



REVIEW ON TRANSDERMAL PATCH CONTAINING ANTI-HISTAMINE AND ANTIEMETIC DRUGS

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ABSTRACT

Transdermal drug delivery systems (TDDS), or patches, are designed to administer drugs through the skin for systemic effects. They enhance patient compliance by avoiding first-pass metabolism, providing controlled and continuous drug release, and minimizing side effects. This innovative, painless method improves therapeutic efficiency and is increasingly favoured over traditional dosage forms. Transdermal drug delivery systems (TDDS) operate by applying a drug within a patch that adheres to the skin for extended periods, ensuring a steady concentration in the bloodstream. Key components include a polymer matrix, drug, and permeation enhancers, with polymers ranging from natural options like Zein and Shellac to synthetic types such as Polybutadiene and Polyvinyl chloride. Various TDDS types exist, including single-layer and multi-layer systems. Antiemetic drugs available as transdermal patches include scopolamine (for motion sickness) and granisetron (for chemotherapy-induced nausea). These patches offer controlled, extended release of medication for convenient nausea management. Evaluation tests for transdermal patches include assessing drug release rate, adhesion strength. Additionally, stability, permeation, and pharmacokinetic studies are conducted to ensure effectiveness and safety.

KEYWORDS: transdermal patch, drug delivery, polymer matrix, adhesives, types.

INTRODUCTION

Transdermal patches have emerged as a leading method for therapeutic delivery. Transdermal drug delivery systems (TDDS) are now recognized as a reliable approach to bypass hepatic first-pass metabolism, particularly for lipophilic drugs. This mode of application not only enhances the bioavailability of these medications but also protects them from enzymatic degradation and acid-mediated decomposition, ensuring more effective and stable therapeutic outcomes.^[1,2]

Transdermal Drug Delivery Systems (TDDS) are defined as self-contained, discrete dosage forms commonly referred to as "patches." When these patches are applied to intact skin, they deliver the drug at a controlled rate directly into the systemic circulation. TDDS are specifically designed to provide a therapeutically effective amount of medication across a patient's skin.^[3]



Fig. 1: Transdermal Patch.

Transdermally administered systems offer several significant advantages, including the ability for self-administration, enhanced patient compliance, controlled release of therapeutics, and the option to instantly cease drug delivery by simply removing the patch. The continuous absorption of drugs through these systems allows for lower dosages, which helps minimize side effects associated with high plasma concentrations. However, despite these numerous benefits, transdermal films also face certain limitations. These include challenges in delivering ionic and macromolecular drugs, potential skin irritability, and complications for patients with reduced peripheral blood circulation.^[4]

Antiemetic drug used as transdermal patch

- 1 **Scopolamine** – Used to prevent nausea and vomiting caused by motion sickness.
- 2 **Granisetron** – Used to prevent nausea and vomiting caused by chemotherapy.
- 3 **Dimenhydrinate** – Sometimes used for motion sickness and nausea.

- 4 Ondansetron** – Although more commonly available in oral forms, there are patches under development for nausea, especially from chemotherapy.^[5]

Scopolamine is available as a patch to be applied to the hairless skin behind your ear. To prevent nausea and vomiting caused by motion sickness, apply the patch at least 4 hours before it's needed and leave it in place for up to 3 days. If treatment is required for more than 3 days to manage nausea and vomiting from motion sickness, consult your healthcare provider.^[6]

ADVANTAGES

Transdermal drug delivery offers several advantages for medication administration:

- **Convenient Administration:** Typically requires application only once a week, improving patient adherence.
- **Alternative for Patients:** Suitable for those who cannot tolerate oral medications.
- **Useful for Unconscious or Nauseated Patients:** Effective for individuals unable to take medications orally due to nausea or unconsciousness.
- **Minimizing Gastrointestinal Effects:** Ideal for drugs that cause gastrointestinal discomfort, as it bypasses the stomach and intestines.
- **Protection from Degradation:** Medications that degrade in the gastrointestinal tract benefit from this method.
- **Avoiding First-Pass metabolism:** Enhances bioavailability by bypassing liver metabolism, allowing more of the drug to enter circulation.
- **Consistent Plasma Levels:** Maintains stable drug levels in the bloodstream, which is crucial for effective long-term treatment.^[7,8]

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.^[8,9]

SKIN

The skin is the largest organ in the human body, covering about 2 square meters and receiving around one-third of the body's blood flow. It acts as a barrier to prevent harmful substances from entering the body and is relatively thin, typically measuring about 2.97 mm thick.

