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Transdermal Pathways for Blood Pressure Control: A New Vision for Hypertension Management

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ABSTRACT

Hypertension continues to challenge global healthcare, especially because many patients depend on daily oral medications that often suffer from inconsistent absorption, first-pass metabolism, and poor long-term adherence. These limitations have encouraged researches to search for more dependable, patient-friendly drug delivery. Transdermal drug delivery systems (TDDS) have emerged as a promising option, using the skin as a controlled route for sustained and predictable drug release. This review discusses the growing interest in TDDS for antihypertensive therapy. It outlines the limitations of oral administration and highlights the key physicochemical properties such as molecular weight, lipophilicity, and solubility that influence a drug's ability to permeate the skin. Drug like clonidine, metoprolol, and losartan serves as practical examples of molecules reformulated into patch-based systems. The design of transdermal patches including the drug matrix or reservoir, adhesive components, backing layers, and permeation enhancers is summarized along with essential evaluation methods. The review also touches on marketed patches and recent advancements, emphasizing TDDS as a promising strategy for more consistent and convenient blood pressure management.

Keywords : Antihypertensive drugs, Transdermal patch, controlled release, drug permeation, skin.

1. INTRODUCTION

Hypertension (HTN) is defined as a pathological disorder characterized by elevated blood pressure (BP), i.e., the systolic around 140-150 or above [1]. One known sign of cardiovascular disease is high blood pressure [2]. When the pressure of blood pushing against the walls of arteries stays higher than normal for a long period is called as hypertension. According to world health organization (WHO), hypertension (HTN) Causes almost 9 million deaths annually and is one of the major causes of death and morbidity worldwide [3]. It increases the risk of various heart related diseases like heart failure, stroke, myocardial infarction, renal failure. Transdermal drug delivery is ideally suited for chronic treatment. Hypertension, a disease equally widespread in the developed and the underdeveloped countries, it required chronic treatment [4]. A transdermal drug bloodstream, which are available in patch form. Rather than taking oral medication or getting delivery system is controlled release medication method that delivers the medication through the skin layers directly into the injection, the medicated patch is applied to the skin. The drug slowly goes through the outer skin layers and enters into the blood, allows the medication to be delivered in a controlled, steady manner [5].

It is the self-contained discrete dosage form which is also known as "patches" [6]. First transdermal patch approved in 1979 (December) by FDA was of scopolamine for motion sickness. The second patch approved in 1981 of the nitroglycerine. Clonidine was first antihypertensive drug in the form of transdermal patch, which approved in 1984 by USFDA, it's brand name is Catapress-TTS, mild-to-moderate hypertension treat by using clonidine patch. At this time, there are number of antihypertensive patches are marketed [7,8]. Recent advancements in polymer engineering, adhesive systems, and permeation-enhancing technologies have significantly broadened the scope of transdermal delivery for antihypertensive drugs. Modern polymers provide better flexibility, durability, and controlled-release properties, while improved adhesives ensure uniform skin contact without irritation. Permeation enhancers and microneedle-assisted designs further strengthen drug transport across the stratum corneum, allowing even poorly permeable or high-molecular-weight molecules to reach systemic circulation efficiently [9].

