IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, November 2025
Impact Factor: 7.67

Formulation and Evaluation of Transdermal Patches of Pantoprazole Sodium

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Abstract: *Transdermal patches represent a promising alternative to conventional oral and parenteral delivery systems for pantoprazole sodium, aiming to enhance patient compliance and therapeutic efficacy in the management of peptic ulcers and related conditions. This review summarizes the various formulation strategies employed, focusing on polymer combinations such as hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP), and Eudragit L100, applied via the solvent evaporation method to develop flexible and uniform patches. Key evaluation parameters, including thickness, folding endurance, weight and content uniformity, swelling index, moisture content and uptake, surface pH, and in vitro release profiles, are discussed based on current research findings. Results from multiple studies demonstrate that these transdermal formulations exhibit controlled and prolonged drug release, with some formulations achieving over 93% release over 24 hours, thus maintaining therapeutic plasma concentrations and bypassing first-pass metabolism. The review also covers critical aspects of drug-polymer compatibility, release kinetics, and skin permeability assessments, affirming that pantoprazole sodium transdermal patches potentially offer enhanced bioavailability and reduced dosing frequency. Overall, transdermal patches are positioned as a feasible and effective system for the sustained delivery of pantoprazole sodium, warranting further clinical investigation and optimization.*

Keywords: Transdermal patches, Pantoprazole sodium, In vitro release, Skin permeability

I. INTRODUCTION

The transdermal drug delivery system (TDDS) has emerged as a well-established and widely accepted mode of drug administration, offering a promising alternative for the treatment of various diseases [1]. Transdermal delivery provides several advantages over oral and parenteral routes, including improved patient compliance, avoidance of first-pass hepatic metabolism, and prevention of gastrointestinal irritation and poor drug absorption associated with oral dosage forms [2]. The primary objective of TDDS is to maximize the flux of the drug through the skin into systemic circulation, while simultaneously minimizing drug retention and metabolism within the skin layers [3–5]. These therapeutic and pharmacokinetic advantages have significantly enhanced the commercial potential and clinical importance of transdermal drug delivery systems [6]. Drug molecules predominantly permeate the skin via intercellular micro pathways, highlighting the importance of permeation enhancers in TDDS. These agents transiently and reversibly reduce the barrier resistance of the stratum corneum without causing damage to viable epidermal or dermal cells, thereby facilitating effective transdermal permeation [7]. The first transdermal patch was approved by the U.S. Food and Drug Administration (FDA) in 1981, developed by Alza Corporation, California, for the treatment of motion sickness using scopolamine (Transderm-Scop). This was subsequently followed by Transderm-Nitro for the management of angina pectoris. Since then, TDDS technology has achieved continuous success, with over 35 approved transdermal products currently available on the market for the management of various conditions, including hypertension, angina pectoris, motion sickness, menopausal symptoms, and hypogonadism [8]. The global market for transdermal delivery was valued at USD 12.7 billion in 2005, increased to USD 21.5 billion by 2010, and reached USD 31.5 billion in 2015, with steady growth continuing each year.

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Pantoprazole, a substituted benzimidazole sulfoxide, is a proton pump inhibitor (PPI) widely used in the treatment of acid-related gastrointestinal disorders such as reflux esophagitis, duodenal ulcers, and gastric ulcers. When administered orally as a 40 mg enteric-coated tablet, pantoprazole demonstrates an absolute bioavailability of approximately 77%, which remains consistent upon multiple dosing [9]. The drug exhibits linear pharmacokinetics following both intravenous and oral administration and undergoes extensive hepatic metabolism. To overcome the limitations associated with its oral administration, such as first-pass metabolism and variable bioavailability, the present study was undertaken to develop and evaluate a transdermal drug delivery system of pantoprazole sodium for sustained and controlled systemic delivery.

Various methods use for the preparations of transdermal patches of pantoprazol sodium

Preparation of Backing Membrane

The backing membrane was prepared using an aqueous solution of 4% w/v PVA. For this, 4 g of PVA was added to 100 ml of warm distilled water and stirred continuously with occasional heating at 60 °C until a clear, uniform solution was formed. About 15 ml of this solution was poured into glass Petri dishes (63.5 cm² area) and dried in a hot air oven at 60 °C for 6 hours to form smooth, transparent membranes [10, 11].

