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Pharmaceutical Sciences
Volume 3 Issue 2, 2023
eISSN No.: 2582-8371

A Short Review on Transdermal Drug Delivery Systems

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ABSTRACT

Transdermal drug delivery system (TDDS) is an integral part of novel drug delivery system. The first transdermal system was approved by FDA in the year 1979 for the prevention of nausea, vomiting associated with travel (motion sickness). Transdermal drug delivery is the administration of therapeutic agents through intact skin for systemic effects. This system was developed to overcome the difficulties that occurred by oral route. A transdermal patch is a medicated adhesive patch that is placed on the skin to deliver controlled release of medication through the skin into blood stream. Patches are active for longer period than tablets. They improve patient compliance. In this present review we will discuss about transdermal patches and their advantages and disadvantages, the polymers which used in the delivery mechanism of TDDS. Transcutaneous permeation of drug in sufficient amount to obtain desirable pharmacological effect leads to the success of TDDS.

Keywords*: TDDS, oral route, transdermal patches, Controlled release, percutaneous absorption.*

INTRODUCTION

Transdermal patches are used to deliver controlled dose of medication through the skin into bloodstream. Transdermal patches are mainly used as they release the active components for several hours to days after applied being applied on skin[1-2]. A transdermal patch is a medicated adhesive patch that is places on the skin to deliver controlled release of medication through skin into blood stream. Many patients feel difficultly for swallowing tablet& getting injections. Using of transdermal patches reduces the difficulties and provide sufficient therapeutic effects [3-4]. Transdermal absorption or bio-availability depends on

1) Physiochemical properties of drug.
2) Ability of drug to penetrate the skin.
3) Physiology of skin.

The skin is the largest organ in the body, through its various layers drug reaches to circulatory system. The transdermal patch is also called skin patch.

Advantages of TDDS[2]

1) Self medication is possible.
2) Avoid First pass metabolism.
3) Avoid gastrointestinal incompatibilities.
4) It offers longer duration of action.
5) Maintain plasma concentration.
6) Avoid fluctuations in drug levels.

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Volume 3 Issue 2, 2023
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Disadvantages of TDDS

1) Skin irritation may occur at the site of application.
2) Ionic drugs are not suitable for transdermal therapy.
3) Transdermal patches can not achieve high plasma levels.
4) These are expensive.
5) Difficult to maintain stability of dosage forms.
6) Technical skills required for the preparation.

Components of Transdermal Patches [5-8]

1) Drug
2) Polymer matrix
3) Permeation enhancers
4) Adhesive layer
5) Backing laminate
6) Release laminate

1) Drugs

For successful development of a transdermal drug delivery, the following are the desirable properties of a drug.

Physicochemical Properties

It is generally accepted that the best drug candidates for passive adhesive Transdermal patches must be:

- Non-ionic.
- Low molecular weight (less than 1000 Daltons),
- Adequate solubility in oil and water.
- Low melting point (less than 200°C)
- Potent (dose ideally less than 10 mg per day).

2) Polymers

Polymers selection is criteria for the preparation of transdermal patches are as they controls the release of drug from the device. The polymers that should possess the following properties.

They are:

- The polymer should be stable.
- The polymers should be non toxic.
- The polymers should show biocompatibility and chemical comparability with the drug.
- Polymers should provide consistent and effective delivery of medicament.

Examples for polymers:

- **Natural polymers**: Cellulose derivatives, gelatin, shellac, sodium alginate, xanthan gum etc.
- **Synthetic polymers:** polyvinyl alcohol, polyvinyl chloride, polyethylene etc.
- **Synthetic elastomers**: Hydrin rubber, butyl rubber etc.
- Most commonly used polymers for transdermal patches are ethylene cellulose, hydroxy propyl methyl cellulose etc. Clopidogrel bisulphate has a shorter Elimination half-life (4 hr) & low oral bio-availability undergoes extensive first pass metabolism & frequent high doses are required to maintain the therapeutic level.

