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**Research Article**

# TRANSDERMAL PATCH: A NEW DRUG DILEVERY SYSTEM APPROACH

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ABSTRACT

A transdermal patch is an adhesive patch with medication applied to the skin that allows a prescribed dosage to enter the bloodstream through the skin. One of the innovative medicine delivery methods that gets around the traditional dosage is the transdermal system. Pharmaceutical preparations of various sizes that contain one or more active components for the systemic circulations are known as transdermal patches. The review provides useful information regarding transdermal patches, including their benefits, drawbacks, mechanisms of action, kinds, fundamental components, evaluation techniques, and application. Nowadays, a large number of medications are offered as transdermal patches.



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## Introduction:

One technique for topical medication delivery that can produce a regulated systemic effect is a transdermal drug delivery system (TDDS)(Pathan IB,Setty CM ,2009). More patient compliance, avoiding first-pass metabolism, maintaining drug delivery, reducing patient variability, maintaining continuous and prolonged drug administration in plasma, and easily stopping drug administration in the event of an allergic reaction or poisoning are some of the benefits of TDDS over oral drug administration (Patel DP et al.2009). Gastric discomfort and other drug-related side effects can be avoided by taking this way. A small molecular size, sufficient solubility in the carrier,

short half-life, low dosage, and appropriate lipophilicity are all necessary for transdermal delivery [3]. The transdermal medication delivery method includes patches as one of its dosing forms. However, the skin's stratum corneum acts as a barrier to the transdermal patch [4]; as a result, only medications with small molecules may pass through it with ease. However, this can be circumvented by adding enhancers [5]. Therefore, the capacity of medications to be released from the patch matrix and enter the stratum corneum determines how effective a patch is. Prior to the drug penetrating the skin, the drug particles must breakdown to create molecules that can diffuse through the matrix [6].

One benefit of using a transdermal drug delivery system (TDDS) is that, in contrast to the oral and intravenous routes' limited controlled release, TDDS offers a steady infusion of the medication for an extended length of time. This makes it appropriate for medications with short biological half-lives that need frequent dosing, which improves patient compliance. Additionally, this approach can prevent adverse effects or treatment failure that are commonly linked to sporadic dosing for chronic disease[7].

**Skin:**

The non-viable epidermis, viable epidermis, viable dermis, and hypodermis are the four separate tissue layers that make up the skin. The skin's strong, comparatively thin outer layer is called the epidermis. Keratinocytes are found in the epidermis. They come from cells in the basal layer, which is the deepest layer of the epidermis. New keratinocytes gradually move upward toward the epidermis' surface. The outermost layer of the epidermis, known as the stratum corneum, is comparatively impervious and, when intact, keeps the majority of germs, viruses, and other external objects out of the body. Additionally, the epidermis shields the blood vessels, muscles, nerves, and internal organs from harm. The epidermis' outermost layer of keratin is somewhat thicker. The skin's viable epidermis layer is between 50 and 100 µm thick. The live epidermis shares physiochemical similarities with other living tissues in terms of cell structure. Ton fibrils hold cells together. About 90% of it is made up of water. The next layer of skin, the dermis, is a thick layer of elastic and fibrous tissue that provides the skin's strength and flexibility. Nerve endings, sweat and oil glands, hair follicles, and blood arteries are all found in the dermis. It is made up of whitish, fibrous, loose-textured connective tissue that contains lymphatic and blood vessels [8].

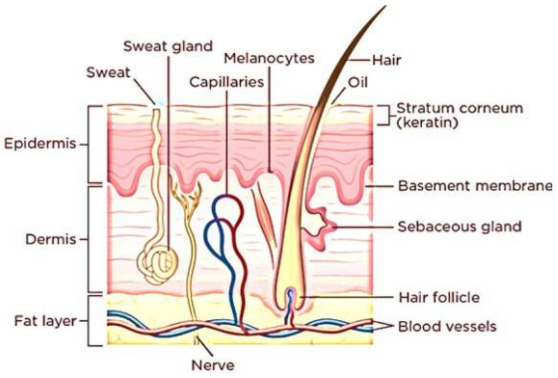


**Fig 1. Cross section through the skin**

**Skin Permeation Pathways:** There are several possible methods for drug molecules to enter the skin, such as through the sweat ducts, hair follicles, sebaceous glands, or directly through the stratum corneum. The relative significance of the appendageal or shunt routes of transport across the stratum corneum has been a topic of discussion among scientists for the past few years. This issue is made more difficult by the absence of an appropriate experimental model that would allow for the separation of these paths. Menon's recent review offers a useful resource. Ten to fifteen layers of corneocytes make up the stratum corneum. [9]

