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A Review : Transdermal Drug Delivery System

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Abstract: *Transdermal medication administration has the benefit of being comparatively painless. Because of its large surface area, systemic access via underlying lymphatic and circulatory networks, and noninvasive drug administration, the skin is an attractive site for drug entrance. When Ciba-Geigy introduced Transdermal V (now known as Transdermal Scope) in 1981, it was the first time transdermal delivery—the administration of medication through the skin for a systemic effect—was used to stop motion sickness-related nausea and vomiting. Transdermal drug delivery allows for a constant blood level profile and regulated release of the medication into the patient, which can lead to less systemic side effects and, occasionally, better efficacy than conventional dose forms. Delivering medications into the systemic circulation through the skin at a predefined rate with little variation between and among patients is the primary goal of transdermal drug delivery systems.*

Keywords: Transdermal Delivery, Patches, Topical

I. INTRODUCTION

The oral route is the most commonly used method for delivering medications, mainly because it's simple and convenient. However, it has significant drawbacks, including poor absorption due to liver metabolism (the "first pass effect") and the tendency to cause sharp fluctuations in blood levels, both too high and too low. This often requires higher or more frequent doses, which can be costly and inconvenient. On the other hand, advancements in drug delivery methods aim to improve the precision of targeting specific areas in the body, reducing the required dosage and minimizing the risk of negative effects like immune system suppression or damage to cells. Transdermal drug delivery involves using specialized dosage forms that, when applied to intact skin, allow medication to pass into the bloodstream at a controlled rate. Traditional drug forms often lead to fluctuations in plasma drug levels, which can cause side effects or reduce effectiveness. These issues, along with the need for repeated dosing and inconsistent absorption, led to the creation of controlled drug delivery systems. A controlled delivery system is a medication form that provides a steady release of one or more drugs into the body, targeting a specific organ or area, in a consistent and predictable pattern over a set period. The main goals of such systems are to improve patient adherence, ensure drug safety, and increase effectiveness by offering less frequent dosing and better control over drug levels in the bloodstream.

Benefits:

Because the transdermal route is safe and convenient, it's an intriguing delivery method. The following are advantages of administering medication through the skin to provide a systemic effect:

- The medications avoid first-pass metabolism, which increases bioavailability, and bypass hepatic and presystemic metabolism.
- IV treatment avoids risks and hassles.
- Self-management is feasible.
- Reducing unwanted side effects.
- Steer clear of medication level fluctuations.
- Keep the powerful drug's plasma concentration constant.

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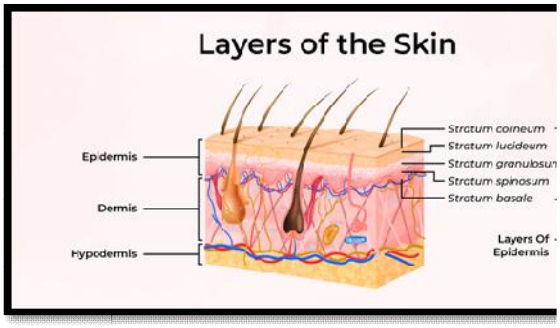
- Therapy can be stopped at any time with ease.
- The capacity to provide the medication to a certain location more precisely.

Drawbacks:

- Transdermal drug delivery systems cannot effectively administer ionic drugs or medications.
- Drugs with a molecular weight over 500 Daltons are not suitable for transdermal administration.
- These systems are limited in their ability to achieve high drug concentrations in the bloodstream or plasma.
- There is a risk of skin irritation, redness, and itching with prolonged use.
- Transdermal delivery is unable to release drugs in a controlled, pulsatile manner.
- Long-term use can cause discomfort for the patient due to the adherence of the system to the skin.

Structure Of Skin :

The skin consists of three primary layers: the epidermis, dermis, and hypodermis (also known as the subcutaneous layer). Each layer has distinct characteristics that play a crucial role in the skin's ability to protect the body and interact with the surrounding environment.



1. Epidermis (Outer Skin Layer):

- **Stratum Corneum:**
  This is the top layer made of dead skin cells full of keratin. It protects the skin from things like germs, sunlight, and chemicals.
- **Stratum Lucidum:**
  A clear, thin layer found only on thick skin like your palms and soles. It gives extra protection.
- **Stratum Granulosum:**
  This layer has small grains that help make the skin waterproof.
- **Stratum Spinosum:**
  This layer helps make the skin strong and holds its shape. It has skin cells (keratinocytes) and immune cells (Langerhans cells).
- **Stratum Basale (Stratum Germinativum):**
  The bottom layer where new skin cells are made. It also has melanocytes, which make melanin — the pigment that gives skin its color.

2. Dermis (Middle Layer of Skin):

- **Papillary Dermis:**
  This is the top part of the dermis. It has lots of tiny blood vessels, nerve endings, and touch sensors (like Meissner's corpuscles). It feeds the top skin layer and helps control body temperature.