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Volume 3 Issue 2, 2023
eISSN No.: 2582-8371

3) **Permeation Enhancers:** These are the chemical compounds that enhances the permeability of drugs by interacting with layers of skin. Ideal properties of permeation enhancers:

- Enhancers should be non-irritant, nontoxic and non-allergic.
- They should not show any pharmacological activity.
- Examples: water, fatty acids, terpenes, surfactants, urea and its derivatives etc.

4) **Adhesive Layer:** It serves to adhere the components of patch to skin.

5) **Backing Laminate**: It protects the patch from the outer environment.

- It should have low water vapour transition rate.
- It should be chemically resistant.
- It should not allow the permeation of any other components into patch.

6) **Release liner:** It protects the patch during storage. It should be removed prior to use.

1) It should consists of two layers, one should be base layer and other should be release coating layer.
2) It consists of two layers, one is base layer and other is release coating layer.

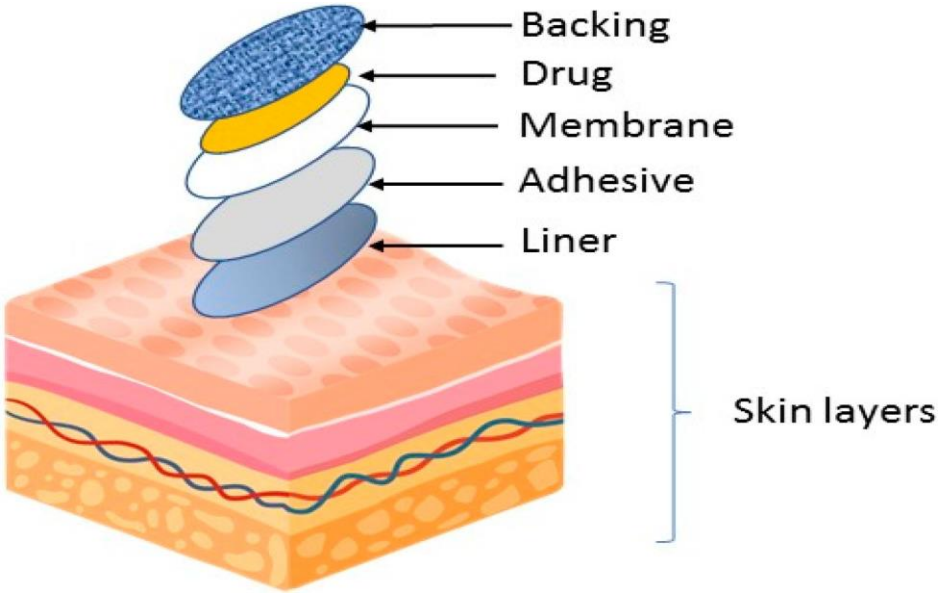

Figure 1: Components of TDDS

Types of Transdermal Patches [9]

There are 5 types of transdermal patches. They are:

- Single layer drug in adhesive.
- Multi layer drug in adhesive.
- Drug reservoir in adhesive.
- Drug matrix in adhesive.
- Vapour phases

Single Layer Drug in Adhesive: The adhesive layer of this system contains the drug. In this the adhesive layer not only serves to adhere the various layers together, but also responsible

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for releasing of the drug. The adhesive layer is surrounded by a temporary liner and a backing.

Multi-layer Drug in Adhesive: The multi-layer drug in adhesive patch is similar to single layer system. The major difference is that it contains another layer of drug in adhesive, usually separated by a membrane.

Drug Reservoir in Adhesive: In this system, the drug reservoir is embedded between an impervious backing layer and a rate controlling membrane. The drug releases only through the rate-controlling Membrane, which can be microporous or nonporous. In the drug reservoir compartment, the drug can be in the form of a solution, suspension, or gel or dispersed in a solid polymer matrix. On the outer surface of the polymeric membrane a thin layer of drug-compatible, hypoallergenic adhesive polymer can be applied.

