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Transdermal Drug Delivery System: A Review of Current Advances and Challenges

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ABSTRACT

Recently, various non-invasive administrations have emerged as alternatives to traditional needle injections. A Transdermal drug delivery system (TDDS) is the most attractive of these due to its low Rejection rate, excellent ease of administration, and superb convenience and persistence among patients. TDDS Could be applicable not only in pharmaceuticals but also in the skin care industry, which includes cosmetics. Since this This method mainly involves local administration. The skin infusion enhancer technique has been advanced to improve the bioavailability of the drugs. So various Transdermal dosage forms have been prepared like: Transdermal patches, Gel, Cream, Ointments, etc. The Transdermal route is a viable option to enhance the variety of drugs. Transdermal drug delivery has become the primary route of delivery for a variety of medications that would otherwise be difficult to supply. There are some Advantages to Transdermal medicine administration. Mainly to avoid first-pass metabolism and a stomach Environment that would make the drug ineffective in drugs prescribed for skin-related problems and for systemic Effects in curing other organs' diseases. Hormone replacement therapy, pain relief, smoking withdrawal, Neurological disorders and angina pectoris such as Parkinson's disease are all under the categories of Transdermal products and Applications. Formulated to release the drug into systemic circulation at the optimal rate, it must be retained in Skin for the required period without inducing sensitization or irritation of the skin. Avoiding first-pass metabolism to achieve Bioavailability with minimal peaks and troughs, Tolerance and dose are being achieved. In the case of Continuous Delivery, maintaining high compliance of the patients is required.

Key words: *Transdermal drug delivery system, physical and chemical method, challenges*

INTRODUCTION

There are several advantages related to transdermal drug delivery. For example, using this route of administration can avoid bypassing pain and presystemic metabolism. In addition, the pharmacokinetic profile of the drug is more uniform with fewer peaks and troughs. However, the stratum corneum. Which is the outermost layer of the skin constituting a powerful barrier, and permeants have difficulty penetrating the skin at clinically relevant rates.

This review addresses progress made over the last 4 decades and challenges ahead. Over this period, regulatory authorities have approved about 35 transdermal products. Almost 19 drugs have been formulated as transdermal patches and are approved by the FDA.

The main challenge lies with the formulation of macromolecules- proteins, small interfering RNA and other products of biotechnology into transdermal delivery systems.

This challenge is being met by approaches that include microneedles, iontophoresis, sonophoresis, and electroporation. Transdermal drug delivery systems is also known as patches are dosage Forms designed to deliver a therapeutically effective amount of drug across a Patient skin.

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In order to deliver therapeutic agents through the human skin for systemic Effect the compressive, morphological, biophysical and physiological Properties of the are to be considered. Transdermal delivery provides Edge over injectables and oral routes by increasing patients' compliance and avoiding first pass metabolism respectively.

Transdermal delivery not only provide controlled, constant administration of the drug but also allows continuous input of drugs with short biological half Life and eliminate pulse entry into systemic circulation.

Earlier we use convectional dosage form but now we use novel drug delivery Systems one of greatest innovation of drug delivery is transdermal patches.

The review enhancement technique based on optimization such as drug Selection prodrug and ion pair, supersaturated drug solution, eutectic Systems, complexion, liposmes vesicles and particles. The goal of creating a Transdermal drug delivery systems was to boost the drug bioavailability and Enable a regulated release of the medication into the bloodstream through the skin. The transdermal drug delivery method involves the incorporation of the drug. To deliver into polymeric membranes which then diffuse the drug to the skin at A controlled and planned rate.

AIM

To develop efficient, targeted and patient friendly drug delivery system That optimize therapeutic outcomes.

OBJECTIVE

1. Enhance bioavailability and efficacy.
2. Reduce systemic side effect.
3. Improve patient compliance and adherence.
4. Develop targets and controlled release system.
5. Overcome skin barrier limitation.

LITERATURE REVIEW

Short for TDDS, transdermal drug delivery systems have come forth to be an alternative drug administration route by directly delivering drugs across the skin into systemic circulation. Unlike oral or intravenous routes that are conventional this is providing a controlled release of medication thus avoiding peaks and troughs of drug levels, but most importantly guaranteeing patients' compliance. However, there is so much to discuss on what the challenges and limitations might be. This review comments on the latest developments in TDDS and the challenges that need to be faced to make it more widely available and clinically successful.

