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Review Article

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A REVIEW ON FORMULATION AND EVALUATION OF TRANSDERMAL PATCH FROM AN ANTI-HYPERTENSIVE DRUG

Pragati G. Sultane, Pranjal V. Sawant, Pranjali D. Katkhede, Pratiksha D. Karwate, Pratiksha V. Gaikwad, Snehal R. Shelke, Kailash R. Biyani

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ABSTRACT

Hypertension remains a major global health concern and requires long-term therapeutic management to maintain optimal blood pressure control. Conventional oral antihypertensive medications often present challenges, including variable gastrointestinal absorption, extensive first-pass metabolism, short dosing intervals, and inconsistent patient adherence. These limitations have encouraged the development of transdermal drug delivery systems (TDDS), which provide a non-invasive and controlled method of drug administration while bypassing hepatic metabolism and improving bioavailability. A wide range of antihypertensive agents—such as clonidine, atenolol, telmisartan, and calcium channel blockers—has been explored for transdermal application using different polymers, plasticizers, and permeation enhancers. Among these, clonidine demonstrates favorable properties for transdermal delivery due to

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its moderate lipophilicity, low molecular weight, and potent therapeutic action. This review highlights the formulation strategies, evaluation parameters, and advancements in transdermal patches aimed at achieving sustained drug release and improved patient compliance. Emerging systems, including nanocarrier-integrated films and modern polymer matrices, further emphasize the growing potential of TDDS in effective antihypertensive therapy.

KEYWORDS

Hypertension, Transdermal drug delivery system, polymer matrix, permeation enhancer, evaluation parameter.

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INTRODUCTION

Hypertension, commonly referred to as high blood pressure, is a major global health concern and a leading contributor to cardiovascular disease, stroke, and renal complications. According to the World Health Organization, nearly one-third of the global population is affected by elevated blood pressure, and its prevalence is expected to increase as aresult of urbanization, lifestyle changes, stress, and aging. Effective management of hypertension is essential to prevent long term organ damage and reduce the risk of severe clinical outcomes.[1] Transdermal drug delivery systems (TDDS) have gained significant attention as an innovative and patient- friendly alternative to conventional oral therapy. These systems deliver medication across the skin in a controlled and sustained manner, providing consistent plasma drug levels and improving therapeutic efficacy (as shown in Figure 1). The transdermal route offers several benefits, including bypassing first-pass hepatic metabolism, enhancing bioavailability, reducing gastrointestinal irritation, and improving patient adherence due to reduced dosing frequency and non-invasive administration[1-3].

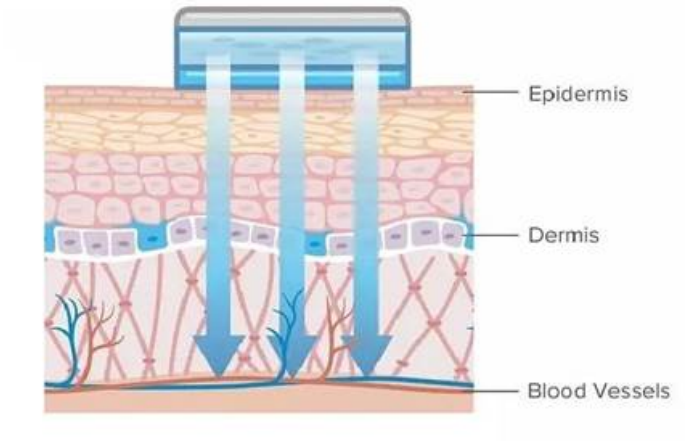


Figure 1.Transdermal Drug Delivery

Recent advances in TDDS incorporate a range of pharmaceutical polymers—such as hydroxypropyl methylcellulose (HPMC), ethyl cellulose, and Eudragit derivatives which help regulate drug release, enhance permeation, and maintain film flexibility. As a result, transdermal technology has emerged as a promising platform for

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achieving sustained antihypertensive therapy while minimizing fluctuations in drug concentration and reducing systemic side effects.[6] Transdermal medicine delivery system, also known as —patches‖ is a lozenge form designed to deliver a therapeutically effective quantum of medicine across a case's skin. TDDS is a effortless system of delivering medicines systemically by applying a medicine expression onto complete and healthy skin. The medicine originally penetrates through the stratum corneum and also passes through the deeper epidermis and dermis without medicine accumulation in the dermal subcaste[1].

