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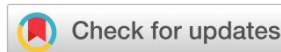
# Journal of Drug Delivery and Therapeutics

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Research Article

## Design and Characterization of a Bilayer Patch Containing Curcumin for Improved Skin Permeation

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### Article Info:



#### Article History:

Received 08 July 2026  
Reviewed 13 Aug 2026  
Accepted 01 Sep 2026  
Published 15 Oct 2026

#### Cite this article as:

Pote A, Giri M, Kute A, Kurhade S, Handge K, Bhalke R, Design and Characterization of a Bilayer Patch Containing Curcumin for Improved Skin Permeation, Journal of Drug Delivery and Therapeutics. 2026; 16(10):82-89  
DOI: <https://doi.org/10.22270/jddtv.16i10.7919>

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### Abstract

Transdermal drug delivery systems (TDDS) have emerged as an effective alternative to conventional dosage forms due to their ability to provide controlled drug release, improved bioavailability, and enhanced patient compliance. The present study aimed to formulate and evaluate a bilayer hydrogel transdermal patch comprising an immediate-release layer containing menthol and camphor, and a sustained-release layer containing thymol and curcumin. The immediate-release layer was formulated using Hydroxypropyl Methylcellulose (HPMC), whereas the sustained-release layer was developed using Carbopol 940 as the polymeric matrix. Menthol and camphor acted as permeation enhancers and provided rapid analgesic activity, while thymol and curcumin offered prolonged anti-inflammatory and antioxidant effects. The prepared hydrogel patches were evaluated for physicochemical properties, surface pH, thickness, moisture content, moisture uptake, folding endurance, tensile strength, drug content uniformity, in-vitro drug release, and stability studies. The patches exhibited satisfactory physicochemical characteristics with uniform drug distribution and acceptable mechanical strength. In-vitro drug release studies demonstrated followed by sustained drug release up to 8–9 hours. Drug release kinetics were found to follow the Higuchi diffusion model. The developed bilayer hydrogel patch demonstrated significant potential as a patient friendly transdermal delivery system for the effective management of pain and inflammatory disorders.

**Keywords:** Transdermal patch, Bilayer system, Menthol, Camphor, Thymol, Curcumin, Sustained release.

## 1. INTRODUCTION

By delivering medications through the skin and into the systemic circulation, transdermal drug delivery devices (TDDS) increase therapeutic efficacy while lowering adverse effects. These devices offer regulated drug release by avoiding hepatic first-pass metabolism. <sup>1</sup>

The stratum corneum, which restricts permeability, is the main obstacle to drug entry. <sup>2</sup> Permeation boosters like camphor and menthol are employed to get around this. <sup>3</sup>

Because of their high-water content, regulated drug release characteristics, and biocompatibility, hydrogels are frequently utilized in transdermal systems. <sup>4</sup>

Although curcumin has a powerful anti-inflammatory effect, transdermal administration methods can increase its bioavailability. <sup>5</sup>

Thymol has anti-inflammatory and antibacterial properties. <sup>6</sup>

Single-layered methods are unable to handle circumstances that call for both instant relief and long-term therapeutic maintenance, even while traditional

transdermal patches successfully avoid hepatic first-pass metabolism and maintain stable plasma levels. <sup>1,4</sup> For example, individuals with acute-on-chronic inflammatory pain have initial discomfort that necessitates quick analgesic intervention. Long-term anti-inflammatory therapy is then required to prevent return. Conventional systems either provide a delayed release that postpones the start of treatment or a fast burst that fades too soon. This work develops an asymmetric, bilayer hydrogel patch to fill this crucial formulation gap. By combining a sustained-release Carbopol 940 matrix (which offers steady, diffusion-controlled administration of thymol and curcumin) with an immediate-release HPMC matrix (which delivers menthol and camphor for fast localized cooling and quick analgesic effect),

this novel system achieves a bi-phase pharmacokinetic profile. This approach eliminates the need for multiple dosage forms, enhances local skin permeability, reduces dosing frequency, and significantly improves long term patient compliance.

