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Transdermal Drug Delivery Systems: Comprehensive Review of Skin Physiology, Patch Technologies, Evaluation, and Therapeutic Applications

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ABSTRACT:

Transdermal drug delivery systems (TDDS) have emerged as a promising, non-invasive alternative to conventional drug administration routes due to their ability to deliver therapeutics through the skin and into systemic circulation in a controlled manner. This approach avoids first-pass metabolism, minimizes gastrointestinal irritation, enhances bioavailability, and improves patient compliance, particularly in populations that struggle with oral or parenteral dosage forms. The structural complexity of human skin, especially the stratum corneum, presents a major barrier to drug permeation, making the design of efficient transdermal systems highly dependent on understanding skin anatomy, physiology, and barrier characteristics. Over the years, significant advancements have been made in the development of formulation strategies and penetration-enhancing techniques to improve drug flux across the skin. Various types of transdermal patches including single-layer, multi-layer drug-in-adhesive, reservoir, and matrix systems have been widely explored and optimized for different therapeutic needs. Complementary technological interventions such as microneedles, iontophoresis, ultrasound (sonophoresis), thermal enhancement, and laser microporation have further expanded the applicability of TDDS to deliver macromolecules, peptides, and hydrophilic drugs that traditionally showed poor permeability. In parallel, formulation innovations involving chemical enhancers, natural permeation agents, eutectic mixtures, Nano emulsions, liposomes, and solid lipid nanoparticles have significantly enhanced drug solubility and transdermal penetration. Evaluation parameters such as folding endurance, moisture content, tack, peel adhesion, and weight uniformity remain critical to ensuring patch quality, performance, and patient acceptability. TDDS have been successfully commercialized for various therapeutic indications including pain management, hormone replacement therapy, smoking cessation, cardiovascular diseases, and neurological disorders. This review highlights the fundamentals, technological advances, formulation approaches, evaluation methods, and current applications of TDDS, emphasizing their growing relevance in modern drug delivery. Continued research in material science, penetration enhancement, and nanotechnology will further broaden the scope of transdermal therapeutics and contribute to more effective, patient-friendly drug delivery solutions.

Key Words: Transdermal Drug Delivery System, Skin Barrier, Penetration Enhancers, Transdermal Patches, Nanocarriers, Controlled Release.

INTRODUCTION

The oral route is sometimes the best, most convenient, and ideal means of medication administration because of its several advantages. This approach of medication delivery, however, also has certain drawbacks including low absorption and bioavailability, gastrointestinal irritation, enzymatic breakdown in the gastrointestinal system, and so on. Some drugs are also dangerous when given orally. People getting injections parenterally, both children and adults, frequently have needle phobia; there is also a risk of infection when the medicine is given [1]. Through the layers of the skin, these patches are meant to be applied to the skin while releasing a therapeutic dose of one or more active components into the systemic circulation[2-3]. Transdermal drug delivery system (TDDS) has been a better interest in the drug administration by the skin for both local therapeutic effects and for systemic delivery of drugs[4]. Transdermal drug delivery offers many benefits over other traditional routes of administration including non-invasiveness, accessibility, avoidance of first-pass metabolism, compliance, ease of drug input termination in problematic cases and controllable drug delivery rates[5-6].There is widespread penetration. Combinations of enhancer excipients are favored in external formulations because they can improve the effect of the active ingredient by ensuring effective drug delivery through the skin[7]. The first transdermal System was FDA-approved in 1979 for preventing Nausea and vomiting. Confirmation of percutaneous drug Absorption can be established through measurable blood Levels, detect excretion of the drug and its metabolites In urine, observing the patient's clinical response to the Administered drug therapy[8].Although there are many other choices available, some of the most frequently used polymers in patches are cellulose derivatives (such as hydroxypropyl methylcellulose (HPMC)), polyvinyl pyrrolidone (PVP), PVA, polyacrylates, acrylate derivatives, and chitosan[9]. Transdermal drug delivery is a very successful way to give medications. The transdermal drug delivery system (TDDS) is a cutting-edge method in the

pharmaceutical industry for administering medications since it has numerous benefits over other methods of drug administration. In order to have therapeutic effects, conventional drug delivery system formulations need higher dosages and regimens, and prolonged regimens may result in significant adverse effects and, eventually, poor patient adherence[10].

ADVANTAGES OF TRANSDERMAL DRUG DELIVERY SYSTEM

- To prevent first-pass metabolism, transdermal delivery Ensures a sustained and continuous permeation of a Substance over an extended period[11].
- Reduce fluctuations of drug in plasma levels. Utilize drug candidates with short half-life and Low Therapeutic index [12].
- Transdermal drug delivery can be used as an alternative route of Administration to accommodate patients who cannot tolerate oral Dosage forms[13].
- The transdermal drug delivery system allows for the utilization of drug candidates with short half-life and low therapeutic index[14].

