



Research Article

Formulation and Evaluation of Transdermal Patch Containing Cyclizine HCl

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ABSTRACT

This study aimed to develop and evaluate transdermal patches of Cyclizine hydrochloride to achieve sustained systemic delivery and improved patient compliance. Patches were formulated using varying ratios of Hydroxypropyl methylcellulose (HPMC) and Polyvinylpyrrolidone (PVP), with polyethylene glycol as a plasticizer. The formulations (F1–F5) were assessed for physicochemical properties such as thickness, weight uniformity, tensile strength, folding endurance, moisture absorption/loss, and drug content. Fourier Transform Infrared Spectroscopy (FTIR) confirmed no significant drug–excipient interactions. In vitro drug release studies using Franz diffusion cells over 12 hours revealed that increasing the hydrophilic polymer content enhanced drug release. Among the formulations, F3 (1:1 polymer ratio) exhibited an optimal release profile with approximately 86% cumulative release at 720 minutes. Kinetic analysis indicated first-order release following the Higuchi model, suggesting diffusion-controlled behavior, while the Korsmeyer–Peppas model indicated non-Fickian transport. The optimized formulation demonstrated desirable mechanical strength and sustained drug release, supporting its potential as an effective transdermal delivery system for Cyclizine hydrochloride.

INTRODUCTION

Oral drug delivery remains the most common and preferred route due to its convenience and non-invasive nature. However, it presents several limitations that can significantly impact drug efficacy and patient compliance. In contrast, transdermal drug delivery systems (TDDS), such as patches, offer a number of distinct advantages

that make them a superior alternative in many clinical scenarios.

One of the primary drawbacks of oral administration is the first-pass metabolism in the liver, which can lead to significant degradation of the active pharmaceutical ingredient (API) before it reaches systemic circulation. This can reduce bioavailability and necessitate higher or more

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frequent dosing. Transdermal delivery bypasses the gastrointestinal tract and hepatic first-pass effect, allowing for more consistent plasma drug concentrations and potentially lower total doses. Additionally, many orally administered drugs are subject to poor gastrointestinal absorption, influenced by factors such as pH, food intake, and motility. Transdermal systems circumvent these variables by delivering the drug directly through the skin, ensuring greater predictability in drug absorption.¹

Transdermal patches also allow for controlled and sustained drug release, which helps maintain steady therapeutic levels over extended periods and reduces the risk of peaks and troughs in plasma concentration that can lead to side effects or sub therapeutic effects. This sustained delivery can improve therapeutic outcomes and patient adherence, especially in chronic conditions.²

ADVANTAGES

- Convenient Administration: Transdermal drug delivery is a user-friendly method that typically requires application only once a week, which can significantly enhance patient adherence to their medication regimen.
- Alternative Route for Patients: This method serves as an effective alternative for patients who are unable to tolerate oral medications.
- Useful for Unconscious or Nauseated Patients: Transdermal delivery is particularly advantageous for individuals who are nauseated or unconscious, as it does not rely on oral intake.
- Minimizing Gastrointestinal Effects: Drugs that may cause gastrointestinal discomfort are ideal candidates for transdermal delivery, as this method bypasses the stomach and intestines entirely.

- Protection from Gastrointestinal Degradation: Medications that are susceptible to degradation by gastrointestinal enzymes and acids can benefit from transdermal administration.
- Avoiding First-Pass Metabolism: Transdermal delivery effectively circumvents first-pass metabolism in the liver, enhancing the bioavailability of certain drugs.
- Maintaining Consistent Plasma Levels: Drugs that require stable plasma concentrations are well-suited for transdermal delivery, allowing for more effective long-term management of conditions.³

DISADVANTAGES

- There is a risk of local irritation at the application site.
- The drug, adhesive, or other excipients in the patch formulation may cause erythema, itching, and local edema.
- Allergic reactions may occur.
- A molecular weight of less than 500 Da is necessary.
- For effective permeation through the stratum corneum and underlying aqueous layers, sufficient aqueous and lipid solubility is required, with a log P (octanol/water) value between 1 and 3.⁴

The objectives of the present work were:

- To perform pre-formulation studies for Drugs, Polymers and other excipients.
- Drug-excipient compatibility studies by FTIR.
- To carryout preparation of transdermal patches.
- To carryout evaluation of transdermal patches like Thickness, Weight Uniformity, Drug Content, Folding Endurance, Tensile

Strength, Percentage Moisture Absorption, Percentage Moisture Loss

- To perform *In vitro* drug release studies.