## Mechanism of Drug Release

Curcumin possesses poor aqueous solubility and limited skin permeability. The combination of menthol, camphor, and thymol transiently modifies the stratum corneum barrier by disrupting lipid packing and increasing membrane fluidity. This creates diffusion pathways that facilitate the transport of curcumin

across the skin, resulting in enhanced permeation and improved therapeutic effectiveness.

The immediate layer releases drug rapidly, providing instant cooling and analgesic effect.

The sustained layer releases drug slowly via diffusion through polymer matrix, following the Higuchi model.<sup>7</sup>

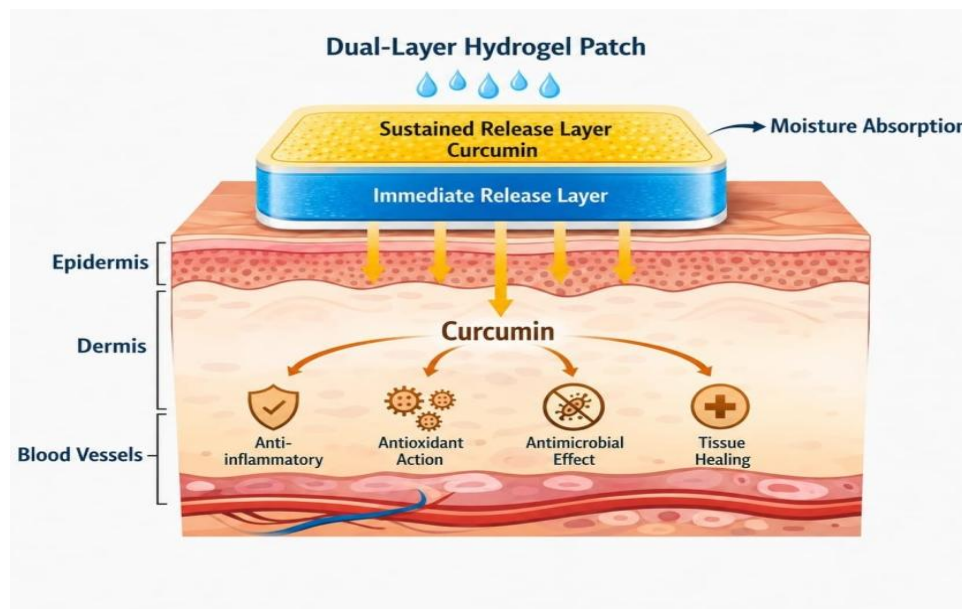


**Figure 1:** Mechanism of bilayer hydrogel patch

## 2. MATERIALS AND METHODS

### 2.1 Materials

Menthol, Camphor, Thymol, Curcumin, HPMC, Carbopol 940, Propylene glycol, Ethanol, Distilled water

**Table No: 1** Composition of Bilayer Hydrogel Patch for Immediate and Sustained Drug Release.

| Component Name        | Immediate-Release Layer (HPMC matrix) | Sustained-Release Layer (Carbopol 940 matrix) | Purpose / Role                   |
|-----------------------|---------------------------------------|-----------------------------------------------|----------------------------------|
| Menthol & Camphor     | 100 mg / 100 mg                       | —                                             | Penetration Enhancers            |
| Thymol & Curcumin     | —                                     | 150 mg / 120 mg                               | Active drugs (Anti-inflammatory) |
| HPMC K100M            | 400 mg                                | —                                             | Hydrophilic polymer base.        |
| Carbopol 940          | —                                     | 350 mg                                        | Gelling polymer matrix           |
| Propylene Glycol      | 0.5 mL                                | 0.6 mL                                        | Plasticizer / Penetration agent  |
| Ethanol (95%)         | 5 mL                                  | 7 mL                                          | Co-solvent                       |
| Triethanolamine (TEA) | —                                     | 3–4 drops (q.s.)                              | Neutralizing agent / pH adjuster |
| Distilled Water       | 25 mL                                 | 35 mL                                         | Primary vehicle / Solvent        |

### 2.2 Preparation of bilayer transdermal patch

The bilayer transdermal patch was prepared by solvent casting method. For the immediate release layer, HPMC polymer solution was prepared initially. Menthol and camphor were dissolved in ethanol separately and added to the polymer solution. Propylene glycol was

incorporated as a plasticizer and the mixture was stirred thoroughly to obtain a uniform solution. The prepared solution was sonicated to remove entrapped air bubbles, casted into a petri plate, and partially dried for 6–8 h.