**TRANSDERMAL PATCH:**

Transdermal patches, also known as skin patches, are medicated adhesive patches applied to the skin that

allow a prescribed dosage of medication to enter the bloodstream through the skin. In December 1979, the U.S. Food and Drug Administration authorized the first prescription patch with scopolamine for motion sickness that was sold commercially. The nicotine patch, which distributes nicotine to aid in quitting tobacco use, was the best-selling transdermal patch in the US. In Europe, the first smoking cessation vapor patch to be sold commercially was authorized in 2007.

Furthermore, a number of additional patches are on the market, such as nitro-glycerine patches for angina, lidocaine patches, also known as Lidoderm, which treat shingles' peripheral pain, fentanyl, an analgesic for extreme pain, and others. Bu Trans, a brand name for buprenorphine, is used as an analgesic for moderate to severe chronic pain. These days, it is also frequently used off-label to treat chronic and severe pain. An NSAID topical patch called a Flector (Diclofenac Epolamine) patch is used to alleviate acute pain from small sprains, contusions, and strains. Additionally, it is being utilized to treat chronic illnesses' pain and inflammation, with the benefits of NSAIDs, such as those for arthritis and fibromyalgia. ADHD stands for hyperactivity disorder. The FDA declared in 2005 that it was looking into reports of fatalities and other severe side effects associated with opioid overdose in patients taking Duragesic, a fentanyl transdermal patch for pain management[10].

**Advantages:**

1. First-pass metabolism can be avoided [11]
2. The action's duration can be prolonged and predicted [11].
3. The use of TDDS is advised to alleviate the difficulties associated with drug absorption in the gastrointestinal tract [12].
4. If the oral route is inappropriate, such as in patients who have diarrhoea and vomiting, TDDS can be used in its place [12].
5. It is possible to sustain the drug's plasma concentration [13].
6. Because TDDS is non-invasive, it can eliminate the nuisance associated with parenteral therapy [12].
7. It lessens the likelihood of volatility [12].
8. It can be applied to medications with a short therapeutic range and half-life [12].
9. Drug therapy can be readily discontinued in the event of toxicity [12].
10. It improves patient compliance by lowering the frequency of drug delivery [12].

**Disadvantages:**

1. Because skin impermeability determines drug entrance limitations, only reasonably powerful medicines can be used for transdermal administration systems[12].
2. Due to their limited permeability, hydrophilic medicines are less appropriate than lipophilic medications [11].
3. Drug absorption is hampered by bigger drug molecules (over 1000) [11]..
4. It is incompatible with high dosages of medications [12].
5. Because the patch's size restricts the amount that may be injected, the drug molecule needs to be robust [14].
6. Local oedema, redness, and itching are examples of adverse reactions that this system may cause at the drug administration site [11].

**Transdermal patch components:**

The polymer matrix or drug reservoir, the active ingredient (drug), permeation enhancers, pressure-

sensitive adhesive (PSA), backing laminates, release liner, and additional excipients including plasticizers and solvents make up the transdermal patch's fundamental components.


