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FORMULATION AND EVALUATION OF TRANSDERMAL PATCHES

Prof. Gajanan. D. Mogal, Miss. Pallavi. B. Bawachkar, Mr. Mayur. S. Bhombe

INTRODUCTION

TDDS is a painless method of delivering drugs systemically by applying a drug formulation onto intact and healthy skin.

The drug initially penetrates through the stratum corneum and then passes through the deeper epidermis and dermis without drug accumulation in the dermal layer.

A transdermal drug delivery system refers to a method of administering therapeutic drugs through the skin into the blood stream, for systemic effects.
It involves the use of patches or devices that contain drug substances and facilitate their absorption.

Compared to oral or systemic dosage systems, TDDS can offer a controlled release of the drugs through the skin into the patients, which could reduce the first-pass metabolism effects, lessen systemic side effects.

Improve the dosage efficacy by enabling steadier blood drug profiles throughout the treatment, and enhance patient compliance. Transdermal drug delivery systems (TDDS) also known as "patches" are dosage forms designed to deliver a therapeutically effective amount of drug across a patient's skin.

In order to deliver therapeutic agents through the human skin for systemic effects, the comprehensive morphological, biophysical and physicochemical properties of the skin are to be considered.

Transdermal deliveryprovides a leading edge over injectables and oral routes by increasing patient compliance and avoiding first pass metabolism respectively.

Transdermal delivery not only provides controlled, constant administration of the drug, but also allows continuous input of drugs with short biological half-lives and eliminates pulsed entry into systemic circulation, which often causes undesirable side effects.

Thus various forms of Noveldrug delivery system such as Transdermal drug delivery systems, Controlled release systems, Trans-mucosal delivery systems etc.emerged.Several important advantages of transdermal drug delivery are limitation of hepatic first pass metabolism, enhancement oftherapeutic efficiency and maintenance of steadyplasma level of the drug.

The first Transdermal system, Transderm-SCOP was approved by FDA in 1979 for the prevention of nausea and vomiting associated with travel etc.
These negative reactions were observed in a focus group of young women that doubted on its effectiveness and feared that it may fall off and stay visible for others. Safety concerns were also noted.

The patch is less used than other contraceptive methods.Regulatory warnings on risks of venous thromboembolism being higher than with other contraceptive methods may contribute to this lower preference among clinicians and women.

Transdermal patches are deliberately designed to deliver predictable and pharmaceutically significant doses of selected drugs.
In the context of this chapter they are primarily of interest in that they illustrate some properties of compounds that are conducive to dermal absorption.

Only a limited subset of pharmaceuticals can be practicably delivered via transdermal patches. The first consideration is whether the drug is sufficiently potent that a relatively small dose can be efficacious.

In addition, transdermal delivery is only feasible if the compound is lipophilic enough to dissolve in the stratum corneum, but not so lipophilic as to be unable to penetrate the viable epidermis. In an adhesive diffusion control system, the molecules disperse into the adhesive polymer, followed by spreading into the reservoir layer.

The matrix dispersion system is another method of dispersing drugs homogeneously in a predefined surface area. In a micro reservoir system, the drug is dissolved in an aqueous solution of the hydrophilic polymer.

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The evidence of drug absorption may be found through measurable blood levels of the drug, detectable excretion of the drug and its metabolites in the urine and through the clinical response of the patient to the administered drug therapy.

Transdermal delivery is the most commonly used and most extensively studied route for topical drug delivery. Transdermal delivery is favoured bypatients as it is self-administrable and painless. The large surface area of skin and easy accessibility makes it a good site for delivery.

The stratum corneum function is to provide a protective barrier for the tissues underlying the skin but this barrier function also limits the number of drugs that are able to pass passively across the skin.

The drugs that most successfully penetratethe skin are those that have a low molecular weight and optimal hydrophilic/lipophilic properties.