For the sustained release layer, Carbopol 940 dispersion was prepared and neutralized using

triethanolamine (TEA) to form a gel. Thymol and curcumin were dissolved in ethanol and mixed with the Carbopol gel containing propylene glycol as plasticizer. The mixture was sonicated and poured over the partially dried immediate release layer. The combined layers were subjected to final drying for 24 h. After complete drying, the prepared bilayer patch was removed carefully and cut into uniform patches of desired size.

## 2.3 Evaluation parameter

### 1)Physical appearance

The prepared bilayer transdermal patches were visually inspected for their physical appearance. The patches were examined against a white and black background under normal daylight conditions to evaluate the following parameters: <sup>18</sup>

- Colour
- Smoothness
- Flexibility
- Transparency/Opacity
- Surface texture
- Presence of air bubbles

### 2)Thickness Measurement

The thickness of the bilayer hydrogel patch was determined using a calibrated digital micrometre screw gauge or digital Vernier caliper with a least count of 0.01 mm.

Three to five patches from each formulation batch were selected randomly. The thickness of each patch was measured at different positions, including the centre and four peripheral points, to ensure uniformity of the hydrogel layers. Care was taken to avoid excessive pressure during measurement to prevent deformation of the hydrogel structure. <sup>13</sup>

The average thickness and standard deviation were calculated and reported in millimetres (mm).

Formula:

$$\text{Average Thickness} = \frac{T1 + T2 + T3 + T4 + T5}{5}$$

### 3)Surface pH Determination:

The surface pH of the bilayer hydrogel patch was determined by allowing the patch to swell in 1–2 mL distilled water for 1 hour. The pH electrode was placed on the hydrated patch surface, and the pH was recorded after stabilization. Measurements were taken at different points and the average value was calculated. <sup>12</sup>

### 4)Moisture uptake

The transdermal patches were dried individually and weighed accurately. The patches were then placed in a desiccator containing saturated potassium chloride solution to maintain 84% relative humidity for 24 h. After incubation, the patches were reweighed and

percentage moisture uptake was calculated. <sup>20</sup>

$$\text{Moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

### 5)Moisture content

Transdermal patches were weighed individually and kept in a desiccator containing fused calcium chloride for 24 h at room temperature. After drying, the patches were reweighed and percentage moisture content was calculated <sup>20</sup>:

$$\text{Moisture content} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

### 6)Weight uniformity

The prepared bilayer hydrogel patches were cut into equal sizes and individually weighed using a digital balance. The weight of each patch was recorded, and the average weight along with variation was calculated to determine weight uniformity among the patches <sup>13</sup>.

### 7)Tensile Strength

Tensile strength and tear characteristics of the polymer films were evaluated using

a Brookfield CT3 texture analyzer instrument. It contained two load cell grips, of which the lower one was secured and the upper one was mobile. Film strips with dimensions of 1 × 1 cm were fixed between the cell grips, and force was increasingly applied until the film broke. Tensile strength was measured in mN. <sup>11</sup>

### 8)Folding endurance

The bilayer hydrogel patch was repeatedly folded at the same place manually until it broke or showed visible cracks. The number of folds required to break the patch was recorded as the folding endurance value. <sup>13</sup>

### 9)Stability Study

The prepared bilayer hydrogel patches were packed in suitable containers and stored under different stability conditions (e.g., room temperature and accelerated conditions) for a specified period. The patches were periodically evaluated for physical appearance, drug content, surface pH, and other evaluation parameters to assess stability. <sup>17</sup>

#### ❖ Stability Conditions

- Temperature: 25 ± 2°C
- Relative Humidity: 60 ± 5% RH
- Study Duration: 30Days.

