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TRANSDERMAL DRUG DELIVERY SYSTEM: IT'S PROS AND CONS

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ABSTRACT

The skin presents a readily accessible surface for drug delivery, covering approximately 2 square meters on the average adult body and receiving approximately one-third of the body's circulating blood. On each square centimeter of skin, there are typically 10-70 hair follicles and 200-250 sweat ducts. One method of drug delivery through the skin is the transdermal patch, which provides a controlled release of medication through either a porous membrane or melting thin layers of medication in the adhesive. Transdermal drug delivery offers an advantage over other types of medication delivery as it can deliver drugs into the systemic circulation through the skin at a predetermined rate, with minimal intra and inter-patient variations, promoting healing to an injured area of the body

Keywords: TDDS, Transdermal patches, new medicine delivery system, penetration enhancers

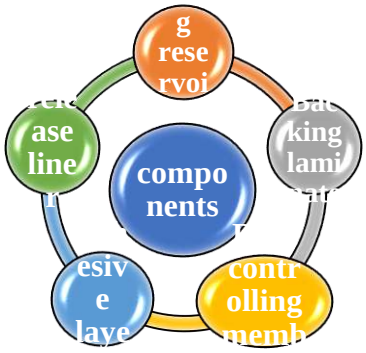
INTRODUCTION

The Transdermal Drug Delivery System (TDDS) is a self-contained, discrete dosage form commonly referred to as "patches." When applied to intact skin, these patches can deliver drugs at a controlled rate to the systemic circulation. The main objective of TDDS is to deliver drugs into the systemic circulation via the skin at a predetermined rate with minimal inter and intra-patient variation. The use of human skin as a port of entry for drug molecules is the basis of transdermal drug delivery, which is currently one of the most promising methods for drug application.[1,2,3] The first transdermal system for systemic delivery was approved for use in the United States in 1979 and was a three-day patch that delivered scopolamine to treat motion sickness. Transdermal drug delivery has gained widespread recognition since the success of nicotine patches as the first transdermal blockbuster nearly a decade ago. This has led to an increase in the availability of transdermal delivery systems for various drugs, including but not limited to estradiol, fentanyl, lidocaine, and testosterone. Combination patches that contain multiple drugs are also available for hormone replacement and contraception. Currently, there are 19 transdermal delivery systems on the market, providing patients with a convenient and effective alternative to oral or injectable medications[4,5] Iontophoretic and ultrasonic delivery systems are also used for analgesia. The transdermal delivery system approval rate has more than tripled in the past 5 years, and it is estimated that more than one billion transdermal patches are manufactured yearly. Most transdermal patches are designed to release the active ingredient at a zero-order rate for a period of several hours to days following application to the skin, making them particularly advantageous for prophylactic therapy in chronic conditions. The evidence of drug absorption through the skin can be determined by measuring blood levels of the drug, detecting excretion of the drug and its metabolites in the urine, and observing the clinical response of the patient to the administered drug therapy.

COMPONENTS OF TRANSDERMAL DELIVERY SYSTEM

The basic components of any transdermal delivery system include the drug dissolved or dispersed in an inert polymer matrix that provides support for drug release. Various components of the transdermal patch are the following:

1. Drug reservoir
2. Backing laminate
3.Rate-controlling membrane
4.Adhesive layer
5.Release liner



TECHNOLOGIES FOR DEVELOPING TRANSDERMAL DRUG DELIVERY SYSTEM:

The technologies for transdermal drug delivery systems (TDDS) can be categorized into four different approaches, These approaches are:[6]

1. Polymer membrane partition-controlled TDDS
2. Polymer matrix diffusion-controlled TDDS
3. Drug reservoir gradient-controlled TDDS
4. Micro reservoir dissolution-controlled TDDS

TRANSDERMAL PATCHES:

Both topical and transdermal products are available for external use, but they serve different purposes. Topical dermatological products are designed for local action, while transdermal drug delivery systems are intended for systemic drug delivery. The transdermal route of drug delivery has become increasingly popular as it enables the delivery of a variety of drugs for the treatment of various diseases. Transdermal patches are currently used to treat pain, assist in smoking cessation, treat heart disease, provide hormone replacement therapy, and manage motion sickness.[7]

EVALUATION OF TRANSDERMAL PATCH:

To evaluate a transdermal patch, there are three main parameters that can be considered:

1.Physiochemical parameters
2.In-vitro evaluation
3.In-vivo evaluation.

Physiochemical parameters-

Transdermal patches can be physio-chemically evaluated by these parameters which are given below:

1. Thickness measurement
2. Uniformity of weight assessment
3. Drug content determination
4. Content uniformity test
5. Moisture content measurement
6. Folding endurance testing
7. Tensile strength measurement
8. Tack testing
9. Thumb tack testing
10. Rolling ball testing

In-vitro evaluation- Transdermal patches can be evaluated in vitro using the Franz diffusion cell, which consists of two compartments:[9]

- Donor compartment
- Receptor compartment.

In-vivo evaluation- Transdermal patches can be accurately evaluated through in vivo studies, which provide a true representation of drug performance. These studies allow for the exploration of variables that cannot be accounted for during in vitro testing. In vivo evaluations can be conducted on animal models or human volunteers.[8]

- **Animal models-**Animal models, such as mice, hairless rats, hairless rhesus monkeys, rabbits, and guinea pigs, are preferred for small-scale evaluations due to the time and resources required for human testing. Rhesus monkeys are considered as a reliable model for in-vivo evaluation in humans.[8]
- **Human model-** Human testing is the final step in the development of transdermal patches, involving the collection of pharmacokinetic and pharmacodynamic data. Clinical trials are conducted to assess efficacy, risk, side effects, and patient compliance. Phase I trials determine volunteer safety, phase II trials determine short-term safety and effectiveness in patients, phase III trials evaluate safety and effectiveness in a large patient population, and phase IV trials involve post-marketing surveillance. Human testing requires significant resources to ensure the best performance of the drug.[8]

Conclusion:

To successfully develop a transdermal drug delivery system, several factors need to be considered. Firstly, it is important to have a comprehensive understanding of the skin's basic functions, which includes its ability to protect against foreign substances. Despite this challenge, advancements in our knowledge of the skin's structure and function have made it

possible to modify its barrier properties, leading to the development and launch of new transdermal drug delivery products in the market. The transdermal drug delivery system has the potential to become one of the most innovative drug delivery systems in the future.

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