

Transdermal Drug Delivery System: A Review**Vaishali K. Ghume¹, Anuradha K. Salunkhe², Smita D. More³, Shashikant N. Dhole⁴, Bhagyashree A. Shingte⁵, Trupti M. Haral⁶**^{1,3,4,6}Department of Pharmaceutics, PES's Modern College of Pharmacy (For Ladies), Moshi affiliated to Savitribai Phule Pune University, Pune, India^{2,5}Department of Pharmaceutics, Satara College of Pharmacy, Satara 415004, DBATU, Lonere, Maharashtra, India

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Abstract

A medicinally potent dose may be administered transdermally by use of patches that adhere to the skin's surface. It is necessary to consider the skin's extensive physicochemical, morphological, and biological characteristics when administering medicinal medications topically for systemic effects. There are less systemic adverse effects and more stable blood level profiles with transdermal medication delivery systems than with other dose forms because of the regulated release of medicinal compounds into the skin. Transdermal application is an easy and pleasant way to provide medication. By bypassing first pass metabolism, it enhances patient compliance and is an improvement over injectables and the oral route. A cutting-edge method of pharmaceutical administration is the transdermal drug delivery system (TDDS).

Keywords: Transdermal System, Mechanism, Metabolism, Microneedles.**DOI:** 10.25258/ijcpr.18.10.17

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Introduction

Topical drugs that, release drug at a regulated & planned pace are known as TDDS. There are several ways that drugs may be given, including orally, intravenously, nasally, transdermally, rectally, intravaginally, ocularly, and others.

In response to these limitations, a new method of drug administration called a transdermal drug delivery system was created. This technique involves combining a drug with a polymer in a way that allows for regulated and predefined release.

One of unique features of transdermal patches is the special membrane that allows the liquid medication contained therein to be released into the blood circulation at a controlled pace. Not only does transdermal delivery allow for the regulated and continual administration of the medication, but it also removes the negative side effects of pulsed distribution into systemic circulation. To lessen the effects of first-pass medication degradation and to find novel uses for current medicines, transdermal patches have proven beneficial. When applied to the skin, a duration ranging from a few hours to a few days. This is particularly helpful for long-term preventative treatment. Measurable drug levels in the blood, detectable drug and metabolite excretion

in urine & clinical reaction of patient to medication treatment are all signs of percutaneous drug absorption. [1-6]

Advantages: [7-11]

- Bypasses issues related to gastrointestinal pH, enzymes, and oral drug absorption.
- Avoids first-pass metabolism and GI incompatibility.
- Reduces unwanted side effects.

Disadvantages: [12-15]

- Limited to ionic & potent drugs due to skin's low permeability.
- Cannot provide pulsatile drug release.

Anatomy & Physiology of Skin: [18-20] [Fig. 1]

The skin, which covers more than two square meters of an adult human body, is the largest organ in the body. Almost a third of the blood that flows through the body goes to this multi-layered organ. An impenetrable barrier between the outside environment and the intricate system of blood circulation lies underneath the millimeter-thick skin. A person's skin is composed of three distinct yet complementary tissues.

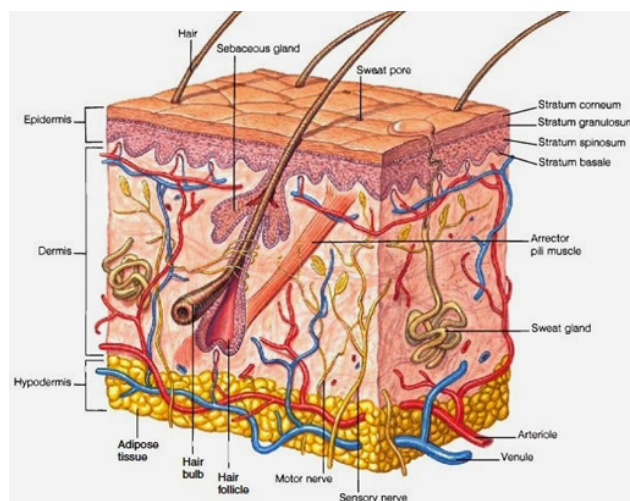


Fig. 1: Skin Structure

Method of Drug Permeation through Skin: [19]

During percutaneous permeation, a medicinal molecule may disperse via shunt pathways, or it can penetrate the epidermis directly. Consequently, two primary pathways for medication absorption exist.

