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DESIGN, DEVELOPMENT AND EVALUATION OF TRANSDERMAL DRUG DELIVERY SYSTEM

RAYAPATI VAISHNAVI*, BORUGADDA BABITHA, BUDAGALA GAYATHRI, CHANDU BABU RAO

Priyadarshini Institute of Pharmaceutical Education and Research, 5th Mile, Pulladigunta, Guntur-522017, Andhra Pradesh, India.

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***CORRESPONDING AUTHOR**
Rayapati Vaishnavi

ABSTRACT

An efficient and patient-friendly substitute for traditional oral and parenteral dosing forms is the transdermal drug delivery system (TDDS). Together, the reviewed papers demonstrate the increasing significance of transdermal patches in providing prolonged and regulated medication release via the skin into the bloodstream. Avoiding first-pass metabolism, increasing bioavailability, decreasing the frequency of doses, minimizing variations in plasma levels, and improving patient compliance are only a few benefits of TDDS.

Keywords: *Transdermal Drug Delivery System (TDDS), Transdermal Patches, Controlled Drug Release, Skin Permeation, Drug–Skin Interaction, Backing Membrane.*

1. INTRODUCTION

Transdermal drug delivery refers to self-contained, discrete dosage forms that are applied to intact skin to deliver medication into the systemic circulation at a controlled and predetermined rate. As an important component of novel drug delivery systems, the transdermal drug delivery system (TDDS) enables the transport of therapeutic agents across the skin for systemic effects. This approach offers several advantages, including sustained and controlled release of drugs, improved patient compliance, easy termination of therapy by patch removal, and avoidance of first-pass hepatic metabolism [1].

The skin is the largest organ of the human body, covering a surface area of approximately 1.5 to 2.0 m² in adults. Since ancient times, the skin has been used as a route for drug administration to manage systemic diseases. Historical records from ancient Egyptian and Babylonian medicine around 3000 BC describe the use of salves, ointments, and patches prepared from plant, animal, and mineral sources for therapeutic purposes [2].

Anatomy and Physiology of Skin

The skin, constituting the largest organ of the human body, spans approximately 2 square meters and receives nearly one-third of the body's blood circulation. The skin is commonly categorized into three primary layers:

(a) The outermost layer, known as the epidermis.
(b) The middle layer, referred to as the dermis; and
(c) The innermost layer, called the hypodermis [3].

Structure of Skin

1.1 Epidermis

The epidermis is the outermost layer of the skin and acts as the body's primary protective barrier. It consists of multiple layers of cells, with the outermost layer forming the stratum corneum, which is composed of dead, keratinized cells that provide strong barrier properties [4].

1.2 Dermis

The dermis, ranging from 3–100 mm thick, constitutes the second layer after the viable epidermis. It consists of a diverse array of cells serving various functions, including connective tissue, vascular tissue, a network of lymphatic vessels, sweat and sebum glands, hair follicles, and macrophages [5].

1.3 Hypodermis (Subcutaneous Fat Layer)

The hypodermis, also known as the subcutis, is the deepest layer of the skin and lies beneath the dermis. It is primarily composed of loose connective tissue and is rich in adipocytes (fat cells), which are responsible for fat storage.

2. ADVANTAGES AND DISADVANTAGES

2.1 Advantages

- Bypasses hepatic first-pass metabolism, improving drug bioavailability
- Provides controlled and sustained drug release, maintaining steady plasma drug levels
- Reduces dosing frequency, improving patient compliance

2.2 Disadvantages [6]

- Only drugs with low molecular weight (generally <500 Da) are suitable

- Limited to drugs requiring low daily dose (usually <10 mg/day)
- Skin irritation, erythema, itching, or allergic reactions may occur

3. BASIC COMPONENTS OF TDDS

A. Polymer Matrix/Drug Reservoir
B. Drug
C. Permeation Enhancers
D. Pressure Sensitive Adhesive
E. Backing Laminates
F. Release Liner and other excipients like Plasticizers and Solvents [7].

3.1 POLYMER MATRIX/DRG RESERVOIR

The polymer matrix plays a crucial role in controlling the release of the drug from a transdermal delivery system.

3.2 DRUG

The transdermal route provides considerable benefits for drugs that possess suitable pharmacological and physicochemical characteristics. It is particularly advantageous for medications that undergo extensive first-pass hepatic metabolism.

3.3 PERMEATION ENHANCERS [8].

Permeation enhancers play a crucial role in augmenting stratum corneum permeability by interacting with its functional elements.

3.4 Release Liner

The release liner is a protective covering applied to the patch during storage and is removed prior to application.

4. VARIOUS METHODS FOR PREPARATION OF TDDS

Transdermal patches are extensively used drug delivery systems that enable controlled and sustained release of drugs through the skin into systemic circulation [9].

4.1 Solvent Evaporation Method

Solvent evaporation method is a simple technique used for the preparation of transdermal patches and films. In this method, the drug and polymer are dissolved in a suitable volatile solvent to form a uniform solution. The solution is poured into a mold or petri dish and allowed to dry at room temperature or in a hot air oven. As the solvent evaporates, a thin, uniform film containing the drug is formed. The dried film is then cut into required sizes and used for further evaluation.