### 10) In - vitro drug release

The bilayer hydrogel patch was placed in a Franz diffusion cell using a dialysis membrane. The receptor compartment was filled with phosphate buffer (pH 7.4) and maintained at 37 ± 0.5°C with continuous stirring. Samples were withdrawn at predetermined intervals and analyzed using UV-Visible spectrophotometry to

determine drug release.<sup>16</sup>

### 11) FTIR Compatibility Study

Fourier Transform Infrared Spectroscopy (FTIR) studies were carried out to evaluate drug-polymer compatibility between menthol, camphor, thymol, curcumin, HPMC, and Carbopol 940.<sup>14</sup>

### 12) SEM Analysis (Surface Morphology)

Surface morphology of the prepared bilayer hydrogel/transdermal patch was evaluated using Scanning Electron Microscopy (SEM). The study was performed to observe the surface characteristics, porosity, homogeneity, and structural integrity of the patch.<sup>15</sup>

## 3.RESULT AND DISCUSSION

### ❖ The prepared patch



**Figure 2:** Prepared bilayer hydrogel patch.

#### 1)Physical appearance

The prepared bilayer hydrogel transdermal patch showed a pale white appearance with a smooth, uniform, and slightly translucent surface. No visible air bubbles, cracks, or surface imperfections were observed. The patch exhibited good flexibility, indicating successful film formation and proper compatibility between the polymeric matrices. The absence of defects suggests uniform solvent evaporation during the casting process and indicates that the prepared patch is suitable for handling and application.

- ☐ Colour: Pale whitish appearance.
- ☐ Smoothness: Smooth.
- ☐ Transparency: Slightly translucent.
- ☐ Flexibility: Flexible.
- ☐ Presence of air bubbles: Free from air bubbles.
- ☐ Cracks or imperfections: Free from cracks and imperfections.

- ☐ Uniformity of surface: Uniform.

#### 2)Thickness Measurement

The average thickness of the optimized bilayer patch was 0.22 mm, demonstrating uniform film formation throughout the casting process. Uniform thickness is an important quality parameter because it ensures consistent drug loading, mechanical strength, and reproducible drug release. The low variation in thickness indicates good control over the formulation process and confirms the successful preparation of the bilayer structure.

#### 3)Surface pH Determination:

The surface pH of the optimized patch was  $6.5 \pm 0.2$ , which lies within the normal physiological skin pH range (5.5–7.0). A near-neutral surface pH minimizes the possibility of skin irritation, redness, or discomfort after topical application. This result indicates that the formulation is compatible with skin and suitable for prolonged transdermal use.

#### 4)Moisture uptake

The percentage moisture uptake of the optimized formulation was 4.32%. This moderate moisture absorption helps maintain flexibility and prevents brittleness during storage without causing excessive swelling. Controlled moisture uptake also contributes to maintaining the structural integrity of the hydrogel matrix under humid environmental conditions..

#### 5)Moisture content

The moisture content of the prepared patch was found to be 3.70%, indicating adequate drying of the formulation. Low residual moisture reduces the possibility of microbial growth and improves the stability and shelf life of the transdermal patch. The obtained value confirms that the drying process was effective while preserving flexibility.

#### 6)Weight Uniformity:

The average weight of the prepared bilayer hydrogel patch was 0.162 g, with negligible variation among different samples. Uniform weight reflects homogeneous distribution of polymers and active ingredients throughout the formulation. This ensures dose uniformity and reproducible therapeutic performance during application.

#### 7)Tensile Strength

The optimized formulation exhibited a tensile strength of  $0.82 \pm 0.04$  kg/mm<sup>2</sup>, demonstrating satisfactory mechanical strength. The obtained value indicates that the patch can withstand normal handling, packaging, and application without tearing. The combined use of HPMC and Carbopol provided sufficient elasticity while maintaining structural integrity.

