Chinese Journal of Health Management
Volume 20 Issue 5, Year of Publication 2026, Page 1096-1108 | DoI-10.5281/zenodo.21273947

ISSN: 1674-0815

Chinese Journal of Health Management

Chinese Medical Association

Transdermal Microneedle Patch

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Article Information
Received: 06-04-2026
Revised: 21-05-2026
Accepted: 14-05-2026
Published: 07-06-2026

Keywords
Microneedle Patch, Transdermal Drug Delivery, Ondansetron HCl, Doxylamine Succinate, Franz Diffusion, Anti-emetic

ABSTRACT:
Transdermal drug delivery offers significant advantages over conventional routes, including the avoidance of first-pass hepatic metabolism and the provision of sustained drug release profiles. However, its clinical efficacy is severely restricted by the impermeable barrier properties of the stratum corneum. To overcome this limitation, this study presents the development and evaluation of a novel transdermal microneedle patch system designed for the painless, controlled delivery of anti-emetic medications. Multi-layered polymeric microneedle patches were successfully formulated utilizing a self-fabricated aluminum mould technique. Pre-formulation identity and drug-excipient compatibility were rigorously confirmed using Fourier-Transform Infrared Spectroscopy (FTIR) and melting point determinations. The patches were subjected to robust quality control evaluations, including weight variation, surface pH, folding endurance, *in-vitro* skin permeation via Franz diffusion cells (at 270 nm), and an antimicrobial zone-of-inhibition assay against *Staphylococcus aureus*.

INTRODUCTION:
Transdermal delivery has the advantage of bypassing the first-pass effect and allowing sustained release of the drug. However, the drug delivery is limited owing to the barrier created by the stratum corneum. Microneedles are a transdermal drug delivery system that is painless, less invasive, and easy to self-administer, with a high drug bioavailability. Microneedle technology overcomes this limitation by creating microscopic channels in the skin, enabling effective drug permeation without pain or bleeding. Dispersible microneedles dissolve after insertion, leaving no sharp waste and improving patient safety and compliance.

Characteristics:
- 50–300 micrometer long
- 1 to 50 micrometer wide at the tip

- Can be solid/hollow and fabricated as single or multi-needle arrays.

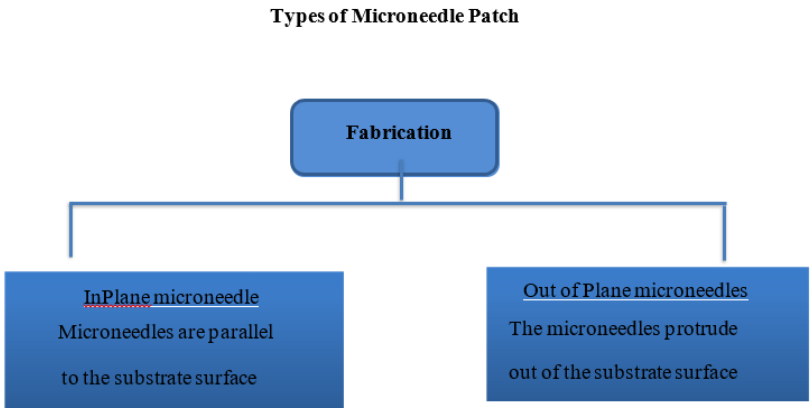

Figure1. Types of Microneedle Patch

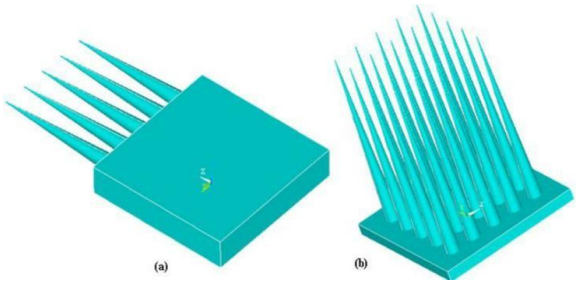

Figure 2. Types of needles

Need:
- An ideal transdermal system should:
1. Maintains skin permeability only for desired time period.
2. It can deliver drug quickly with minimal discomfort.
3. It is self-administrable.
4. It has responsive pharmacokinetics and pharmacodynamics.
5. It can create sustained delivery.