Preparation of Placebo Films

Different placebo films (films without drug) were prepared using various combinations of hydrophilic and hydrophobic polymers by the trial-and-error method [12]. The polymer combinations that produced smooth and flexible films were selected for making drug-loaded matrix systems. All films were prepared using the solvent evaporation method. Matrix-type transdermal patches containing pantoprazole sodium were prepared using different ratios of HPMC E5 with PVP, ethyl cellulose, Eudragit L100, and Eudragit S100.

Formulation of Transdermal Patches

Transdermal films containing pantoprazole sodium were prepared by the solvent evaporation technique in Petri dishes using different polymer combinations — HPMC E5:PVP K30 and HPMC E5:Eudragit L100 [13]. The drug-to-polymer ratio was kept constant at 1:1, while the polymer-to-polymer ratio was varied as 1:1, 1:2, and 2:1. A total of six formulations were prepared. In each formulation, HPMC E5 was used in three concentrations, and the second polymer (PVP K30 or Eudragit L100) was varied accordingly (Table 1).

N-dibutyl phthalate and propylene glycol were used as plasticizers, and 1% DMSO was added as a skin permeation enhancer in all formulations [14].

$$\text{Percentage Elongation} = \frac{\text{Final length of strip} - \text{Intial length of strip}}{\text{Intial length of strip}} \text{x100}$$

Ingredients	Formulations F1	F2	F3	F4	F5	F6
Pantoprazole Sodium (mg)	635	635	635	635	635	635
HPMC (E5) (mg)	300	200	400	300	200	400
PVP K 30 (mg)	300	400	200	-	-	-
Eudragit L 100 (mg)	-	-	-	300	400	200
Ethanol (ml	10	10	10	10	10	10
Chloroform: Methanol (1:1) (ml)	-	-	-	6	6	6
n-Dibutyl Phthalate (ml)	8.5	8.5	8.5	8.5	8.5	8.5
Propylene glycol (ml) 0.5 0.5 0.5 0.5 0.5 0.5	0.5	0.5	0.5	0.5	0.5	0.5
DMSO (ml)	0.1	0.1	0.1	0.1	0.1	0.1

Table 1: Formulation details of pantoprazole sodium transdermal films

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Thickness Measurement

The thickness of the transdermal patches was determined using a digital micrometer screw gauge. Measurements were taken at three different points on each patch to ensure uniformity, and the mean thickness along with the standard deviation (SD) was calculated and reported [16,20].

Drug Content Determination

A section of the transdermal patch measuring 2 × 2 cm was accurately cut and dissolved in 100 mL of methanol. The solution was subjected to continuous shaking for 24 hours, followed by ultrasonication for 15 minutes to ensure complete extraction of the drug. The resulting solution was then filtered, and the drug content was analyzed spectrophotometrically at 292 nm using methanol as a blank [21].

Percentage Moisture Content

Each prepared transdermal film was weighed accurately and placed in a desiccator containing fused calcium chloride at room temperature for 24 hours. After the specified time, the films were reweighed, and the percentage moisture content was calculated using the following formula [16]:

This parameter indicates the hygroscopic nature of the patches and their ability to absorb moisture under humid conditions.

$$\text{Percentage Moisture Content} = \frac{\text{Inital weight} - \text{Final weight}}{\text{Final weight}} \text{x100}$$

Swelling Study

Individually weighed patches (W_1) were placed on 2% agar gel plates and incubated at 37 ± 0.5 °C. At regular intervals of 15 minutes, up to 1 hour, the patches were removed, and any surface moisture was carefully blotted off with filter paper. The swollen patches were reweighed (W_2), and the swelling index was calculated using the formula [22,23]:

$$\text{Swelling index} = \frac{W2 - W1}{W1} \text{ x } 100$$

In Vitro Drug Release Studies

The in vitro drug release of the prepared transdermal matrix-type patches was evaluated using a Franz diffusion cell with a receptor compartment capacity of 60 mL [24]. A cellulose acetate membrane with a pore size of 0.45 µm was employed to separate the donor and receptor compartments. The transdermal patch was carefully mounted onto the membrane to ensure intimate contact and subsequently sealed with aluminum foil to prevent solvent evaporation. The receptor compartment was filled with phosphate buffer (pH 7.4), which served as the diffusion medium.

