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Research

Emerging Trends in TDDS: A Focus on Amoxicillin-Loaded Transdermal Patch

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Abstract

Transdermal drug delivery is a non-invasive method of administering therapeutic agents through the skin into systemic circulation. It offers controlled and sustained release of drugs over extended periods, thereby maintaining consistent plasma concentrations and improving patient compliance. By delivering drugs directly into the bloodstream via the skin, transdermal systems bypass the gastrointestinal tract and hepatic first-pass metabolism, which can degrade or inactivate drugs when given orally. Transdermal patches are flexible pharmaceutical preparations designed to adhere to intact skin and facilitate diffusion of the active ingredient into systemic circulation. This route reduces the need for frequent dosing and avoids many limitations of other routes, such as pain and infection risk associated with injections. Patches such as nicotine and scopolamine were among the earliest in clinical use, demonstrating the practicality and therapeutic benefits of transdermal drug delivery. Despite challenges like skin barrier permeability and limited drug molecule properties, ongoing advancements in formulation and materials continue to expand their clinical applications.

Keywords: Transdermal patches, Skin permeation, Systemic drug delivery, First-pass metabolism, Controlled drug release, Diffusion mechanism, and Oral drug delivery.

NTRODUCTION

Transdermal drug delivery is an alternative way of delivering drugs via the skin layer the drug is carried through the skin into the bloodstream and circulates systemically in the body before reaching the target site. The transdermal drug delivery method has several advantages over other routes of administration. Examples include the ability to deliver continuous doses of drugs over an extended period of time, the ability to bypass the digestive system, and the ability to avoid first-pass metabolism in the liver Other drug administration routes, such as intravenous, can cause pain and increase the risk of infection.(3) Oral drug delivery system

is the most used route of drug delivery system but it has some disadvantages including first pass metabolism, drug degradation etc in digestive tract because of enzymes, pH etc.(8) Transdermal patches are flexible pharmaceutical preparation of varying sizes, containing, one or more active ingredients. They are intended to be applied to the broken skin in order to deliver the active ingredient to the systemic circulation after passing through the skin barriers. These devices allow for pharmaceuticals to be delivered across the skin barrier. Theoretically, transdermal patches works in a very simple way. A drug is applied in a relatively high dosage to the inside of patch, which is worn on the skin for an extended period of time. Though a diffusion process, the drug enters the bloodstream directly though the skin. Since there is high concentration on the patch and low concentration in the blood, the drug will keep diffusing into the blood, the drug will keep diffusing into the blood for a long period of time, maintaining the constant concentration of drug in the blood flow. Nicotine patch was the very first transdermal patch in market of India. The first transdermal patch, scopolamine was approved in 1979. (9)

ADVANTAGES

i. They can avoid gastrointestinal drug absorption difficulties covered by gastrointestinal pH, enzymatic activity and drug interaction with food, drink and other orally administration drug.
ii. They can substitute for oral administration of medication when the route is unsuitable as with vomiting and diarrhea.
iii. To avoid the first pass effect e.g. Transdermal Nitroglycerin. It is rapidly metabolized by the liner when taken orally.
iv. They are noninvasive, avoiding the inconvenience of parenteral therapy.
v. They provided extended therapy with a single application, improving compliance over other dosage forms requiring more frequent dose administration e.g. Tradermal clonidine 7 day.
vi. The activity of drugs having a start half life is extended through the reservoir of drug in the therapeutic delivery system and its controlled release.
vii. Drug therapy may be terminated rapidly by removal of the application from the surface of the skin**.(10)**

DISADVANTAGES

i. Some patients develop contact dermatitis at the site of application from one or more of the system components, necessitating discontinuation.
ii. Only potent drugs are suitable candidates for transdermal patch because of the natural limits of drug entry imposed by the skin's importability.
iii. Some drugs e.g. scopolamine transdermal patch placed behind the ear, it is uncomfortable.
iv. Long time adhere is difficult.(11)

BASIC COMPONENTS OF T. D. D .S

1. Polymer Matrix

The Polymer controls the release of the drug from the device.

a) **Natural Polymers**: Cellulose derivatives, Zein, Gelatin, Shellac, Waxes, Proteins, Gums and their derivatives, Natural rubber, Starch etc.
b) **Synthetic Elastomers:** Polybutadiene, Hydrin rubber, Polysiloxane, Silicone rubber, Nitrile, Acrylonitrile, Butyl rubber, Styrenebutadieine rubber, Neoprene etc.
c) **Synthetic Polymers**: Polyvinyl alcohol, Polyvinyl chloride, Polyethylene, Polypropylene, Polyacrylate, Polyamide, Polyurea, Polyvinylpyrrolidone, Polymethylmethacrylate, Epoxy etc.(12)

2. Drug

Drug solution in direct contact with release liner.