**Fig 2.** Components of Transdermal patch

**Common material uses for making patches:**

1. **Drug reservoir and polymer matrix:** The TDDS polymer regulates the drug's release from the patch. As a result, the polymers employed in TDDS need to be chemically and biocompatible with medications and other system elements like PSA and penetration enhancers. In addition, polymers need to deliver drugs consistently and effectively. Natural and synthetic polymers are the two categories into which polymers are separated according to the source. The following table lists some examples of polymers that are frequently utilized in transdermal preparations [(14)].
2. **Membrane:** In a multilayer patch, the membrane regulates the discharge of drugs from the reservoir. The membrane's diffusion characteristics are employed to regulate the skin's accessibility to medications and/or excipients. Polyurethane, silicone rubber, and ethylene vinyl acetate are a few examples. These function as a membrane to control the release of drugs [(14)].
3. **Drugs:** The medication to be used also affects how well TDDS development goes. Transdermal patches, for instance, provide numerous benefits for medications with a limited therapeutic window, high first-pass metabolism, or short half-lives, which prevent adherence because of frequent dosing [(14)].
4. **Permeation Enhancer:** In order to achieve the intended therapeutic level, enhancers work to increase skin permeability. Non-toxic, non-allergic, non-irritating, controlled and reversible enhancing action, pharmacological inertness, the capacity to act precisely over a predictable duration, chemical and physical compatibility with medications and other pharmaceutical excipients, and colourless and odourless are the ideal characteristics of enhancers [(15)].
5. **Pressure sensitive Adhesive (PSA):** PSA is a substance that sticks to the substrate—in this example, leather—when applied lightly and removes without leaving any residue. Polyacrylate, polyacrylate, polyisobutylene, and silicon-based adhesives are PSA polymers that are frequently utilized in TDDS [(15).]
6. **Backing films:** This are chosen based on their flexibility, appearance, and occlusion requirements. Consequently, while creating a backing layer, the material's chemical resistance must be taken into account. Furthermore, excipient compatibility should be taken into account because extended interaction between the excipient and the backing layer may result in the excipient's detachment from the backing layer or in the excipient, drug, or enhancer diffusing through the layer Vinyl, polyethylene,

polyester, aluminium, and polyolefin films are some examples of these materials [14].

7. **Additional excipients such as plasticizers or solvents:**

(a) Solvents: Drug reservoirs are made with chloroform, methanol, acetone, isopropanol, and dichloromethane [15].

(b) Plasticizers: to provide the transdermal patch its plasticity, dibutyl phthalate, triethyl citrate, polyethylene glycol, and propylene glycol are also added [15].

**Table 1. Polymers used in the preparation of transdermal patches [31,32,33].**

| Polymer | **Category** |
|---|---|
| Sodium alginate | Natural Polymer |
| Chitosan | |
| Gelatine | |
| Gum Arabic | |
| Gum tragacanth | |
| Hyaluronic acid | |
| Hydroxypropyl methylcellulose | Semi-synthetic Polymer |
| Methylcellulose | |
| Carboxymethyl cellulose | |
| Carmel loses | |
| Polyvinylprrolidone (PVP) | Synthetic Polymer |
| Polyhydroxyethyl methacrylate (PHMA) | |
| Polyvinyl alcohol | |
| Polyvinly chloride (PVC) | |
| Polyethylene | |
| Polypropylene glycol | |
| Polystynene | |

**Types and methods of creating a patch:**

1. **Single-layer Drug Adhesive:**

The adhesive layer in this kind of patch is in charge of drug release and works to stick the several layers and the complete system to the skin. A temporary liner and backing surround the adhesive layer.

2. **Multi-layer Drug in Adhesive**:

In that both sticky layers are in charge of medication release, this kind of patch is comparable to a single-layer patch. But in this structure, the medicine must cling to an additional layer that is often (though not always) divided by a membrane. Additionally, this patch contains both permanent and temporary liner layers.

3. **Reservoir:** The drug is delivered through the micropore rate-controlled membrane in this system after a drug reservoir is placed between the support layer and the rate-control membrane. The medication may be distributed throughout the reservoir compartment in a solid polymer matrix or as a solution, suspension, gel, or other form.
4. **Matrix: The** adhesive and backing material, which serves as the formulation's outer layer, are the primary constituents of the matrix system. Drugs and additional ingredients, like enhancers and polymers, are first combined to create an

adhesive solution, which is subsequently evaporated to create a matrix film. The backing film is then covered with the matrix film and glue. The most popular transdermal patch on the market is the matrix-type patch. This matrix approach has the benefit of forming a thin and elegant preparation for the patch, which makes it easy to use and the production process quick, simple, and affordable.