The entire assembly was placed on a thermostatically controlled magnetic stirrer, and the contents of the receptor compartment were continuously stirred at 50 rpm using a magnetic bead, as described by Simon et al. [25]. The temperature was maintained at 37 ± 0.5 °C, simulating normal human physiological conditions.

Samples were withdrawn from the receptor compartment at predetermined time intervals and analyzed spectrophotometrically to determine the drug concentration. During sampling, special care was taken to prevent the entry of air bubbles into the receptor compartment, as these could affect diffusion dynamics. After each withdrawal, the receptor phase was immediately replenished with an equal volume of fresh phosphate buffer (pH 7.4) to maintain a constant volume and sink conditions throughout the experiment.

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In Vitro Permeation Study

The in vitro skin permeation study was performed using a Franz diffusion cell with full-thickness abdominal skin excised from male Wistar rats weighing 200–250 g [26]. The hair on the abdominal region was carefully removed using an electric clipper, and the dermal side of the excised skin was thoroughly washed with distilled water to remove adhering tissues or blood residues. The skin was then equilibrated in phosphate-buffered saline (PBS, pH 7.4) for one hour prior to the experiment to ensure physiological stability.

During the experiment, the temperature of the diffusion cell was maintained at 37 ± 0.5 °C using a thermostatically controlled water bath, simulating normal human body temperature [27,28]. The skin was mounted between the donor and receptor compartments of the diffusion cell, with the epidermal surface facing the donor compartment [29].

Aliquots of 1 mL were withdrawn from the receptor compartment at predetermined time intervals of 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 16, 20, and 24 hours. After each withdrawal, an equal volume of fresh phosphate buffer (pH 7.4) was added to maintain sink conditions. The collected samples were filtered through Whatman filter paper, and the drug concentration was determined spectrophotometrically at 292 nm using a Shimadzu UV-1800 double-beam spectrophotometer (Shimadzu, Kyoto, Japan).

Drug Release Kinetics

The data obtained from in vitro drug release studies were analyzed using various kinetic models to determine the mechanism and rate of drug release. The models applied included:

Zero-order kinetics: Cumulative percentage of drug released versus time.

First-order kinetics: Log cumulative percentage of drug remaining versus time.

Higuchi model: Cumulative percentage of drug released versus square root of time [30–32].

The best-fit model was determined based on the correlation coefficient (R^2) values for each kinetic model.

Mechanism of Drug Release

The mechanism of drug release from the prepared transdermal patches was evaluated using the Korsmeyer–Peppas model, by plotting log cumulative percentage of drug released versus log time. The release exponent (n) was calculated from the slope of the regression line to determine the drug release mechanism. An n value between 0.5 and 1.0 indicated a non-Fickian (anomalous) diffusion mechanism, whereas n = 0.5 and n = 1.0 corresponded to Fickian diffusion and case II transport, respectively [33].

Statistical Analysis

All experiments were conducted in triplicate, and the results are expressed as mean ± standard deviation (SD). Statistical analysis was performed using one-way analysis of variance (ANOVA) to assess significant differences among formulations. Where applicable, Student's t-test was used to compare the means between two groups, and $p < 0.05$ was considered statistically significant.

Results and Discussion

Oral site-specific drug delivery systems have recently gained significant attention due to their ability to provide localized treatment for a variety of gastrointestinal disorders, improving therapeutic efficacy and minimizing systemic side effects.Transdermal drug delivery systems have been explored for the treatment of various diseases and to enhance the systemic absorption of drugs that are unstable in the gastric environment [34, 35]. However, the complex microenvironment of the gastrointestinal tract and the variability in absorption mechanisms often pose significant challenges for formulation scientists in the development and optimization of effective oral drug delivery systems [36].

In the preliminary placebo batches, different combinations and concentrations of both hydrophilic and hydrophobic polymers were evaluated. Based on the ability to form smooth, transparent, uniform, and flexible films, the polymer combinations HPMC E5:PVP K30 and HPMC E5:Eudragit L100 were selected for further formulation studies in the ratios of 1:1, 1:2, and 2:1. Transdermal patches of Pantoprazole sodium were subsequently prepared using the solvent evaporation method to achieve controlled drug release and improved bioavailability of the therapeutic agent.