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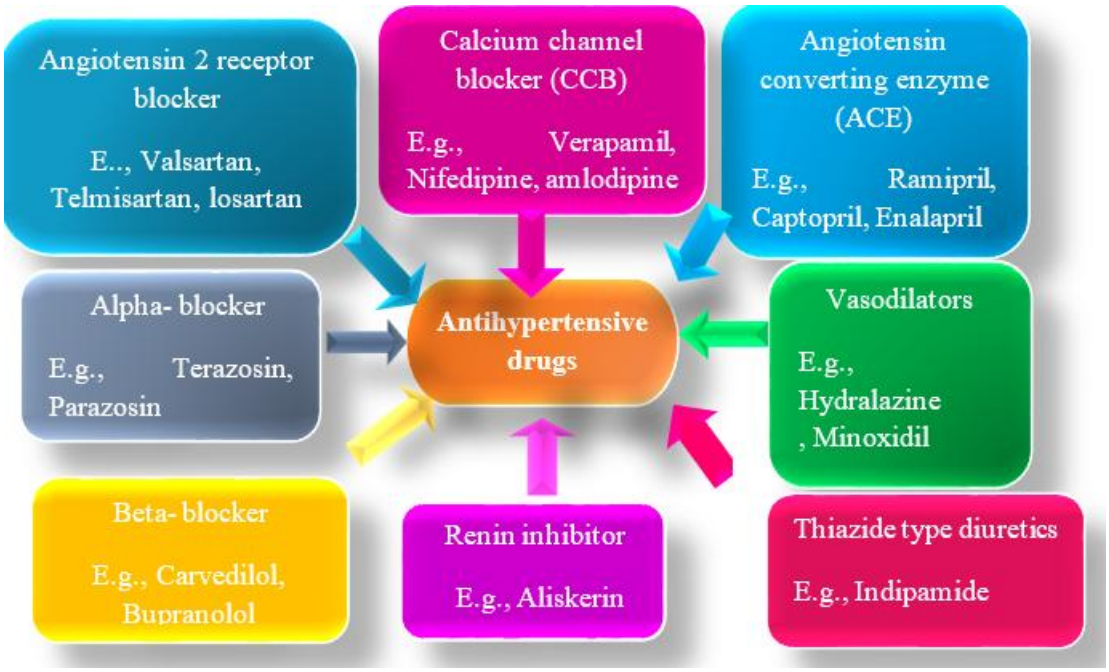

Figure.1: Classification of drugs used in hypertension

ADVANTAGES OF TRANSDERMAL PATCHES

Compared to traditional routes of administration namely, intravenous (IV), intramuscular (IM), topical, oral delivery, the transdermal routes deliver various advantages. The key advantages of transdermal drug delivery are given below-

- The drug's systemic bioavailability is enhanced by avoiding the initial hepatic metabolism and continuously infusing the drug for extended periods of time without interference from GIT fluids [10].
- Steady drug penetration through the skin, enabling steady plasma levels that are non-invasive.
- It provides comfort via non-invasive, painless and simple application and also enhance patient compliance through the implementation of the simplified treatment regimen.
- Transdermal drug delivery is best choice for medications that can distress the gastrointestinal tract [11].
- By removing the medication from the skin surface, drug therapy can be stopped right away.
- It may be possible to administer medications with shorter biological half-lives.
- Transdermal patches can be readily removed from the skin's surface in the event that poisoning has any negative effects.
- It increases the therapeutic efficacy because it is independent of both intra and inter-individual variation [12].

DISADVANTAGES OF TRANDERMAL PATCHES

The main drawback of transdermal delivery techniques is that the skin acts as a very effective barrier, so only medications with small molecules enough to pass through the skin can be given in this manner. Additional drawbacks of transdermal patches are listed below –

- The drug, adhesive, or other excipients used in transdermal application may cause allergic reactions to the skin.
- Large molecular size drugs have trouble in absorption.

- Transdermal delivery could be more expensive [13].
- Drugs in ionic form which frequently show reduced absorption due to their limited ability to cross biological membrane.
- The skin acts as a protective barrier, significantly reducing the passage of most drugs. As a result, only molecules with high potency can be effectively delivered through this route.
- Lipophilic drugs are better suited as due to their low permeability when compared to drugs with lipophilic characters.
- Drugs with a high or extremely low partition coefficient are unable to enter the bloodstream [14].

2. SKIN AND ITS COMPOSITION

The largest organ of body is skin, with around 1.5- 2 sq. meters of its surface area and entire part of the human body is enveloped by skin.

There are various functions –

- It acts as a continuous protective barrier between the physiological system and external environment.
- Body's temperature regulates by the skin, also maintains electrolyte balance and guarded from viral attack.
- It acts as a controlled penetration barrier, that enables limited transdermal translocation of physical and chemical agents.
- It shields the body from environmental hazards and physical, chemical, biological insults [15].

There are three main regions of skin. i.e., epidermis, dermis and hypodermis (subcutaneous tissue). As seen in the fig., the whole body's surface covers by the epidermis, which is outermost layer of skin. The epidermis contains viable and non-viable parts. The viable epidermis is composed of four layers. i.e., stratum lucidum, stratum granulosum, stratum spinosum and stratum germinativum. The self- regenerating and multi-layered squamous epithelium composed of non- viable outer layer termed as a stratum corneum. The stratum corneum, consisting of approximately 15-20 layers of flattened keratinocytes incorporated in a lipophilic intercellular matrix, behaves as a major rate-limiting barrier controlling transdermal drug diffusion.

