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Review Article

Transdermal Drug Delivery System - Transdermal Patches

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ABSTRACT

These days, about 74% of medicines are taken by mouth, but many of them do not work as well as expected. To overcome these problems, the transdermal drug delivery system (TDDS) was developed. Transdermal drug delivery means giving a drug through the skin so it can enter the bloodstream and produce a whole-body (systemic) effect. This is different from traditional topical treatments, which mainly act on the skin surface. TDDS are dosage forms designed to deliver drugs into the deeper layers of the skin (the viable epidermis or dermis) for local action, while a significant amount of the drug also reaches the bloodstream. The adhesive used in transdermal patches is very important because it affects the product's safety, effectiveness, and quality. Applying drugs through the skin has several advantages over oral or injectable routes. These include avoiding first-pass metabolism in the liver, improving the drug's effectiveness, and maintaining a steady level of the drug in the blood. This review gives an overview of TDDS, their benefits compared to traditional dosage forms, how drugs pass through the skin, different types of permeation enhancers, components of transdermal patches, types of patches, methods for preparing them, and ways to evaluate them.

INTRODUCTION

The oral route is the most common way to administer drugs, but it has certain problems. For example, enzymes and pH levels in the gastrointestinal tract can break down drugs and cause them to be less effective. Chien, Banker, and Guy all worked on a new medication delivery system in 1990, 1992, and 1996, respectively.[1] Transdermal patches or a transdermal delivery device were used. In this approach, medicated adhesive patches are made that release a therapeutic dose of medication into the skin when they are put on. They come in varied sizes and have more than one ingredient. Once they are applied to unbroken skin, they transfer active chemicals into the bloodstream by going through skin barriers.[2]

Drug can penetrate through skin via three pathways-

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a) Through hair follicals.
b) Through sebaceous glands
c) Through sweat duct

Transdermal Drug Delivery System Types :-

1. Drug-in-Adhesive Single-layer System: The medication is contained in the system's sticky layer in this kind of patch. The adhesive layer is in charge of releasing the medication in addition to binding the several layers and the complete system to the skin. A backing and a temporary liner encircle the adhesive layer.

2. Reservoir System: This system maintains the drug reservoir between a rate- controlling membrane and a backing layer. Additionally, medication is released via a microporous rate-controlled membrane. In the reservoir compartment, the drug may be distributed in a solid polymer matrix or present as a solution, suspension, or gel.

3. Matrix Organization: There are two types of this system.

a) **Drug-in-Adhesive System:** The drug is disseminated in an adhesive polymer to create a drug reservoir. The medicated polymer adhesive is then spread by solvent casting or, in the case of hot-melt adhesives, by melting the adhesive onto an impermeable backing layer.

b) Matrix-Dispersion technology: This technology uses a hydrophilic or lipophilic polymer matrix to uniformly distribute the medication. And this includes both the medicine and polymer[3]

4. Micro-Reservoir System: This system is a combination of reservoir and matrix- dispersion systems. In which drug is suspended in an aqueous solution of water- soluble polymer and then dispersing the solution homogeneously in a lipophilic polymer to form thousands of unleachable, microscopic spheres of drug reservoirs[4]