MATERIALS AND METHODOLOGY

Table 1: Materials

Drug	Cyclizine hydrochloride
Polymer	Hpmc k15
Polymer	Pvp k30
Plasticizer	Peg 400
Permeation enhancer	Oleic acid
Backing membrane	Polyvinyl alcohol

Preparation of PVA Backing Membrane

Polyvinyl alcohol (PVA) was used as a backing layer. Accurately weighed 4 g of PVA was dissolved in 100 mL of distilled water with continuous stirring at 70–80 °C until a clear solution formed. A Petri dish was coated with glycerin to prevent adhesion and enhance flexibility. The hot PVA solution was poured and

spread evenly, then dried at room temperature or in a hot air oven (40–45 °C) to obtain a transparent, uniform film.⁵

Preparation of Drug–Polymer Matrix Layer

Hydroxypropyl methylcellulose (HPMC) and Polyvinylpyrrolidone (PVP) were dissolved in an ethanol–water mixture (7:3) with stirring to form a clear solution. The drug, pre-dissolved in ethanol, was added to the polymer solution with continuous mixing. PEG 400 (20% w/w of polymer) and oleic acid (5% w/w of polymer) were incorporated as plasticizer and permeation enhancer, respectively. The solution was sonicated to remove air bubbles and cast onto the dried PVA backing membrane. Films were dried at 40–45 °C to yield smooth, flexible drug-loaded patches, which were then peeled off and stored in a desiccator for evaluation.⁶

Table 2: Composition of transdermal patch (F1-F5)

Formulation	Polymer ratio (HPMC:PVP)	Cyclizine HCl (mg)	HPMC K15 (mg)	PVP K30 (mg)	PEG 400 (mg)	Oleic acid (mg)	Solvent
F1	3:1	50	450	150	90	30	Ethanol: Water (7:3)
F2	2:1	50	400	200	90	30	Ethanol: Water (7:3)
F3	1:1	50	300	300	90	30	Ethanol: Water (7:3)
F4	1:2	50	200	400	90	30	Ethanol: Water (7:3)
F5	4:1 (higher plasticizer)	50	480	120	120	30	Ethanol: Water (7:3)

PREFORMULATION STUDIES

Organoleptic properties

The drug's colour, odour and taste were characterized and recorded using descriptive technologies.

Determination of Melting Point of Cyclizine Hydrochloride

A small quantity of cyclizine HCl was introduced into a capillary tube sealed at one end. The capillary tube was then placed into a calibrated melting point apparatus. The sample was heated gradually, and the temperature at which the cyclizine HCl transitioned from solid to liquid was recorded as the melting point. This procedure was repeated three times to ensure accuracy and reproducibility. The average of the three recorded



temperatures was calculated and documented as the final melting point of the drug.⁷

Solubility Analysis

Cyclizine's solubility was tested in various solvents, including water, methanol, ethanol, chloroform and ethyl acetate (Table 4).

Standard calibration curve

A stock solution of cyclizine HCl was prepared by accurately weighing 50.0 mg and dissolving in methanol; the volume was adjusted to 50.0 mL in a volumetric flask to yield 1000 µg/mL. The UV spectrum of the stock (200–300 nm) was scanned on a Shimadzu UV 2450 to determine the λ_{max} . Working standards (2, 4, 6, 8, 10 µg/mL) were prepared by appropriate dilutions of the stock in methanol using calibrated pipettes and volumetric flasks; solutions were filtered (0.45 µm) prior to measurement. Absorbance of each standard (n=3) was measured against a methanol blank in quartz cuvettes at the determined λ_{max} . A calibration curve was constructed by plotting concentration (µg/mL) versus mean absorbance (Y) and linear regression used to calculate slope, intercept.⁸

Drug and excipients compatibility

Fourier Transform Infrared (FTIR) spectroscopy (Paragon 1000, Perkin Elmer, UK) was used to assess possible drug-excipient, drug-polymer, and polymer-polymer interactions. The drug and polymer were accurately weighed, finely powdered, and uniformly mixed with dry potassium bromide (KBr) using a mortar and pestle. About 100 mg of the mixture was compressed into a transparent KBr disc using a hydraulic press. A pure KBr disc was used for baseline correction to eliminate background interference. FTIR spectra were recorded in the 2000–400 cm⁻¹ range and analyzed for

characteristic peaks or shifts indicating potential physicochemical interactions.⁹

Evaluation of transdermal patches of cyclizine HCl

Physical appearance

The colour, clarity, flexibility, and smoothness of each prepared transdermal patch were evaluated.