Components of patch: -A transdermal patch is a medical adhesive patch applied to the skin to deliver a specific dose of medication through the skin and into the bloodstream. The key components of a transdermal patch include:

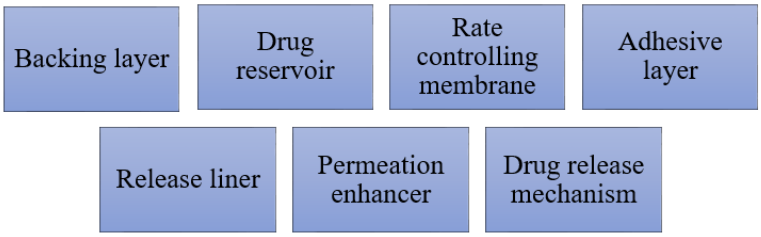

Figure 3. components of patch

1. **Backing Layer:** The outermost layer of the patch that provides structural support and protects the medication from environmental factors. It is impermeable and typically made from materials like plastic or fabric.
2. **Drug Reservoir or Matrix:** This layer contains the active drug that will be released over time. The drug can be stored in different ways, such as in a liquid reservoir, a semi-solid matrix, or directly mixed into an adhesive.
3. **Rate-Control Membrane:** In some patches, this membrane regulates the rate at which the drug is released into the skin. It ensures a controlled and consistent release of medication over a specified period.
4. **Adhesive Layer:** This is the part of the patch that sticks to the skin. It must be skin-friendly and, in some

cases, may also contain the drug, which diffuses from the adhesive into the skin.

5. **Release Liner:** This is a protective layer that covers the adhesive and drug layer before application. It is removed just before the patch is applied to the skin to prevent contamination and protect the patch's integrity.
6. **Permeation Enhancers:** These substances are sometimes added to improve the skin's ability to absorb the drug. They help in increasing the permeability of the skin to facilitate drug delivery.
7. **Drug Release Mechanism:** Some patches use a multi-layer system where the drug moves through various layers before reaching the skin, ensuring a timed release over several hours or days.

Microneedle patch:

Microneedle patches are a groundbreaking approach to delivering medications and vaccines through the skin. These patches are made up of tiny needles, often so small you can barely see them, that painlessly penetrate the outer layer of the skin. Imagine a patch that feels like a band-aid but works like a needle. Instead of using a syringe to inject medication, you simply place the patch on your skin. The tiny needles create microchannels that allow the medication to enter your bloodstream quickly and efficiently. This method offers several advantages: it's less painful than traditional injections, can be self-administered, and is easier to transport and store than liquid vaccines. Microneedle patches have great potential for improving vaccination rates and making treatments more accessible, especially in remote areas or for people who fear needles. Overall, microneedle technology represents a significant step forward in healthcare, providing a simple, effective, and less intimidating way to deliver essential medications and vaccines.

Types of microneedle patch:

Solid Microneedles: Made from materials like metal or polymer, they create microchannels for drug delivery through the skin.

1. Dissolvable Microneedles: Made from biocompatible materials that dissolve upon contact, releasing medication directly into the bloodstream.
2. Coated Microneedles: These have a drug or vaccine coating that is delivered as the needles penetrate the skin.
3. Solid Microneedles: They do not contain the drug themselves; instead, they enhance skin permeability. This technique is often called "poke and patch."
4. Hollow Microneedles: Hollow microneedles are tiny needles with a central lumen (hollow channel) that deliver liquid drugs directly into the skin, similar to miniature injections.

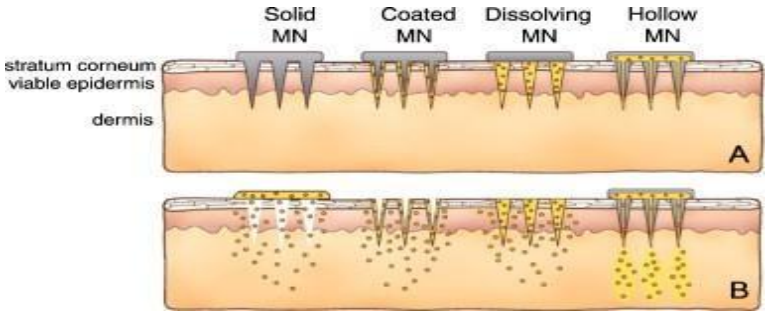

Figure 4. Schematic illustration of the types of microneedles and their drug delivery methods

Anti-emetic patches:

1. Backing Layer: The outermost layer of the patch that provides structural support and protects the medication from environmental factors. It is impermeable and typically made from materials like plastic or fabric.
2. Drug Reservoir or Matrix: This layer contains the active drug that will be released over time. The drug can be stored in different ways, such as in a liquid reservoir, a semi-solid matrix, or directly mixed into an adhesive.
3. Rate-Control Membrane: In some patches, this membrane regulates the rate at which the drug is released into the skin. It ensures a controlled and consistent release of medication over a specified period.
4. Adhesive Layer: This is the part of the patch that sticks to the skin. It must be skin-friendly and, in some cases, may also contain the drug, which diffuses from the adhesive into the skin.
5. Release Liner: This is a protective layer that covers the adhesive and drug layer before application. It is removed just before the patch is applied to the skin to prevent contamination and protect the patch's integrity.
6. Permeation Enhancers: These substances are sometimes added to improve the skin's ability to absorb the drug. They help in increasing the permeability of the skin to facilitate drug delivery.
7. Drug Release Mechanism: Some patches use a multi-layer system where the drug moves through various layers

before reaching the skin, ensuring a timed release over several hours or days.