The middle layer of skin is dermis, which around 2-3 mm thick. The dermis predominantly consists of collagenous connective tissue embedded with elastic fibers accounting for approximately 70% of it's composition. This structural organization provides the skin with remarkable tensile strength, flexibility and resiliencene. It also contains nerves, blood vessels, and lymph vessels. The dermal layer provides slight hindrance to the transdermal transport of polar drugs. Whereas, the SC serves as a major resistance to the permeation of drug through the skin. The innermost layer of skin is subcutaneous layer, composed of fat cells. It serves as a crucial function in a regulating thermal balance, imparts structural endurance to prevent external pressure or trauma and nourishes underlying tissues. To achieve systemic absorption, the TDDS must efficiently transverse all three layers of the skin [16].

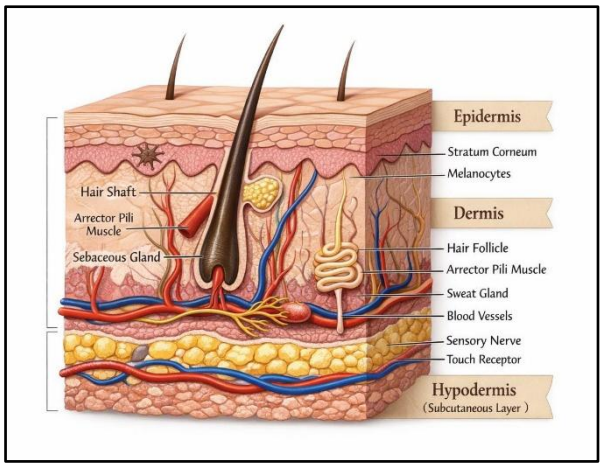

Figure.2: Physiology of Skin

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3. PERMEATION PROCESS

The 3 different routes are available to penetrate the transdermal drug across the skin into systemic circulation.

It includes – 1. Trans-appendageal route

2. Transcellular route

3. Intercellular route

- **TRANSAPPENDAGEAL ROUTE** - This pathway, often designated as the "shunt route", which enables permeation of drug molecules across the skin appendages namely, hair follicles, sebaceous gland and sweat ducts. A clear patch passes the stratum corneum due to the presence of skin appendages the transport of drugs via appendages including key parameter's such as follicular volume and opening width etc.

- **TRANSCELLULAR ROUTE –** Even through it is considered as a "quickest pathway", drug molecules encounter substantial barriers due to the demand of diffusing across both hydrophilic and lipophilic structural domain of the skin. The drug molecules to permeate through this pathway, it must integrate into and migrate across the corneocytes. After integration into the cellular membrane, small lipophilic molecules are capable of transfer to this route efficiently due to their affinity for the lipid environment. Small size hydrophilic molecules can penetrate via this route and receptor-mediated transporters are used. The integration of hydrophilic molecules is minimal in cell membrane.

- **INTERCELLULAR ROUTE –** This route, commonly referred as "paracellular route" to the presence of tight junctions, the diffusion of drugs is minimal via this route. The molecules with smaller particle size is capable for this pathway, ensuring their efficacy for permeation [17].