Trans corneal Permeation:

a. Intracellular permeation: Hydrophilic drugs pass directly through cells of stratum corneum. When it is hydrated, water collects around protein filaments, allowing polar molecules to move.

b. Intercellular permeation: Diffusing through lipid layers located between the protein filaments.

Transappendageal Permeation: One other name for this is the shunt route. This channel allows the

medication molecule to pass through many biological structures, such as hair follicles, sebaceous glands, or salt glands that secrete water. But for big polar molecules, this method could be useful. The penetration route is significantly affected by the penetrant's physicochemical characteristics, especially its relative partitioning ability into each skin phase. The peripheral circulation is adequate, and the capillaries and viable tissue layer have a moderate level of permeability. Therefore, diffusion through stratum corneum is phase that limits rate. A passive diffusion medium is stratum corneum. So, a simple multilayer model may be used to simulate the different layers of skin for transdermal drug transport, as illustrated in Fig. 2.

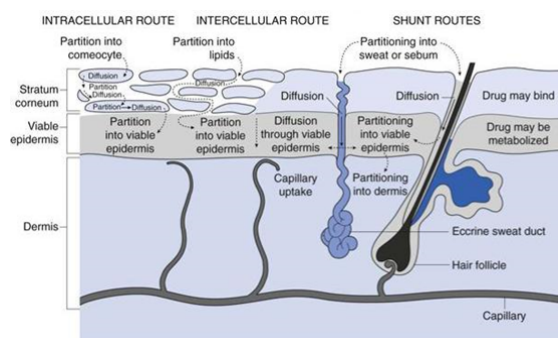


Figure 2: Route of drug permeation in skin

Factors Distressing Transdermal Permeation: [21-22]

A. Drug Physicochemical Properties:

- Degree of ionization
- Molecular shape and size
- Partition coefficient
- Drug concentration
- pH conditions

B. Delivery System Physicochemical Properties:

- Compatibility of vehicle with drug and skin
- Use of permeation enhancers
- Formulation composition

C. Skin's Physiological and Pathological Conditions:

- Skin hydration
- Lipid levels

- Age-related factors
- Skin temperature
- Local blood flow
- Skin metabolism and enzyme activity

- Species differences
- Presence of injuries or disorders

Basic Components of TDDS: [23-24] [Fig. 4]

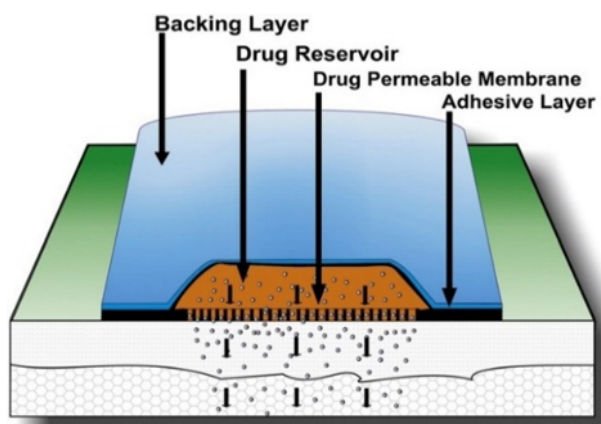


Fig 3: Basic mechanisms of TDDS

The mechanisms of TDDS contain:

Drug substance:

Table 1: Characteristics for drug in TDDS

Parameter	Ideal Property
Dose	< 20 mg/day
Mol. Wt.	Below 1000 Daltons
Half life	<10 h
Partition coefficient	1-4
Shelf-life	Up to 2 years

Polymer matrix:

Table 2: Polymers used in transdermal devices

Natural Polymers	Synthetic Elastomers	Synthetic Polymers
Waxes	Polybutadiene	Polyethylene
Cellulose derivatives	Hydrin rubber	Polyvinyl alcohol
Gelatin	Silicone rubber	Polyvinyl chloride
Gums	Acrylonitrile	Polyamide
Proteins	Nitrile	Polypropylene
Natural rubber	Chloroprene	Acetal copolymer
Shellac	Neoprene	Polyurea
Chitosan	—	Epoxy
Starch	Polysiloxane	Polystyrene

Penetration Enhancers as well as Pressure sensitive adhesive: Absorption promoters, accelerants, or penetration enhancers are popular names for the chemicals that help medications applied topically penetrate the skin. One substance that aids in keeping the transdermal system in close proximity to the skin's surface is a pressure sensitive adhesive (PSA).