Uses of Transdermal Anti-Emetic Patches:
1. Motion Sickness
2. Post-operative Nausea and Vomiting (PONV)
3. Chemotherapy-Induced Nausea and Vomiting (CINV)
4. Situations "Where Oral Administration Is Difficult."
5. Patients who cannot swallow tablets.
6. Patients with severe vomiting, unconsciousness, or feeding tubes.

Components of Patch:
1.Ondansetron HCL (Drug A):
Ondansetron is a widely used anti-emetic drug belonging to the class of 5-HT_3 (serotonin) receptor antagonists. It works by blocking serotonin receptors present in the Chemoreceptor Trigger Zone (CTZ) and on vagal afferent nerves in the gastrointestinal tract, thereby preventing the vomiting reflex. Ondansetron is highly effective in controlling chemotherapy-induced, radiotherapy-induced, and post-operative nausea and vomiting, and may also be used for drug-induced or gastroenteritis-related vomiting. Common side effects include headache, constipation, dizziness, and in some cases QT-interval prolongation, so caution is needed in patients with cardiac conditions or hepatic impairment. Overall, ondansetron is considered one of the safest and most effective modern anti-emetic agents.

2.Doxylamine Succinate (Drug B):
Doxylamine succinate is a first-generation antihistamine with strong anti-emetic properties, primarily acting by blocking H_1 histamine receptors in the vomiting center of the brain and exhibiting additional anticholinergic effects. It is commonly used to treat pregnancy-induced nausea and vomiting (NVP), and as considered a first-line therapy for morning sickness. Besides its anti-emetic use, doxylamine is also employed as an OTC sleep aid and for relief of mild allergic symptoms. It is available in tablets, capsules, and syrups. Major side effects include drowsiness, dry mouth, blurred vision, & constipation. Despite its sedative nature, doxylamine remains a safe and effective option, particularly in managing nausea during pregnancy.

Pre-formulation Studies:
1.Organoleptic Properties:
Table 1. Organoleptic Properties

Parameter	Drug A (Ondansetron)	Drug B (Doxylamine Succinate)
Appearance	White to off-white crystalline powder	White crystalline powder
Odor	Odourless	Odourless

2. Melting Point Determination:
The melting point indicates the purity and thermal behaviour of the drug.
DRUG A - 175°C to 179°C
- The value matches with the reported literature M.P., conforming the identity of the drug.
- So, our result indicates purity and authenticity of drug A
- Melting Point- 178°C

DRUG B - 100°C to 108°C
- The value matches with the reported literature M.P., conforming the identity of the drug.
- So, our result indicates purity and authenticity of drug B
- Melting Point- 108°C

3.Solubility Studies:
Table 2. Solubility Studies of drug

Solvent	Ondansetron (Drug A)	Doxylamine Succinate (Drug B)
Water	Slightly soluble	Insoluble
0.1 N HCl	Freely soluble	Soluble

4.FTIR Analysis- (Drug A):
To determine the characteristic functional groups, present in Drug A and evaluate drug–excipient compatibility using Fourier Transform Infrared Spectroscopy (FTIR). FTIR spectral analysis of Drug A was performed using a **Shimadzu FTIR spectrophotometer**. The sample was scanned in the **mid-infrared region (4000–400 cm^{-1})**

using the following instrument parameters:

Table 3. FTIR Drug A Result

	Item	Value
1	Sample name	Ondansetron
2	Sample ID	Ondansetron
3	Option	Ondansetron
4	Intensity Mode	%Transmittance
5	Apodization	Happ-Genzel
6	No. of Scans	45