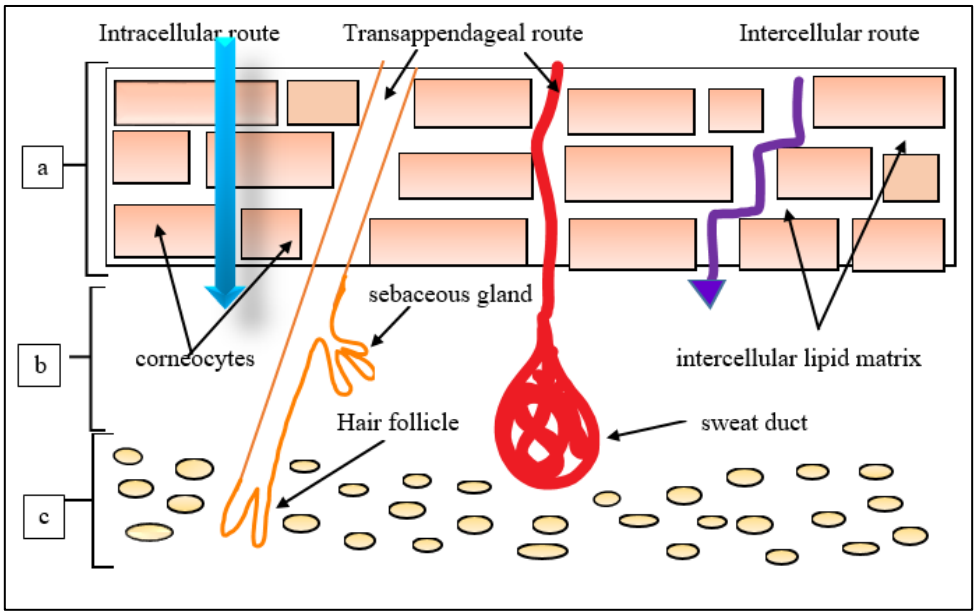

Figure.3 Pathways through the skin a) Epidermis b) Dermis c) Subcutaneous layer

4. FACTORS AFFECTING TRANSDERMAL PERMEABILITY SKIN PERMEATION

The largest organ in the human body, the skin serves as an essential barrier to keep out environmental dangers. Apart from its structural and physiological functions, chemicals can be absorbed and transferred into the bloodstream by the skin's dynamic surface. The methods by which a chemical penetrates the layers of skin and is referred to as skin permeability if it either has local effects or enters the systemic circulation. A clear understanding of skin permeation is crucial for developing effective transdermal delivery systems, safe cosmetics formulations, and reliable dermal risk assessments [1].

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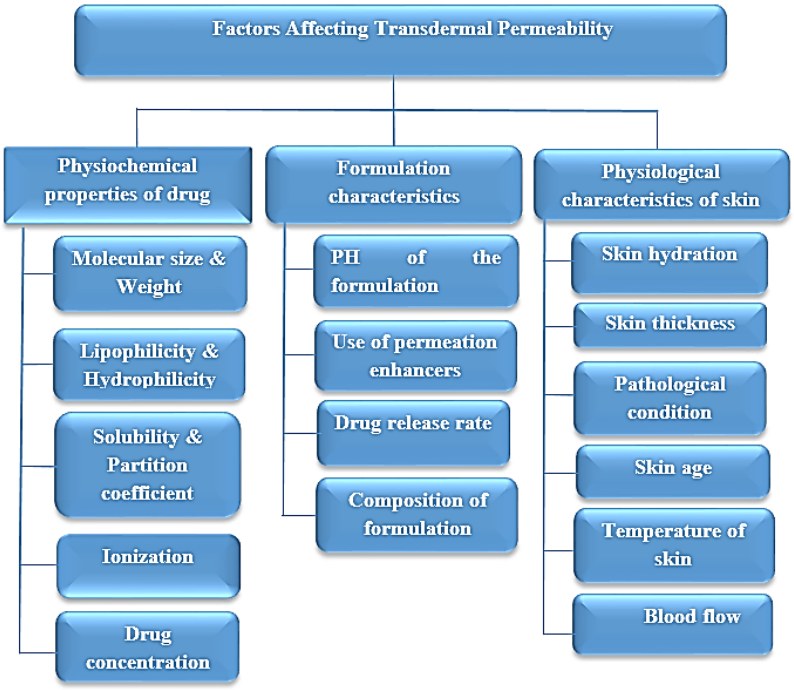
Table-1: Factors affecting Trans dermal Permeability



1. PHYSIOLOGICAL PROPERTIES OF DRUG

I. Molecular size & Weight- According to physiochemistry, drug molecules that weight less than 500 Daltons are more likely to pass through the skin.

II. Hydrophilicity and Lipophilicity- It's critical to strike the ideal balance between hydrophilicity (water solubility) and lipophilicity (fat solubility).

III. Solubility and Partition coefficient- The optimal molecules for transdermal dispersion have a modest Log P, usually in the range of 1 to 3.

IV. Ionization- Non-ionized (neutral) molecules are more easily absorbed by the skin than ionized molecules [19].

2. FORMULATION CHARACTERISTICS

I. PH of the Formulation- The PH should ideally favor the non-ionized form of the medication because non-ionized molecules can more readily pass through the lipid-rich stratum corneum than ionized molecules. The PH should be in line with skin physiology, which is between PH 5 and 6, to prevent irritation or harm to the barrier function.