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Table 2: Physicochemical evaluation of transdermal patches of pantoprazole sodium

Formulation	Thickness (mm)	Folding endurance	Content uniformity (%)	Weight (mg)
F1	0.322±0.008	175.5±11.65	99.96±4.30	84.3±2.36
F2	0.360±0.022	157.2±16.69	99.49±3.95	87.8±3.12
F3	0.464±0.011	141.6±15.39	101.67±4.78	85.3±2.06
F4	0.442±0.007	179.0±9.48	99.98±4.38	90.2±3.77
F5	0.484±0.012	160.8±15.08	98.86±4.08	92.3±2.06
F6	0.479±0.015	162.2±14.94	100.67±2.61	93.3±2.00

All the prepared drug-loaded patches exhibited uniformity in thickness, which ranged from 0.322±0.008 mm to 0.484±0.012 mm, as presented in Table 2. The maximum thickness was observed in formulation F5, whereas the minimum thickness was noted in F1. These observations indicate that the thickness of the patch is influenced by the solubility and concentration of the polymer; as the solubility decreases and concentration increases, the overall thickness of the patch tends to increase [5]. Hence, the selection of an appropriate polymer is a critical step in formulating a patch of optimum thickness capable of sustaining the drug release profile.

The weight variation of all the transdermal formulations ranged between 84.3±2.36 mg and 93.3±2 mg, while the drug content uniformity was found to be between 98.86±4.08% and 101.67±4.78% of Pantoprazole sodium. The low standard deviation (SD) values indicate excellent uniformity of the patches prepared by the solvent evaporation technique, confirming minimal variation in drug content among the formulations. This demonstrates that the preparation method was effective in producing consistent and homogeneous patches.

The folding endurance of the formulations ranged from 141.6±15.39 to 179±9.48, with all values exceeding 140, signifying that the prepared patches possessed adequate mechanical strength and flexibility to withstand repeated folding without breaking. Among the tested formulations, those containing Eudragit L100 exhibited the highest folding endurance compared to those containing PVP, indicating that both the type and concentration of polymer play a crucial role in determining the mechanical properties of the transdermal patches.

The percent flatness of the prepared transdermal patches was found to be within the ideal range, as presented in Table 3. The percentage flatness values varied from 96.67±2.89% to 99.67±0.58%, indicating that all the formulated films were uniform and free from physical imperfections such as wrinkles or folds. An increase in moisture uptake was observed for all the formulations, ranging from 7.67±3.05% to 11.32±6.5%. This increase can be attributed to the hygroscopic nature of the polymers used in the formulation. All the patches demonstrated a gradual increase in weight over time, confirming their ability to absorb atmospheric moisture. The surface pH of the formulated patches was found to be uniform, ranging between 5.1 and 5.2, which lies within the normal pH range of the skin and thus suggests that the patches are unlikely to cause skin irritation upon application. The percent elongation of the formulations (F1–F6) was observed to range between 38.33±2.89% and 80.83±2.89%, indicating good flexibility and mechanical strength of the films. Among all the formulations, F6 exhibited the highest percentage elongation, suggesting superior elasticity and tensile properties compared to the other formulations.

Table 3: Evaluation of transdermal patches

Formulation	**Surface pH**	**% Flatness**	**% Elongation**	**Moisture content (%)**	**Moisture uptake (%)**
F1	5.13±0.06	97.67±2.08	38.33±2.89	7.58±0.66	8.2±0.76
F2	5.17±0.06	97.33±2.31	53.33±1.44	7.61±1.09	8.25±1.27
F3	5.23±0.06	97.67±2.52	58.33±1.44	7.78±1.11	8.44±1.31
F4	5.27±0.06	98.67±1.15	61.67±1.44	9.97±5.08	11.32±6.5
F5	5.2±0.1	96.67±2.89	66.67±1.44	7.41±1.54	8.02±1.81
F6	5.23±0.06	99.67±0.58	80.83±2.89	7.07±2.67	7.67±3.05

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Swelling index studies were conducted on the prepared transdermal films, and the results are presented in Table 4. The swelling behavior of the films demonstrated a progressive increase in the swelling index with time. Furthermore, the extent of swelling varied depending on the type and concentration of polymers used in the formulation [37].