Thickness of the patch

Using a screw gauge, three distinct patch thicknesses were measured, and mean values were calculated.

Weight Uniformity

The patches measuring 2 × 2 cm² were cut and weighed using an electronic balance. The average weight was calculated and recorded.¹⁰

Tensile strength¹¹

Using a Universal Strength Testing Machine, the tensile strength of the patches was assessed. The device had 1-gram sensitivity. There were two load cell grips in it. The upper one could be moved, but the lower one was fixed. A test film (4 × 1 cm²) was placed between these cell grips, and force was gradually applied until the film broke. The kilogram dial reading was used to determine the film's tensile strength. Tensile strength is expressed as follows

$$\text{Tensile Strength} = \frac{\text{Tensile load at break}}{\text{Cross sectional area}}$$

Folding endurance

This was identified by repeatedly folding one film until it broke in the same spot. The value of folding endurance was determined by how many times the

film could be folded in the same location without breaking.¹²

Percentage moisture absorption¹³

The patches were precisely weighed and put in a desiccator with a saturated potassium chloride solution that was kept at room temperature to maintain a humidity state of 80–90% RH. The patches were stored until a steady weight was reached, then they were taken out and weighed. The difference between the final and original weights with regard to the initial weight was used to compute the percentage of moisture uptake.

$$\text{Percentage moisture absorption} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

Percentage moisture loss

The patches were weighed separately and stored at room temperature in a desiccator containing anhydrous calcium chloride. When there was no change in the individual patch's weight, the final weight was recorded. The difference between the initial and final weights compared to the initial weight was used to compute the percentage of moisture loss.

$$\text{Percentage moisture loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Drug content

A transdermal patch was cut into 5 equal parts and put in a 50 ml buffer (pH 7.4). This was then shaken in a mechanical shaker for 24 h to get a homogeneous solution and filtered. The drug content was determined spectrophotometrically at the experimentally determined λ_{max} (230 nm) after suitable dilution.¹⁴

In vitro drug release

Patches of cyclizine HCl were cut into 5 cm² pieces (2 × 2 cm) and mounted on regenerated

cellulose membranes (pre-soaked overnight in distilled water). The membrane was fixed to a cylindrical diffusion cell open at both ends, with the drug-releasing surface oriented toward the receptor compartment. The receptor contained 50 mL phosphate buffer (pH 7.4), maintained at 32 ± 1 °C, and stirred continuously with a magnetic stirrer. At predetermined intervals, aliquots of receptor medium (e.g., 2 mL) were withdrawn and immediately replaced with fresh buffer to maintain sink conditions. Samples were analyzed for cyclizine HCl content using a UV spectrophotometer at the experimentally determined λ_{max} (Table 10).¹⁵

In-vitro drug release kinetics

Kinetic analysis of drug release from the formulated transdermal patches was carried out by fitting the in vitro release data to various mathematical models in order to determine the most appropriate release kinetics. The release data of cyclizine HCl patches containing HPMC and PVP as polymers and PEG 400 as plasticizer were evaluated using different kinetic models, namely zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. Based on the correlation coefficient (R^2) and release rate constant (k) values obtained for each model, the best-fit model was identified. This analysis was further used to elucidate the drug release mechanism from the transdermal system.¹⁶

RESULT AND DISCUSSION

The colour, odour and taste of the drug were characterized and recorded using descriptive terminology; the results are shown below:

Table 3: Organoleptic Properties of Cyclizine HCl

Sr. No.	Parameter	Observation
1	Colour	White
2	Odour	Odourless
3	Appearance	Crystalline powder



The melting point of Cyclizine HCl was found by the capillary technique to be 247.95° C.