II. Permeation enhancers- By changing the conformations of proteins or improving the fluidity of lipid bilayers, these enhancers facilitate molecular transport. Take EDTA, polyacrylates, and sodium lauryl sulphate, for instance.

III. Formulation composition- The solvent or vehicle used to dissolve the active ingredient may have a direct effect on how well it penetrates the skin. By solubilizing the medication and preserving its permeability, vehicles can function.

- Changing the barrier characteristics by interacting with the lipids in the skin.
- Modifying the drug's thermodynamic effect. Oleic acid [20].

3. PHYSIOLOGICAL FEATURES OF SKIN

I. Skin hydration- keeps the skin hydrated and modifies the stratum corneum's tightly packed structure, increasing its permeability. The concept is widely applied in cosmetics and transdermal drug delivery.

II. Skin thickness- It influence the rate and degree of drug absorption, which has an impact on the effectiveness of transdermal patches for hypertension. The main obstacle to drug penetration is the stratum corneum, the skin's outermost and thinnest layer.

III. Pathological condition- Skin that is damaged, ill (such as psoriasis or eczema), or inflamed can show markedly increased permeability when the barrier function is compromised.

IV. Skin age- Because older skin has a lower barrier and lower lipid levels than younger skin, the permeability patterns may cause occasionally differ.

V. Skin temperature- By increasing the fluidity of lipid structures and accelerating the rates of molecular diffusion, elevated skin temperatures increase permeability.

VI. Blood flow- Increased cutaneous blood flow promotes better systemic absorption of penetration drugs while maintaining a discernible concentration gradient [21].

5. COMPONENTS OF TRANSDERMAL PATCH

1. POLYMER MATRIX - When creating a medication administration system polymers are essential transdermally, the drug reservoir, also known as the polymer matrix, is positioned between two polymers: an outer impermeable polymeric layer that serves as a membrane that controls rate and is adhesive. It is crucial to consider the polymers used and their construction when creating efficient transdermal delivery systems. Optimizing the drug-loaded matrix for release qualities, adhesion, and physicochemical properties is the main challenge in polymer matrix design. Stability and general compatibility with the skin and other components of the system. Synthetic polymers, synthetic elastomers, and natural polymers are used.

2. DRUG - For TDDS to work, the medication must have the proper pharmacokinetic, chemical and physical characteristics. Transdermal patches allow for the gradual release of medications through the skin. This is especially crucial for medications that have a short half-life, a narrow therapeutic window, or significant first-pass metabolism, all of which increase the risk that people will neglect to take their medications as directed. Examples include benztropine for parkinson's disease, imipramine hydrochloride for depression of newly approved drugs.

3. PERMEATION ENHANCERS - Enhancers continue to increase permeability and achieve higher therapeutic drug levels by utilizing proteins or lipids, which are structural components of the stratum corneum. Enhancers increase permeability and therapeutic drug levels by interacting with proteins or lipids in the stratum corneum. This is probably how enhancers facilitate the skin's absorption of oil-soluble medications. Chemical enhancers increase the skin's permeability to oil-soluble medications by removing some of its lipids. This makes the skin more permeable to liquids, both transcutaneously and transfollicularly. The effectiveness of water-soluble medications is absorbed through the skin may be related to the solubility and miscibility of the permeation enhancers used. physical techniques like iontophoresis, electroporation, sonophoresis, and microscopic projection make it easier for drugs to enter the skin. Transdermal patches are applied using a variety of techniques, including thermal magnetophoresis, permeation, photomechanical waves [22].

4. PRESSURE SENSITIVE ADHESIVE - The patch is kept firmly attached to the skin by a pressure-sensing adhesive (PSA). It should feel aggressive when you press down, stick fast when you press your finger on it, and remain firmly in place. This group includes silicon-based adhesives polyacrylates, and polyisobutylene. When choosing an adhesive, there are numerous factors to take into account, including the patch design and the drug's composition. Adjuncts for physical stability (PSA) should not interfere with drug release and be biocompatible. Although PSA can be located anywhere on the device, it is typically found on the front (as in a reservoir system) or the back (with a peripheral extension),

5. BACKING LAMINATE - The main purpose of backing laminate is to provide support. The adhesive needs to be compatible with the excipients and chemically stable. If the backing layer is in contact with the excipients, medication, or permeation enhancers for a long time, the additives may seep out and pass through. Less moisture vapour should pass through them. They need to be strong, adaptable, and extremely resilient.