These findings indicate that the polymer composition significantly influences the hydration characteristics and dimensional stability of the transdermal patches. The in vitro drug release profile of the formulated transdermal patches was evaluated using a cellulose acetate membrane as the diffusion barrier. The formulations F1–F6 exhibited cumulative drug release percentages of 98.99% at 24 h, 97.95% at 20 h, 99.57% at 12 h, 99.58% at 24 h, 99.10% at 20 h, and 101.68% at 10 h, respectively (Figure 1).Formulations F3 and F6 showed complete drug release within 10 and 12 hours, respectively, which may be attributed to their lower viscosity and the higher concentration of HPMC E5 polymer, facilitating faster diffusion of the drug. In contrast, formulations F2 and F5 exhibited drug release of 97.95% and 99.10% at 20 hours, whereas formulations F1 and F4 achieved 98.99% and 99.58% release at 24 hours, respectively. The sustained drug release observed in formulations F1 and F4 can be attributed to the 1:1 polymer-to-polymer ratio, which likely provided an optimal balance between hydrophilic and hydrophobic components, resulting in prolonged release over 24 hours. Considering additional factors such as the formation of a smooth, transparent, uniform, and flexible film, formulation F1 was selected for further in vitro permeation studies.

Table 4: Swelling studies of transdermal patches of pantoprazole sodium

Formulation	Swelling index			
	15 min	30 min	45 min	60 min
F1	60.05±4.68	67.63±2.11	71.06±3.3	76.58±2.4
F2	48.59±3.79	56.5±3.68	60.62±1.6	66.02±3.08
F3	61.67±3.43	64.34±3.26	67.58±2.35	72.72±2.19
F4	61.76±2.84	64.7±2.44	68.85±1.68	74.88±2.52
F5	50.57±5.37	56.37±1.85	59.85±0.37	66.03±1.94
F6	49.28±7.76	66.63±1.86	70.35±2.37	75.96±3.4