Key Functions of the Skin

- **Barrier Protection:** The skin protects against physical injuries, chemicals, and germs.
- **Temperature Control:** It helps regulate body temperature by sweating and adjusting blood flow.
- **Blood Pressure Regulation:** The skin plays a role in managing blood pressure.
- **UV Protection:** It shields the body from harmful ultraviolet rays from the sun.
- **Drug Absorption:** The skin is important for how drugs are delivered into the body, affecting how well they can be absorbed through its layers.^[10,11]

Anatomy of Skin

The structure of human skin is primarily composed of three main layers:

1. The epidermis,
2. Dermis, and
3. Subcutaneous layer (hypodermis).

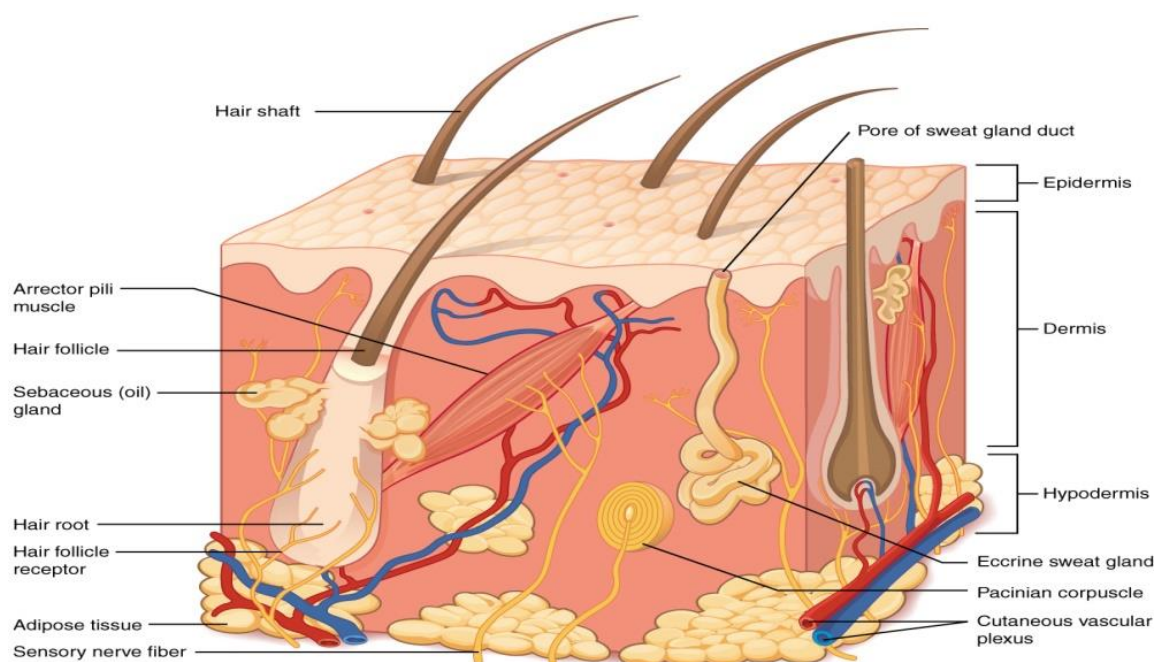


Fig. 2: Skin.

The skin consists of three main layers, each with distinct functions:

1. **Epidermis:** The outermost layer that acts as a protective barrier. It contains various cell types, including keratinocytes, which produce keratin. The epidermis has multiple layers:
 - Stratum Basale: The deepest layer where new skin cells are formed.
 - Stratum Spinosum: Contains spiny cells that provide strength.
 - Stratum Granulosum: Cells begin to die and form keratin.
 - Stratum Lucidum: Found only in thick skin areas like palms and soles.
 - Stratum Corneum: The outermost layer made up of dead, flattened cells that are shed regularly.
2. **Dermis:** Located beneath the epidermis, this thicker layer contains connective tissue, blood vessels, hair follicles, sweat glands, and nerve endings. It provides strength and elasticity due to collagen and elastin fibers.
3. **Hypodermis (Subcutaneous Layer):** The deepest layer that connects the skin to underlying tissues such as muscles and bones. It is primarily composed of fat and connective tissue, offering insulation and cushioning for the body.^[11,12]