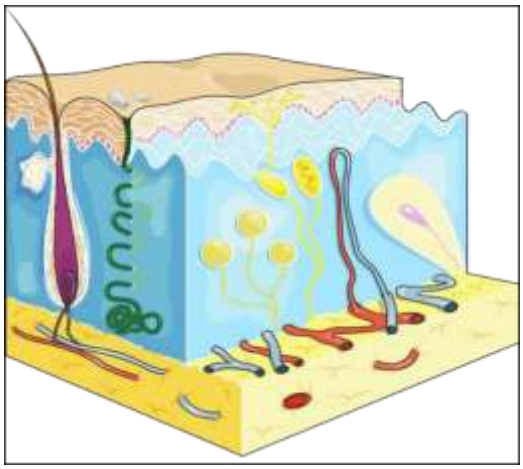


Figure - Structure of skin

Ideal Properties of Transdermal Drug Delivery System

Table-1: Ideal properties of TDDS

Sr. No	Property	Ideal Range/ Requirement
1	Shelf life	Should be upto 2.5 year

2	Patch size	Should be less than 40 cm 2
3	Dose Frequency	Once daily to once weekly
4	Appearances	Should be clear or white in colour
5	Packaging Properties	Release liner should be easily removable
6	Skin Reaction	Should be non – irritating
7	Release Properties	Consistent Pharmacokinetics and pharmacodynamic profile over time

Components of Transdermal Drug Delivery System

a) Polymer matrix/ Drug reservoir

b) Permeation enhancers.

c) Pressure sensitive adhesive (PSA).

d) Backing laminate

e) Release liner.

f) Other excipients like plasticizers and solvents

1. Polymer Matrix/Drug Reservoir:

It is made by dispersing the medication in a synthetic polymer basis that is either liquid or solid. It should be chemically and biocompatible with the medication and other system elements like penetration enhancers. 5They should also be safe and deliver a medication consistently and effectively for the duration of the product's stated shelf life. Transdermal medication delivery techniques employ polymers that are categorized as

a) Natural polymers, such as chitosan, cellulose derivatives, zein, gelatin, shellac, waxes, gums, and natural rubber.

b) Synthetic elastomers, such as butyl rubber, polybutadiene, hydrin rubber, silicon rubber, polyisobutylene, acrylonitrile, and neoprene.

c) Synthetic polymers, such as polyvinyl alcohol, polyvinyl chloride, polyethylene, polypropylene, polyacrylate, polyamide, polyurea, polyvinylpyrrolidone, and polymethylmethacrylate.[6]

2. Permeation Enhancers:

Chemical substances that increase the stratum corneum's permeability in order to reach the drug candidate's therapeutic levels. Through their interaction with the stratum corneum, they increase permeability.

a) Permeation Enhancers' Optimal Properties

i. They must be non-toxic, non-irritating, and non-allergic.

ii. They shouldn't exhibit any pharmacological activity by binding to the receptor location.

iii. They should have a suitable skin sensation and be aesthetically pleasing. [7]

3. Pressure Sensitive Adhesives (PSA):

Aids in improving transdermal patch adherence to the skin's surface. Without leaving any residue behind, it is simple to remove from the smooth surface.

a) Polyacrylates

b) Polyisobutylene

c) adhesives based on silicon

4. Backing laminate :

It is a material that provides support and is impervious to medications. Backing laminate is a supportive material that is impervious to both permeation enhancers and medications. They must be chemically compatible with the medication, adhesive, enhancer, and other excipients. For example, films made of vinyl, polyethylene, and polyester. The main packing material that can shield the patch during application is the release liner. It consists of a base layer that could be;

1. Non-occlusive (paper cloth),

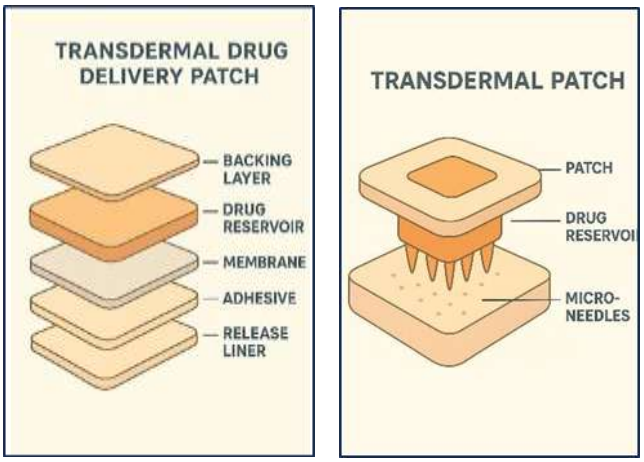
2. Occlusive (polyethylene, polyvinyl chloride, etc.)