Backing membrane: Backing laminate mostly serves to stabilize the patch and stop the medication from leaking out of the top. Drugs and any permeation enhancers must be able to pass through it unimpeded.

Release linear: When not in use, the patch's protective lining is peeled off. It usually has a silicone or Teflon release coating and protects the patch.

Approaches in Progress of TDDS: [26-27] [Fig. 9]

Membrane permeation controlled: Here, a polymeric membrane that regulates the flow rate encases the drug reservoir in a backing layer that is impervious to the drug. Diffusion via this membrane allows the medication to be released. Within the reservoir, the medication is either made into a gel-like suspension in a non-leachable viscous fluid (like silicone fluid) or dissolved in

solvent to produce a gel-like solution. Matrix may be solid polymer (like polyisobutylene) or a solvent-less solution. The flow rate-regulating membrane might be microporous or non-porous, with a predetermined permeability, for example, an ethylene-vinyl acetate copolymer. For optimal skin contact, the membrane is coated with a thin layer of a skin-friendly adhesive, such as silicone glue. Changing the adhesive layer, thickness, permeability, or polymer type of the membrane may alter the rate of medication release.

Matrix diffusion controlled: A hydrophilic, lipophilic, or mixed polymer matrix is used to evenly distribute drug particles therein, thereby creating the drug reservoir in this system. Discs with a predetermined thickness and surface area are made from this medicated polymer. Some methods for drug dispersion include combining drug by a viscous or liquid polymer, then cross-linking the mixture, or blending the medication with a rubbery polymer while subjected to high heat or a vacuum.

The finished polymer disc is housed in a drug-impermeable compartment and attached to an occlusive base plate. A coating of adhesive is put around perimeter of the disc to ensure that it makes skin contact.

Adhesive dispersion type: A drug reservoir is created via distributing medication directly into an adhesive polymer and a drug-impermeable backing membrane are both components of this method. After that, a thin layer containing the medicine is created by applying the medicated adhesive to the backing layer using any solvent casting otherwise hot melt processes.

On top of it, there is a rate-controlling membrane made of an evenly thick layer of non-medicated adhesive. A removable liner covers the patch, which is removed only before it is put to the skin for the designated time.

Microreservoir type controlled: Reservoir and matrix-dispersion types are both represented in this system. Here, high-energy shear pressures are used to evenly distribute the medication into a lipophilic polymer (such as silicone elastomers) after it has been suspended in an aqueous liquid polymer. As a result, the polymer matrix becomes filled with countless small, discrete micro-reservoirs containing the medication. Depending on how drug dissolves in liquid phase compared to polymer matrix, drug release may happen by matrix diffusion or partition control.

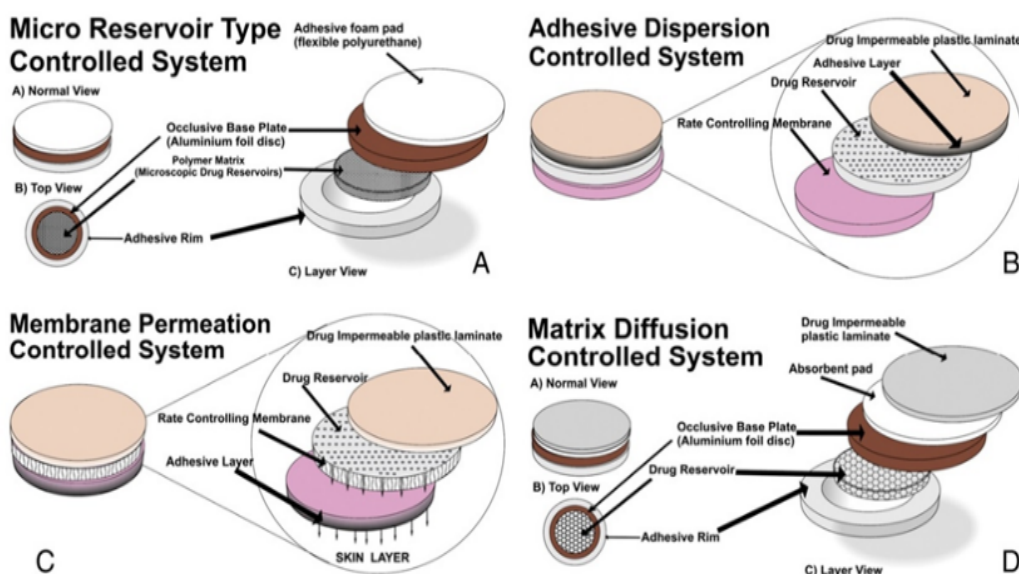


Fig 4: (A) Drug reservoir, (B) Adhesive dispersion (C) Membrane permeation controlled system, (D) Matrix type TDDS