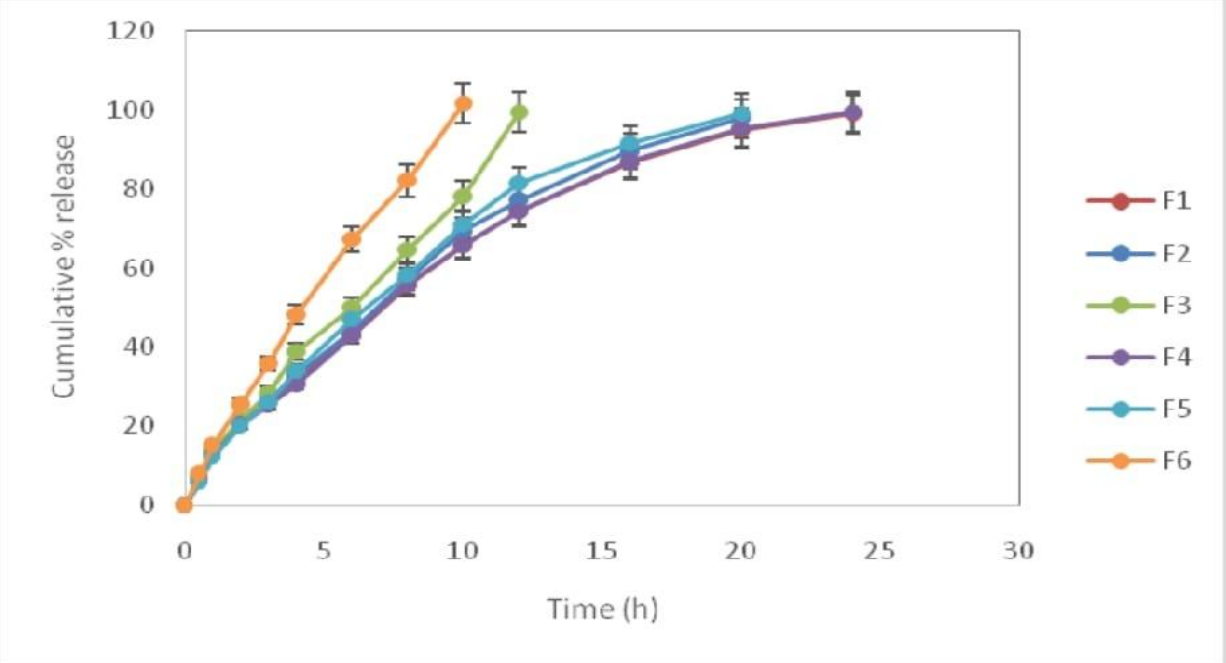

Fig. 1: In vitro release profile of pantoprazole sodium transdermal patches (mean±SD; n=3)

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The formulation F1 exhibited a drug permeation of 96.26% of Pantoprazole sodium through rat abdominal skin within 24 hours. The permeation profile suggested that the release kinetics of Pantoprazole sodium followed a zero-order model, as indicated by the correlation coefficient (r^2 = 0.9714), which demonstrated a better fit than the first-order model (r^2 = 0.9383) and was comparable to the Higuchi model (r^2 = 0.9946). These findings are consistent with previous reports by various researchers [38–40].

According to the Korsmeyer–Peppas model, the slope value (n = 0.7672) for formulation F1 was found to be between 0.5 and 0.85, indicating that the drug release mechanism followed non-Fickian (anomalous) diffusion, involving a combination of diffusion- and polymer relaxation-controlled processes. The in vitro drug release studies of all the Pantoprazole sodium transdermal formulations further confirmed that the release followed zero-order kinetics, as evidenced by the high linearity of the plots with r^2 values of 0.9385, 0.9584, 0.9936, 0.9398, 0.9552, and 0.994 for formulations F1, F2, F3, F4, F5, and F6, respectively. This indicates that the drug release rate was independent of concentration, characteristic of a controlled-release system.

Moreover, analysis using the Korsmeyer–Peppas model revealed slope values (n) between 0.5 and 0.85 for all six formulations, further confirming that the release mechanism followed non-Fickian diffusion, where both diffusion and polymer relaxation contributed to the overall release process (Table 5).

Table 5: Release kinetics of transdermal patches of pantoprazole sodium

Formulations	First-order Slope	R^2	Zero-order Slope	R^2	Higuchi Slope	R^2	Peppas Slope	R^2
F1	0.0745	0.934	4.2436	0.9385	23.717	0.9909	0.6963	0.9929
F2	0.0755	0.9269	5.0132	0.9584	25.589	0.9917	0.7278	0.9945
F3	0.0625	0.9736	7.7296	0.9936	31.656	0.9647	0.7767	0.9956
F4	0.0845	0.8926	4.294	0.9398	24.03	0.9899	0.7078	0.9935
F5	0.0881	0.9065	5.2119	0.9552	26.749	0.9918	0.7704	0.9939
F6	0.0935	0.9775	9.9666	0.994	38.036	0.9834	0.8376	0.9992

II. CONCLUSION

The transdermal drug delivery systems of Pantoprazole sodium formulated using different polymers—HPMC E5, PVP K30, and Eudragit L100—exhibited promising results across all evaluated physicochemical and performance parameters. Based on the results of various characterization and evaluation studies, including film thickness, film weight, percentage elongation, folding endurance, and in vitro drug release over a 24-hour period, it can be concluded that the polymer combinations HPMC E5:PVP K30 and HPMC E5:Eudragit L100 in a 1:1 ratio are optimal for the development of a sustained-release transdermal delivery system of Pantoprazole sodium.

These findings suggest that such formulations have the potential to provide prolonged therapeutic effects, improve bioavailability, and enhance patient compliance compared to conventional oral dosage forms.The study successfully developed a matrix-type transdermal patch formulation of Pantoprazole sodium. The results of the in vitro drug permeation studies through rat abdominal skin confirmed that Pantoprazole sodium was effectively released from the formulated patches and permeated across the skin barrier. These findings suggest that the drug possesses the potential to similarly permeate through human skin, indicating the feasibility of transdermal delivery for systemic therapeutic application.

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