The components of transdermal patches

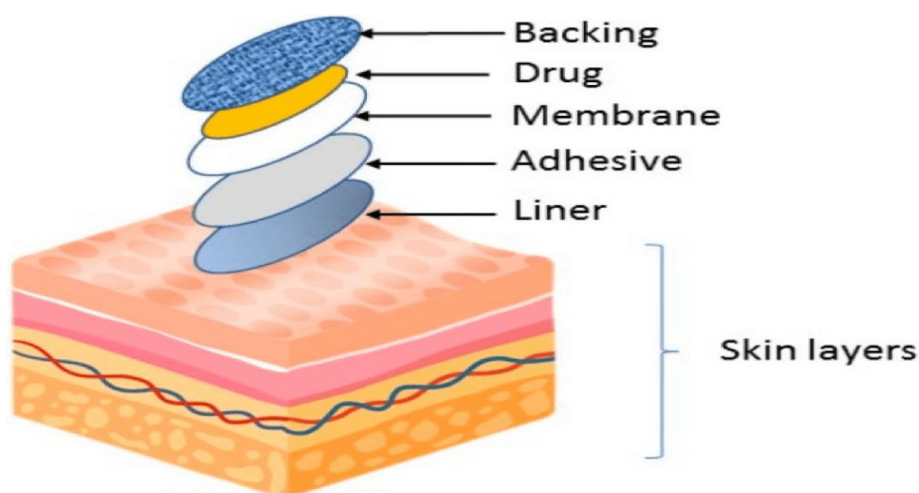
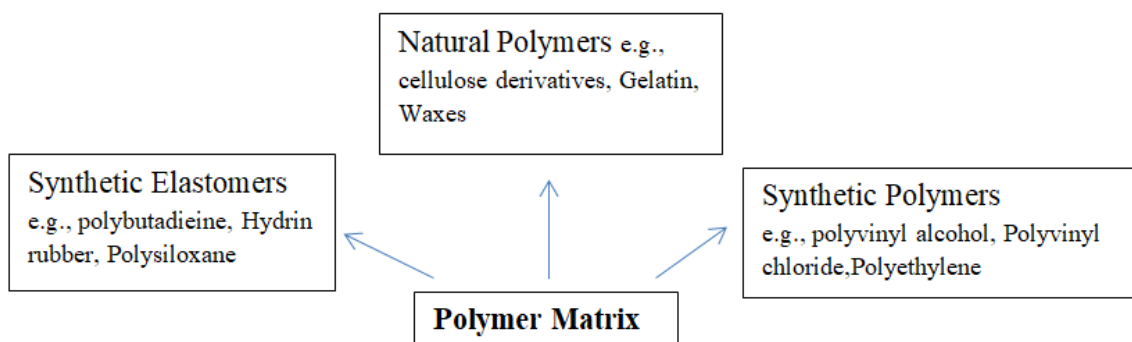


Fig. 3: Components of Transdermal Patch.

The components of the transdermal drug delivery system include

1. Polymer matrix or membrane
2. The drug
3. The permeation enhancers
4. Other excipients

1. Polymer Matrix: The Polymer controls the release of the drug from the device. Possible useful polymers for transdermal devices are: ^[13,14]



2. Drug: For a drug to be effectively delivered through the skin using transdermal patches, it must have certain important characteristics:

Non-ionic: The drug should not have a charge, which helps in better absorption through the skin.

Low Molecular Weight: Ideally, the drug should weigh less than 500 Daltons, making it easier for the skin to absorb.

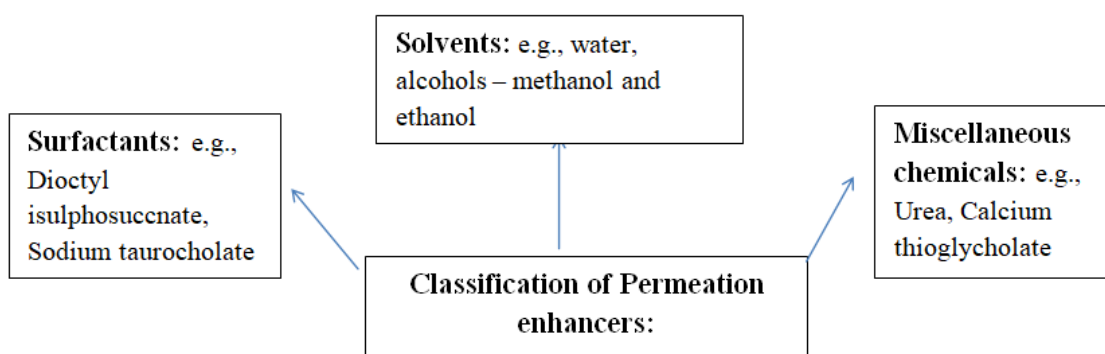
Solubility: The drug should dissolve well in both oil and water, allowing it to penetrate the skin effectively.