A brief structure of Skin

The skin is the largest organ of the human body, which covers a surface area of nearly 2 sq.m, and receives about one third of the blood circulation around the body. It acts as a permeability barrier against the transdermal absorption of various chemical and biological agents.

Skin can be divided into 3 main layers:

- Epidermis
- Dermis
- Hypodermis

1. **Epidermis:** The multilayered epidermis is of varying thickness. Depending on cell size and number of cell layers of Epidermis, as thin as 0.08 mm on palms of hands and soles of feet, down to This is 0.06 mm on the eyelids. Table 1 gives thickness and water Permeability and diffusivity of water through the epidermis. The living or viable cells of the Malpighian layer (viable epidermis) and the dead Cells of the stratum corneum commonly referred to as the horny layer Viable epidermal.

Stratum corneum

It is the outer -most layer of skin also known as the horny layer. It is the rate limiting barrier that Restricts the inward and outward movement of Chemical substances. The barrier nature of the Thorny layer depends fundamentally on its constituents: 75-80% proteins, 5-15% lipids, and 5-10% Nondansetron material on a dry weight basis.

2. **Dermis:** Dermis is the layer of skin just beneath the Epidermis which is 3 to 5 mm thick layer and is Composed of a matrix of connective tissues, which

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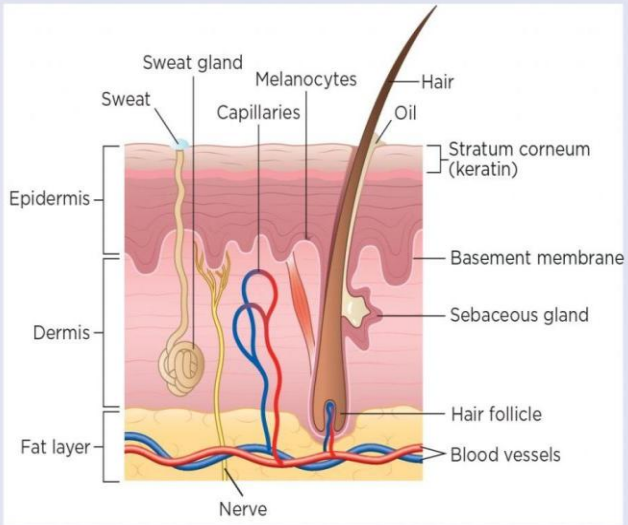
Contains blood vessels, lymph vessels, and nerves. The cutaneous blood supply has essential function in regulation of body temperature.

Fig 1. **Cross-section through the skin**



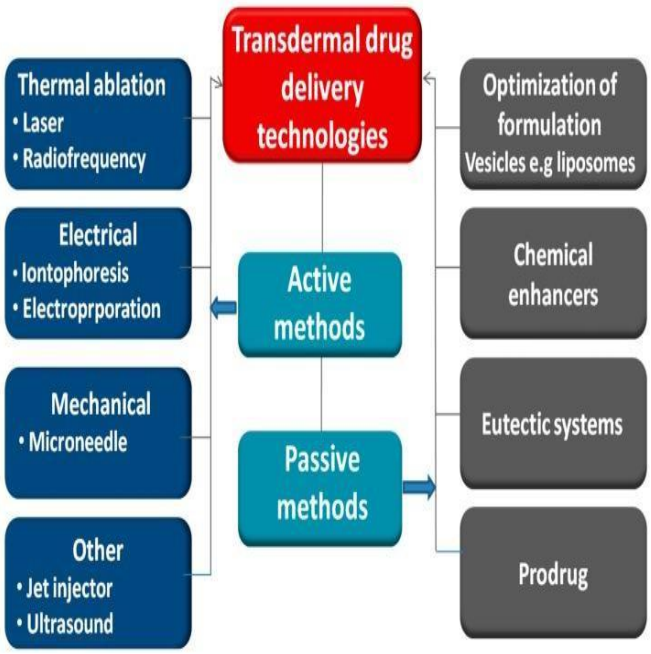
Hypodermis:

The hypodermis or the subcutaneous fat tissue supports Dermis and epidermis. It is also a fat storage area. This layer of skin assists in regulating heat, providing nutritional Support, and mechanical protection. It carries the principal Blood vessels and nerves to skin and may contain sensory Pressure organs. For transdermal drug delivery, drug has to Penetrate through all three layers and reach in systemic Circulation.