Components of a Transdermal Patch

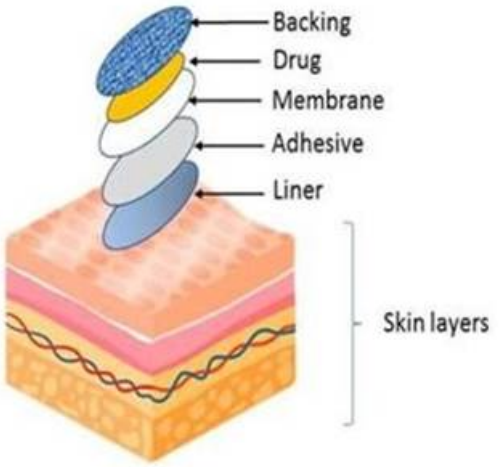


Figure 2.Components of a transdermal patch

1. Drug (Active Agent)

The drug is the core element of any TDDS. Its physicochemical characteristics—such as molecular size, potency, lipophilicity, and stability—determine its suitability for transdermal transport. Ideal candidates usually require small doses and possess adequate solubility in both lipophilic and hydrophilic environments to effectively cross the skin barrier.

2. Polymeric Matrix / Reservoir

Polymers form the structural basis of the patch and either entrap the drug within a matrix or hold it in a reservoir system. They control the diffusion of the drug and provide mechanical stability.

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Ex. Hydroxypropyl methylcellulose (HPMC), Polyvinyl alcohol (PVA), Ethyl cellulose, Eudragit

3. Permeation Enhancer

Permeation enhancers facilitate drug movement through the stratum corneum, which is the primary barrier to transdermal delivery (as shown in fig.1). They function by modifying skin lipids, improving hydration, or altering drug partitioning. Ex. Oleic acid, Isopropyl myristate, Propylene glycol, Ethanol.

4. Adhesive Layer

The adhesive ensures proper attachment of the patch to the skin for the intended duration of therapy. It must maintain adherence without causing discomfort or leaving residue.[3] Ex. Acrylic-based adhesives, Silicone adhesives, Polyisobutylene adhesives

5. Backing Membrane

The backing membrane protects the formulation from environmental effects such as moisture, oxygen, and physical damage. It also prevents the drug from escaping outward. Ex. Polyethylene (PE) films, Polyester films, Polypropylene

6. Release Liner

The release liner covers the adhesive layer until the patch is applied. It must be easily removable and should not react with the drug or adhesive components.[1]
Ex. Silicone-coated papers, Polyethylene terephthalate (PET) films

7. Plasticizers

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Plasticizers are included to improve the elasticity, smoothness, and film-forming ability of the polymer matrix. They also influence drug diffusion. Ex. Polyethylene glycol (PEG), Glycerol, Dibutyl phthalate

8. Solvents and Co-Solvents

Solvents help dissolve polymers and drug components during the formulation process. Some solvents also enhance drug permeation.

Ex. Ethanol, methanol, chloroform, water

Advantages

1. **Bypasses first-pass hepatic metabolism.**
2. **Maintains consistent plasma drug levels for an extended period.**
3. **Reduces dosing frequency.**
4. **Minimizes side effects.**
5. **Enhances patient compliance.**
6. **Allows easy discontinuation of therapy in case of adverse reactions.**

Disadvantages

1. **Drug must have some desirable physico-chemical properties to penetrate through stratum corneum.**
2. **Drugs for daily dose less than 5 mg/day are preferred, If drug dose is more than 10–25 mg/day the TDD will be difficult.**
3. **Local irritation at the site of administration may be caused by drug, adhesive/ other excipients in patch.**
4. **Clinical need must be clearly established.**

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MATERIALS AND METHODS

This review was developed by carefully gathering, evaluating, and interpreting scientific literature related to transdermal drug delivery systems (TDDS) and antihypertensive transdermal patches. Relevant information was sourced from research articles, review papers, clinical studies, and scientific reports available on databases such as Google Scholar, PubMed, ScienceDirect, and other peer-reviewed pharmaceutical journals. Preference was given to publications focusing on the formulation of transdermal patches, polymeric systems, permeation enhancement techniques, evaluation parameters, and therapeutic applications of drugs like clonidine and other antihypertensive agents.Once the literature was collected, the extracted data were organized into major themes, including fundamentals of transdermal drug transport, structural components of patches, formulation procedures (matrix, reservoir, and drug-in-adhesive systems), role of polymers and additives, permeation enhancers, and standard evaluation tests. The selected studies were compared to identify common formulation trends, differences in experimental approaches, and reported outcomes regarding release behavior and clinical effectiveness. Only authentic, peer-reviewed, and scientifically supported publications were considered to ensure accuracy and reliability. The final review integrates these findings to provide a clear and comprehensive overview of the formulation strategies, evaluation techniques, therapeutic potential, and recent innovations in antihypertensive transdermal patch delivery.