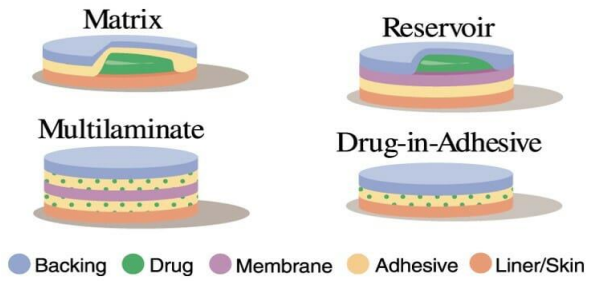


**Fig 3**. Types of transdermal patch.

**Various methods used for preparation of TDDS:**

1. **The circular Teflon Mold method (Baker and Heller 1989):** Uses an organic solvent and solutions with polymers in different ratios. Half as much of the same organic solvent is used to dissolve the calculated amount of the medication. The second half of the organic solvent is used to dissolve enhancers at varying quantities before they are applied. The drug-polymer solution is mixed with the plasticizer. After 12 hours of stirring, the entire mixture should be put into a circular Teflon Mold. To regulate solvent vaporization in a laminar flow hood model with an airspeed of 0.5 m/s, the Molds must be set up on a level surface and covered with the inverted funnel. For twenty-four hours, the solvent is left to evaporate. To remove aging effects, the dried films must be kept in a desiccator with silica gel for an additional 24 hours at 25±0.5°C prior to examination. These films must be assessed within a week of manufacture. Ketorolac-containing bio adhesive films have been researched. Several bio adhesive polymers, including sodium carboxymethyl cellulose (Na-CMC), hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC), and Carbopol 934, were used to cast films from organic and aqueous solvents. Investigations on the produced films' mechanical and physical characteristics, swelling patterns, in-vitro bio adhesion, drug penetration via the buccal mucosa of cows, and in-vitro drug release were conducted [16].
2. **Asymmetric TPX membrane approach (Berner and John 1994):** A heat-sealable polyester sheet with a concave 1 cm diameter will be utilized as the backing membrane, and a prototype patch can be made for this. An adhesive is used to seal the TPX {poly (4-methyl-1-pentene)} asymmetric membrane after the drug sample has been dispensed into the concave membrane. The dry/wet inversion method is used to make them. To create a polymer, TPX is dissolved at 60°C in a solution of solvent (cyclohexane) and nonsolvent additives solution. The polymer solution is kept at 40°C for 24 hrs and cast on a glass plate to a predetermined thickness with a Gardner knife. After that the casting film is evaporated at 50°C for 30 sec, then the glass plate is to be immersed immediately in a coagulation bath. After 10 minutes of immersion, the membrane can be removed, air-dried in a circulation oven at 50°C for 12 h [17].
3. **Mercury substrate method:** The medication and plasticizer are dissolved in a polymer solution. After 10 to 15 minutes of stirring to

create a uniform dispersion, the mixture is poured onto a flat mercury surface and covered with an inverted funnel to regulate solvent evaporation. According to research by Rathore et al., cellulose acetate and ethyl cellulose were used to create transdermal matrix-style terbutaline sulphate patches. Using a mercury substrate and the solvent casting technique, terbutaline sulphate transdermal patches were created. Different polymeric terbutaline sulphate transdermal patches were made for the current study. It was investigated how permeability enhancers affected the permeability of medications made from cellulose acetate and ethyl cellulose patches. The casting process on a mercury substrate produced nice films, and the polymeric combinations demonstrated good film-forming qualities [18].

4. **"IPM membranes" method:** Using a magnetic stirrer, the medication is dissolved in a solution of water and propylene glycol that contains carbomer-940 polymers and agitated for 12 hours. Tri-ethanolamine is to be added in order to neutralize the dispersion and make it viscous. If the drug's solubility in an aqueous solution is extremely low, buffer can be used to create solution gel. After researching the drug-in-adhesive transdermal patch and assessing its potential for site-specific anastrozole delivery, the generated gel will be integrated into the IPM membrane. In order to facilitate the passage of anastrozole through rat skin in vitro, several sticky matrixes, permeation enhancers, and anastrozole concentrations were examined [19].
5. **The "EVAC membranes" technique Methods**

**Approaches used in Transdermal Patch Development**

A. Systems regulated by membranes

B. Diffusion-controlled adhesive system

C. System of matrix dispersion:

D. Systems for micro reservoirs [20]

**Evaluation of transdermal patch:**

**a) physical Characteristics**:

1. *Observations of organoleptic:* Visual characteristics of organoleptic patches include colour, odour, flexibility, and surface texture [21].
2. *Test of thickness*: Using a calliper, divide the five sections to be measured to determine the patch's thickness. After measuring the thickness of each side of the section, the average is calculated [22].
3. *The test for weight uniformity*: Each patch is weighed on a digital scale for this test, and the average value is then calculated [22].