Low Melting Point: A melting point below 200°C is preferred to ensure that the drug remains in a suitable form for absorption.

Potency: The drug should be very effective at low doses, ideally requiring less than 10 mg per day for therapeutic effects. ^[15]

3. Permeation Enhancers:

These are compounds which promote skin permeability by altering the skin as a barrier to the flux of a desired penetrant. ^[16,17]



4. Other excipients

Adhesives: The fastening of the transdermal device is usually done by the adhesive. For a transdermal patch to work effectively, the adhesive used must meet several important criteria:

- The adhesive should not cause irritation or allergic reactions on the skin.
- It must stick to the skin throughout the duration of use.
- The patch should be simple to take off without causing discomfort.
- It should not leave any sticky or uncleanable marks on the skin after removal.
- The adhesive must work well with the drug, other ingredients, and any penetration enhancers used.^[18]

Backing membrane: The backing membrane of a transdermal patch plays a crucial role and has several important features:

- It is flexible and securely attaches to the drug reservoir, preventing the drug from escaping from the top.
- The membrane is impermeable, protecting the product while it is on the skin.
- It keeps the formulation intact throughout its shelf life and while being worn.
- The backing must be compatible with the formulation, meaning it should not absorb any of the ingredients.
- The material can be printed on for branding or instructions.

Examples: metallic plastic laminates and plastic backings with absorbent pads or adhesive foam pads.^[19,20]

Release liner: A release liner is a protective layer on drug patches that keeps the medicine safe during storage.

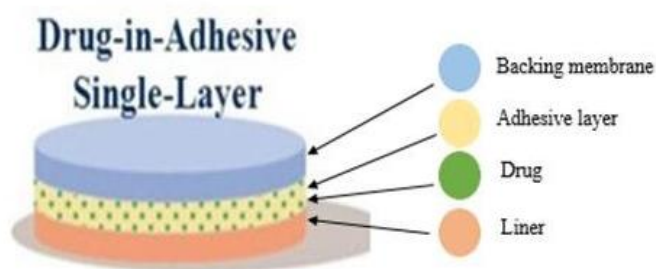
- It prevents the drug from leaking into the sticky part of the patch.
- It protects the patch from dirt and contamination.
- The release liner is part of the packaging, not part of the patch that delivers the medicine. It's removed before using the patch.^[20]

TYPES OF TRANSDERMAL PATCHES

Single-layer Drug-in-Adhesive

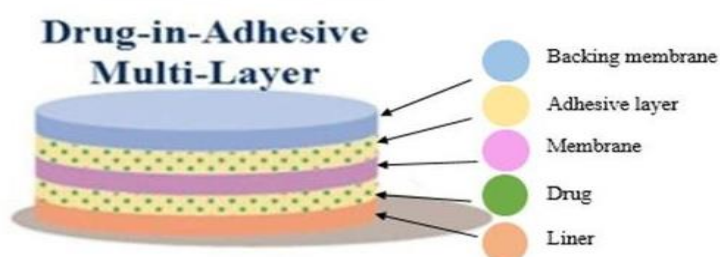
In a single-layer drug-in-adhesive system, the adhesive layer contains the drug itself, serving multiple functions. This adhesive layer not only binds the various components of the patch together but also adheres the entire system to the skin while facilitating drug release.