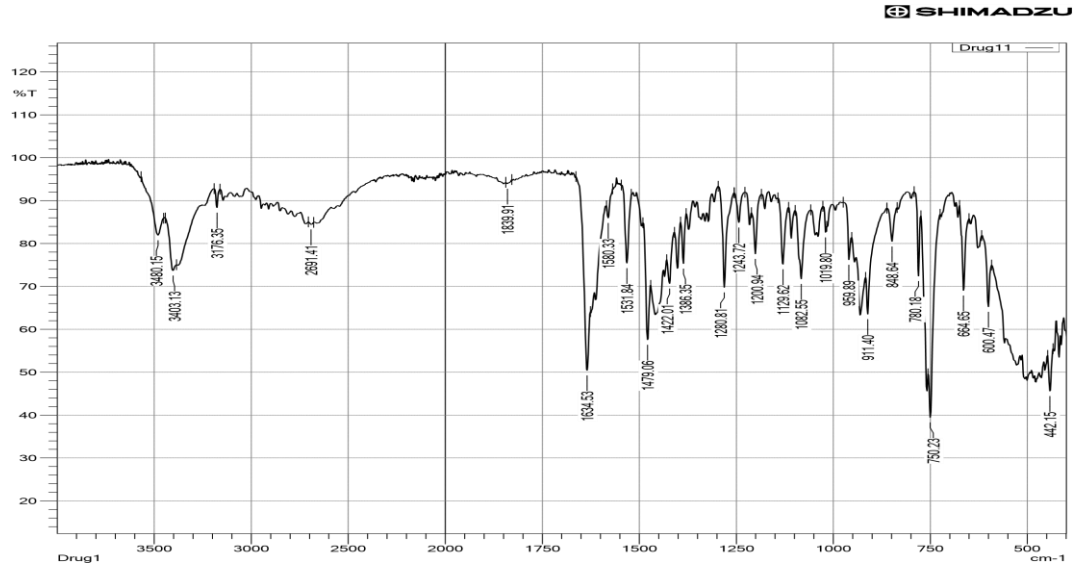

Figure 5. FTIR Drug A Graph

The FTIR analysis confirmed the identity and purity of Drug A. All characteristic peaks matched standard literature values, and no significant interactions with the excipients were observed. Thus, Drug A is chemically stable and compatible for use in transdermal patch formulation.

Drug B:

To identify the functional groups, present in Drug B and to assess the compatibility of Drug B with selected excipients using Fourier Transform Infrared Spectroscopy (FTIR). FTIR analysis of Drug B was carried out using a **Shimadzu FTIR spectrophotometer** in the range of **4000–400 cm⁻¹**. The parameters used for the study are shown below.

Table 4. FTIR Drug B Result

	Item	Value
1	Sample name	Doxylamine Succinate
2	Sample ID	Doxylamine Succinate
3	Option	Doxylamine Succinate
4	Intensity Mode	%Transmittance
5	Apodization	Happ-Genzel
6	No. of Scans	45

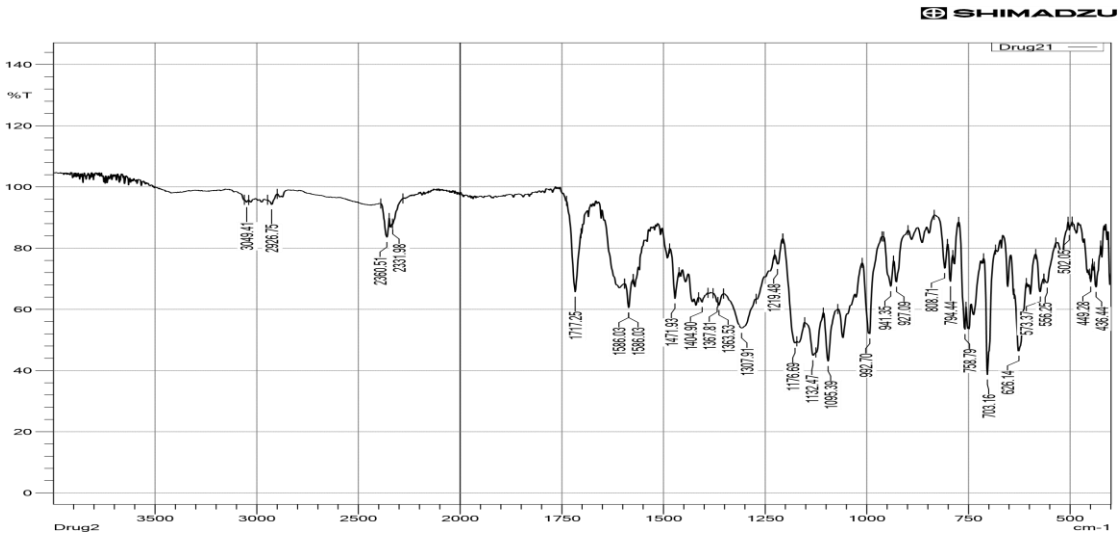

Figure 6. FTIR Drug B Graph

The FTIR spectrum of Drug B confirmed all characteristic functional groups and matched reported literature values. No significant interactions were observed with the excipients, confirming its chemical stability and compatibility for use in the transdermal patch formulation.