#### 8)Folding Endurance

The folding endurance of the optimized bilayer patch was 120 folds, indicating excellent flexibility and resistance to repeated mechanical stress. A high folding endurance value suggests that the formulation possesses good elasticity and is unlikely to crack during storage or patient use, thereby improving patient compliance.

#### 9)Stability Study:

The optimized formulation remained stable throughout the 30-day storage period at  $25 \pm 2^\circ\text{C}$  and  $60 \pm 5\%$  RH. No noticeable changes in colour, appearance, flexibility, or texture were observed. The surface pH changed only slightly from 6.0 to 6.1, while drug content decreased marginally from 98% to 96%, indicating excellent formulation stability. These findings suggest that the prepared bilayer patch maintains its physicochemical properties under normal storage conditions.

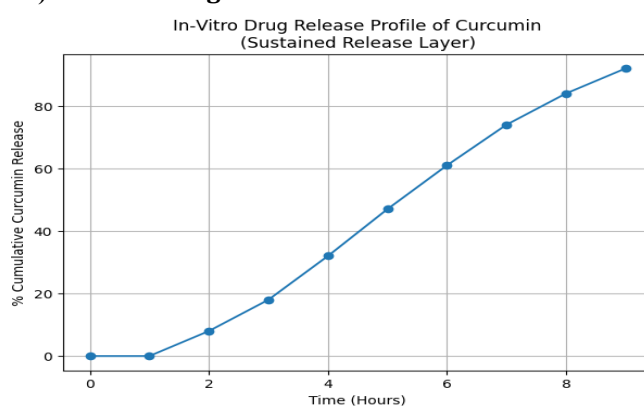
No significant changes in colour, texture, flexibility, or surface appearance were observed during storage.

**Table 4:** Stability Study of Bilayer Hydrogel Patch Under Accelerated Storage Conditions.

| Parameter    | Initial    | After 30 days |
|--------------|------------|---------------|
| Colour       | Pale white | No change     |
| Surface Ph   | 6.0        | 6.1           |
| Flexibility  | Flexible   | Flexible      |
| Drug content | 98%        | 96%           |
| Appearance   | Smooth     | No change     |

The prepared formulation was found to be stable under room temperature storage conditions.