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RESULTS

Different Types of Methods of Preparation

1. Solvent Evaporation Method

In this technique, polymers are dissolved in a suitable organic solvent to form a clear solution. The drug, plasticizer, and enhancer are mixed into this polymer solution with continuous stirring until an even mixture is obtained. This prepared solution is carefully poured over a flat plate. As the solvent slowly disappears, a thin film forms on the surface. Once dried, the film is removed and cut into patch-sized pieces.[23]

2. Solvent Casting Method

In this method, the polymer is allowed to swell in the solvent for a long period to ensure proper dissolution. The drug is dissolved separately and then blended with the polymer mixture. To maintain uniformity, the solution is filtered and sonicated to remove all air bubbles. The clear, bubble-free solution is spread over a smooth substrate and left to dry. After solvent loss, a uniform flexible film is obtained, which is then trimmed into patch.[6]

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5. Hot-Melt Method

Both the drug and polymer are melted at an elevated temperature until they combine into a thick liquid. The warm mixture is poured or spread onto a backing surface. As it cools, the mass transforms into a solid flexible film. This dried film is peeled off and cut into patches.

6. Micro reservoir Dispersion Technique

In this approach, the drug is first dissolved in water or an aqueous

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solution. This drug solution is then mixed vigorously with a polymer solution to create tiny drug droplets dispersed throughout the polymer. These microdroplets act as small reservoirs inside the matrix. The final dispersion is cast onto a suitable surface and dried to form a patch containing microscopic pockets of drug.[16]

7. Microneedle-Assisted Patch Preparation

Microneedles are formed using polymers like HPMC, PVA, or PVP by filling them into molds. The drug is loaded either inside the microneedle tips or the supporting layer. These microneedles are then attached to a backing film. When applied, the microneedles create microscopic openings in the skin, allowing the drug to enter more easily without causing pain.[1]

8. Drug-in-Adhesive Method

In this method, the drug is directly mixed with a pressure-sensitive adhesive, such as acrylic or silicone adhesive. The mixture is coated onto a backing layer and allowed to dry. As the solvent evaporates, a single- layer patch is formed where both the drug and adhesive are present together.

This method is popular because it gives strong adhesion and is easy to manufacture.

Table 1.Formulation Parameters and Pharmacokinetics Profile of Antihypertensive Transdermal Patches

Sr. No	Drug Name	Patch Type	Polymer Used	Permeation Enhancer	Pharmacokinetics	Ref.
1	Clonidine (Alpha 2 adrenergic Agonist)	Reservoir and matrix type Patches	Pressure sensitive adhesive	Few enhancer, Design allow steady release	Constant plasma level for 7 days Effective BP control	[16, 24]

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2	Nifedine (Calcium channel blocker)	Matrix Patch	Ethyl cellulose, HPMC	Oleic acid, propylene glycol	Controlled release, improve skin permeation	[17]
3	Propranolol Non selective B blocker	Matrix film, hot melt printed patch	HPMC, PVP, ethyl	Ethanol, propylene glycol	Sustained release over 24 hour, better bioavailability	[20]
4	Captopril ACE inhibitor	Matrix patch	PVP, cellulose ethyl cellulose, Eudragit	Propylene glycol, PEG	Controlled Release	[21]
5	Atenolol B1 blocker	Matrix or reservoir system	HPMC, PVP	DMSO, ethanol	Prolonged drug release	[22]

Mechanism

The mechanism of drug release and absorption from a transdermal drug delivery system involves a series of well defined physicochemical and biological processes. Initially, the drug is released from the polymeric matrix or reservoir of the patch by diffusion. The release rate Is governed by the nature of the polymer, drug-polymer interaction, and

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presence of plasticizers or permeation enhancers.
Once released, the drug penetrates through the outermost layer of the skin, the stratum corneum, which serves as the principal barrier to drug permeation. Drug molecules diffuse through the skin via three primary pathways:

1. Transcellular route – passage directly through the corneocytes.
2. Intercellular route – movement between the lipid domains surrounding skin cell
3. Appendageal route – transport through skin appendages such as hair follicles, sweat glands, and sebaceous glands.