It is composed of either Teflon or silicon. In addition to being permeable to drugs, penetration enhancers, and water, the release liner should be chemically inert.[8]

5. Other Excipients Like Plasticizers and Solvents

a) Solvents: Chloroform, methanol, acetone, isopropanol and dichloromethane.

b) Plasticizers: Dibutylpthalate, triethylcitrate, polyethylene glycol and propylene glycol.



Methods of Preparation of TDDS

a) Asymmetric TPX membrane method.

b) Circular Teflon mould method.

c) Mercury substrate method.

d) By using "IPM membranes" method.

e) By using "EVAC membranes" method.

f) Preparation of TDDS by using Proliposomes.

g) By using free film method.

The Asymmetric TPX Membrane Method was developed in 1994 by Berner and John. Using heat-sealable polyester film (type 1009, 3m) with a concave diameter of 1cm as the backing membrane, a prototype patch can be made using this procedure. A TPX [poly (4-methyl-1-pentene)] asymmetric membrane covers the drug-dispersed concave membrane, which is then sealed with an adhesive.[9]

a) Preparation:

The dry or wet inversion method is used to prepare them. In order to create a polymer solution, TPX is dissolved in a mixture of solvent (cyclohexane) and non-solvent additives at 60°C. After 24 hours at 40°C, the polymer solution is cast onto a glass plate. The glass plate must then be submerged right away in a coagulation bath (temperature maintained at 25°C) after the casting film has been evaporated at 50°C for 30 seconds. The membrane can be removed after 10 minutes of immersion and allowed to air dry for 12 hours at 50°C in a circulation oven.[10] Baker and Heller discovered the circular Teflon Mould Method in 1989. An organic solvent is a polymeric solution in different ratios. After then, the solution is split into two sections. A certain amount of medication is dissolved in one portion, enhancers in varying concentrations are dissolved in another, and the

two parts are then combined. The drug polymer solution is then mixed with plasticizer, such as Di-Nbutylphthalate. After 12 hours of stirring, the entire mixture must be put into a circular Teflon mold. To regulate solvent vaporization in a laminar flow hood model with an air speed of 0.5 m/s, the molds must be set on a flat surface and covered with an inverted funnel. For a whole day, the solvent is left to evaporate. Following the formation of a dried film, it must be kept in a desiccator with silica gel for an additional 24 hours at 25±0.5°C before being evaluated in order to remove the effects of aging.[11]

1. Mercury Substrate Method

In this method, the drug and plasticizer are mixed in a polymer solution and stirred for 10–15 minutes to make a uniform mixture. This mixture is then poured onto a flat layer of mercury. An inverted funnel is placed over it to slow down solvent evaporation. After drying, a thin film is formed.

2. IPM Membrane Method

Here, the drug is mixed in a water–polymer mixture made of propylene glycol and Carbomer 940, and stirred for 12 hours using a magnetic stirrer. The mixture is then neutralized using triethanolamine to make it thick like a gel.

If the drug does not dissolve well in water, a buffer of pH 7.4 is used to make the gel. This prepared gel is then added into the IPM membrane to form the patch.[12]

3. EVAC Membrane Method

To prepare the transdermal system, a gel reservoir is made using 1% carbopol, polyethylene (PE), and an EVAC membrane (which controls the drug release rate).

If the drug is poorly soluble in water, propylene glycol is used. The drug is dissolved in propylene glycol, carbopol is added, and the mixture is neutralized using 5% sodium hydroxide to form a gel. The gel is spread onto a backing layer, and a rate-controlling EVAC membrane is placed on top. The edges are sealed with heat to make a leak-proof patch.