#### 10) In-Vitro Drug Release

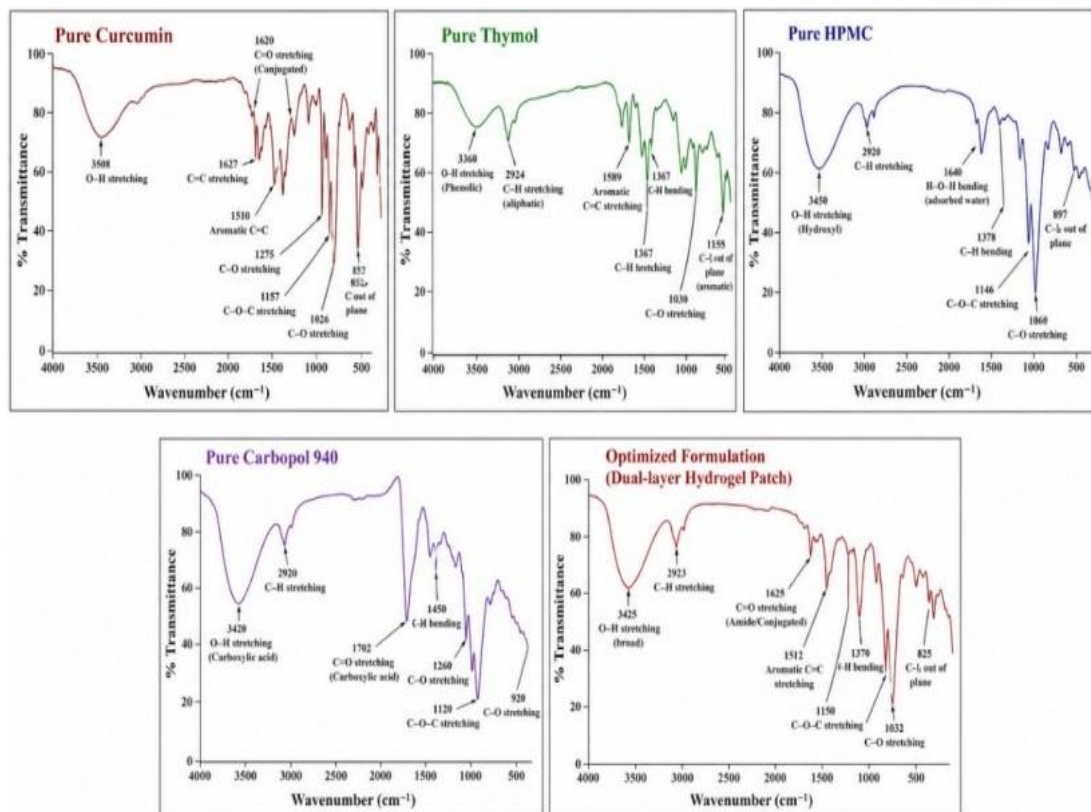


**Graph 1:** In-Vitro Drug Release Profile of Bilayer Hydrogel Patch.

The in-vitro drug release study demonstrated an initial slow release during the first hour, followed by a gradual increase in cumulative drug release from the second hour onward. Approximately 92% of the drug was released over 9 hours, confirming effective sustained-release behaviour. The immediate-release HPMC layer containing menthol and camphor provided rapid initial therapeutic action, whereas the Carbopol layer containing thymol and curcumin maintained prolonged drug release. The release profile followed the Higuchi diffusion model, indicating diffusion-controlled drug release through the polymeric matrix.

#### 11) FTIR Compatibility Study

FTIR spectra of the optimized formulation retained all characteristic absorption peaks of curcumin, thymol, HPMC, and Carbopol 940 without significant peak shifting or disappearance. This confirms that no chemical interaction occurred between the drugs and polymers during formulation. The compatibility of formulation components indicates the chemical stability of the bilayer hydrogel system.



**Graph 2:** FTIR spectra for-Pure Curcumin, Pure Thymol, HPMC, Carbopol 940 Optimized formulation.

Important Peaks Observed:

**Table 2:** FTIR Characteristic Peaks and Functional Groups of Formulation Components.

| Compound     | Characteristic Peak                                                                                                                           | Functional Group                                                                                         |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Curcumin     | 3508 cm <sup>-1</sup><br>1625–1650 cm <sup>-1</sup><br>1600–1500 cm <sup>-1</sup><br>1270–1150 cm <sup>-1</sup>                               | O-H stretching<br>Conjugated C=O stretching Aromatic C=C stretching<br>C-O stretching (phenolic/methoxy) |
| Thymol       | 3200–3400 cm <sup>-1</sup><br>2950–2850 cm <sup>-1</sup><br>1600–1450 cm <sup>-1</sup><br>1260–1200 cm <sup>-1</sup>                          | Phenolic O–H stretching Aliphatic C–H stretching Aromatic C=C stretching C–O stretching                  |
| Menthol      | 3200–3500 cm <sup>-1</sup><br>2920 cm <sup>-1</sup><br>2950–2850 cm <sup>-1</sup><br>1100–1050 cm <sup>-1</sup>                               | Alcoholic O–H stretching C–H stretching<br>Aliphatic C–H stretching C–O stretching (alcohol)             |
| Carbopol 940 | 1700 cm <sup>-1</sup><br>1700–1725 cm <sup>-1</sup><br>3200–3500 cm <sup>-1</sup><br>1450–1400 cm <sup>-1</sup><br>1250–1150 cm <sup>-1</sup> | C=O stretching<br>Carboxylic acid C=O stretching O–H stretching<br>O–H bending C–O stretching            |
| HPMC         | 3450 cm <sup>-1</sup><br>2920 cm <sup>-1</sup><br>1450–1370 cm <sup>-1</sup><br>1150–1050 cm <sup>-1</sup><br>1060–1020 cm <sup>-1</sup>      | Hydroxyl group C–H stretching CH <sub>2</sub> bending<br>Ether C–O–C stretching<br>C–O stretching        |

FTIR analysis confirmed compatibility between drugs and polymers.