4.2 Microwave Assisted Method

Microwave-assisted method is a rapid technique used in formulation and synthesis processes. In this method, drug and polymer (or other ingredients) are exposed to microwave radiation, which produces uniform and quick heating. The microwaves enhance molecular movement, leading to faster reaction, better mixing, and reduced processing time. This method improves efficiency, increases yield, and minimizes solvent usage compared to conventional heating methods [10].

4.3 Reverse Phase Evaporation Technique (RPE)

Reverse phase evaporation technique is used mainly for the preparation of vesicular systems like liposomes. In this method, phospholipids are dissolved in an organic solvent, and the aqueous phase containing the drug is added to form water-in-oil (W/O) emulsion. The organic solvent is then removed under reduced pressure using a rotary evaporator. As the solvent evaporates, a gel-like structure forms and finally converts into liposomes encapsulating the drug. This method provides high drug entrapment efficiency [11].

5. TRANSDERMAL PATCHES

A transdermal patch is a medicated adhesive dosage form that is applied to the surface of the skin to deliver a specific amount of drug into the systemic circulation at a controlled and predetermined rate (12). These patches are designed to maintain consistent plasma drug levels by allowing the drug to pass through the skin layers and enter the bloodstream over an extended period.

6. TYPES OF TRANSDERMAL PATCHES

- Single layer drug in adhesive.
- The Multi-layer drug in adhesive.
- Drug reservoir -in-Adhesive.
- Drug Matrix -in-Adhesive
- Vapour patch.

6.1 Single layer drug in adhesive

In a single-layer drug-in-adhesive system, the adhesive layer performs a dual function by acting both as the pressure-sensitive adhesive and as the carrier for the drug.

6.2 Multi-layer drug in adhesive [13].

The multilayer drug-in-adhesive system is similar to the single-layer design; however, it contains more than one drug-loaded adhesive layer.

6.3 Drug reservoir in adhesive

The drug reservoir system consists of a distinct drug reservoir compartment, an impermeable backing layer made of metallic plastic laminate, and a rate-controlling polymeric membrane.

6.4 Drug matrix in adhesive [14].

In the drug matrix system, the patch contains a semisolid matrix layer in which the drug is dispersed as a solution or suspension.

6.5 Vapour patch

In vapour patches, the adhesive layer not only holds the different layers of the patch together but also facilitates the release of vapours.

7. MECHANISM OF TRANSDERMAL DRUG PENETRATION OF PATCH

Release of Base Material of Patch
↓
Diffusion into stratum corneum
↓
Diffusion into epidermis
↓
Diffusion into dermis
↓
Migration of capillaries
↓
Migration into lesion

8. FACTORS AFFECTING TRANSDERMAL DRUG DELIVERY SYSTEM (TDDS) [15]

8.1 Drug factors – Molecular weight, lipophilicity, solubility, melting point.
8.2 Skin factors – Thickness of stratum corneum, hydration, age, blood flow.
8.3 Physiological factors – Skin pH, temperature, site of

application.
8.4 Formulation factors – Polymer type, adhesive, penetration enhancers, drug concentration.
8.5 Environmental & patient factors – Humidity, temperature, skin condition, application method.

9. LIMITATIONS

- Skin Barrier and Permeability: The stratum corneum acts as a major barrier to drug penetration, limiting the entry of most drugs. Only molecules with suitable physicochemical properties, such as low molecular weight (generally below 500 Da) and optimal lipophilicity (log P between 1 and 3), are appropriate for transdermal delivery [16].
- Skin Irritation and Adhesion Issues: Prolonged application may cause local skin irritation, redness, rashes, or allergic reactions due to adhesives or other formulation components. Poor adhesion or excessive sweating may also cause the patch to detach prematurely, reducing therapeutic efficacy.
- Drug Type and Dose Limitations: Transdermal systems are mainly suitable for potent drugs that require low daily doses. They are not appropriate for drugs requiring high doses, rapid onset of action, or pulsatile drug release.
- Lag Time: There is usually a delay in the onset of therapeutic action because the drug must first penetrate the skin layers and reach systemic circulation, making it unsuitable for emergency or acute conditions [17].

10. FUTURE DIRECTIONS

- **Advanced Microneedle Technology**: Development of dissolvable, hollow, and hydrogel-forming microneedles that can safely bypass the stratum corneum and enable the delivery of larger molecules such as vaccines and proteins without damaging deeper tissues [18].
- **Smart and On-Demand Systems**: Design of intelligent patches integrated with sensors to monitor physiological biomarkers and automatically regulate drug release, such as glucose-responsive systems for diabetes management.
- **Active Enhancement Techniques**: Increasing use of methods like iontophoresis (electrical current), sonophoresis (ultrasound), and electroporation (electrical pulses) to enhance skin permeability, especially for hydrophilic and high molecular weight drugs [19].
- **Nanotechnology Integration**: Incorporation of advanced carriers such as lipid-polymer hybrid nanoparticles, liposomes, and ethosomes to improve drug stability, solubility, and skin penetration efficiency [20].

11. CONCLUSION

Transdermal Drug Delivery Systems (TDDS) represent a highly promising and innovative approach in modern pharmaceutical research. Review articles in this field serve as valuable resources for research scientists, as they provide comprehensive insights into formulation strategies, evaluation parameters, drug release mechanisms, and optimization techniques essential for the successful development of transdermal systems. Such reviews support researchers in understanding both theoretical concepts and practical considerations involved in TDDS design.

12. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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None

14. DECLARTION COMPETING INTEREST

The authors have no conflicts of interest to declare.

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