DISADVANTAGES TRANSDERMAL DRUG DELIVERY SYSTEM

- The patch's longer stay on the skin Surface leads to a higher risk of skin maceration and negative cutaneous reactions[15].
- Many drugs with a hydrophilic structure permeate the skin too slowly to be of therapeutic benefit[16].
- It is possible that the skin will get irritated, and the reaction will be hypersensitive[17].
- Ionic medicines cannot be delivered by a transdermal drug delivery method[18].

ANATOMY AND PHYSIOLOGY OF SKIN LAYER

The anatomy and physiology of the skin can be used to guide the creation of strong methods for drug delivery systems. In humans, the skin is the biggest organ. One-third of all the blood that passes through the human body is found in the skin, which has a total area of 20 square feet[19].

Human skin is made up of epidermis, dermis, subcutaneous tissue, sebum, and sweat glands. The stratified epithelium known as the epidermis is made up of layers of spinous and basal granular cells that combine to form the stratum corneum. The stratum corneum, which is between 15 and 20 layers thick and has a dense interlocking structure with proteins and lipids that look like bricks and mortar, is compacted with metabolically inert cells. Important lipids found in it include fatty acids, cholesterol, and ceramides, with ceramides making up about half of the lipids. Free fatty acids (10–15%) are saturated and have a very long chain. These lipids are essential to the Stratum corneum barrier's function[20].

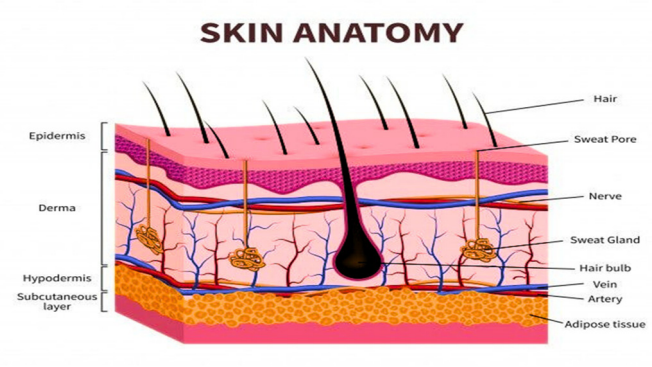

Fig 1: Skin Anatomy

Epidermis

The epidermis, the outermost layer of skin, acts as a vital tissue barrier. Keratinocytes, which proliferate in the suprabasal area with basal differentiation, make up the stratified epithelium. Although the thickness of the epidermis varies, it is often approximately 0.8 mm thick on the soles of the feet and the palms of the hands. The epidermis is made up of many layers of epithelial cells, and the viable epidermis is the name given to the lower layers. Most epidermal cells are keratinocytes [21].

Dermis

The dermis, which is in the middle of the skin [23]. The dermis is a complicated fibro-elastic structure that gives the skin its mechanical strength. A vast network of nerves and blood arteries may be found inside this stratum. Pain Possible harm to the nerve endings in the dermis during parenteral medication delivery may be experienced[22].

Hypodermis

The hypodermis, also known as subcutaneous adipose tissue, is essential for maintaining the integrity of the dermis and epidermis. It functions as a fat storage area, aids in temperature control, provides nutritional support, and offers physical protection. This layer may contain sensory pressure organs in addition to significant nerves and blood vessels that reach the skin. The medication must pass through all three layers [epidermis, dermis, and hypodermis] to enter the systemic circulation through transdermal drug delivery. In contrast, the main need for topical drug delivery is penetration through the stratum corneum, with the goal of keeping the drug in the skin layers[23].

Transdermal patches

Patches continue to be helpful for longer than tablets, reducing the need for frequent dosage, and several patients struggle with taking tablets or receiving injections. Patches are used in a variety of therapeutic fields, including hormone replacement therapy, smoking cessation, pain management, heart disease treatment, and motion sickness management[24].