Physiochemical properties

a) The drug should have a molecular weight less than 1000 Daltons.
b) The drug should have affinity for both lipophilic and hydrophilic phases. (c) The drug should have a low melting point.

Biological properties

a) The drug should be potent with a daily dose of the order of a few mg/day.
b) The half-life (t½) of the drug should be short.
c) The drug must not produce allergic response.
d) Tolerance to the drug must not develop under the near zero-order release Profile of transdermal patches.(13)

3. Permeation Enhancers:

The chemical compounds that enhance the permeability of stratum corneum so as to attain therapeutic levels of the drug candidate. They improve the permeability by interacting with Stratum corneum.

a) Ideal Properties of Permeation Enhancers

i. They should be non-irritating, non-toxic & non- allergic.
ii. They should not bind to receptor site i.e. not showing any pharmacological activity.
iii. They should be cosmetically acceptable with an appropriate skin feel.(14)

4. Pressure-sensitive adhesive:

The PSA patch maintains close contact with the skin's surface. It should adhere with only finger pressure, be aggressively and persistently sticky, and have a strong holding force. Adhesives based on polyacrylates, polyisobutylene, and silicon are some examples. A variety of factors influence adhesive choices, including patch design and medication formulation. PSA should be physic chemically and physiologically compatible while not interfering with medication release. The PSA can be placed on the device's front (as in a reservoir system) or on its back and extending peripherally (as in a matrix system).(15)

5. Backing Laminate:-

Backing Laminate or backing membrane are flexible and providing a good bond to the drug reservoir. It is a supportive material which is permeable to the drugs and also enhances the permeation. It prevents drug from leaving dosage form through the top. It is impermeable substance and it protects the product during use on to the skin. They should be chemically compatible with the drug, enhancer, adhesive and other excipients.
Ex:- Vinyl, Polyethylene and polyester films (16)

6. Release liner:

During the storage, the release liner prevents drug loss and contamination from the adhesive layer. It is thus considered a component of the principal packaging material rather than a component of the dosage form used to deliver the medicine. The release liner consists of a non occlusive base layer (paper fabric) or an occlusive layer (polyethylene and polyvinyl chloride) and a silicon or Teflon coating. Polyester foil and metalized laminate are also utilized to make TDDS release liners.(17)

7. Other Excipients:-

Other Excipients like plasticizers and Solvents are used :-
Plasticizers:- Triethylcitrate, propylene Glycol, Dibutylpthalate, Polyethylene Glycol.
Solvents:- Isopropanol, Dichloromethane, Acetone, Chloroform, Methanol.(18)

TYPES OF TDDS:

Single-layer Drug-in-Adhesive:

The Single-layer Drug-in-Adhesive system is characterized by the inclusion of the drug directly within the skin contacting adhesive. In this transdermal system design, the adhesive not only serves to affix the system to the skin, but also serves as the formulation foundation, containing the drug and all the excipients under a single backing film. The rate of release of drug from this type of system is dependent on the diffusion across the skin (19).

Multi-layer drug in adhesive:

In adhesive patch is similar to the single-layer system in that both adhesive layers are also responsible for the releasing of the drug .But it is different however that it adds another layer of drug in adhesive, usually separated by a membrane. This patch also has a temporary liner layer and a permanent backing (19).

Drug Reservoir-in-Adhesive:

The Reservoir transdermal system design is characterized by the inclusion of a liquid compartment containing a drug solution or suspension separated from the release liner by a semi-permeable membrane and adhesive. The adhesive component of the product responsible for skin adhesion can either be incorporated as a continuous layer between the membrane and the release liner or in a concentric configuration around the membrane (20).

