3 | F3 | 2.33±0.049 |

**Table 9: Determination of Swelling Index after 2 hour.**

| Sr. No | Sample | Swelling Index (%) |
|---|---|---|
| 1 | F1 | 2.97±0.083 |
| 2 | F2 | **2.23±0.107** |
| 3 | F3 | 3.54±0.053 |

Swelling index after completion of 2 hour was found that F3 has more percentage of swelling index in couple of hour and also film gets erode firstly as compare to other formulated patches.

## 7. Moisture Uptake:

Moisture uptake of prepared transdermal patch F1 to F3 were determined.

**The results were tabulated in Table 10.**

| Sr. No | Sample | Moisture uptake |
|---|---|---|
| 1 | F1 | 2.98% |
| 2 | F2 | **2.11%** |
| 3 | F3 | 2.75% |

Moisture contents in various formulated patch were determined. It shows that F1 (2.98%) has more moisture content and F2 (2.11%) shows less moisture content.

## 8. Moisture Loss:

Moisture loss of prepared transdermal patch F1 to F3 were determined. The results are tabulated in Table 11.

**Table 11: Determination of Moisture Loss.**

| Sr. No | Sample | Moisture Loss |
|---|---|---|
| 1 | F1 | 0.82% |
| 2 | F2 | **0.79%** |
| 3 | F3 | 0.98% |

Moisture loss were determined and found that F3 (0.98%) shows more moisture loss and F2 (0.79%) shows less loss in moisture.

## 9. Content Uniformity:

Test The Content uniformity of the samples are given below in the Table 12.

**Table 12: Determination of Content Uniformity Test.**

| Sr. No | Sample | Content Uniformity |
|---|---|---|
| 1 | F1 | 96.4% |
| 2 | F2 | **98%** |
| 3 | F3 | 95.0% |

## 10. Drug Content:

Drug content determination of F1 to F3 formulations were measured spectrophotometrically at 284 nm. The drug content is calculated and results are tabulated in Table 13.

**Table 13: Determination of Drug Content.**

| Sr. No | Sample | Drug content |
|---|---|---|
| 1 | F1 | 91% |
| 2 | F2 | **98%** |
| 3 | F3 | 97% |

Drug content were determined. It shows that F2 with (98%) drug content and F1 (91%) shows less drug content.

## 11. Stability Studies:

The Stability of the various formulations at different period of time and in different temperature are tabulated below in the Table.14-17.

**Table 14: Stability data after 7 days.**

| Sr. No | Sample | Temperature °C | | |
|---|---|---|---|---|
| | | **2-4°C** | **20-25°C** | **35-40°C** |
| 1 | F1 | Stable | Stable | Stable |
| 2 | F2 | **Stable** | **Stable** | **Stable** |
| 3 | F3 | Stable | Unstable | Stable |

**Table 15: Stability data after 14 days.**

| Sr. No | Sample | Temperature °C | | |
|---|---|---|---|---|
| | | **2-4°C** | **20-25°C** | **35-40°C** |
| 1 | F1 | Stable | Stable | Unstable |
| 2 | F2 | **Stable** | **Stable** | **Stable** |
| 3 | F3 | Stable | Unstable | Unstable |

**Table 16: Stability data after 21 days.**

| Sr. No | Sample | Temperature °C | | |
|---|---|---|---|---|
| | | 2-4°C | 20-25°C | 35-40°C |
| 1 | F1 | Stable | Stable | Unstable |
| 2 | F2 | **Stable** | **Stable** | **Stable** |
| 3 | F3 | Unstable | Unstable | Unstable |

**Table 17: Stability data after 28 days.**

| Sr. No | Sample | Temperature °C | | |
|---|---|---|---|---|
| | | 2-4°C | 20-25°C | 35-40°C |
| 1 | F1 | Stable | Stable | Unstable |
| 2 | F2 | **Stable** | **Stable** | **Stable** |
| 3 | F3 | Stable | Unstable | Unstable |

## CONCLUSION:

The development of transdermal patches for diclofenac sodium represents a significant advancement in drug delivery, offering a promising solution to overcome the limitations of conventional oral therapy. By leveraging the advantages of controlled transdermal permeation, these patches provide sustained drug release, improve patient compliance, and minimize adverse gastrointestinal effects. The formulation process necessitates careful selection and optimization of various components, including polymers, plasticizers, and crucial penetration enhancers, tailored to the physicochemical properties of diclofenac sodium. Rigorous evaluation through a battery of in-vitro, ex-vivo, and in-vivo studies is indispensable to ensure the patch's quality, efficacy, safety, and stability. While challenges such as adequate drug permeation across the formidable skin barrier remain, continuous research into novel penetration enhancement strategies and advanced patch designs holds immense potential for developing highly effective and patient-friendly diclofenac sodium transdermal delivery systems.

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