6. RELEASE LINER - The release liner keeps the medication from getting lost or contaminated while being stored because it is now inside the sticky layer. As a result, it is regarded as primary packaging rather than a part of the drug's dosage form. A non-obstructive base layer (usually paper cloth) and a release coating layer (usually silicon or teflon) make up the released liner, which helps release the product. TDDS-release liners can also be constructed using metalized laminate or polyester foil.

7. OTHER EXCIPIENTS - Acetone, isopropanol, methanol, chloroform, and solvents that can be used to create a drug reservoir include dichloromethane. To make the transdermal patch easier to apply and more flexible, plasticizers like propanediol, polyethylene glycol, triethyl citrate, and dibutyl phthalate are added [23].

6. TYPES OF TRANSDERMAL PATCHES

1. THE DRUG IN TDDS ADHESIVE - The medication is distributed throughout the pond's adhesive layer in the system. The adhesive layer controls the rate of drug delivery in addition to adhering the patch to the skin. A liner encircles the adhesive layer. There are two kinds,

- SINGLE LAYER ADHESIVE - The medication is contained in this kind of adhesive layer. In addition to holding the different layers together, the adhesive layer is also in charge of releasing the medication onto the skin. A backing and a temporary liner encircle the adhesive layer.

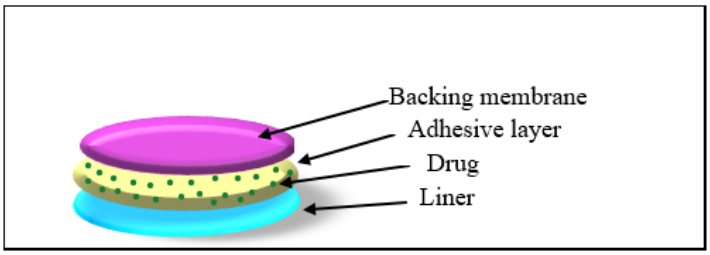


Figure.4: Schematic representation of single layer adhesive

- MULTIPLE LAYER IN ADHESIVE - In contrast to the other type, which will have a controlled release in addition to the adhesive layer, this type is always similar to the single layer but has an immediate drug release layer. Additionally, this patch has a permanent backing and a temporary liner layer.

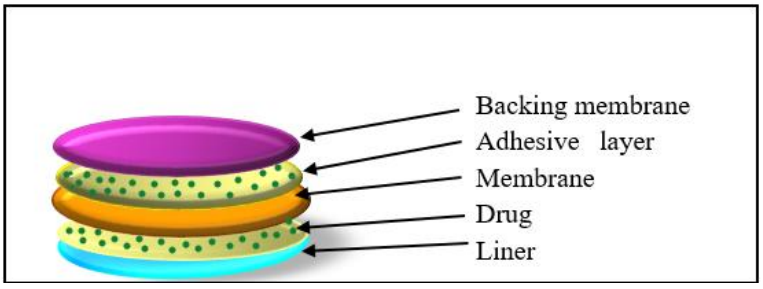


Figure.5: Schematic representation of multilayer adhesive

2. VAPOUR PATCH - The adhesive layer in this kind of patch not only holds the different layers together but also releases vapour; vapour patches are a relatively new product. It is frequently used to release essential oils for up to six hours [24].

3. RESERVOIR SYSTEM - The drug reservoir in this system can be positioned between the rate-controlling membrane and the backing layer. The drug may be a gel, solution, or suspension. On the solid polymeric matrix, these medications are distributed.

4. MATRIX SYSTEM - A semisolid matrix that is in direct contact with the release liner and contains a drug solution or suspension is what distinguishes the matrix system design.

5. DRUG IN ADHESIVE SYSTEM - The drug is dispersed onto an adhesive polymer and then spreads over the medicated adhesive polymer to create the drug reservoir.

6. MATRIX DISPERSION SYSTEM - Within the hydrophilic or lipophilic polymer matrix, the medications are uniformly distributed. The polymer-containing drugs are placed on a specific base plate in a compartment made of a backing layer that is impermeable to drugs. Rather than covering the drug's reservoir face, the adhesive is applied along it's circumference to create an adhesive rim strip.