A Transdermal Drug Delivery System (TDDS) is a method of delivering medication through the skin in a controlled and continuous manner. Unlike oral or injectable drug delivery methods.

TDDS allows the active pharmaceutical ingredient (API) to be absorbed through the skin into the bloodstream, bypassing the digestive system and liver (known as the first-pass effect). This system is designed to provide a steady release of the drug over an extended period.

A transdermal drug delivery system (TDDS) or transdermal patch is a flexible pharmaceutical preparation of different size containing one or more active substance(s) to be applied on the intact skin for systemic availability.

Transdermal drug delivery systems (TDDS), commonly known as transdermal patches,are innovative pharmaceutical dosage forms designed to deliver drugs through the skin and into systemic circulation.

They offer several advantages over conventional oral and parenteral routes, including improved patient compliance, controlled and sustained drug release, avoidance of first-pass metabolism, and reduced side effects.

The formulation of transdermal patches involves incorporating an active pharmaceutical ingredient into a patch system using suitable polymers, permeation enhancers, and adhesives.

These components must be carefully selected to ensure proper drug release, skin permeation, and stability. Common types of transdermal patches include reservoir, matrix, and adhesive dispersion systems.

Evaluation of transdermal patches is crucial to ensure their safety, efficacy, and consistency. This includes both **physicochemical characterization** (such as thickness, weight variation, drug content, and moisture content) and **in vitro/in vivo performance testing** (such as drug release studies, skin permeation studies, and irritation tests).

TDDS represent a growing area in drug delivery, offering a non-invasive, patient-friendly alternative for both systemic and local therapeutic applications.

Transdermal patches are attractive as they are noninvasive, easy to use, and can also deliver multiple doses for an extended time period, while also showing patient compliance and cost-effectiveness.

The approach to transdermal patches may either be matrix or reservoir approach polymeric systems that house the drug such that it diffuses through the polymer by the way of skin beneath for reaching the systemic circulation in a controlled manner.

A transdermal patch is an interesting approach for breast cancer since it can act as a reservoir for the drug at the required site.

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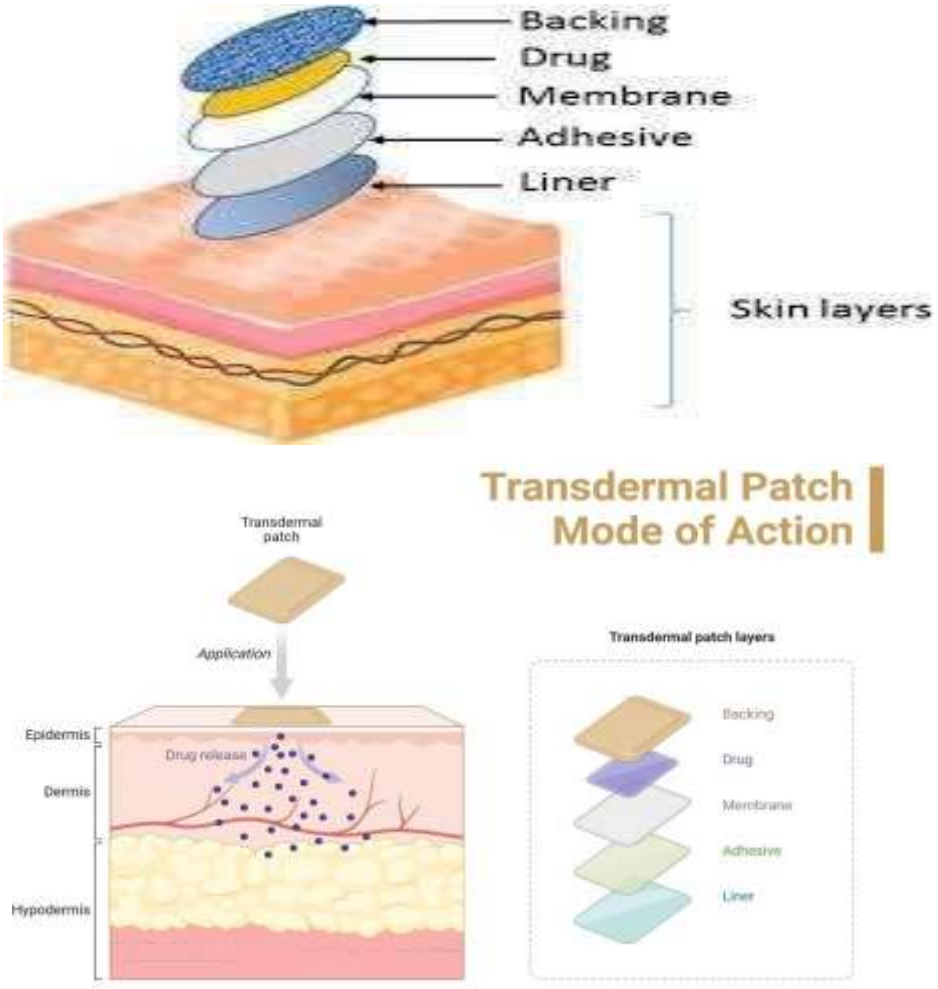