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- **Reticular Dermis:**
  This is the lower and thicker part of the dermis. It contains strong fibers (collagen and elastin) that keep the skin firm, stretchy, and flexible. It also holds sweat glands, oil glands, and hair roots.

3. Hypodermis (Bottom Layer of Skin):

- This is the deepest layer of the skin. It's made up of soft connective tissue and fat cells.
- It stores energy, keeps the body warm, and acts like a cushion to protect muscles and bones underneath.
- It also helps attach the skin to the muscles and bones below it.

Technologies Used in Making Transdermal Drug Delivery Systems (TDDS):-

These technologies are mainly grouped into four types:

1. **Polymer Membrane-Controlled System:**
   The drug passes through a thin membrane (like a filter) made of polymer, which controls how fast the drug moves into the skin.
2. **Polymer Matrix-Controlled System:**
   The drug is mixed into a solid or gel-like material (a polymer matrix), and it slowly spreads out from this material into the skin.
3. **Drug Reservoir Gradient-Controlled System:**
   The drug is stored in a separate reservoir or compartment, and it moves into the skin based on the concentration difference (gradient) between the reservoir and the skin.
4. **Micro-Reservoir Dissolution-Controlled System:**
   The drug is kept in many tiny reservoirs inside a gel or polymer. These small reservoirs slowly release the drug as it dissolves, allowing for controlled delivery into the skin.

Membrane Permeation–Controlled Systems

In this type of system, the drug is stored in a special compartment that's sealed off using a material that doesn't let the drug pass through (like a metal-plastic layer).On top of that, there's a special membrane (which could have tiny pores or be solid) — for example, made of ethylene vinyl acetate (EVA) — that controls how fast the drug can pass through. The drug can only leave the system by moving through this membrane at a steady, controlled rate.

Adhesive Dispersion Type Systems:

This system is a simpler version of the membrane-controlled type. Here, the drug is mixed directly into a sticky material (called an adhesive), like poly(isobutylene) or poly(acrylate). This drug-loaded adhesive is then spread as a thin layer onto a backing layer made of plastic and metal that doesn't let the drug pass through .On top of the drug layer, a thin layer of plain (non-medicated) adhesive is added. This top layer controls how fast the drug moves out of the patch and into the skin.

Matrix Diffusion Controlled Systems:

In this type of system, the drug is evenly mixed into a polymer material that can either attract water **(hydrophilic)** or repel it (**lipophilic**).This drug-polymer mixture is then shaped into a thin disc with a specific size and thickness.
To create the mixture, there are two common methods:

- Mix fine drug particles with a liquid or thick polymer base, then let the polymer harden (cross-link).
- Or, mix the drug with a soft, rubber-like polymer while heating it, so the drug spreads evenly throughout. The drug slowly moves out (diffuses) from this solid matrix into the skin over time.

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A. Polymer Matrix

The **polymer** is a very important part of the transdermal patch. It controls how the drug is released through the skin. Different types of polymers can be used, depending on the drug and how the patch is made.

For a polymer to be used in TDDS, it should meet these conditions:

1. **It must allow the drug to pass through it.**
   This depends on the polymer's chemical makeup, softness (glass transition temperature), and size (molecular weight).
2. **It should be able to hold a good amount of the drug.**
3. **It should not react with the drug** neither physically nor chemically.
4. **It should be affordable and easy to turn into the final patch.**

B. Drug Substance

Picking the right drug is very important for making a good transdermal patch. The drug's important properties affect how well it can pass through the patch and the skin.

C. Penetration Enhancers

Penetration enhancers are important parts of most transdermal patches because they help the drug pass through the skin better. They work by changing how the skin blocks substances, either by acting on the skin's surface or the drug itself.

An ideal penetration enhancer should have these qualities:

1. Safe, affordable, and looks/feels good on the skin.
2. Not toxic.
3. Doesn't cause irritation.
4. Doesn't cause allergic reactions.
5. Works quickly and lasts just the right amount of time for the drug.
6. Changes the skin barrier in a way that can be reversed after use.
7. Works well with the patch materials without causing problems.
8. Easy to include in the patch.

Design of Transdermal Delivery Systems:-

Every transdermal patch has a few key parts: the drug mixed or dissolved in a safe polymer that supports the patch and controls how the drug is released.

There are two main types of patch designs that affect how the drug comes out and how the patch works:

1. **Matrix (or Monolithic) Design:**
   The drug is mixed into the polymer, and this polymer controls how the drug is released from the patch.
2. **Reservoir (or Membrane) Design:**
   The drug is kept separate from the polymer that controls release. Instead, there is a special membrane between the drug and the sticky layer that controls how fast the drug leaves the patch.

Technologies for Developing Transdermal Drug Delivery Systems:-

Many methods have been created to control how fast drugs are released and absorbed through the skin. These methods can be grouped into four main types.