Solubility study of cyclizine HCl in different solvents revealed that it is freely soluble in water, DMSO, soluble in ethanol, methanol, but insoluble in chloroform and ether.

Table 4: Solubility study of Cyclizine HCl

Sr. No.	Solvent	Solubility Description
1	Water	Freely soluble
2	DMSO	Freely soluble
3	Ethanol (95%)	Soluble

4	Methanol	Soluble
5	Chloroform	Practically insoluble
6	Ether	Practically insoluble

Determination of Absorption maxima for Cyclizine HCl

A UV spectrophotometric analysis established that the maximum absorption wavelength (λ_{max}) for Cyclizine HCl in methanol is 255 nm. The obtained peak closely matched the values reported in the literature. This wavelength was chosen for further analysis.

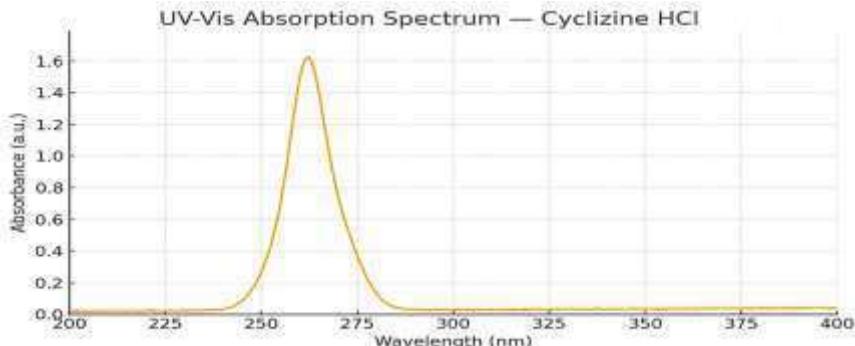


Figure No. 1: Absorption maxima of Cyclizine HCl in methanol

Standard calibration curve

A drug solution with concentrations ranging from 2 $\mu\text{g}/\text{ml}$ to 10 $\mu\text{g}/\text{ml}$ was prepared using methanol, and absorbance was measured using a UV spectrophotometer at the absorption maximum (λ_{max}) of 255 nm against a blank (methanol). A calibration curve was then constructed by plotting

concentration on the x-axis and absorbance on the y-axis.

Table 5: Data of Standard calibration curve of Cyclizine HCl

SL No.	Concentration($\mu\text{g}/\text{ml}$)	Absorbance
1	2	0.115
2	4	0.245
3	6	0.298
4	8	0.403
5	10	0.551

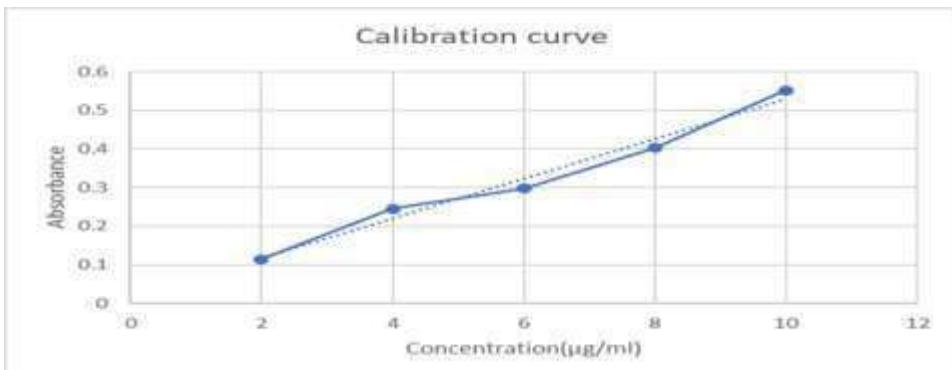


Figure No. 2: standard calibration curve of Cyclizine HCl



FTIR Spectra data

All characteristic peaks of Cyclizine HCl are retained in the polymer mixture with only minor

shifts or broadening, mainly due to hydrogen bonding and overlapping with polymer functional groups. No new peaks were observed, confirming drug–polymer compatibility.