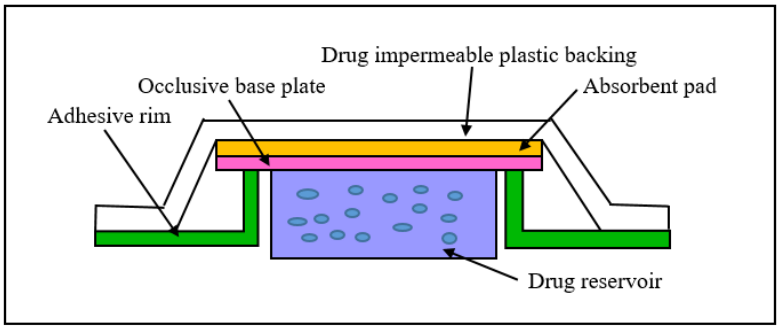


Figure.6: Schematic representation of matrix dispersion system

7. MICRO RESERVOIR SYSTEM - The combination of reservoir and matrix dispersion systems is referred to as this system. The medication is suspended in a water-soluble polymer aqueous solution, which is then uniformly distributed in a lipophilic polymer to create thousands of tiny, unleachable spheres of drug reservoirs [25].

7. FORMULATION OF TRANSDERMAL PATCHES

1. MERCURY SUBSTRATE METHOD - This method involves preparing a uniform polymer–drug solution and pouring it onto a casting surface made of mercury. The mercury provides a perfectly smooth and non-adhesive base, allowing the liquid mixture to spread evenly and form a film of consistent thickness. After controlled drying, the film is carefully lifted from the surface, trimmed, and stored under protected conditions. The major benefit of this technique is the production of highly smooth patches with minimal surface defects [26].

2. CIRCULAR TEFLON METHOD - In this process, the dissolved drug and polymer mixture is poured into a circular mould made of Teflon. The mould prevents sticking and ensures uniform shaping of the patch. The solvent is allowed to evaporate slowly under a covered environment, enabling the patch to dry without cracks. Once dried, the film is removed and placed in a desiccator to stabilize it. This method is practical for large-scale preparation because the mould design improves reproducibility and handling.

3. IPM MEMBRANE METHOD - This method is ideal for drugs with limited aqueous solubility. The drug is first incorporated into a gel base consisting of penetration-enhancing components such as propylene glycol and thickening polymers. The prepared gel is then applied onto an IPM (isopropyl myristate) membrane, which functions both as a support and a permeation-controlling layer. The membrane slowly releases the drug when placed on the skin, enabling controlled transdermal delivery [27].

4. EVAC MEMBRANE TECHNIQUE - This method focuses on regulating the rate at which the drug leaves the patch. First, a reservoir gel containing the drug and other excipients is prepared. The gel is placed on the backing layer, and on its surface a thin EVAC membrane is applied. The EVAC layer functions as a diffusion-controlling barrier, so the drug is released gradually instead of all at once. The membrane is sealed carefully to avoid any leakage of the gel. This technique is particularly helpful when a long therapeutic effect is desired and when the drug needs to be released in a predictable and sustained manner.

5. ALUMINIUM-BACKED ADHESIVE FILM TECHNIQUE - This approach is mainly preferred when the drug needs additional protection from environmental conditions such as moisture or light. The drug is dissolved together with an adhesive in a volatile organic solvent to form a uniform mixture. After casting the solution, solvent evaporation results in a thin adhesive film containing the drug. The dried film is reinforced with aluminium foil on the backside, which acts as a protective and impermeable support. The aluminium backing reduces drug loss, improves patch stability, and provides strong adhesion, making it suitable for formulations that contain higher drug loads [28].

8. EVALUATION OF TRANSDERRMAL DRUG DELIVERY SYSTEM

1. THICKNESS - After calculating the average thickness, measurements at different locations throughout the skin using a screw gauge.

2. WEIGHT VARIATION - After weighing each individual 2 x 2 cm2 patch, the average weight was determined.

3. FOLDING ENDURANCE - A patch was folded and opened at the same location until it broke at the folding site in order to determine how long it could be folded. The significance was expressed as a number that indicated the number of times the patch needed to be folded in order to create a break.

4. LOSS OF MOISTURE - The moisture content of the 1 x 1 cm2 patches was measured after they were dried overnight at room temperature in a desiccator filled with calcium chloride. We knew we had reached the target weight when there was no longer a weight difference between patches. By dividing the weight change from start to finish by the final weight, the percentage of water loss was calculated.