Methods of Preparation of TDDS:

1. Asymmetric TPX Membrane Method

Developed by: Berner and John (1994): The backing is a polyester sheet that may be heat-sealed and has a concave well. An adhesive is used to seal drug-filled TPX (poly[4-methyl-1-pentene]) asymmetric membrane over the concave surface.

To prepare the membrane, dissolve TPX in a solvent mixture including cyclohexane at 60°C.

Chill at 40°C for 24 hours. Pour the mixture onto glass. Let it partly evaporate at 50°C. Finally, coagulate it in a bath at 25°C. Membrane is let to dry in the air at 50°C for 12 hours.

2. Circular Teflon Mould Method

Developed by: Baker & Heller (1989): One portion of the polymer solution contains the dissolved medicine, while the other portion contains the enhancers. A plasticizer (s Di-N-butylphthalate) is added to both components and agitated for 12 hours. To regulate amount of solvent evaporation, mixture is transferred to a circular Teflon mold and then protected by an inverted funnel. Prior to being used, film is dried for 24 hours and then kept in a desiccator for further 24 hours at $25 \pm 0.5^\circ\text{C}$.

3. Mercury Substrate Method: After dissolving drug and plasticizer in polymer solution, stirring the mixture for 10-15 minutes to ensure uniform mixing, it is placed onto a flat surface made of mercury. The evaporation of solvent is controlled by an inverted funnel.

4. Using IPM Membranes: After 12 hours of stirring, the medication is distributed throughout a solution of water and a polymer. An increase in viscosity and neutralization are achieved by adding triethanolamine. Incorporating a gel formed by a buffer pH of 7.4 into IPM membrane is an option for medications that are not very water-soluble.

5. Using EVAC Membranes: The reservoir is a 1% carbopol gel. PEG is used when medication cannot be dissolved in water.

A solution of propylene glycol, Carbopol, and 5% sodium hydroxide is prepared by dissolving the medicine in the former. A heat-sealed EVAC (ethylene vinyl acetate copolymer) membrane is used to cover the gel with a backing layer, making the patch impermeable.

6. Preparation Using Proliposomes: The film deposition method is used to make proliposomes. Vacuum drying at $60\text{--}70^\circ\text{C}$ with rotation is used to dry a mannitol carrier.

Using an organic solvent, dissolve the medication and lecithin in a ratio of 0.1 to 2.0. Add tiny portions to the rotating flask at 37°C , drying in between each addition. After lyophilization, sieving, and low-temperature storage, the finished proliposomes are prepared.

7. Free Film Method: An alternative to using cellulose acetate in film production is to cast a 2% w/w polymer solution (in chloroform) onto a mercury surface. Composed of 40% polymer by weight, the ingredient is a plasticizer. Following its pouring into a glass ring resting on mercury inside a Petri dish, the solvent's evaporation may be controlled using an inverted funnel. The film is kept between wax paper layers using a desiccator. Changing the volume of the solution allows one to control the film thickness. [11-12]

Recent Advances in TDDS:

Iontophoresis: Iontophoresis uses a mild electrical current (typically $0.1\text{--}1.0\text{ mA/cm}^2$) to drive charged drugs through the skin by creating an electrostatic potential gradient. It combines both a drug's concentration gradient and an electric field to improve permeation. Besides ionic drugs, it can also enhance the delivery of uncharged molecules via electro-osmosis.

Electroporation: Electroporation involves applying short, high-voltage DC pulses (over 100 volts for milliseconds) to temporarily create microscopic pores in lipid-bilayer of stratum corneum. This increases permeation & facilitates transport of small, charged drugs that otherwise have limited skin penetration.

Sonophoresis: Sonophoresis (or phonophoresis) uses ultrasound waves (typically $20\text{--}16\text{ kHz}$) to augment drug permeation by warming skin & disrupting its barrier structure. A coupling agent (gel or cream) is used to transmit the ultrasound energy effectively. This method enables deeper drug delivery (up to 4–6 cm) and is also applied in treating muscle and tendon conditions.