Drug Matrix in Adhesive: The matrix system design is characterized by the inclusion of a semi solid matrix containing a drug solution (or) suspension which is in direct contact with the release liner. The compartment responsible for skin adhesive is incorporated in an overlay & forms a concentric configuration around the semi solid matrix.

Vapour Patches: In this type of patch, the adhesive layer not only servers to adhesive the various layers together but also to release vapour. The vapour patches are new on the market & they release essential ails for up to 6hrs. The vapour patches release essential oils & are used in case of decongestion mainly.

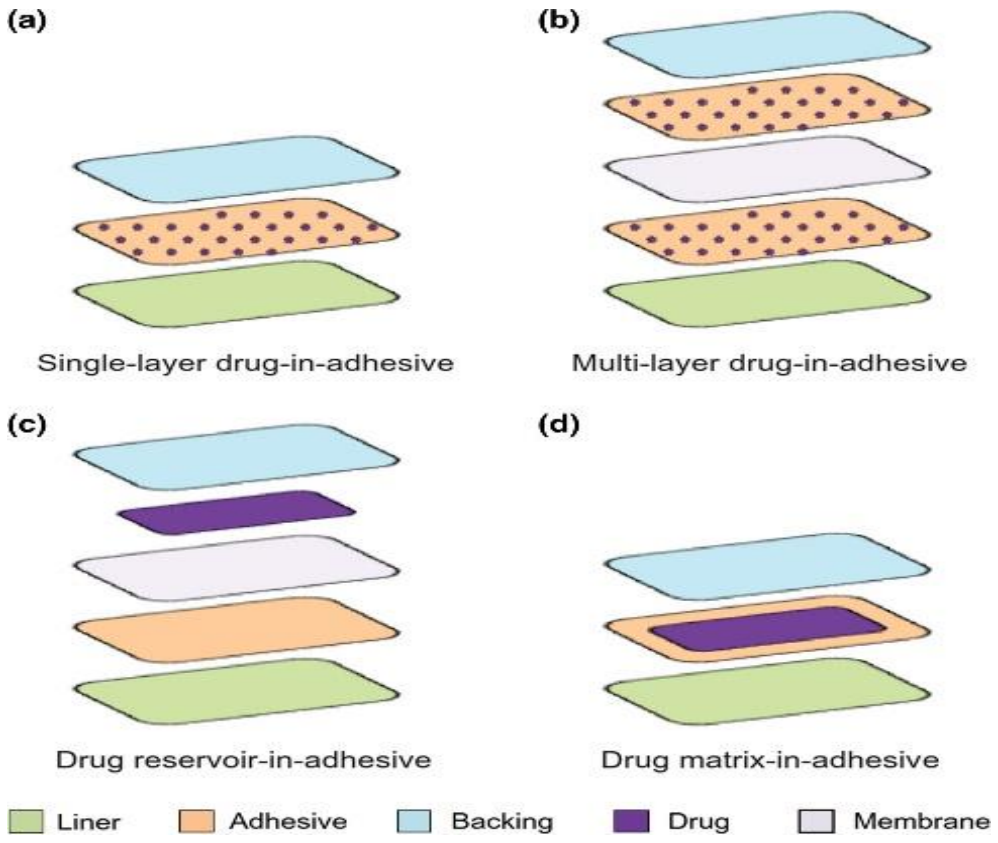

Figure 2: Various Types of TDDS

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Volume 3 Issue 2, 2023
eISSN No.: 2582-8371