Recent Advances in Transdermal Drug Delivery Systems:

It is reported that external stimulation such as electrical, or physical stimulations increases the drug and biomolecule permeability through the skin, compared topical application on the skin for the delivery of drugs. Technologies utilized for modifying the barrier functions of stratum corneum can be broadly categorized into Passive/chemical or active/physical methods. Passive methods include the influencing Physical interactions between drugs and vehicles during formulation optimization, with the objective of modifying the stratum corneum structure.

Active or physical method: Active methods for skin permeabilization include, ultrasound, electrically assisted methods (electroporation and iontophoresis), velocity-based devices (powder injection, jet injectors), thermal approaches (lasers and radio-frequency heating) and mechanical methodologies such as microneedles (MN) and tape stripping. These approaches allow a broader class of drugs to be delivered into the skin. Active techniques utilize external energy to provide a driving force for drug transport across the skin or by the disruption of the stratum corneum by mechanical means. The techniques significantly increase the numbers of drugs that can be delivered successfully across the skin.



Electrical method:

a) Iontophoresis

Iontophoresis has been shown to improve the penetration in the skin and to enhance the rate of release of various drugs with Poor absorption /permeation profiles, as the ions move across the membrane under the A small externally applied potential difference. This method has been applied to the in vivo It involves the transport of ionic or non-ionic drugs by employing an electrochemical potential gradient. This technique enhances the distribution of neutral or charged particles at the skin surface, and high transdermal delivery. The Current used is restricted, short-planned, and limited milliampere current (0.1–1.0 mA/cm2) is applied to the

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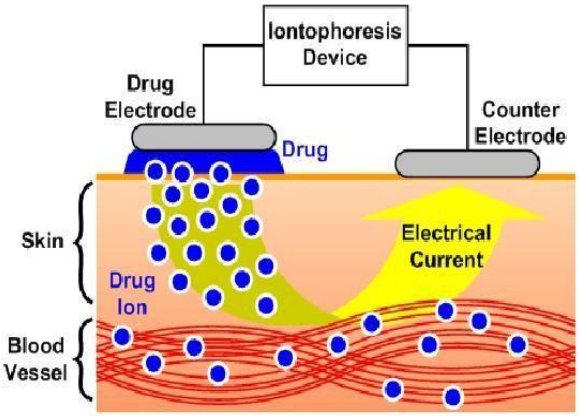


Figure 1. Conceptual diagram of iontophoresis treatment.

b) Electroporation

This method uses the application of high voltage electrical Pulses, in the range from 5 to 500 V during short exposure Times (about ms) to the skin, creating pores of small Size in the SC that enhance permeability and facilitate The diffusion of drugs . To ensure safe and painless Drug administration, electric pulses are introduced to the body through Closely placed electrodes. It is a very safe painless Procedure, involving skin permeabilization and has Has been used in a number of works to demonstrate the successful delivery of no only the low MW drugs, like doxorubicin, mannitol, or Calcein, but also high MW ones such as antiangiogenic Peptides, oligonucleotides, and the negatively charged Anticoagulant heparin.