Table 6: FTIR Spectra data of Cyclizine HCl

Functional Groups	Reference Peaks (cm ⁻¹)	Cyclizine HCl (cm ⁻¹)	Cyclizine HCl + HPMC + PVP (cm ⁻¹)
N–H stretching (salt form)	3300–3500	3320	3385
Aromatic C–H stretching	3050–3100	3060	3072
Aliphatic C–H stretching	3000–2850	2925	2930
Aromatic C=C stretching / N–H bending	1700–1500	1600	1635
C–H bending (CH ₂ /CH ₃)	1450–1350	1450	1450
C–N stretching (piperazine)	1350–1200	1224	1236
CO ₂ artefact (not a functional group)	2400–2300	2350	2350
Aromatic C–H out-of-plane bending	900–600	800–650	800–650

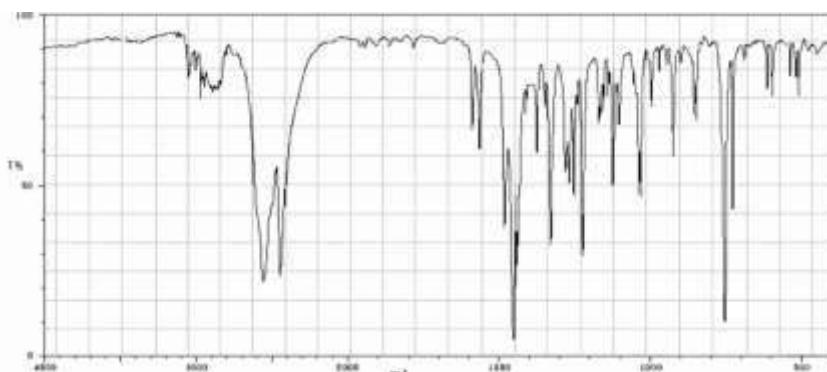


Figure No.3: FTIR Spectrum of Cyclizine HCl

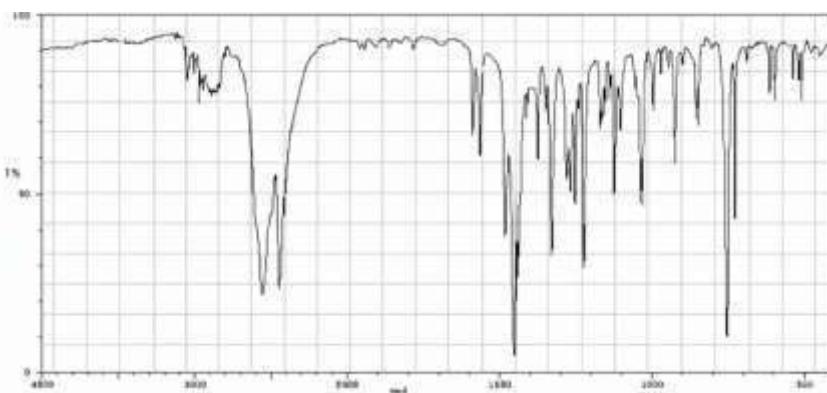


Figure No.4: FTIR Spectrum of PVP K30

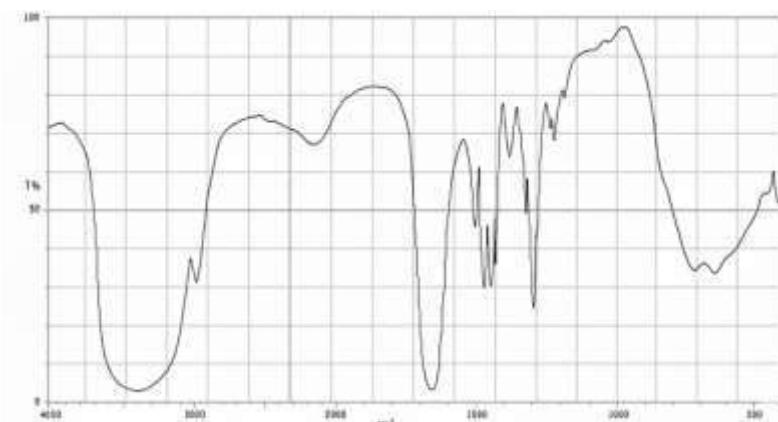


Figure No.5: FTIR Spectrum of HPMC K15

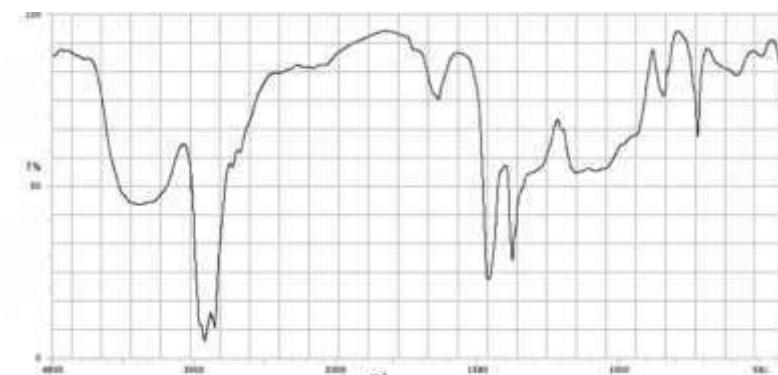


Figure No.6: FTIR Spectrum Cyclizine HCl+HPMC+PVP

Physical appearance of the patches

Table 7: Physical appearance of the transdermal patches

Formulation	Colour	Transparency	Surface	Flexibility
F1 (HPMC: PVP 3:1)	Colourless	Semi-transparent	Smooth, uniform	Good
F2 (HPMC: PVP 2:1)	Slightly white	Semi-transparent	Smooth	Good
F3 (HPMC: PVP 1:1)	Colourless	Semi-Transparent	Smooth, glossy	Very good
F4 (HPMC: PVP 1:2)	Colourless to faint white	Translucent	Smooth but slightly sticky	Excellent