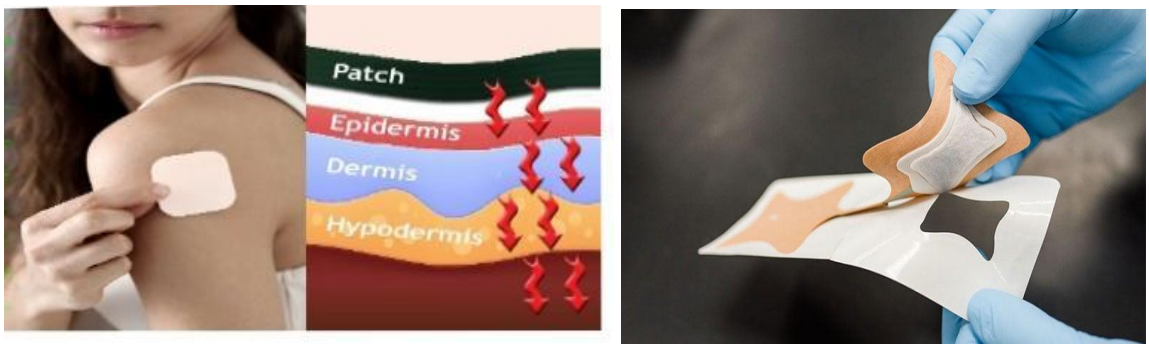

Figure 3: Marketed Patches

Recent Technologies of TDDS [10]

- Asymmetric TPX method.
- Circular teflon mould method.
- Mercury substrate method.
- By using IPM membrane method.
- By using EVAC membrane method.
- Aluminium backed adhesive film method.

Characterization of TDDS [2-8]

Physicochemical evaluation tests were performed as follows

- Thickness
- Uniformity of weight
- Drug content determination
- Drug content uniformity test
- Moisture content
- Moisture uptake
- Flatness
- Folding endurance
- Swelling index

Thickness

- Film thickness: It can be measured by using vernier callipers, with a least count of 0.01mm.
- Patch thickness: It can be measured by using screw guage, digital micrometer at 3 different places and mean value is calculated.

Uniformity of Weight: It is also called weight variation test. It can be done by taking individual weights of 10 patches, then noted down the average weight of the patches. The individual weight should not exceed the average weight of the patches.

Drug Content Uniformity: the patches were selected randomly, and the content is determined for patches individually. The results should be like this, out of these10 patches, 9 should be in the range between 85% and 115% of the Specified value and remaining 1 patch should be in the range of 75–125%, then, it is considered as the patches have passed the test. If three patches have the content in the range of 75–125%, then other 20 Patches should be taken and those should be present in the range of 85–125% to pass the test.

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Moisture Content: prepared films are weighed individually & kept in desiccators containing calcium chloride after a specialized time of 24 hours at room temperature. And again weigh and note down the weights of all films.

Moisture Uptake: Weigh the films first and then these films were kept in the desiccator at the room temperature for 24 hours. The relative humidity of 84% is exposed to those patches using the saturated solution of potassium chloride in the desiccator until the constant weight is achieved. The moisture Uptake is determined by using the formula.

% of moisture uptake = (initial weight – final weight)/initial weight ×100

Flatness [5]: A transdermal patch should posses a smooth surface which not constrict with time. It can be studied by flatness test. In this test, one strip is cut from centre and two strips are cutted from right and left sides. The length of each strip is measured. The variation in length is measured by percentage constriction. If the percentage constriction is 0%, it indicates 100% flatness.

Folding Endurance [5]: A specific area of the patch is cut evenly and folds it repeatedly at the same place till it broke. The number of folding is noted before the breaking of patch. It will give the folding endurance.

Drugs as Available as TDDS in Market

Brand Name	Drug	Manufacturer	Indications
DuragesicR	Fentanyl	Janssen Pharmaceutical	Moderate/severe Pain
NuPatch 100	Diclofenac	Zydus Cadila	Anti Inflammatory
Alora	Estradiol	TheraTech	Postmenstrual Syndrome
Catapres TTSR	Clonidine	Boehinger Ing lheim	Hypertension
Neupro	Rotigotine	Schwarz Pharma	Parkinson‟s Disease
Oxytrol	Oxybutynin	Watson Pharma	Overactive Bladder
Androde Rm	Testosterone	TheraTech/ GSK	Hypogonadism in males

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Volume 3 Issue 2, 2023
eISSN No.: 2582-8371

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