LAYERS OF SKIN

TRANSDERMAL PA

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➢ PLAN OF WORK

Developing a Transdermal Drug Delivery System (TDDS) involves a systematic approach to ensure effective and controlled drug release through the skin. The plan of work typically encompasses the following stages:

1. **Pre-formulation Studies**
   - **Drug Selection**: Choose a drug suitable for transdermaldelivery, considering factors like molecular size, lipophilicity, and skin permeability.
   - **Physicochemical Characterization**: Analyze the drug's solubility, stability, and compatibility with potential excipients.

2. **Formulation Development**
   - **Design of Delivery System**: Decide on the type of TDDS (e.g., matrix, reservoir, microneedle) based on the drug's properties and desired release profile.
   - **Selection of Polymers and Excipients**: Choose appropriate polymers for the backing layer, adhesive, and rate-controlling membrane. Polymers playa crucial role in controlling the release rate and ensuring skin adhesion.
   - **Incorporation of Penetration Enhancers**: If necessary, include chemical or physical enhancers to improve skin permeability.

3. **Manufacturing Process**
   - **Preparation of Drug Reservoir**: Formulate the drug in the desired state (e.g., solution, gel, solid) and incorporate it into the delivery system.
   - **Layer Assembly**: Assemble the backing layer, drug reservoir, and adhesive layers to form the complete patch.
   - **Quality Control**: Implement stringent quality control measures to ensure uniformity, stability, and performance of the patches.

4. **Characterization and Evaluation**
   - **In Vitro Release Studies**: Conduct studies to assess the drug release profile under controlled conditions.
   - **Skin Permeation Studies**: Evaluate the extent and rateof drug permeation through human or animal skin models.
   - **Stability Testing**: Assess the physical, chemical, and microbiological stability of the TDDS over time.

5. **Clinical Evaluation**
   - **Human Trials**: Conduct clinical studies to evaluate the safety, efficacy, and user acceptability of the TDDS.
   - **Regulatory Compliance**: Ensure the product meets regulatory standards for approvaland commercialization.