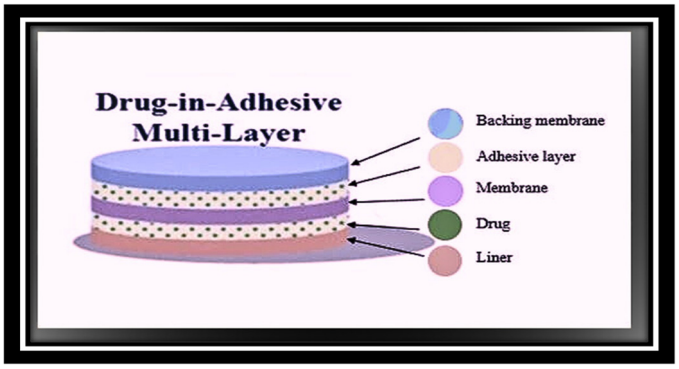

Fig 2: Drug-in-Adhesive Multi-Layer

TYPES OF TRANSDERMAL PATCHES

1. Single-layer Drug-in-Adhesive: The medication is included in the adhesive layer of this device. The adhesive layer in this kind of patch is not just responsible for holding the entire system to the skin and the different layers together, but it is also in charge of releasing the medication.

2. Multi-layer Drug-in-Adhesive: The multi-layer drug-in adhesive patch is comparable to the single-layer System in that the adhesive layers of both systems are also in charge of the medication release. The medication is released immediately from one layer, while the other layer regulates the drug release from the reservoir.

3. Reservoir: In contrast to the Multi-layer and Single-layer Drug-in-adhesive systems, the transdermal reservoir system has a separate layer for the drug. The Drug layer, which is a liquid compartment, is separated from a drug solution or suspension by the adhesive layer.

4. Matrix: The Matrix system consists of a semisolid matrix that contains either a drug solution or suspension. The adhesive layer of this patch partially envelops the drug layer, resting on top of it.

Evaluation of transdermal patches

Physical appearance[25]

Each of the formulated patches underwent visual inspection to assess factors such as color, clarity, opacity, transparency, Flexibility, and smoothness.

Folding endurance[26]

Folding endurance is assessed by repetitively folding a strip of the patch or film at a specific area until it either breaks or is folded up to 300 times. The number of times the patch can Be folded without breaking provides the folding endurance of the patch. This measurement indicates the flexibility of The patch.

Weight uniformity[27-28]

The patches are dried at 60◦C before weighing. To assess weight uniformity, 1 cm2 pieces are cut from three patches and weighed individually. The weight variation is calculated, ensuring that the individual weights do not significantly deviate from the average weight. The average weight of the three pieces is considered the weight of the patch.

Percentage Moisture content [29-30]

The prepared films are to be weighed individually and to be kept in a Desiccators containing fused calcium chloride at room temperature for 24 hrs. After 24 hrs the films are to be reweighed and determine the Percentage moisture content from the below mentioned formula.

$$\% \text{ Moisture content} = \frac{\text{Initial weight} - \text{Final weight x100}}{\text{Final weight}}$$

Rolling ball tack test[31]

This test measures the softness of a polymer that relates to talk. In This test, stainless steel ball of 7/16 inches in diameter is released on an inclined track so that it rolls down and meets Horizontal, upward facing adhesive. The distance the ball travels Along the adhesive provides the measurement of tack, which is Expressed in inch

Peel Adhesion test[32]

In this test, the force required to remove an adhesive coating from a Test substrate is referred to as peel adhesion. Molecular weight of Adhesive polymer, the type and number of additives are the Variables that determined the peel adhesion properties. A single Tape is applied to a stainless-steel plate or a backing membrane of Choice and then tape is pulled from the substrate at a 180º angle, And the force required for tape removed is measured.

APPLICATIONS OF TRANSDERMAL DRUG DELIVERY SYSTEM

- Nicotine transdermal patch marketed as Nico dermis to help in smoking cessation. It is the highest selling Patch in United State.
- Two opioid medications Fentanyl (marketed as Duragesic) and Buprenorphine (marketed as BuTrans) Used to provide round-the-clock relief for severe pain Available in patch form
- Nitroglycerin transdermal patches for the treatment of angina pectoris, prescribed in place of sublingual pills.
- Transdermal patch of the selegiline (MAO inhibitor) Became the first transdermal delivery agent for major Depressive disorder
- Estradiol patches available as Estraderm for treating menopausal symptoms as well as postmenopausal osteoporosis. It is also available in combination with levonorgestrel as Climara Pro for menopausal symptoms.

MECHANISM OF TRANSDERMAL DRUG DELIVERY SYSTEM

Fig 3: methods of transdermal drug delivery system

Fig 2: Mechanism of transdermal drug delivery system

1.Mechanism Method

Microneedle

Microneedles (MNs) create microchannels in the stratum corneum enabling painless delivery of peptides, proteins, vaccines, and hydrophilic drugs. Dissolving MNs release drug upon skin insertion, while coated MNs provide rapid onset[33].