Drug A+ Polymer:

To evaluate the compatibility of Drug A with the selected polymers (HPMC / PVP) used in the transdermal patch formulation through FTIR spectroscopy. FTIR analysis of the **Drug A + Polymer mixture** was performed using a **Shimadzu FTIR spectrophotometer** in the range of **4000–400 cm⁻¹**. The optimized parameters used during scanning are listed below:

Table 5. FTIR Drug A + Polymer Result

	Item	Value
1	Sample name	Polymer+ Ondansetron
2	Sample ID	Polymer+ Ondansetron
3	Option	Polymer+ Ondansetron
4	Intensity Mode	%Transmittance
5	Apodization	Happ-Genzel
6	No. of Scans	45

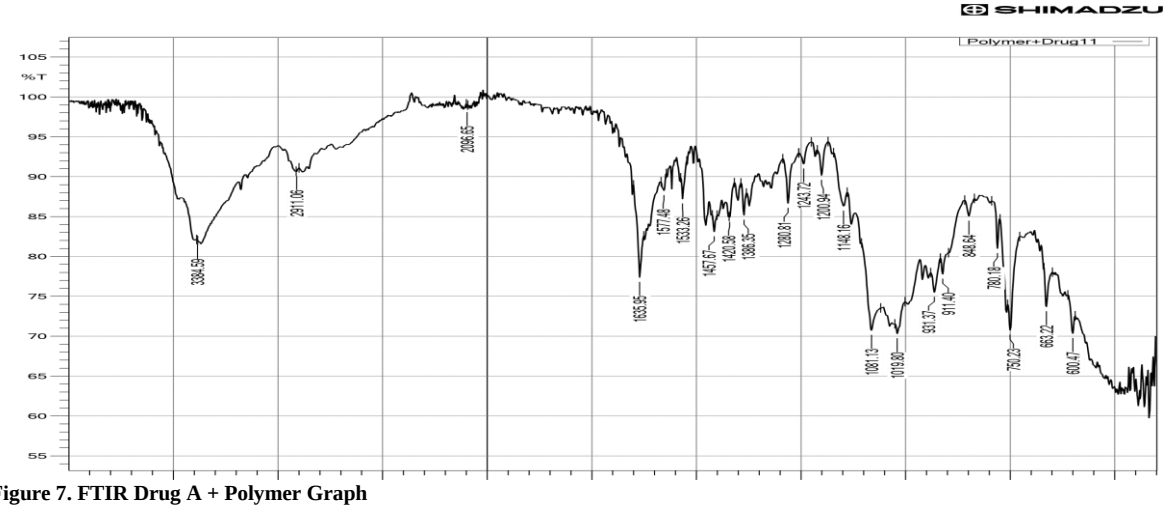

Figure 7. FTIR Drug A + Polymer Graph

FTIR confirmed that Drug A shows excellent compatibility with the selected polymer, making it suitable for incorporation into a stable transdermal patch system.

Drug B + Polymer-

To evaluate the compatibility of Drug B (Doxylamine Succinate) with the selected polymer (HPMC/PVP) used in the formulation of the transdermal patch. FTIR analysis of the **Drug B + Polymer mixture** was carried out using a **Shimadzu FTIR spectrophotometer** in the range of **4000–400 cm⁻¹**. The instrument parameters were:

Table 6. FTIR Drug B + Polymer Result

	Item	Value
1	Sample name	polymer B+ Doxylamine Succinate
2	Sample ID	polymer B+ Doxylamine Succinate
3	Option	polymer B+ Doxylamine Succinate
4	Intensity Mode	%Transmittance
5	Apodization	Happ-Genzel
6	No. of Scans	45

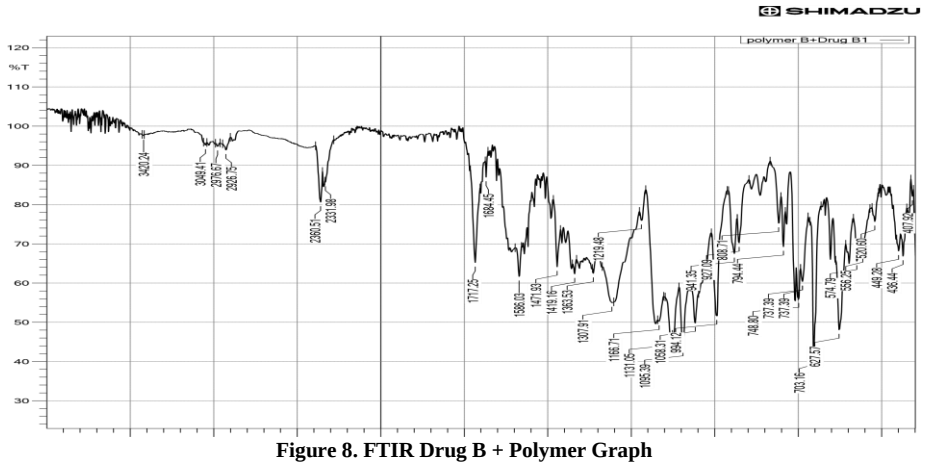

Figure 8. FTIR Drug B + Polymer Graph

The FTIR spectrum of Drug B + Polymer showed that all major functional group peaks of Drug B were preserved without significant shifts or loss. The absence of additional peaks confirms that Drug B is compatible with the polymer selected for transdermal patch formulation.