Drugs which can be administered by this method:

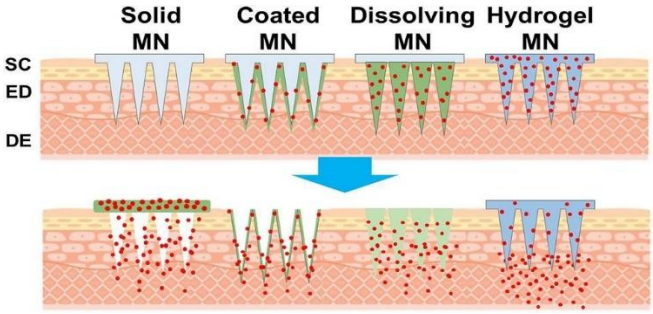
1. Insulin, Growth Hormone: Hormones
2. Bleomycin, Cisplatin: Antineoplastic Agent
3. Diclofenac: NSAIDS
4. Gentamycin, Acyclovir: Antiviral

Mechanical Method

a) Microneedle:

One of the reasons why drug delivery systems through microneedles have been much in focus is their potential of avoiding the first-pass metabolism within the gastrointestinal tract and liver as well as avoiding the invasive and painful approach provided by the intravenous route of drug delivery. Furthermore, microneedles offer a higher bioavailability of drugs as compared to creams and transdermal patches as they pierce the SC and deliver the These active ingredients are delivered, then, directly to the viable epidermis. Microneedles are microscopic arrays of needles, with a height of 10-1000 µm, long enough to puncture the outer most layer of skin, stratum corneum, but too short to reach receptors of pain in the dermis, making it nearly painless.

1. **Solid Microneedles:** These are typically employed for forming microchannels in the skin through which drugs are delivered across the skin via patches or topical drug formulations.
2. **Dissolving Microneedles:** Made from biodegradable materials, these microneedles dissolve once inside the skin and release the drug payload. They find great utility in reducing the risk of sharps disposal and have been explored for vaccine, insulin, and other biologic deliveries.
3. **Hydrogel-forming microneedles:** These do not dissolve but swell upon insertion and allow drug release in a time-dependent manner from the hydrogel matrix. Such an approach can be well-suited for sustained drug delivery, but often it requires longer wear times.
4. **3D printed Microneedles:** Advances in 3D printing have made possible the construction of extremely large and well-characterized geometries of microneedles that can be designed or customized to formulate particular drug formulations. For mass production, 3D printing enables rapid and inexpensive manufacturing of Microneeedle arrays.



Drugs which can be administered by this method

1. Influnza, HIV: Vaccine
2. prilocaine, lidocaine: Local anesthetic

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3. hydrocortisone, Triamcinolone: Steroids
4. growth hormone, Antibodies: Proteins
5. fentyl, morphine: Analgesics

Thermal Ablation:

Drugs used in this method:

1. Monoclonal Antibodies
2. NSAIDS: Ibuprofen, Ketoprofen
3. Dermatan Sulfate

Laser Technique: Clinical therapies for the treatment of dermatological conditions such as pigmented lesions have employed laser methodologies. The primary mechanism of laser thermal ablation of the skin is through the selective removal of the stratum corneum without damaging deeper tissues, hence improving delivery of lipophilic and hydrophilic drugs into skin layers

Lasers ablate the Stratum corneum by deposition of optical energy, which causes evaporation of water and formation of Microchannel in the skin. Additionally, such methods have been utilized to extract interstitial fluid for subsequent measurement of glucose levels in diabetic patient. However, the level of Barrier disruption achieved is controlled by wavelength, pulse length, tissue thickness, pulse energy, tissue It involves laser absorption coefficient, number of pulses, laser exposure time, rate of pulse repetition.

Drugs which can be administered by these routes:

1. Nicotine: Smoking sensation
2. 5, fluorouracil, methotrexate: Antineoplastic agent
3. testosterone, Estradiol: Hormone Replacement therapy
4. Gentamicin, Ciprofloxacin: Antibodies

Other Method:

Ultrasound: Ultrasound techniques were investigated Since the 1950s, when hydrocortisone was first used to treat Digital polyarthritis. Ultrasonic waves are pressure waves with a frequency of 20 kilohertz, which means above the limit In the human hearing range.

Jet injector: Jet The first known use of these injectable drugs was when they were used over 50 years ago for parenteral delivery of vaccines, as well as small Molecules, including anesthetics and antibiotics. A jet injector is a needle-free device capable of Delivering electronically controlled doses of medication results in delivering improved consistency. And hence suffering for the patient

Passive or Chemical method:

For better transdermal delivery and - Therefore, drug MW should be low (less than 1 kDa or approximately 1000 g/mol). Mw, an affinity toward lipophilic and hydrophilic phases, Short half- life, and has no skin irritability. Recent studies that have focused on aspects of trans-dermal drug delivery technologies, from the development of chemical enhancers that enhanced the spread of drugs across the skin or increased the solubility of drugs in the skin to novel innovative approaches that extend this concept to design super-strong formulations, microemulsions, and vesicles.