➢ REVIEW ON LITERATURE

1. Transdermal Drug Delivery and Patches—An Overview" (**2020**): This study provides an overview of skin anatomy and the natural barrier it presents for pharmaceuticals administered transdermally.
2. Recent Advances in Transdermal Drug Delivery Systems: A Review" (**2021**)by lang X: This review discusses various non-invasive transdermal drug delivery methods, highlighting their advantages, disadvantages, characterization.
3. Nira SS, Rajan BM. Formulation and evaluation of transdermal patches This review discusses the latest advancements in transdermal patch technologies, including formulation strategies, evaluation parameters, and applications.**2021**.
4. "Beneath the Skin: A Review of Current Trends and Future Prospects of Transdermal Drug Delivery Systems" (**2022**)by Zeng L: This comprehensive review examines the latest trends and future directions in transdermal drug delivery, focusing on innovative approaches to overcome skin barrier challenges and enhance drug permeation.
5. "A Review on the Mechanisms, Applications, and Clinical Trials of Advanced Technologies in the Transdermal Drug Delivery System" (**2023**)by Malaiya MK : This article explores advanced technologies in transdermal drug delivery, including microneedle.
6. Transdermal Drug Delivery: A Comprehensive Review" **(2024)**: This review delves into various physical penetration enhancement techniques, including sonophoresis, iontophoresis, magnetophoresis, thermophoresis, needle-free injection, and microneedles.
7. "Transdermal Drug Delivery Systems: Integrating Modern Technologies to Enhance Efficacy" **(2025)**: This article examines technological advancements in TDDS, focusing on regulatory considerations, safety profiles, and patient compliance.

➢ AIM

The Aim of a transdermal drug deliverysystem is to deliver medication into the bloodstream through the skin at a controlled rate.

This method of drug administration has several advantages over other routes. Avoiding other routes of drug administration.

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➢ OBJECTIVES

1. Painless and Minimally Invasive Delivery
2. Enhanced Drug Permeation:
3. Increase Patient Compliance:
4. Targeted and Controlled Drug Release:
5. Reduction of Side Effects and Infection Risk:
6. Improve Stability of Drugs and Vaccines
7. Wider Applications in Global Health:
8. Cost-Effective Manufacturing:
9. Disease Diagnosis
10. Patient Health Monitoring

➢ IDEAL FEATURES OF (TDDS)

1. Painless.
2. Effective Drug Delivery.
3. Biocompatibility and Safety.
4. Ease of Application and Use.
5. Stability and Shelf Life.
6. Multifunctionality.
7. Cost-Effective.
8. Fast onset of action.
9. Controlled and sustained drug release
10. Easy to manufacture
11. Avoids first-pass metabolism

➢ TYPES OF (TDDS)

1. **Reservoir**: A drug reservoir separates fromthe adhesive layer and delivers the drug at a controlled rate.
2. **Matrix**: The drug is dispersed in a semi-solid matrix that gradually releases the drug over time.
3. **Micro-reservoir**: Combines features of boththe reservoir and matrix systems.
4. **Membrane-permeation controlled**: A widely used system for transdermal drug delivery.
5. **Microsealed**: A partition-controlled delivery system that uses a silicone elastomer matrix.
6. **Gradient-charged**: A recently made available system for transdermal drug delivery.
7. **Microneedles:** Tiny needles create microchannels in the skin for drug absorption (e.g., insulin delivery).
8. **Nanoparticle-based TDDS**: Uses polymeric, lipid, or metallic nanoparticles for controlled drug release.
9. **Hydrogel-based patches**: Provide sustained drug release and hydration.
10. **Electroporation:** Uses short electrical pulses to create temporary skin pores for drug penetration.

➢ FACTORS AFFECTING TRANSDERMAL PATCHES:

1. Drug-Related Factors

Molecular Size: Ideal drugs for transdermal delivery typically have a molecular weight < 500 Da.
Lipophilicity: A balance between lipophilic and hydrophilic properties is needed for the drug to cross the stratum corneum and reach the bloodstream.
Potency: Drugs must be potent (effective at low doses), since only limited quantities can be absorbed through the skin.
Stability: The drug must be stable in both the patch formulation and the skin environment.

2. Formulation-Related Factors

Patch Design: Types include reservoir, matrix, and adhesive dispersion. Each affects drug release differently.
Penetration Enhancers: Chemicals such as alcohols, fatty acids, and surfactants can increase skin permeability.
Adhesive Quality: Good adhesion is critical to maintain consistent drug delivery and user compliance.
Release Rate Control: Controlled-release materials (e.g., polymers) manage how quickly the drug is delivered.
Backing Layer & Liner: These provide protection and control release; materials must be compatible with the drug.