Microneedles: Microneedle technology, first conceptualized in 1976 and advanced by ALZA Corp's Macroflux system, delivers drugs via tiny needles that painlessly pierce the outer skin layers. Variants include solid microneedles and microneedle patches, as well as dissolving or hydrogel microneedles, providing versatile options for controlled transdermal delivery.

Assessment of TDDS: [25-35]

Transdermal systems must undergo systematic assessment under controlled conditions. The evaluations are broadly classified into:

A) Physicochemical Assessment

- Thickness measurement
- Drug content uniformity
- Determination of drug content
- Evaluation of water vapour transmission
- Flatness test
- Shear adhesion test
- Moisture content analysis
- Surface pH assessment
- Homogeneous weight
- Moisture absorption (uptake)
- Folding endurance test
- Adhesion Evaluation:
- Peel adhesion test
- Tack Evaluation

B) In Vitro Assessment

- In Vitro Drug Release Studies
- In Vitro Permeation Studies

C) In Vivo Assessment

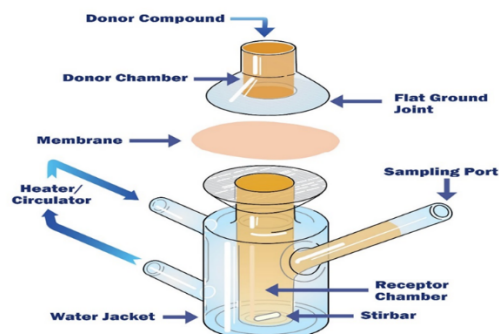


Fig 5: Franz Diffusion Cell

Applications of Transdermal Patches:

- Nicotine patches
- Antihypertensive & NSAID patches
- Nitroglycerin patches
- ADHD patches
- Selegiline patch: First transdermal MAO inhibitor approved for major depressive disorder.
- Hormone patches: Include contraceptive patches for birth control.

Future Aspects: The future of drug delivery is expanding to include advanced systems like liposomes, niosomes, and microemulsions, aimed at improving the delivery of poorly soluble drugs.

Transdermal patch market is projected to continue its rapid growth, with an estimated annual increase of about 25%, which is expected to rise further as new devices and drugs enter the market. Transdermal delivery of analgesics, in particular, is

anticipated to gain popularity with advancements in patch design, enhancing patient comfort and ensuring more precise and sustained drug release.

Active enhancement techniques such as iontophoresis, electroporation (short high-voltage pulses creating temporary skin pores), sonophoresis (low-frequency ultrasound) & magnetic energy methods to boost drug flux.

Improved materials and designs to maximize safety, efficacy, and user convenience.

Given these advancements, transdermal patches are becoming an increasingly valuable option for both acute and chronic pain management. The transdermal route offers key advantages over oral delivery, including stable plasma drug levels, reduced side effects, bypassing first-pass metabolism. [36-38]

Marketed Products: [39]

Table 3: Commercial products of TDDS

Brand Name	Drug	Manufacturer
Estraderm	Estradiol	Novartis
Oxytrol	Oxybutynin	Watson Pharma
Nicoderm	Nicotine	GlaxoSmithKline
Habitrol	Nicotine	Novartis
SonoPrep	Peptides	Sontra Medical Corporation
Alora	Estradiol	TheraTech
E-Trans	Fentanyl	Alza Corporation
Androderm	Testosterone	TheraTech / GSK
Nitrodisc	Nitroglycerin	Roberts Pharmaceuticals
Neupro®	Rotigotine	UCB / Schwarz Pharma
Climaderm	Estradiol	Wyeth-Ayerst
Matrifen®	Fentanyl	Nycomed
Nicotinell®	Nicotine	Novartis
Transderm Scop®	Scopolamine	Alza / Novartis
NuPatch 100	Diclofenac diethylamine	Zydus Cadila
SonoDerm	Insulin	Imarx
Transderm Nitro	Nitroglycerin	Novartis

Conclusion

TDDS are the subject of this article, which is a great resource for researchers because to its

detailed description of the assessment procedure. Researchers have shown that transdermal medication delivery has a lot of promise for

transforming hydrophilic and hydrophobic active substances into effective pharmaceuticals. There are a lot of new studies happening right now to find ways to include newer medications into TDDS, as it has huge potential as the future generation of drug delivery systems.

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