Polymer Membrane Permeation-Controlled TDDS:

In this system, the drug is kept between two layers: a backing layer made of metal and plastic that the drug can't pass through, and a special polymer membrane that controls how fast the drug is released. The drug can only leave the patch by passing through this polymer membrane, which can be either tiny-hole (microporous) or solid (nonporous), like **ethylene-vinyl acetate copolymer.** On top of this membrane, there's a thin sticky layer made of skin-friendly, non-

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irritating adhesive (like silicone) that helps the patch stick closely to the skin .Examples of this kind of system include **Transdermal-Nitro, Transdermal-Scope, Catapres TTS, Estraderm,** and **Duragesic.**

Polymer Matrix Diffusion-Controlled TDDS:

In this method, the drug is evenly mixed into a water-loving (hydrophilic) or fat-loving (lipophilic) polymer to make a medicated material. This mixture is shaped into thin discs with a set size and thickness. The drug-filled polymer disc is placed onto a base that doesn't let the drug pass through, inside a special compartment. Around the edge of the disc, a sticky adhesive is applied to help the patch stick to the skin. Examples of this type of system include **Nitro-Dur** and **NTS**.

Drug Reservoir Gradient-Controlled TDDS:

To get a more consistent drug release (instead of a changing rate), the amount of drug in the polymer matrix is gradually changed step by step. This creates a drug concentration gradient along the path the drug takes through the layers of the patch. An example of this system is the **Deponit** patch.

Microreservoir Dissolution-Controlled TDDS:

This system is a mix between the reservoir and matrix types First, the drug particles are suspended in a water-friendly solution, like **polyethylene glycol**. Then, this mixture is evenly spread into a fat-loving (lipophilic) polymer using strong mixing. This creates thousands of tiny drug pockets (microreservoirs) inside the polymer that slowly release the drug. To keep this mix stable, the polymer chains are quickly linked together (cross-linked), forming a medicated disc with a fixed size and thickness.

EVALUATION TEST OF TRANSDERMAL PATCH:-

Drug-Excipients Interaction Studies: The drug and other ingredients (excipients) used in the product must work well together to make a stable final product. It's very important to check if they might react physically or chemically. To do this, scientists use tests like thermal analysis, FT-IR (a type of infrared test), UV light analysis, and chromatography. These tests compare things like the drug's purity, melting points, unique chemical signals, and light absorption to see if any changes or reactions happen.

Drug Content: A certain part of the patch is dissolved in the right amount of a liquid solvent. Then, the solution is filtered to remove any solids. After that, the amount of drug in the solution is measured using a method like UV light analysis or HPLC (High-Performance Liquid Chromatography). The results are based on the average of three samples.

Weight Uniformity: Before testing, the patches are dried at 60°C for 4 hours. Then, pieces of a specific size are cut from different areas of the patch and weighed using a digital scale. The average weight and the variation (standard deviation) are calculated from these individual weights.

Thickness of the Patch: The thickness of the drug patch is measured at different spots using a digital micrometer. Then, the average thickness and the variation (standard deviation) are calculated to make sure the patch thickness is consistent.

Moisture Loss: First, each prepared film is weighed. Then, the films are placed in a container with calcium chloride at 40°C to keep them dry. After 24 hours, the films are weighed again. The percentage of moisture lost is calculated using this formula:

$$\%\text{Moisture Loss} = \text{Final weight Initial weight} - \text{Final weight} \times 100$$

Applications of TDDS (Transdermal Patches):-

1. **Nicotine Patch (NicoDerm):**
   Helps people quit smoking. It's one of the top-selling patches in the U.S.
2. **Pain Relief Patches (Duragesic & BuTrans):**
   Contain strong painkillers like **Fentanyl** and **Buprenorphine** to give constant pain relief, especially for severe pain.

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3. **Hormone Patches (Estraderm & Climara Pro):**
   Contain **Estradiol** to treat menopause symptoms and prevent bone loss after menopause.
   Climara Pro also includes **Levonorgestrel** for added hormone balance.
4. **Nitroglycerin Patch:**
   Used to treat **chest pain (angina)** instead of using under-the-tongue pills.
5. **Clonidine Patch:**
   Used to help control **high blood pressure.**
6. **Selegiline Patch:**
   This was the first patch used to treat **depression** (a type of MAO inhibitor).
7. **Methylphenidate Patch:**
   Used to treat **ADHD (Attention Deficit Hyperactivity Disorder)** in children and adults.

II. CONCLUSION

This review shows that giving old drugs a new form, like transdermal patches, has sparked interest among researchers. If a drug has the right chemical and pharmacological properties, **transdermal drug delivery** can be a very effective way to deliver it. Transdermal patches are made up of several key parts—like the **drug reservoir, liner, adhesive, penetration enhancers**, **backing layer, plasticizers**, and **solvents**—all of which help control how the drug is released through the skin.

Once the patches are prepared, they are tested through various studies such as:

- **Physicochemical tests**
- **In-vitro (lab-based) skin permeation studies**
- **Skin irritation tests**
- **Animal and human trials**
- **Stability studies** to check shelf life

In the future, TDDS technology will likely improve further with better control of drug release and more types of drugs becoming available in patch form.

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