Perforation

Mechanical perforation devices produce micro-holes that disrupt the skin barrier. This increases penetration of large molecular drugs[34].

Skin Stretching

Skin stretching transiently disrupts lipid packing in the stratum corneum, enhancing passive diffusion[35].

2.Physical Method

Ultrasound (Sonophoresis)

Low-frequency ultrasound induces cavitation, increases fluidity, and enhances drug diffusion across the skin[36].

Radiation

Lasers (CO_2, Er:YAG) remove the stratum corneum in controlled micrometer layers, improving permeability for macromolecules[37].

Thermophoresis

Heating the skin increases kinetic energy, improves vasodilation, and enhances drug flux[38].

3.Electrical Method

Iontophoresis

Low electrical current drives charged molecules into the skin, suitable for peptides, insulin, anti-inflammatory drugs[39].

Electrophoresis

Electric fields move ions across skin barriers, improving penetration of hydrophilic molecules [40].

Radiofrequency (RF)

RF uses alternating current to create microchannels by localized heating, enhancing drug permeation[41].

4.Drug/Vehicle Approach

Prodrug Approach

Chemical modification increases lipophilicity and permeability before conversion to active drug in systemic circulation[42].

Chemical Enhancers

Surfactants, alcohols, terpenes, and fatty acids disrupt lipid bilayers and enhance solute diffusion [43].

Natural Enhancers

Eucalyptus oil, menthol, clove oil, aloe vera improve permeability with lower irritation potential.[44].

Ion Pairing

Ion pairs increase permeability of ionic drugs by improving lipophilicity[45].

Eutectic Mixtures

Eutectic systems reduce melting point and enhance solubility (e.g., lidocaine–prilocaine)[46].

5.Formulation Approach

Patch

Patch systems allow sustained and controlled drug release (matrix, reservoir, adhesive dispersion)[47].

Gel

Gels hydrate skin and increase drug diffusion. They are suitable for topical NSAIDs, hormones, and anesthetics[48].

Ointment

Ointments form occlusive layers, increasing skin hydration and penetration[49].

Cream

Creams offer improved patient compliance and suitability for both hydrophilic and lipophilic drugs [50].

Nano emulsion

Nano-sized droplets improve solubility, enhance permeation, and increase stability [51].

6.**Lipid Carrier Systems**

Liposomes

Phospholipid vesicles that improve incorporation of hydrophilic/lipophilic drugs and enhance penetration[52].

Solid Lipid Nanoparticles (SLNs)

SLNs offer controlled release, occlusive effect, high stability, and increased drug penetration[53].

Nano emulsion

Nano emulsions enhance solubility, stability, and permeation of poorly soluble drug.

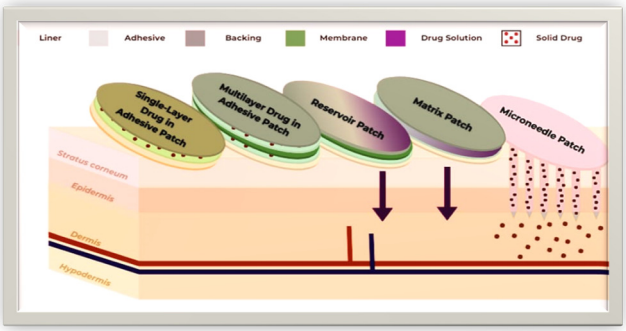

Fig 4 : transdermal patch types and skin penetration

CONCLUSION

Transdermal drug delivery systems represent a significant advancement in modern pharmaceutics by offering a non-invasive, controlled, and patient-friendly method of drug administration. The unique ability of TDDS to bypass first-pass metabolism, maintain steady plasma concentrations, and improve therapeutic outcomes makes them highly advantageous compared to traditional oral and parenteral routes. Despite the natural barrier posed by the stratum corneum, continuous progress in formulation technologies—such as chemical enhancers, lipid-based carriers, nano emulsions, and advanced physical enhancement methods like microneedles, iontophoresis, and sonophoresis—has expanded the range of drugs that can be successfully delivered through the skin. Furthermore, innovations in patch design, including matrix, reservoir, and drug-in-adhesive systems, have enabled improved drug loading, enhanced adhesion, and better patient compliance.

Transdermal patches have already demonstrated clinical success in areas such as pain management, hormonal therapy, cardiovascular disorders, and smoking cessation. As research in material science, nanotechnology, and transdermal enhancement strategies continues to grow, TDDS are expected to support the delivery of more complex molecules such as peptides, proteins, and vaccines. Overall, transdermal systems hold great promise for future drug delivery, offering safer, more effective, and more convenient therapeutic options for diverse patient populations.

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