Vesicles are colloidal particles filled with water and consist of amphiphilic molecules in bilayer arrangement. Vesicles can carry water soluble and fat-soluble drugs to achieve transdermal absorption. when we utilizes for transdermal absorption. Vesicles can be divided into several types such as liposmes, vtransferosomes, ethosomes depending on the properties of the constituent substances. The conventional delivery systems containing the prolonged release dosage forms cannot meet any of these. The new drug delivery system maintains drug action at a pre ordinaterate, relatively constant (zero order kinetics), efficient drug level in the body, and simultaneously reduces the undesirable side effects. It may also localize the drug action in the diseased tissue or organ by targeted drug delivery through carriers or chemical derivatization. Various categories of pharmaceutical carriers include polymeric micelles, particulate systems, and macro and macromolecules are introduced as new drug delivery system in the form of targeted drug delivery. Particulate type carrier, colloidal carrier system includes lipid particles, micro- and nanoparticles, micro- and nanospheres, polymeric micelles, and vesicular systems.

It includes the following vesicular system:

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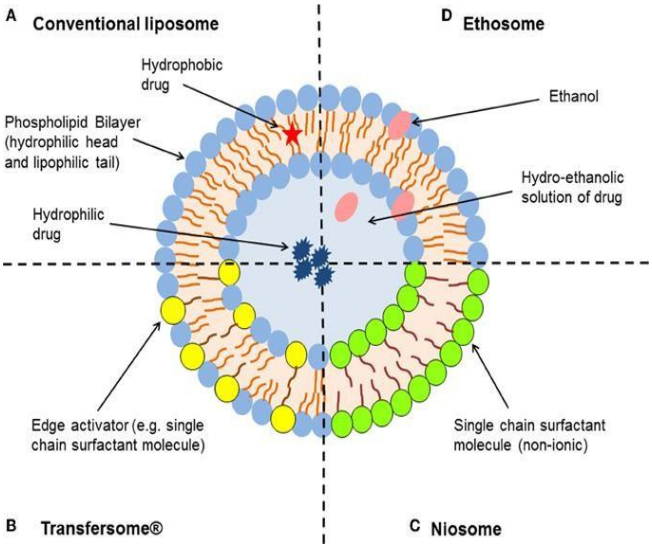
1. Liposome
2. Ethosome
3. Niosome
4. Transferosome



Liposomes have been applied for transdermal drug delivery to treat a variety of disease such as tumours, rheumatoid arthritis.

a. Ethosomes:

Ethosomes are organized as a bilayer spherical core containing phosphatidylcholine, cholesterol, ethanol, and water. As compared to conventional liposomes, the use of alcohol in ethosomes renders them more flexible, and alcohol acts as a CPE which depletes SC lipids, reduces the structure of the SC lipid layer and enhances drug distribution. At the same time, ethanol provides a negative charge on the outside of the structure of a vesicle to prevent adhesion of the vesicles by static electricity ..

b. Transferosomes

Transferosomes consist of phospholipids, surfactants, ethanol, and water and represent a very elastic-deformable aqueous core with lipid bilayer including an edge activator covering. Surfactant serves as an edge activator, showing high value of curvature radius and increases deformability of a membrane through the destabilizing effect on lipid bilayers thus making liposome vesicles more elastic and shows good deformability.

c. Nisosomes

Niosomes are single or multilayer orbicular structures, cholesterol and nonionic surfactants. They can interact with the lipophilic layer to enhance the fluidity of skin membranes. Noisome induce alterations in SC characteristics: SC hydration increased its cell structure that closely packed loosens while through a reduction in the water loss from the epidermis.