F5 (HPMC: PVP 4:1, higher plasticizer)	Colourless	Transparent	Smooth	Very soft, highly flexible

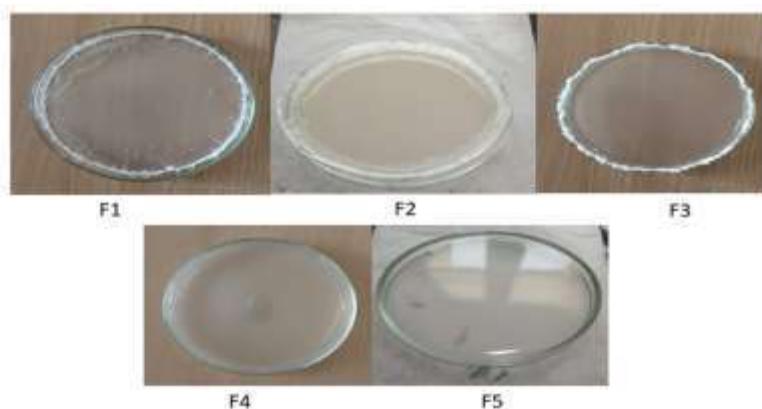


Figure 7: Physical appearance of Cyclizine HCl transdermal patches F1–F5.

Physicochemical evaluation of transdermal patches

All formulations showed uniform thickness (125–192 μm) and weight (55–60 mg), confirming consistent casting. Tensile strength decreased with higher PVP and PEG (8.5–4.2 MPa), while folding endurance (124–152 folds) improved, indicating

greater flexibility. PVP-rich patches (F3, F4) absorbed more moisture, whereas HPMC-based films (F1, F2, F5) showed better stability. Drug content was uniform (97–99.5%). Overall, HPMC provided strength, and PVP–PEG enhanced flexibility; F3 (1:1) showed the most balanced performance for transdermal delivery.

Table 8: Physicochemical evaluation of transdermal patches (1)

Formulation	HPMC:PVP Ratio	Thickness (μm , mean \pm SD, n=3)	Weight Uniformity (mg, mean \pm SD, n=3, %RSD)	Tensile Strength (MPa)	Folding Endurance (folds)
F1	3:1	125 \pm 2	55 \pm 2 (3.6%)	8.5	124
F2	2:1	130 \pm 3	57 \pm 2 (3.5%)	7.8	127
F3	1:1	155 \pm 4	58 \pm 3 (5.2%)	6.5	135
F4	1:2	140 \pm 3	56 \pm 2 (3.6%)	5.8	138
F5	4:1, high PEG	192 \pm 4	60 \pm 3 (5.0%)	4.2	152