Formulation of Transdermal Patch

The formulation involves selecting appropriate polymers, plasticizers, solvents, and enhancers to ensure effective drug release and adhesion(As shown in Table 1). Hydroxypropyl methylcellulose (HPMC) and ethyl cellulose (EC) are commonly used as film forming polymers, while polyethylene glycol (PEG 400) acts as a plasticizer. Oleic acid or propylene glycol can be added as permeation enhancers. The solvent casting method is widely employed: polymers are dissolved in ethanol–water mixtures, followed by incorporation of the drug and additives. The solution is cast on a glass plate and dried at 40°C to form uniform films, which are then cut and stored in desiccators for evaluation.
Matrix based Clonidine hydrochloride patches were developed using different proportions of EL 100-55 with PVP and EL 100-55 with HPC. The required quantity of polymers (totaling 600 mg) was dissolved in 95% ethanol. Clonidine hydrochloride, equivalent to 1.38% w/w of the polymer weight, was added gradually to this solution with continuous stirring to achieve uniform dispersion. PEG-400 was incorporated as the plasticizing agent.

Evaluation of Transdermal Patches
Evaluation of transdermal patches is a critical component in assessing their physicochemical stability, mechanical integrity, adhesive performance, release characteristics, and overall suitability as drug-delivery systems.
1. Physical Appearance
Patches are examined visually for surface uniformity, color, flexibility,

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transparency, and the absence of air bubbles or crystallization. A smooth and homogenous surface indicates proper polymer–excipient compatibility and uniform film formation [5].

2. Thickness Uniformity

Film thickness is measured at multiple points using a digital micrometer. Consistent thickness ensures uniform diffusional pathways and predictable release characteristics. Variability in thickness has been shown to influence permeation and mechanical behavior of transdermal systems [6,17].

3. Weight Variation

Patches of identical size are individually weighed, and mean values with standard deviation are calculated. Minimal weight variation reflects homogeneous distribution of polymers, plasticizers, and other excipients throughout the film [8].

4. Moisture Content and Moisture Uptake

Moisture content is determined by keeping patches in desiccators containing anhydrous calcium chloride, while moisture uptake is assessed under high humidity conditions (75% RH). These parameters influence film brittleness, flexibility, and adhesive properties. Hydrophilic polymeric films are particularly sensitive to moisture fluctuations [6].

5. Folding Endurance

Folding endurance is determined by repeatedly folding the patch at the same point until a break occurs. High folding endurance values indicate adequate elasticity and mechanical stability, which are essential for patient handling and wearability [11,17].

6. Tensile Strength and Percentage Elongation

Tensile strength is measured using a tensile tester or texture analyzer. The incorporation of plasticizers enhances polymer chain mobility, improving tensile strength and elongation capacity. These properties contribute to patch durability and resistance to tearing [11].

7. Flatness / Dimensional Stability

Flatness is assessed by determining the percentage of shrinkage or expansion after storage. Ideal patches exhibit zero or minimal dimensional change. Polymers such as Eudragit and similar film-formers demonstrate high stability and minimal deformation [11].

8. Adhesion Studies

Adhesive performance is evaluated using tack, peel, and shear adhesion tests. Adequate adhesion is necessary to ensure consistent skin contact

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without causing discomfort. These tests follow standard protocols described in transdermal formulation methodology texts [4,25].

9. Content Uniformity

Patches are dissolved in suitable solvents and analyzed spectrophotometrically to determine uniformity of incorporated components. Uniform content ensures dose consistency and reproducibility across batches [19,22].

10. In-Vitro Release Studies

In-vitro drug-release studies are typically conducted using Franz diffusion cells or the paddle-over-disk method. The receptor medium commonly consists of phosphate buffer (pH 7.4) maintained at 32 ± 0.5°C. Release kinetics reported in TDDS literature frequently conform to diffusion-controlled models such as Higuchi [5–7,17].

11. In-Vitro Skin Permeation Studies

Excised animal skin (rat, mouse, or porcine) is used to assess permeation behavior. Permeation enhancers such as oleic acid, propylene glycol, or DMSO increase flux by modifying lipid packing in the stratum corneum. Classical studies have demonstrated significant enhancement of permeation through such lipid-modifying mechanisms [16,17].

12. Skin Irritation Studies

Dermal irritation is evaluated in rabbits or rodents under OECD guidelines. Parameters such as erythema, edema, and overall skin tolerance are recorded. Patches prepared with biocompatible polymers and mild enhancers generally show negligible irritation [5,22].