Surrounding this adhesive layer are a temporary liner, which protects it during storage, and a backing layer that provides additional protection once the patch is applied. This design ensures effective delivery of medication through the skin while maintaining user comfort and safety.^[21,22]



Multi-layer Drug-in-Adhesive

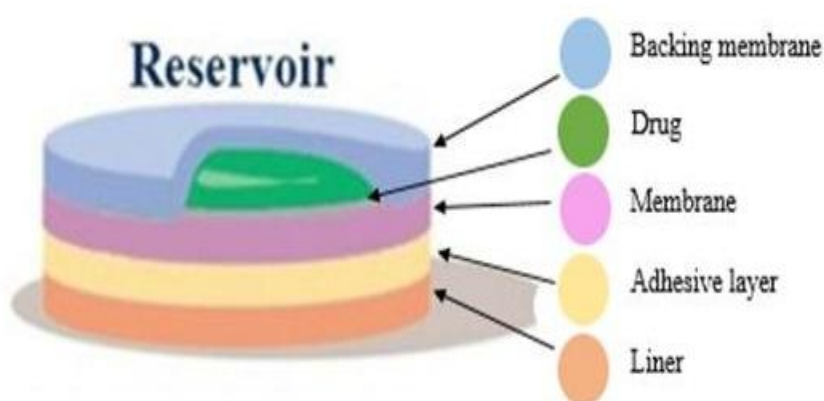
The multi-layer drug-in-adhesive patch is similar to the single-layer version, as both use adhesive layers to release drugs. However, the multi-layer patch has an extra drug-containing adhesive layer, often separated by a membrane, though not always. This setup allows one layer for immediate drug release and another for controlled release over time. Like the single-layer patch, it has a temporary liner to protect the adhesive and a permanent backing to shield the patch. This design improves the patch's versatility and effectiveness in delivering drugs through the skin.^[22]



Reservoir

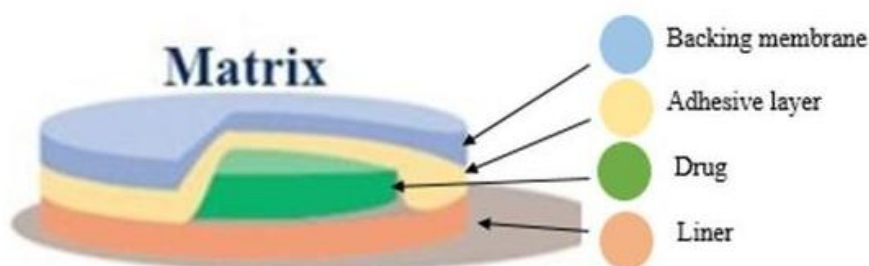
Unlike single-layer and multi-layer drug-in-adhesive systems, the reservoir transdermal system features a distinct drug layer. This drug layer acts as a liquid compartment that holds either a solution or suspension of the drug, which is separated from the adhesive layer.

Additionally, the patch is protected by a backing layer that ensures its integrity. A key characteristic of this system is its zero-order release kinetics, meaning that the drug is delivered at a constant rate over time, providing consistent therapeutic effects. This design enhances the efficacy of drug delivery while improving patient compliance.^[23,24]



Matrix

The matrix transdermal system consists of a drug layer made from a semisolid matrix that contains either a drug solution or suspension. In this design, the adhesive layer partially surrounds the drug layer, providing secure adhesion while allowing for effective drug delivery. This configuration facilitates the controlled release of the medication through the skin, ensuring a steady therapeutic effect.^[25]



METHODOLOGY

Solvent evaporation technique

A transdermal patch was developed using the solvent evaporation technique. In this method, a mixture of the polymer and drug solution is spread as a film on a suitable support, such as glass, mercury, or aluminium foil. The solvent is then allowed to evaporate by leaving the petri dish at room temperature for a specific period. Once the solvent has evaporated, the remaining dried residue forms the patch, which contains the drug embedded in the polymer matrix.^[26,27]

Circular Teflon Mould Method

The Circular Teflon Mould Method, developed by Baker and Heller in 1989, creates transdermal drug delivery films. Two solutions are prepared: one with the drug and the other with enhancers and polymers. These are mixed, and a plasticizer is added for flexibility. The mixture is poured into a Teflon mould and placed in a laminar flow hood for solvent evaporation over 24 hours. Afterward, the film is stored for 24 hours in a desiccator to eliminate moisture. This method ensures a uniform, stable, and effective drug delivery system for skin application, providing controlled and consistent release.^[27,28]

IPM Membranes Method

The IPM Membranes Method for transdermal drug delivery involves several steps to ensure effective drug release. First, the drug is mixed with water, propylene glycol, and Carbomer 940 polymer, and stirred for 12 hours for uniformity. Triethanolamine is added to increase viscosity and neutralize the mixture. If the drug doesn't dissolve well in water, a buffer with a pH of 7.4 is used to form a gel. This gel is then placed into the IPM membrane, which controls the drug release through the skin, enhancing effectiveness and reducing side effects.^[29]