5. DRUG CONTENT - To gauge the quantity of medication, 1-cm2 Patches are applied. To improve drug extraction, 1-cm2 transdermal patches were cut into tiny pieces and mixed for 30 minutes. After being cleaned with a small amount of 0.1% sodium hydroxide, the contents and the mortar were moved to a 10 mL volumetric flask. After the solution was filtered through Whatmann-1 filter paper and shaken for half an hour, the drug concentration in the filtered solution was measured at 254 nm.

6. WEIGHT UNIFORMITY - The patches were also dehydrated for four hours at 60°C prior to the tests. Each piece of the patch that has been cut off is weighed using a computerized scale. The average weight and weight standard deviation are calculated using the individual weights [29].

7. PERCENT MOISTURE CONTENT- Completed patches are kept at room temperature in a desiccator with compound calcium chloride and are routinely weighed. You reweigh the film after a day and apply the following formula to determine the amount of water in it.

$$\% \text{ moisture content} = [(\text{Initial weight} - \text{Final weight}) / \text{Final weight} \times 100.$$

8. % MOISTURE UPTAKE - After being measured, each completed patch is kept in a desiccator with a saturated potassium chloride solution to maintain a RH of 84% for a full day. We can use the following computation to find out how much moisture the films have absorbed after reweighing them.

$$\% \text{ moisture uptake} = [(\text{Final weight} - \text{Initial weight}) / \text{Initial weight} \times 100 \text{ [30].}$$

9. RECENT ADVANCEMENTS: NOVEL ENHANCEMENT TECHNOLOGIES

1. IONTOPHORESIS - Utilizes a mild electric current to actively push antihypertensive drugs across the skin. Allows real-time dose modulation and provides rapid attainment of therapeutic levels. Especially useful for drugs with poor passive permeability [31].

2. MICRONEEDLE-BASED SYSTEM - Consist of miniature needle arrays that create reversible micro-channels in the stratum corneum. Enable delivery of high-molecular-weight and hydrophilic antihypertensive drugs. Offer painless application, minimal irritation, and improved patient acceptance [32].

3. NANOTECHNOLOGY-DRIVEN CARRIERS - Involves nanoparticles, nanoemulsions, nanogels, and lipid-based nanosystems for improved drug penetration. Enhance solubility, protect drugs from degradation, and provide prolonged and controlled release. Reduce dosing frequency and support better long-term adherence [33].

4. ULTRASOUND- ASSISTED DELIVERY (SONOPHORESIS) - Uses acoustic waves to temporarily disturb the lipid organization of the stratum corneum. Increases permeability without tissue damage and supports deep diffusion of APIs. Can be combined with patches or gels for non-invasive application [34].

10. CONCLUSION

Transdermal drug delivery has emerged as a promising alternative to conventional oral therapy for hypertension, particularly due to its ability to maintain steady plasma drug concentrations and bypass first-pass metabolism. By using the skin as a controlled gateway rather than simply a protective barrier, TDDS improves patient compliance, minimizes dosing fluctuations, and supports long-term therapeutic management- benefits that are critically important in chronic disorders like hypertension. The success of marketed systems such as clonidine patches demonstrates that this route can reliably modulate blood pressure with greater consistency than traditional oral regimens. Despite these advantages, the therapeutic landscape continues to evolve. A deeper understanding of skin

permeation, route-dependent transport, and formulation variables has encouraged the design of advanced delivery systems that overcome diffusional resistance and enhance drug uptake. Emerging technologies- including microneedle arrays, nanocarrier-loaded patches, smart hydrogels, and hybrid combination systems- are reshaping the potential of TDDS by improving delivery of molecules that were previously unsuitable for transdermal absorption. These innovations aim not only to increase permeability but also to tailor drug release in response to physiological signals, ultimately supporting more personalized and responsive hypertension management.

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12. AUTHORSHIP

All author have made substantial and meaningful contributions to the conception and planning of the review work, comprehensive literature search, critical evaluation of published studies, and interpretation of the collected data. The author actively participated in drafting the manuscript and revising it critically for important intellectual and scientific content. All author have reviewed and approved the final version of the manuscript for publication and agree to take responsibility for the accuracy, integrity, and originality of the work. The author further confirm that this manuscript has not been previously published and is not under consideration for publication in any other journal.

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