4. Proliposome Method (Film Deposition Technique)

Proliposomes are prepared using a round-bottom flask. Mannitol powder (5 mg) is taken and dried by rotating the flask at 60–70°C under vacuum for 30 minutes. Then the temperature is lowered to 20–30°C. Drug and lecithin are dissolved in an organic solvent. A small amount of this solution (0.5 ml) is added to the flask at 37°C and dried. Another 0.5 ml is added and dried again. After the final loading, the proliposome mixture is freeze-dried (lyophilized). The resulting powder is kept in a desiccator overnight and sieved through a 100- mesh screen. The final proliposome powder is stored in a glass bottle in a freezer until further testing.

5. Free Film Method

In this method, a free polymer film is made by pouring a 2% cellulose acetate solution (prepared in chloroform with 40% plasticizer) onto a mercury surface. The solution is poured inside a glass ring placed on the mercury. An inverted funnel is used to slow down solvent evaporation. Once the solvent evaporates completely, the film formed on the mercury surface is removed. The dry film is stored between wax papers in a desiccator. Different film thicknesses can be made by using different volumes of polymer solution.[13]

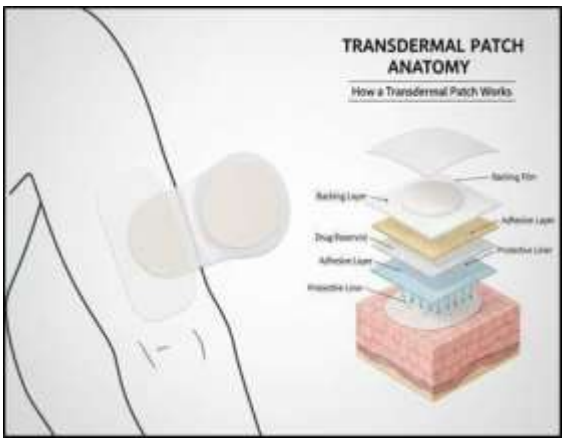


Figure : Transdermal patch Anatomy

Evaluation Parameter

1. Thickness of the Patch

The thickness of each patch is checked at different points using tools like a digital micrometer, screw gauge, or traveling microscope. The average thickness and standard deviation are calculated to ensure uniformity.

2. Weight Uniformity

Before testing, patches are dried at 60°C for 4 hours. Small pieces of equal size are cut from different areas, weighed on a digital balance, and their average weight and standard deviation are recorded.

3. Folding Endurance

A strip of the patch is repeatedly folded at the same spot until it breaks. The number of times it can be folded without breaking indicates its folding endurance.

4. Percentage Moisture Content

Each patch is weighed and placed in a desiccator containing calcium chloride for 24 hours. Afterward, the patch is reweighed. The moisture content is calculated using:

% Moisture content = (Initial weight – Final weight) / Final weight × 100

5. Content Uniformity Test

Ten patches are checked for drug content. The batch passes if:

- 9 out of 10 patches contain 85%–115% of the desired drug amount.
- The remaining patch is between 75%–125%.

If 3 or more patches fall between 75%–125%, 20 more patches must be tested. If these 20 fall within 85%–115%, the batch passes.

6. Moisture Uptake

Patches are first kept in a desiccator for 24 hours, then exposed to 84% relative humidity until they reach constant weight. Moisture uptake is calculated as:

% Moisture uptake = (Final weight – Initial weight) / Initial weight × 100

7. Drug Content

A measured area of the patch is dissolved in a suitable solvent, filtered, and analyzed using UV spectroscopy or HPLC to determine drug content. Results are reported as the average of three samples.[14]

8. Shear Adhesion Test

This test measures how strongly the adhesive holds together. A tape with adhesive is stuck to a steel plate, and a weight pulls it parallel to the plate. The time taken for the tape to come off indicates shear strength—the longer it stays, the stronger it is.

9. Peel Adhesion Test

The force required to peel the adhesive tape from a steel plate at a 180° angle is measured. Factors such as polymer type, additives, and molecular weight affect peel strength.