5. Drug – Excipient Compatibility Study:

Table 7. Excipient Compatibility Studies

Drug A	**Drug B**
Drug + HPMC	Drug + HPMC
Drug + PVP	Drug + PVP
Drug + Gelatin	Drug + Gelatin
Drug + Preservatives (Methylparaben)	Drug + Preservatives (Methylparaben)

Result- After mixing these components the formulation was clear which required for him formation.

Formulation of Microneedle patch:

1. Start by preparing the solvent mixture.
2. Take 2 beaker of 150ml & label it as Drug A & Drug B.
3. Weigh these compounds: 0.2 gm HPMC, 0.25gm PVP, 0.1gm Gelatin, 0.1gm Paraben (F4).
4.Take these measured compounds in both of the beakers respectively.
5. Now weigh & add 0.1 gm of ondansetron HCL (Drug A &0.1gm of DC drug in respective beakers.
6. Solvents: - Add 10md Distilled Water as Solvent in the beakers.
7. Stirring: - stir the formulation vigorously. Yor 2 minutes
8. Now add 1-2 drop of Concentrated Hydrochloric acid.
9. Sonication: sonicate the beakers in sonicate for 15 to 20 minutes to reduce lumps & air bubbles
10.Pouring: After sonication pour the formulation into self-Fabricated mold.
11.Pouring method: Firstly, pour formulation of Drug in a small quantity so that it can reach the tip of the pores.
12. Let it settle down and dry it for 10 minutes. Now add formulation of drug A in small quantity as 2nd layer. Now remove the excess formulation from the edges Leave the mold at room temperature for 24 hrs. for the

formation of fm.

Formulations:

Table 8. Formulation Table

Ingredients	F1	F2	F3
D1 + D2	0.2	0.2	0.2
HPMC K4M	0.2	0.5	0.7
Chitosan	0.5	0.75	1.0
PVP	0.25	0.25	0.25
Citric Acid	0.1	0.1	0.1

Table 9. Formulation Table

Ingredients	F4	F5
D1 + D2	**0.2**	0.2
HPMC K4M	**0.2**	0.2
PVP	**0.25**	0.4
Gelatin	**0.1**	-

Evaluation Parameters of Patch:

1.Physical Appearance:

The physical appearance of the patch is checked for color, smoothness, flexibility, and uniformity. The thickness and weight uniformity of the patch are then measured to ensure consistent drug distribution and uniformity among batches. Moisture content and moisture uptake studies determine the amount of water present in the patch and its ability to absorb moisture from the environment, which directly affects stability and adhesion. Mechanical properties such as folding endurance and tensile strength are evaluated to assess the patch's flexibility and its ability to withstand handling without breaking. Flatness is examined to ensure the patch does not show signs of shrinking or wrinkling, as this can affect adhesion to the skin. Finally, the swelling index is measured to understand how much the patch swells upon contact with fluids, which may influence drug release and adherence. These physical parameters collectively ensure that the TDDS is safe, stable, and effective for transdermal application.

Table 10. Physical Appearance

Parameters	**Result**
Transparency	Transparent
Homogeneity	Homogeneous
Patch Area	15*15
Tackiness	Non-Tacky

2.Weight Variation:

To ensure quality, weight variation testing is performed by randomly selecting patches from a batch and weighing them on a calibrated analytical balance. The mean weight is calculated, and deviations are assessed to confirm that they fall within acceptable limits, typically around ±5% of the average weight for pharmaceutical patches.

Figure 9. Weight variation test

Table 11. Weight variation of patch

Formulation	**Individual Wt. (g)**	**Avg. Weight (g)**	**Weight variation (Individual – Avg. weight)**

F1	0.31	0.30	0.01
F2	0.33	0.30	0.03
F3	0.34	0.30	0.04
F4	0.28	0.30	0.02

3.Surface pH determination:

The surface pH of transdermal patches is a crucial characteristic that influences their compatibility with the skin, drug release, and overall efficacy. Ideally, the surface pH of these patches should be maintained within the range of 4.5 to 5.5, which aligns with the natural slightly acidic pH of human skin. This compatibility is essential to minimize skin irritation and ensure user comfort.

Drug A

The pH of Formulation for drug A is Determined to be 4.7

Drug B

The pH of formulation for Drug B is determined to be 5.47

Figure 10. pH reading of formulation

The surface pH was calculated by calculation the pH of formulation which are used to prepare the patch by calculating the pH on a calibrated digital pH meter at room temperature.