8. Matrix System: This system is of two type

a) Drug-in-Adhesive System:

For the formation of drug reservoir, the drug dispersed in an adhesive polymer and then spreading the medicated polymer adhesive by solvent casting or by melting the adhesive (in the case of hot-melt adhesives) on to an impervious backing layer (21).

b) Matrix-dispersion system:

The drug is dispersed homogeneously in a hydrophilic or lipophilic polymer matrix. It is then altered into a medicated disc with a definite shape and thickness. This drug-containing polymer disk is fixed onto an occlusive base plate in a compartment fabricated from a drug impermeable backing layer. Instead of applying theadhesive on the face of the drug reservoir, it is spread along with the circumference to form a strip of the adhesive rim(22).

Preparation of Transdermal Drug Delivery Systems (TDDS)

Transdermal drug delivery systems (TDDS) can be prepared using different techniques depending on the type of drug, polymer, and the desired release profile. The most commonly used methods include:

1. Solvent Casting / Film Casting Method

In this method, the drug is dissolved or dispersed in a polymer solution, and a plasticizer is added to improve flexibility. The mixture is then cast into thin films and allowed to dry by solvent evaporation, forming a uniform transdermal patch. This method is widely used due to its simplicity and cost-effectiveness (7)

2. Hot Melt / Fusion Method

Here, the drug and polymer are melted together without the use of solvents and then solidified to form a patch. This method is ideal for drugs that are stable at high temperatures and avoids the potential hazards of organic solvents.

3. Coating / Solvent Evaporation Method

Primarily used for reservoir-type TDDS, this technique involves coating the drug solution onto a backing membrane, followed by drying. A rate-controlling polymer membrane is applied over the drug layer, and the edges are sealed to ensure controlled release.

4. Hydrogel / Matrix Dispersion Method

In this approach, the drug is dispersed in a hydrogel polymer, which is then applied over a backing membrane. This method is suitable for gel-based or flexible patches and provides good adhesion and patient comfort.

5. Microemulsion / Nanoemulsion-Based TDDS

This method uses nano-sized droplets to enhance the solubility and skin penetration of poorly soluble drugs. The drug-loaded micro- or Nano emulsion is incorporated into a gel or film matrix, improving permeation and controlled release.

6. Physical Enhancement Techniques

Advanced TDDS can use external physical methods to increase drug delivery across the skin, such as:

Iontophoresis: Using a small electric current

Microneedles: Tiny needles create microchannel in the skin

Ultrasound (Sonophoresis): Enhances drug permeability

These techniques are particularly useful for delivering macromolecules or drugs with poor skin penetration.

Evaluation of Transdermal patches:

Physicochemical evaluation:

Transdermal patches can be physic chemically evaluated in terms of these parameters**:**

Thickness:

The thickness of transdermal film is determined by travelling microscope, dial gauge, screw gauge or micrometer at different points of the film.(23)

Weight Uniformity:

This test makes sure the consistency of the created patch. From the whole patch three small-scaled portable pieces were cut randomly. Each having area of about 4 Cm' square (2*2 cm) and separately weighed. The standard diversionance from the mean value will be detailed. (24)

Folding endurance:

In order to identify the type of plasticizer, the folding endurance of the patches is crucial. The prepared patches were continuously folded in the same spot until a break or fracture showed up. The value for folding durability was obtained by folding the patches in the same location.(25)

Drug content uniformity:

It is determined by taking specific no. of patches and completely dissolving then in specific media. Resulting solution is filtered out through membrane filter. The samples so obtained is analyzed by HPLC or U.V. spectrophotometer.(26)

Moisture content:

The prepared films are weighed individually and kept in a desiccators containing calcium chloride at room temperature for 24 h. The films are weighed

again after a specified interval until they show a constant weight. The percent moisture content is calculated using following formula.(27)% Moisture content = Initial weight – Final weight X 100

Flatness:- A Transdermal patches will be cut into three longitudinal strips from left side, right side and the centre. The length of each strip was determined and measured. The flatness of Transdermal Patch will be determined by using equation:- Construction (%) = (L1-L2) ×100
Where, L1= initial length of the strip and L2 = final length of the strip(28).

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