**Table 2.** ideal medicinal properties of TDDS [15, 21, 30]

| **Proerties** | **Comments** |
|---|---|
| Self-life | Up to 2 years |
| Patch size | <40 cm |
| Dose frequency | Once a daily to once a week |
| Packaging | Easy removal of release liner and minimum number of steps required to apply |
| Skin reaction | Non irritating and non-sensitizing |

| | |
|---|---|
| Release | Consistent pharmacokinetic and pharmacodynamic profiles |
| Dose | Should be low |
| Half-life (h) | 10 or less |
| Molecular weight | < 400 |
| Skin reaction | Non irritating and non-sensitizing |
| Oral bioavailability | Low |
| Therapeutic index | Low |

4. *Drug content:* involves fully dissolving a tiny portion of polymeric film in an appropriate solvent with a specific volume. The medication is freely soluble in the solvent that is used. The chosen region is weighed prior to being dissolved in the solvent. After being continually shaken for twenty-four hours in a shaker incubator, the entire contents are sonicated and filtered. The proper analytical technique is used to evaluate the medication in solution.
5. *Moisture content (%):* After being individually weighed, the produced films are stored for 24 hours at room temperature in a desiccator filled with calcium chloride. After a predetermined amount of time, the films are weighed once more until their weight remains constant. The following formula is used to determine the percentage moisture content.
6. *Surface morphology Test:* A scanning electron microscope (SEM) is used to assess the surface morphology of patch preparations in order to see the preparation surface more clearly at different magnifications [(14)].

**b) Test of in vitro release:** it can identify the cumulative drug levels that can be released from the carrier matrix, the patch release test is significant. The purpose of this test is to ascertain whether a patch can sustain a steady level of drug penetration by keeping the concentration of the drug in the stratum corneum of the skin significantly greater than the concentration of the drug in the body. With 500 millilitres of phosphate saline buffer pH 7.4 ± 0.5 as the dissolution media, a transdermal patch release test can be carried out using the paddle over disc method from USP equipment V brand Parmeq. Initially, the CD contains samples. After that, the paddle was positioned 2.5 cm from the container and the disc was submerged in 500 ml of dissolving media. The paddle was then revolved at 50 rpm while the temperature remained at 37±0.5 °C. Five millilitre samples were collected at various points during the course of a day, examined using a UV or HPLC spectrophotometer, reproduced three times, and the average value could be calculated ([23, 24, 25]).

**c) Test of in vitro penetration:** The Franz diffusion cell method can be used to examine drug penetration into mouse skin in vitro and perform a patch penetration test. The rat's stomach hair had to be carefully removed first, and then the skin had to be completely cleansed with distilled water to get rid of any blood vessels or sticking tissue that would later serve as the membrane in the Franz diffusion cell procedure. This device is made up of a water jacket, a donor compartment, and a receptor

chamber. Throughout the Franz diffusion cell's operation, the water jacket keeps the temperature steady. Both in the donor compartment and the Rat skin is positioned with the epidermis facing up in the receptor compartment. A thermostatically controlled heater was utilized to keep the cell temperature at 37±0.5 °C, and phosphate saline buffer pH 7.4 ±0.5 was the medium. The volume is periodically removed from the receptor compartment at a specific minute and replaced with fresh media of the same volume. After passing through a filtering media, the sample was examined using either HPLC or spectrophotometry [26, 27].

**d)Test for skin irritation:** Mice, rats, and rabbits in good health can all be used for skin irritation and sensitization studies. Mice and rabbits can have patches applied to their backs. After mice and rabbits have been completely cleansed and dehaired, the patch mixture can be placed to their skin. The backs of mice and rabbits need to be thoroughly cleansed before applying the patch. The skin of mice and rabbits is examined for indications of erythema (redness and swelling) and/or oedema 24 hours after the patch is applied. A symptom's severity is compared to the typical 0.8% formalin irritation in order to be divided into four severity levels: none, mild, moderate, and severe [24,28,29].

**Conclusion:**

Compared to traditional medication administration, a transdermal patch has numerous benefits, including improved bioavailability, prevention of first-pass metabolism, avoidance of harmful gastrointestinal side effects, drug retention in plasma, and improved patient compliance. The properties of the patch made from different polymers, as well as in vitro release and penetration studies, are what determine if a patch is suitable for transdermal distribution.

**Conflict of interest: -**

The authors declare that they have no conflict of interest. No funding was received for this literature review, and the authors have no financial or personal relationships with any organizations or individuals that could have influenced the conclusions of this review.

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