4.Folding endurance:

Folding endurance is typically measured by subjecting the patch to repeated folds at a specified angle (usually 180º) until visible damage occurs, with a higher number of folds indicating better durability. Factors influencing folding endurance include the material composition of the patch, such as the type of polymers and adhesives used, as well as the patch thickness and hydration levels. The patch folding endurance was assessed by repetitively folding a small strip (15 x 15 cm^2) without causing it break. The folding endurance value is determined by the number of times the patch folded at the same spot without fracturing.

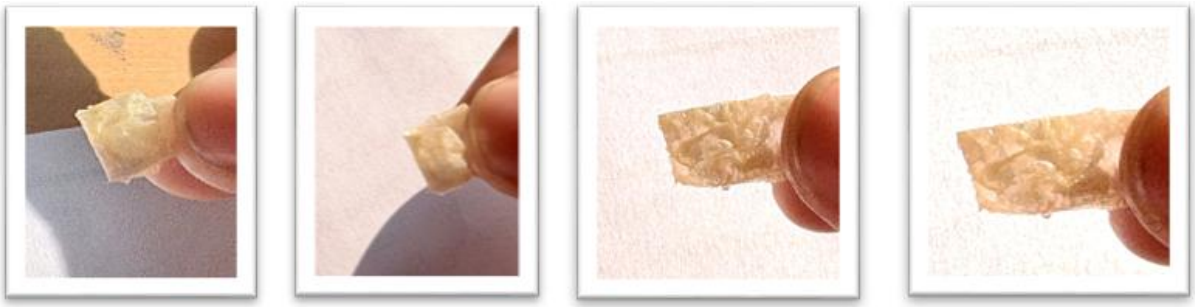

Figure 11. TDDS Patch Folding Endurance

5.In-vitro drug permeation study (Franz Diffusion):

Franz diffusion cells is used to study the rate at which a drug diffuses across a membrane. Set up two compartments: a donor compartment, place a patch, and a receptor compartment, which contains a solvent (often a buffer like phosphate-buffered saline). A cellophane membrane separates the two compartments. The drug will diffuse from the donor side, across the membrane, into the receptor compartment over time. Measuring Drug Concentration at Intervals At regular time intervals (e.g., every 5 minutes), collect a small sample from the receptor compartment. These samples are analyzed using UV spectroscopy to determine the drug concentration

in the receptor compartment, based on how much drug has diffused across the membrane by each time point.

Figure 12. Franz Diffusion Apparatus

Table 12. Franz Diffusion Reading

Time(min)	Wavelength (nm)	Absorbance (Drug A)
30	270	1.007
60	270	1.076
90	270	1.374
Time(min)	Wavelength (nm)	Absorbance (Drug B)
30	270	1.007
60	270	1.088
90	270	1.463

Drug A	**Drug B**
For the Franz diffusion test of a microneedle patch measured at 270 nm, absorbance was recorded at intervals of 30, 60 & 90 minutes. The initial absorbance at 30 minutes was 1.007, reflecting the beginning phase of drug diffusion. By 60 minutes, the absorbance rise to 1.076, and finally, at 90 minutes, it reached 1.374. This trend suggests that the drug diffused steadily from the microneedle patch into the receptor compartment throughout the 90-minute period.	For the Franz diffusion test of a microneedle patch measured at 270 nm, absorbance was recorded at intervals of 30, 60&90 minutes. The initial absorbance at 30 minutes was 1.007 reflecting the beginning phase of drug diffusion. By minutes, the 60 absorbance rise to 1.088, showing a steady increase as the drug diffused through the membrane. and finally, at 90 minutes, it reached 1.463. This trend suggests that the drug diffused steadily from the microneedle patch into the receptor compartment throughout the 90minute period.

Formula,

$$\text{Diffusion rate} = \frac{\text{Absorbance}}{\text{Time}}$$

The calculated diffusion rate is 0.0384 absorbance units per minute for Drug A & b respectively. This value represents the average rate of change in absorbance over the 90-minute period, indicating the steady rate at which the drug diffuses through the membrane in the Franz diffusion cell.

6. Anti-Microbial Assay:

Transdermal patches with antimicrobial activity represent a novel approach in the field of drug delivery, combining the benefits of sustained medication release with the ability to prevent or treat infections at the application site. These patches are designed to deliver therapeutic agents through the skin while simultaneously incorporating antimicrobial agents to inhibit microbial growth, thus reducing the risk of infections associated with the skin or underlying tissues.