## 12) SEM Analysis (Surface Morphology)

SEM analysis revealed a smooth, homogeneous, and porous surface morphology without visible drug crystals or phase separation. The porous network facilitates diffusion of the drug through the polymer matrix and supports sustained drug release. The

uniform distribution of pores indicates successful incorporation of active ingredients and confirms the structural integrity of the optimized bilayer hydrogel patch.

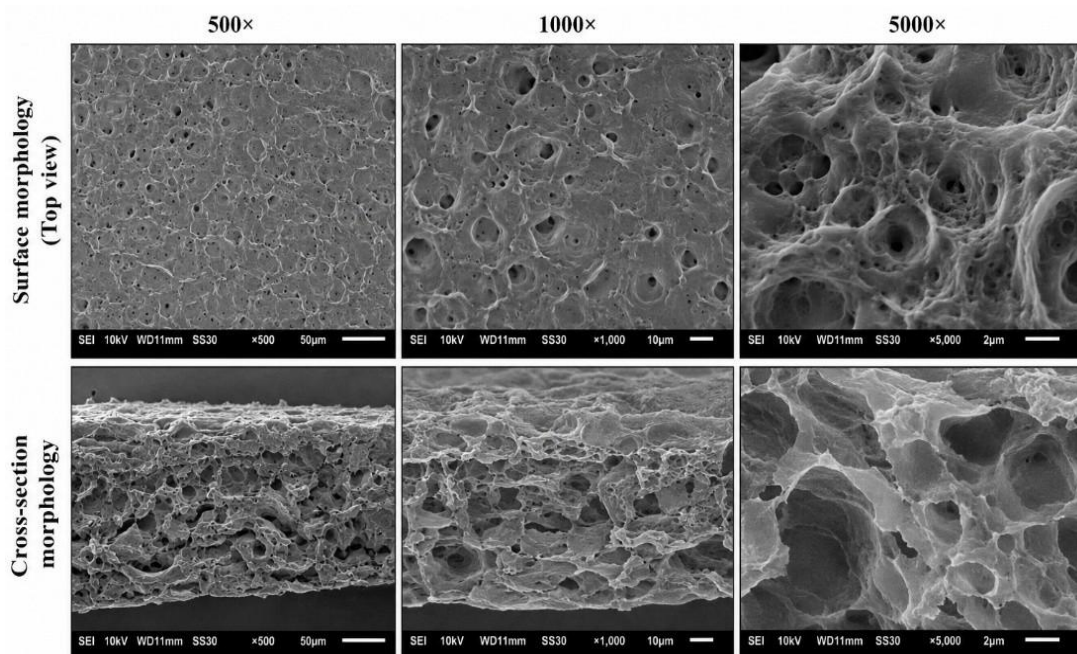


**Figure 3:** SEM analysis of optimized bilayer hydrogel patch.

## CONCLUSION

A bilayer hydrogel transdermal patch that can deliver both immediate and prolonged medication release was effectively created and assessed in this work. The improved formulation demonstrated acceptable mechanical strength, stability, drug content homogeneity, and physicochemical characteristics.

While the Carbopol-based sustained-release layer sustained anti-inflammatory activity for up to nine hours, the immediate-release HPMC layer efficiently produced quick analgesic action. Higuchi diffusion kinetics were followed by the drug release, indicating regulated release behaviour.

FTIR, and SEM analytical characterization examinations verified the formulation's stability and compatibility. All things considered, the created transdermal hydrogel patch showed great promise as a practical, patient-friendly method of managing pain and inflammation.

Future research involving in-vivo pharmacokinetic analysis and ex-vivo permeability may confirm the new formulation's clinical suitability.

**Acknowledgement:** The authors are thankful to the Principal and Management of Matoshri Institute of Pharmacy for providing the necessary facilities and support to carry out this research work. The authors also acknowledge the guidance and encouragement received from faculty members involved in the study.

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