3. Physiological (Skin-Related) Factors

Stratum Corneum Integrity: Damage or hydration of this outermost skin layer can increase drug permeability.
Skin Thickness: Varies by body site and affects absorption (thinner areas = better absorption).
Skin Temperature: Higher temperatures can increase blood flow and permeability, enhancing absorption.
Skin Hydration: More hydrated skin generally increases permeability. Age, Gender, and Ethnicity: These can influence skin structure and permeability.
Application Site: Areas with less hair and more consistent temperature (e.g., upper arm, back) are preferred.

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➢ FORMULATION & EVALUATION

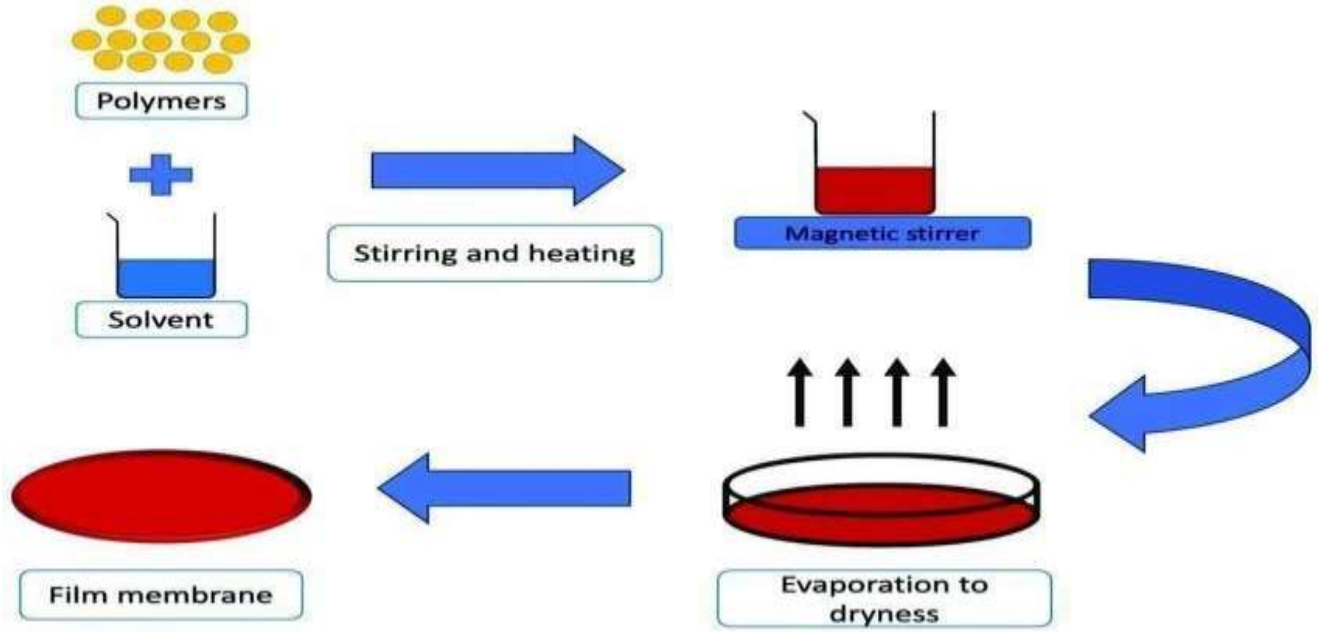
❖ Ingredients Used in Transdermal Patches:

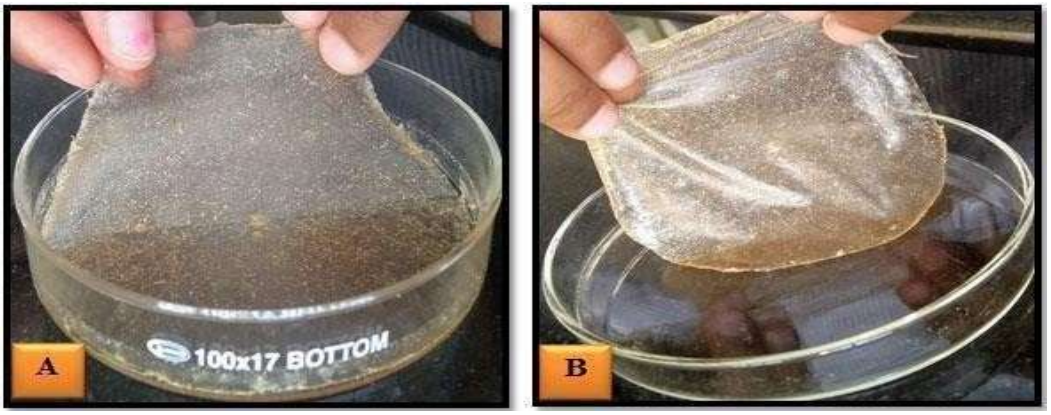
1. **Active Pharmaceutical Ingredient (API) (Drug):** Metronedazole (to treat skin infections, rosacea and mouth infections)
2. **Polymers (Drug Reservoir or Matrix):**
   Matrix-forming polymers: polyethylene glycol (PEG) Reservoir-forming polymers: EVA(ethylene-vinyl acetate)
3. **Penetration Enhancers**: Fattyacids (Oleic acid, linoleic acid) Alcohols (Ethanol, propylene glycol)
4. **Backing Layer**: Provides structuralsupport and prevents drug loss. Polyester film, Polyethylene film
5. **Plasticizers**: Enhance flexibility and durability ofthe patch. Glycerol, Propylene glycol
6. **Solvents:** Used in drug-polymer mixing and patch preparation. Ethanol, Chloroform.

❖ INSTRUMENT REQUIREMENT'S

Sr.no	Apparatus Name
1.	Sonicator
2.	Magnetic Stirrer
3.	Hot air oven
4.	Rotary Cutter / Punching Machine
5.	HPLC / UV Spectrophotometer
6.	Beaker

SOLVENT CASTING METHOD





Prepared Transdermal Patch

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First we take 10ml of water in a beaker, and add 10ml of ethanol in a beaker.

Then add 50mg ie.(0.5gm) Polymer ie.(Starch) in the beaker.

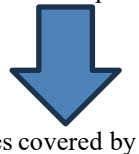
Stir it well by using stirrer.

Take metronidazole drug which is (50mg which is 0.5gm), placed drug in the beaker and Stir it well.

Transfer this solution into 2 beakers ie. (1st PVA and 2nd PVP).

Then take 2 petri dish clean well with help of glycerol.

Pour the mixture into petri dish properly.



Both dishes covered by funnel.

Then leave it for 24 hours for converting it into transdermal patch.

EVALUATION

1. **Pre-Formulation Studies**
   Physicochemical properties: Solubility, partition coefficient, pH, and melting point of the drug. Polymer selection: Ensures appropriate adhesion, drug release, and mechanical properties.
2. **Physicochemical Evaluation**
   Appearance: Smoothness, transparency, and uniformity. Thickness:
   Measured using a micrometer or Vernier caliper. Weight variation:
   Ensures uniform distribution of components.
3. **Adhesion and Mechanical Properties Tensile strength:** Determines mechanical strength.
4. **Permeation Studies**
   Skin permeation: Evaluated using excised animal or human cadaver skin in Franz diffusion cells. Enhancement studies: Effect of permeation enhancers is analyzed.
5. **In-Vivo Evaluation**
   Skin irritation/sensitization:
   Therapeutic efficacy: Measured in clinical trials.
6. **Stability Studies**
   Conducted as per ICH guidelines under accelerated conditions (temperature and humidity variations) to ensure patch integrity, adhesion, and drug content stability.