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Volume 20 Issue 5, Year of Publication 2026, Page 1096-1108 | DoI-10.5281/zenodo.21273947

Figure 13. Nutrient Agar

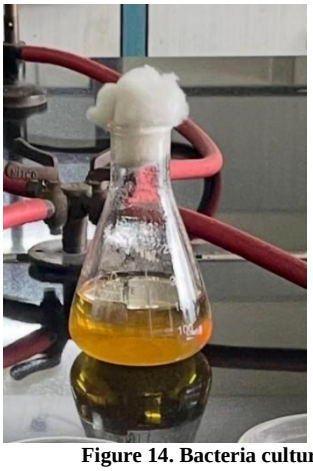

Figure 14. Bacteria culture

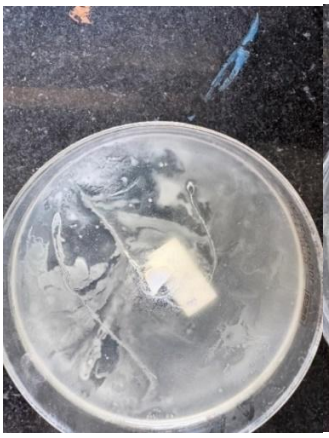

Figure 15. Drug B Formulation

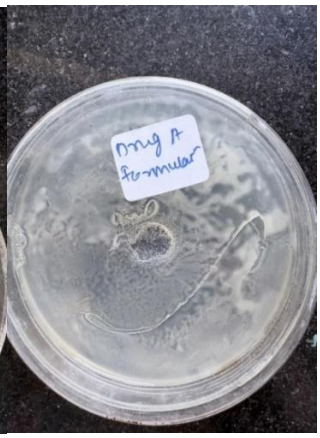

Figure 16. Drug A Formulation

Figure 17. Bacterial Growth in Formulation

Table 13. Zone of inhibition

Sample	Zone of inhibition (cm)
Streptomycin	2.4
Patch (p1)	1.6
Patch (p2)	1.5

Relative activity (%) = (zone of inhibition of sample /zone of inhibition standard) X 100
Calculation: -
Patch 1 (P1): (1.6 / 2.4) × 100 = 66.6%
Patch 2 (P2): (1.5 / 2.4) × 100 = 62.5%

The calculated relative activities show that the patch 1exhibits 66.60% activity relative to Streptomycin, Patch 2 has 62.50% activity. These results indicate moderate antimicrobial potential for the tested samples.

Drug Content per unit area of patch:

- Concentration of drug = 0.001 mg/ml
- Volume of solvent = 10 ml
- Patch dimension = 1.5cm x 1.5cm

Total Drug content: -
Drug Content (mg): - Volume x Concentration
Drug Content (mg): - 10ml x 0.001mg/ml
Total drug content is 0.01mg

Total Surface Area: -
Surface area = length x Width = 1.5cm x 1.5cm = 2.25 cm^2

Drug Content Per Unit Area: -
Drug Content Per Unit Area = Total Drug content (mg) / Total surface area (cm^2)
= 0.01mg / 2.25 cm^2

The drug content per unit area of patch is 0.005mg/cm^2.

CONCLUSION:

The study successfully demonstrated the potential of microneedle patches formulated with 5HT3-antagonist drugs for transdermal drug delivery, specifically targeting the treatment of emesis. The patches were developed using self-fabricated Aluminum mold, along with excipients such as Distilled water, concentrated hydrochloric acid, hydroxypropyl methylcellulose (HPMC), polyvinyl pyrrolidine, gelatin, and methyl Paraben. Comprehensive evaluations were performed to determine their physicochemical and mechanical properties. Physicochemical studies, including weight variation, and surface pH, indicated that the patches are stable and compatible with skin application. The surface pH of the patches was within the physiological range, minimizing the risk of irritation or discomfort during use. The pH of formulation was optimized to maintain patch flexibility & ensuring long-term stability. The mechanical properties of the patches were also evaluated, with high folding endurance values confirming their durability and resistance to cracking or breaking during handling and application.

This makes the patches suitable for practical use in clinical and patient settings. Drug release studies using the Franz diffusion cell demonstrated a sustained release profile of 5HT3 Antagonist API, which is critical for prolonged therapeutic action in Emesis. This sustained release reduces the need for frequent applications, improving patient compliance and ensuring consistent therapeutic levels. Antimicrobial activity was tested using streptococcus aureus (*S. aureus*) as a model organism, and the microneedle patches exhibited significant antibacterial activity. The observed activity highlights the potential of the patches to prevent or treat bacterial infections & further enhancing their therapeutic value. In conclusion, the study underscores the feasibility and effectiveness of utilizing microneedle patches formulated with 5HT3 antagonist and supporting excipients for the treatment of Emesis. These patches combine multiple advantages, including chemical, mechanical strength, sustained drug release, and significant antimicrobial activity against *S. aureus*. These patches are promising for prophylactic or treatment of emesis. Further in vivo studies and clinical trials are recommended to validate the efficacy, safety, and long-term benefits of these patches in managing emesis and related dermatological conditions.

CONFLICT OF INTEREST:

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

ACKNOWLEDGMENT:

The authors gratefuly acknowledge the support and facilities provided by Ideal College of Pharmacy & Research, Mumbai. We also thank our colleagues and students for their helpful discussions and insights throughout this project.

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