13. Stability Studies

Stability testing is conducted at 25°C/60% RH and 40°C/75% RH according to ICH guidelines. Evaluated parameters include physical appearance, adhesive strength, content uniformity, and release profile. Stable formulations exhibit minimal change under both accelerated and long-term conditions [21,22].

14. In-Vivo Pharmacokinetic and Pharmacodynamic Evaluation

In-vivo studies assess systemic absorption, maintenance of therapeutic plasma levels, and sustained pharmacological effect. Transdermal systems often provide steady-state delivery, reduced peak–trough fluctuations, and avoidance of first-pass metabolism, contributing to improved therapeutic consistency [5,16].

Clinical Efficacity and Safety

Clinical trials have verified that transdermal systems produce significant

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reductions in both systolic and diastolic blood pressure similar to oral remedy. The transdermal route also provides reduced threat of answer hypertension upon termination due to the gradational decline in tube attention after patch junking. Lower prevalence of side goods similar as dry mouth and doziness, along with advanced case adherence, particularly among senior or cognitively disabled cases. [5,7]

Recent Advances and unborn Prospects

Ultramodern developments in TDDS focus on enhancing skin saturation and case comfort. Approaches include nano- carrier systems (liposomes, niosomes, ethosomes), microneedle supported delivery, iontophoresis, and bio responsive smart polymers. Unborn systems may integrate biosensors and 3D printing to allow substantiated, real- time controlled medicine release. [10,13,15]

Challenges and Limitations

Despite their advantages, transdermal patches face challenges including implicit skin vexation, limited medicine lading capacity, and the need for precise control of tenacious parcels. Environmental factors similar as moisture and temperature can affect film integrity and medicine release. Also, nonsupervisory blessing requires expansive stability and bioequivalence testing before clinical restatement. [3,4]

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DISCUSSION

Formulating effective antihypertensive transdermal patches requires selecting suitable polymers, plasticizers, adhesives, and permeation enhancers to achieve uniform films, sustained release, and adequate skin permeation. Polymers such as HPMC, PVP, and Eudragit provide mechanical strength and controlled diffusion, while plasticizers like PEG 400 improve flexibility(as shown in Table 1). Permeation enhancers—including oleic acid, propylene glycol, and DMSO—facilitate drug transport through the stratum corneum and enhance absorption of drugs such as clonidine, atenolol, and nifedipine.

Along with formulation, evaluation plays a critical role in determining the quality and performance of the patches. Parameters such as thickness uniformity, weight variation, tensile strength, folding endurance, and moisture content confirm the physical and mechanical reliability of the films. Adhesion studies ensure adequate skin contact, while content uniformity, in-vitro release, and permeation tests provide insight into drug-delivery efficiency and therapeutic consistency. Stability studies confirm the durability of the formulation under storage conditions.

Collectively, findings from formulation and evaluation studies indicate that antihypertensive drugs with favorable physicochemical properties—especially clonidine—are suitable for transdermal delivery. Emerging technologies like microneedle-assisted systems and nanocarrier-based films continue to improve both formulation performance and evaluation outcomes, offering more controlled and efficient drug delivery.

CONCLUSION

Transdermal patches are a promising alternative to oral antihypertensive therapy due to their ability to deliver drugs steadily, improve bioavailability, and enhance patient compliance. Effective systems depend on optimized formulation using appropriate polymers, enhancers, and fabrication methods, together with comprehensive evaluation to ensure stability, adhesion, uniformity, and efficient drug release. Continued advancements in materials and delivery technologies are expected to further strengthen the therapeutic potential and clinical acceptance of antihypertensive transdermal patches.

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ABBREVIATIONS

ACE - Angiotensin-Converting Enzyme

BP - Blood Pressure

DMSO - Dimethyl Sulfoxide

EC - Ethyl Cellulose

HCl - Hydrochloride

HPMC - Hydroxypropyl Methylcellulose

HPC - Hydroxypropyl Cellulose

ICH - International Council for Harmonisation

OECD - Organisation for Economic Co-operation and Development

PEG - Polyethylene Glycol

PEG 400 - Polyethylene Glycol 400

PE - Polyethylene

PET - Polyethylene Terephthalate

PVA - Polyvinyl Alcohol

PVP - Polyvinylpyrrolidone

RH - Relative Humidity

TDDS - Transdermal Drug Delivery System

WHO - World Health Organization

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CONFLICT OF INTERESTS

The author has declared no conflict of interest.

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