1. **Prodrug:** prodrug could improve transdermal delivery of drugs which have unfavorable partition coefficient. Prodrug to increase transdermal permeation income operate functional group in the porosity that will increase not only lipid but also aq. solubility The permeability of 5-fluorouracil significantly increased forming a prodrug. A porosity is added to increase the transport of drug across the stratum Corneum.
2. **Nanoemulsion:** Nanoemulsions are a mixture characterized by low viscosity and isotropic, thermodynamic, and dynamic stability. It comprises transparent or trans-lucent oil globules dispersed in an aqueous phase stabilized by an interfacial membrane formed by surfactant or co-surfactant molecules of extremely small drop-let size. The particle size of commonly used Nano-emulsions ranges from 100 to 1000 nm, although an upper limit to the particle size has been proposed on with its nanoscale dimensions.
3. **Salt Formation:** The molecule could be converted to the right Form of salt for enhancement of physico chemical Properties. Salts of piroxicam with mono-, di- and tri- Ethanolamine were prepared and permeation of the Salts through hairless mouse skin has been compared with Parent compound.

4. Other Innovations:

a) Transdermal Patches Dispenser:

Recently, 3M core n.pop-up dispensing technology is utilized for the manufacture of compact transdermal patch dispensers. The patented dispenser dispenses patches in a method in which makes patches extremely convenient to apply. The look and feel, dimensions,

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design, and number of patches contained in the dispenser can be customized to the patient's requirements.

b) Magnetophoresis with Chemical enhancers:

Recently, magnetophoretic is combined with chemical enhancers which enhanced the permeation of drug across the skin., investigated the effect of combination of a novel physical permeation enhancement technique, magnetophoretic with chemical permeation enhancers on the transdermal delivery of lidocaine hydrochloride and found that the flux of lidocaine from magnetophoretic patch was ~3-fold higher than that of the control (non-Magnetophoretic patch). Addition of chemical permeation enhancers to the gel increased the magnetophoretic delivery flux by ~4 to 7- fold and concluded that the enhancement factor due to combination of chemical permeation enhancer was additive

Challenges in transdermal drug delivery systems:

1. **Skin Barrier:** The main limitation is the natural barrier provided by the skin, especially stratum corneum that restricts the diffusion of majority of drugs. Only small, lipophilic molecules easily permeate the skin layer
2. **Properties of Drugs:** The drugs have to possess certain properties-low molecular weight, adequate lipophilicity, and potency-to be released trans dermally. Hydrophilic or large drugs are least able to penetrate the skin.
3. **Low Drug Dosages:** TDDS is not ideal for drugs that need high doses because only a certain amount of the drug can be absorbed through the skin at any given time.
4. **Variable Skin Permeability:** The permeability of the skin can be variable for all individuals, varying between different parts of the body, or due to a factor of age, race, or existing health conditions. As a result, it leads to inconsistent drug absorption.
5. **Adhesion Issues:** The patches or systems used in the TDDS should have good adhesion to the skin over an extended period. Sweat, friction, and irritation of the skin can impede patch adhesion and consequently drug delivery efficiency.
6. Irritation and Sensitization Local irritation, allergic responses, or sensitization might occur from prolonged skin contact; this is primarily due to the adhesive components or the drug.
7. **Slow Onset of Action:** Though TDDS may deliver a steady release, the onset of action is often slower than the oral or parenteral route, thereby not being ideal for drugs that have an immediate need for therapeutic effect.
8. **Drug Stability:** The drug must remain chemically stable during storage and during the delivery period; however, if the patch is exposed to environmental factors such as heat or moisture, then it becomes difficult.
9. **Complexities of production:** With TDS, specialized technology will be involved to ensure that the drug is released at a constant rate. It could be very technologically demanding and pricey.
10. **Very narrow spectrum of drugs:** TDDS can only be applied to highly potent drugs which can deliver the same effect at a small dosage.

Future prospects

The development of transdermal delivery systems Involves balancing increased transdermal transport with patient safety/comfort and cost. Because intact Skin is not sufficiently permeable to the large majority of drugs, enhancement methods are needed. Despite Extensive research during the past few decades, chemical Enhancers have achieved only limited success in Increasing transdermal transport of small molecules and have only a relatively poor ability to increase Macromolecular transport under conditions likely to Be clinically acceptable. Methods involving ultrasound and electric fields, including iontophoresis and electro-poration, have more extensively increased transdermal Delivery for small drugs and macromolecules. The Ability of these technologies to deliver drugs effectively Is partially counterbalanced by their reliance on electronically controlled devices that require an energy Source, which constrains applications and cost.