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➢ RESULT AND DISCUSSION

After the formulation of transdermal patches, several results and observations are typically recorded to assess their quality, performance, and effectiveness. These observations ensure that the patch delivers the drug as intended and remains stable and effective over time.

Example of Observation (e.g., A metronidazole transdermal patch):
Physical Appearance: Smooth, uniform patch with a clear backing film.
Drug Content Uniformity: Metronidazole is evenly distributed acrossthe patch matrix.
Drug Release Profile: Controlled release over 24 hours, with an initial burst release followed by a steady release.
Adhesion: Firm adhesion to the skin, with minimal residue left after removal.
Skin Irritation: No redness or irritation observed after 24-hour wear. Skin Compatibility: Normal skin pH is around **4.5 to 6.0**.
pH Range: Most transdermal drug formulations are designed to maintain a pH of **4-7**, depending on the drug.
Storage Conditions: Typically stored at controlled roomtemperature (**20-25°C**), away from moisture and direct sunlight.
Shelf Life: Usually ranges from **1 to 3** years, depending onthe drug and formulation.

➢ CONCLUSION

Transdermaldrug delivery addresses the low bioavailability of oral drugs.
Eliminates the pain and inconvenience of injections and addresses the limited release options of both.

This article provide an valuable information regarding the transdermal drug deliverysystems and its evaluation process details as a readyreference for the research scientist who are involved in TDDS.

The foregoing shows that TDDS have great potentials, being able to use for both hydrophobic and hydrophilic active substance into promising deliverable drugs.

To optimize this drug delivery system, greater understanding ofthe different mechanisms of biological interactions, and polymer are required.

TDDS a realistic practical application as the next generation of drug delivery system. Successful transdermal drug application requires numerous considerations.

Bearing in mind that the basic functions ofthe skin are protection and containment, it would seem exceptionally difficult to target the skin for drug delivery.
Transdermal delivery is a potential and attractive route of administration for peptides and proteins.

However, physical or chemical enhancement technologies are necessary to enable successful delivery of these hydrophilic macromolecules.

Patches can bypass the digestive system and first-pass metabolism to provide continuous dosing of drugs over an extended period of time.
They are commonly used to deliver drugs for various indications such as chronic pain, motion sickness, and hormone replacement therapy.

The solvent casting approach was employed to formulate a transdermal patch of astaxanthin using polymers and the varying ratio of permeation enhancers and plasticizers.

Physicochemical characteristics including Drug Content, Patch Thickness, Weight Variation, and Folding Endurance were reported satisfactory in all the formulations.

The *in-vitro* release results demonstrated that the kind and concentration ofthe polymer had an impact on the drug release from the patch.

In the development of transdermal patches of Carvedilol, it was concluded that transdermal patch is superior over oral administration and deliver the drug for prolonged duration and also best option for treatment and management of hypertension and thereby in Heart failure. for their efficacy at clinical level needed to be studied further.

Transdermal patches represent a significant advancement in drug delivery systems, offering a non-invasive, controlled, and sustained release of medication through the skin.

They improve patient compliance by reducing dosing frequency and minimizing gastrointestinal side effects associated with oral medications.

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While they have limitations—such as skin irritation, limited drug types suitable for transdermal delivery, and slow onset of action—their benefits in specific therapeutic areas, such as pain management, hormone replacement, and smoking cessation, are well established.

Ongoing research and development are expanding their potential, making transdermal patches a valuable component of modern pharmacotherapy.

Transdermal patch technology is a valuable drug delivery method with many advantages over other delivery routes. Patches can bypass the digestive system and first-pass metabolism to provide continuous dosing of drugs over an extended period of time. They are commonly used to deliver drugs for various indications such as chronic pain, motion sickness, and hormone replacement therapy.

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