10. Water Vapor Transmission (WVT) Study

A vial containing calcium chloride is sealed with the patch film and placed in a humidity chamber. The vial is weighed daily for up to 7 days. The increase in weight shows the amount of moisture passing through the patch. WVT is calculated as:

WVT = W / (S × T)

Where W = weight gain in 24 hours, S = exposed area, T = time.

11. Rolling Ball Tack Test

A steel ball is rolled down an inclined plane onto the adhesive surface. The distance the ball travels before stopping indicates tackiness (stickiness). Shorter distance = higher tack.

12. Quick Stick Test (Peel-Tack Test)

The tape is pulled from the surface at 90° at a speed of 12 inches/min. The force needed to break the adhesive bond is recorded as the tack value.

13. Probe Tack Test

A metal probe touches the adhesive and is then pulled away at a fixed speed. The force required to separate the probe from the adhesive shows tack strength.

14. In Vitro Drug Release Study

The paddle-over-disc method is used. A piece of the patch is placed on a glass plate and immersed in phosphate buffer (pH 7.4) at 32°C. The paddle rotates at 50 rpm. Samples are taken at intervals up to 24 hours and analyzed (UV or HPLC). The test is performed three times and the average is reported.

15. In Vitro Skin Permeation Studies

Skin permeation testing is usually performed using a diffusion cell. Full-thickness abdominal skin from male Wistar rats (200–250 g) is used. Hair from the abdominal area is carefully trimmed with an electric clipper, and the skin's underside (dermal side) is washed with distilled water to clear any attached tissues or blood vessels. The skin is then soaked in phosphate buffer (pH 7.4) for about one hour before the experiment.

During the test, the diffusion cell is kept at 32 ± 0.5°C with continuous stirring for uniform mixing. The rat skin is placed between the donor and receptor compartments with the epidermis facing the donor side. At regular time intervals, small samples are withdrawn from the receptor compartment and replaced with fresh medium. These samples are filtered and analyzed using UV or HPLC.

The flux (rate of drug permeation) is calculated from the steady-state slope of the graph plotting amount of drug permeated (mg/cm²) against time (hours), and the permeability coefficient is obtained by dividing the flux by the initial drug concentration.[15]

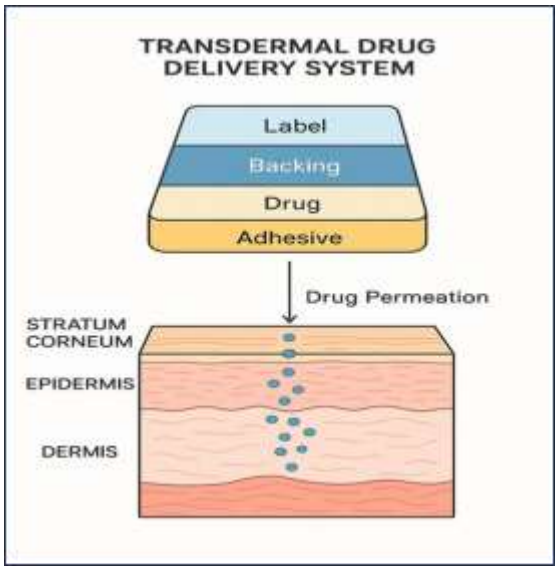
16. Skin Irritation Study

Skin irritation and sensitization tests are carried out on healthy rabbits weighing 1.2–1.5 kg. An area of about 50 cm² on the rabbit's back is shaved and cleaned with rectified spirit. The test formulation or patch is applied to this area, kept for 24 hours, and then removed. After removal, the skin is examined for any irritation or injury and

graded into five levels based on the severity of the reaction.[16]

17. Stability Studies

Stability testing is carried out following ICH guidelines. The transdermal patch samples are stored at 40 ± 0.5°C and 75 ± 5% RH for six months. Samples are taken out on days 0, 30, 60, 90, and 180, and analyzed for drug content and other parameters to ensure the patch remains stable over time.[17]