Table 9: Physicochemical evaluation of transdermal patches (2)

Formulation	% Moisture absorption	% Moisture loss	Drug content (%)
F1	2.5	3.0	98.5
F2	3.1	3.5	97.8
F3	4.2	4.0	99.2
F4	5.0	4.5	98.0
F5	3.8	3.2	99.5

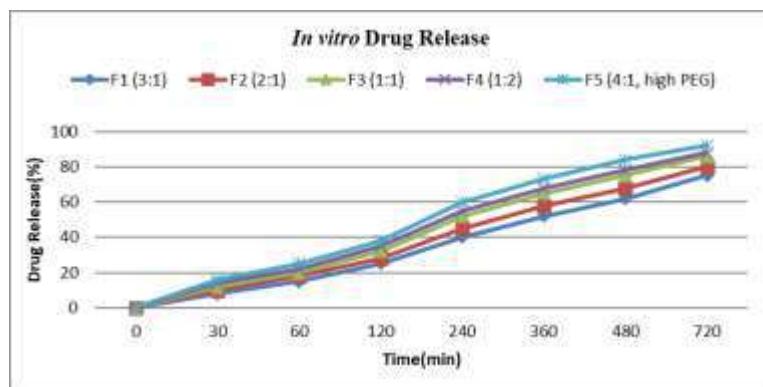
In vitro Drug release

The *in vitro* drug release profiles (F1–F5) demonstrated the influence of polymer ratio and excipient composition on drug release. After 720 minutes, cumulative release ranged from 75% (F1) to 92% (F5). A reduction in polymer content or increase in hydrophilic excipient accelerated drug

release. F1 (3:1 ratio) showed the slowest release, whereas F5 (4:1 with high PEG) achieved the fastest, highlighting PEG's role in promoting hydration and diffusion. F3 (1:1) exhibited a balanced, sustained profile (86%). Overall, modulation of polymer and PEG ratios effectively governed release kinetics, with F5 providing maximum and F3 optimized sustained release.

Table 10: In vitro Release data of transdermal patches

Time (min)	F1 (3:1)	F2 (2:1)	F3 (1:1)	F4 (1:2)	F5 (4:1, high PEG)
0	0	0	0	0	0
30	8.0	10.0	12.0	14.0	16.0
60	15.0	18.0	20.0	22.0	25.0
120	25.0	28.0	32.0	35.0	38.0
240	40.0	45.0	52.0	55.0	60.0
360	52.0	58.0	65.0	68.0	73.0
480	62.0	68.0	75.0	78.0	84.0
720	75.0	80.0	86.0	88.0	92.0

Figure No.7: *In vitro* Drug Release

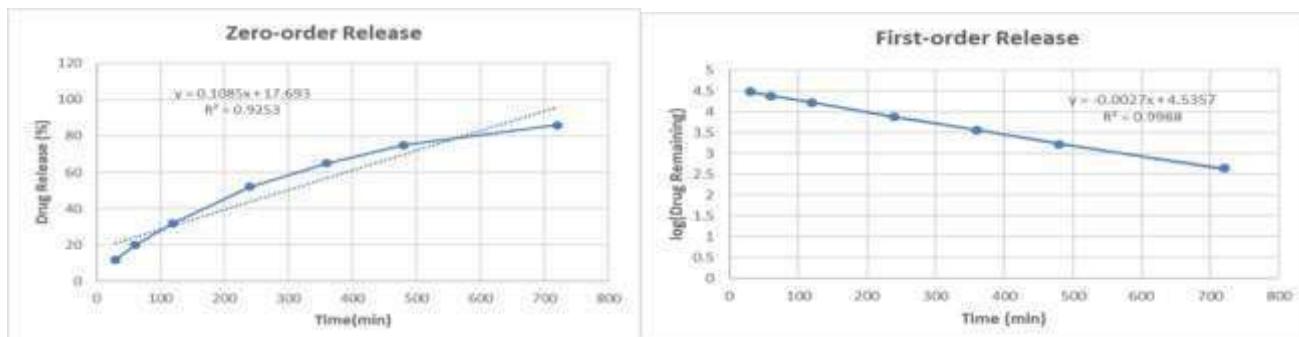
Drug Release Kinetics

The drug release profile of formulation F3 (1:1 polymer ratio) was subjected to kinetic modeling to elucidate the mechanism of drug release. The *in vitro* data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. The obtained regression coefficient (R^2) values indicated that the first-order model ($R^2 = 0.9988$) provided the best fit compared to other models. This suggests that the release of the drug from the formulation is concentration-dependent, i.e., the rate of drug release decreases as the concentration of the drug in the system declines.