EVALUATION OF TRANSDERMAL PATCH

Physicochemical evaluation

Transdermal patches can be physicochemically evaluated in terms of these parameters:

Thickness

The thickness of transdermal films is assessed using various instruments, including a traveling microscope, dial gauge, screw gauge, or micrometer. Measurements are taken at multiple points across the film to ensure accuracy and uniformity.^[30]

Uniformity of Weight

The uniformity of weight in transdermal patches is evaluated by individually weighing 10 randomly selected patches. The average weight is then calculated, and it is essential that the individual weights do not deviate significantly from this average. This ensures consistency and quality across the patches.^[30,31]

Drug Content Determination

To determine the drug content in a transdermal film, an accurately weighed portion of approximately 100 mg is dissolved in 100 mL of an appropriate solvent in which the drug is soluble. The solution is continuously shaken for 24 hours in a shaker incubator. Following this, the entire solution is subjected to sonication to ensure complete dissolution. After sonication, the solution is filtered, and the concentration of the drug in the resulting solution is measured spectrophotometrically, with necessary dilutions made as required.^[32,33]

Thumb tack test

The force required to remove thumb from adhesive is a measure of tack.^[34]

Folding Endurance

Folding endurance is assessed by evaluating the film's capacity to withstand repeated folding under extreme conditions. This is done by repeatedly folding the film at the same location until it breaks. The folding endurance value is defined as the number of times the film can be folded at that point without breaking. This measurement provides insight into the film's mechanical properties and durability.^[35]

Content Uniformity Test

In the content uniformity test for transdermal patches, 10 patches are selected, and the drug content of each patch is determined. The patches pass the test if 9 out of the 10 have a drug content ranging from 85% to 115% of the specified value, while one patch has a content not less than 75% and not exceeding 125% of that value. If three patches fall within the 75% to 125% range, an additional 20 patches are tested for drug content. For these additional patches to pass, their drug content must also fall between 85% and 115%.^[36,37]

Moisture Content

To determine the moisture content of the prepared films, each film is weighed individually and then placed in a desiccator containing calcium chloride at room temperature for 24 hours.

After this period, the films are weighed at specified intervals until they reach a constant weight. The percentage of moisture content is calculated using the following formula: ^[38,39]

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

Moisture Uptake

The weighed films are placed in a desiccator at room temperature for 24 hours. After this initial drying period, the films are removed and exposed to 84% relative humidity by using a saturated solution of potassium chloride in a desiccator. This exposure continues until the films reach a constant weight. The percentage of moisture uptake is then calculated using the formula provided below. ^[38,39]

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

In vitro permeation studies

Franz diffusion cell

The cell is composed of two compartments: donor and receptor. The receptor compartment has a volume of 5-12ml and effective surface area of 1-5 cm². The diffusion buffer is continuously stirred at 600rpm by a magnetic bar. The temperature in the bulk of the solution is maintained by circulating thermostated water through a water jacket that surrounds the receptor compartment. ^[40,41]

Flow-through diffusion cell

Flow through diffusion cells have the advantage that they can be used when the drug has lower solubility in the receptor compartment. This cell can be fully automated and connected directly to HPLC. They have large capacity donor chamber to allow appropriate loading of the applied compound and a low volume (0.3ml) receiving chamber that ensures rapid removal of penetrant at relatively low pumping rates. ^[41,42]

CONCLUSION AND FUTURE OUTLOOK

This review concludes that the transdermal drug delivery systems (TDDS) represent a significant advancement in drug administration, utilizing patches that adhere to the skin for effective drug release, providing a controlled and continuous medication flow, bypassing the first-pass metabolism of oral drugs. As a result, they improve bioavailability, increase patient compliance by reducing dosing frequency, and help minimize side effects.

The physicochemical evaluation of transdermal patches ensures they are consistent, high-quality, and effective. Testing factors like thickness, weight, drug content, and mechanical properties helps assess their performance. Moisture content and uptake tests check stability, while *in vitro* permeation studies confirm how well the drug is released and absorbed.

With innovations like microneedles and chemical enhancers, TDDS are expanding in use, improving drug delivery and outcomes. As technology advances, transdermal delivery is becoming more popular and may soon replace needles for many types of medications, offering a more convenient and less invasive option for patients.

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