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Methods that pierce micron-scale holes in skin, such As microneedles, thermal poration and jet injection, can dramatically increase transdermal delivery of small drugs, macromolecules and even particles, but more work is needed to establish safety/skin damage And cost effectiveness. Each of these technologies is likely to suit the needs of different applications and, in some cases, combinations of enhancers might be the given the progress being made on novel enhancement methods, it seems that transdermal drug delivery Has only scratched the surface of possible clinical impact. The defining feature of transdermal Delivery that motivates the development of enhancement methods is that the drug reservoir remains outside. By contrast, it is difficult to alter drug-release kinetics After administration by other routes, such as the gastro-Intestinal tract, the lungs or inside the body. An external Transdermal device also has fewer cost and materials. Limitations compared with some other approaches. Degradation and excretion of device materials are not relevant, and costly electronics or other features can be designed into a re-usable transdermal system. For These reasons, transdermal delivery arguably offers the greatest facility for controlled release of drugs.

Regulatory consideration

Transdermal drug delivery systems are a new promising technology in delivering drugs transdermally from the skin, which has advantages such as avoidance of the gastrointestinal tract and direct, steady release of drugs. However, the systems pose considerable regulatory problems, mainly due to formulation difficulties, variability of skin permeability, and safety concerns. Several of the key considerations in regulation of TDDS are discussed below, taking into account the latest advances and challenges:

1. **Product Formulation and Design Drug Properties:** The FDA and EMA analyse the drug molecule for suitability for delivery across the skin. Molecular size, lipophilicity and, consequently, skin permeability are important factors.
2. **Excipients:** Excipients must be safe and non-irritating. Some examples include enhancers which enhance skin permeability. They should also be stable and tested for efficacy at the site of application as well as systemically.
3. **Patch Design safety:** designed to minimize irritation, sensitization, or failure of adhesion at the time of application or during service, adhesive properties, size, and wearability.
4. **Post-Market Surveillance Adverse Event Reporting:** Because late reactions, such as sensitization or systemic toxicity, may occur for some products such as those composed of systemically reactive chemicals or because of localized bioactivity, long-term monitoring for safety is necessary.
5. **Patch Removal Residue:** The risk from residual drug remaining in the skin at patch removal or an insufficient release may be present and necessitate monitoring during a clinical trial.
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Discussion

Advanced techniques for the efficient penetration of drug formulations through a transdermal patch via the skin were discussed. This research is valuable and will have a significant impact on novel drug delivery systems in future applications.

Transdermal drug delivery systems (TDDS) transfer drugs from the surface of the skin into the bloodstream. They offer several advantages compared to traditional oral or injectable delivery methods: improved patient compliance, avoidance of first-pass metabolism, and extended-release drug delivery.

Transdermal drug delivery is the administration of drugs through systemic delivery by applying a drug formulation to intact and healthy skin. The drug penetrates the stratum corneum and then moves further into the deeper epidermis and dermis without significantly concentrating in the dermis.

Conclusion

There are various techniques, including chemical, electric fields, and ultrasound used to increase transdermal drug transport. These technologies have made transdermal delivery a practical route of systemically delivering drugs. Scientific interest in this field has gained a lot of attention over the past two decades. Numerous studies have been conducted to safely break the barrier function of the skin to facilitate administration of a therapeutic amount of the drug. However, the applicability of such studies is limited because they have used solution or suspension formulations. There is a need for the design of transdermal systems based on functional and practicable properties of the system. However, the probable best transdermal drug delivery systems would be the one that integrates electronic or mechanical device-induced skin penetration techniques with advanced formulations including chemical penetration enhancers or nano-drug delivery systems. Future research Should be able to ensure improved delivery through better understanding of physicochemical properties of Drug, physiology of skin, mechanism of action of Enhancers, and the interaction between formulation Components. In addition, through improvised design of Devices, a greater range of molecules could be covered In transdermal delivery system.

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