The Higuchi model ($R^2 = 0.9906$) also showed a good correlation, implying that the drug release is significantly governed by a diffusion-controlled

mechanism through the polymeric matrix. Furthermore, fitting the data to the Korsmeyer–Peppas model yielded an R^2 of 0.9917 with a release exponent ($n = 0.635$). Since the value of n lies between 0.5 and 1.0, the mechanism can be characterized as non-Fickian (anomalous) transport, indicating that both diffusion and polymer relaxation/erosion contribute to the overall release mechanism.

The zero-order model ($R^2 = 0.925$) showed comparatively lower correlation, indicating that the system does not follow a constant drug release pattern over time. Instead, the release is better explained by a combination of diffusion and erosion, which aligns with the biphasic nature of the polymeric film.



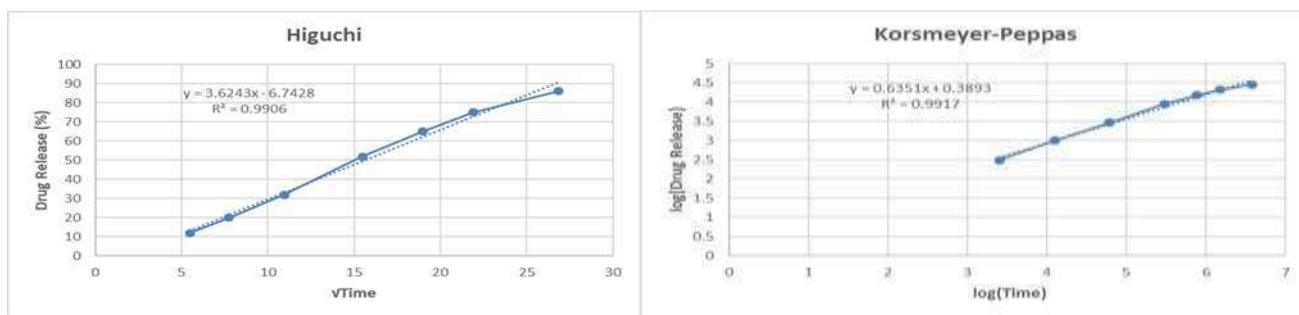


Figure No.8: Drug release kinetics

Table 11: *In vitro* drug release kinetics for F3 formulation

Model	Slope (k ₀)	Intercept	R ²
Zero-order	0.1085	17.693	0.9253
First-order	-0.00268	4.536	0.9988
Higuchi	3.6243	-6.743	0.9906
Korsmeyer-Peppas	0.6351 (n)	0.389	0.9917

Overall, the release kinetics study confirms that formulation F3 follows predominantly first-order kinetics with a diffusion–erosion-controlled mechanism, which is desirable for achieving sustained drug delivery. The anomalous transport behavior is particularly important for topical/transdermal delivery, as it ensures a balance between maintaining therapeutic drug levels and prolonging release.

CONCLUSION

The present study successfully developed and characterized transdermal patches of Cyclizine HCl using HPMC and PVP as film-forming polymers with PEG 400 as plasticizer. Preformulation and compatibility studies confirmed the suitability of the selected drug and excipients for formulation. The prepared patches were uniform, flexible, and stable, meeting the basic requirements of a transdermal system. *In vitro* release studies and kinetic modeling demonstrated that the formulation (F3) provided sustained drug release with a non-Fickian diffusion mechanism, indicating the involvement of both diffusion and polymer relaxation. Overall,

the research establishes that Cyclizine HCl can be effectively delivered through the transdermal route, offering advantages such as avoidance of first-pass metabolism, improved patient compliance, and prolonged therapeutic effect. This approach holds promise as an alternative to conventional oral administration.

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