Advantages :

1. This method is easy to use because you only have to apply it once a week, which helps patients remember and stick to their treatment
2. Transdermal delivery (through the skin) is useful for people who cannot take medicines by mouth.
3. It is especially helpful for patients who are vomiting, feel very sick, or are unconscious.
4. Medicines that usually upset the stomach can work better through the skin because they don't go directly into the stomach or intestines.
5. Drugs that get broken down by stomach acids or digestive enzymes can be more effective when delivered through the skin.
6. Transdermal delivery avoids first-pass metabolism, a problem that happens when drugs taken by mouth are broken down by the liver before entering the bloodstream.
7. Medicines that need steady, consistent levels in the blood are good choices for transdermal delivery.[17]

Disadvantages :

1. The skin where the patch is applied may get irritated.
2. Redness, itching, or swelling can happen because of the medicine, the patch adhesive, or other ingredients in the patch.
3. Some people may have allergic reactions to the patch.
4. The drug must be small in size — its molecular weight should be under 500 Da.
5. The drug needs to dissolve well in both water and fats. A log P value between one and three helps it pass through the outer skin layer and the layers beneath it.[18]

Application:

1. Pain Management

- One of the most common uses of transdermal patches.
- Opioid analgesics: Fentanyl patches for chronic cancer or non-cancer pain
- NSAIDs: Diclofenac patches for localized musculoskeletal pain

2. Hormone Replacement Therapy

- Transdermal patches help maintain stable hormone levels.
- Estrogen patches for menopausal symptoms
- Testosterone patches for hypogonadism
- Contraceptive patches (ethinyl estradiol + norelgestromin)

3. Cardiovascular Treatments

- Used to manage conditions like angina and hypertension.
- Nitroglycerin patches for prevention of angina
- Clonidine patches for hypertension management

4. Smoking Cessation

- Nicotine patches provide steady systemic nicotine levels to reduce withdrawal symptoms.
- Helps people quit smoking gradually
- Available in multiple strengths

5. Neurological Disorders

- Used to improve cognitive and neurological function.
- Rivastigmine patch for Alzheimer's and Parkinson's dementia
- Rotigotine patch for Parkinson's disease and restless legs syndrome

6. Motion Sickness

- Scopolamine patches placed behind the ear help prevent nausea and vomiting due to motion sickness

7. Anti-emetic Therapy

- Useful for patients who cannot take oral medications.
- Granisetron patches for chemotherapy-induced nausea and vomiting

8. Cardiovascular Risk Management

- Lidocaine + Epinephrine patches for localized anesthetic action
- Lidocaine patches for neuropathic pain (e.g., post-herpetic neuralgia)

9. Diabetes Management (Emerging Application)

- Research and prototype patches for insulin delivery, especially microneedle- based patches

10. Contraception & Fertility Regulation

- Continuous and controlled hormone release helps improve compliance[19]

CONCLUSION :

Transdermal medicine delivery represents one of the most fleetly advancing areas of new medicine delivery. Due to recent advances in technology and the capability to deliver the medicine systemically without rupturing the skin membrane, transdermal route is getting a extensively accepted route of medicine administration.

TDDS are designed for controlled release of medicine through the skin into systemic rotation maintaining harmonious efficacity. It offers the

delivery of medicine at lowered cure that can save the philanthropist from the detriment of large boluses with bettered bioavailability. This may be achieved by by- passing the hepatic first metabolism. nearly all major and minor pharmaceutical companies are developing TDDS. Implicit development in medicine delivery systems include the use of bettered tenacious and/ or enhancer technologies; and systems that exploit thermal, electrical, ultrasonic, or other forms of energy to " drive " motes through the stratum corneum or microneedles to bypass the occlusive nature of the stratum corneum in a controlled fashion.

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