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FORMULATION AND EVALUATION OF A TRANSDERMAL PATCH CONTAINING HERBAL AGENT: A REVIEW

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Keywords:

Transdermal Drug Delivery System (TDDS), Herbal transdermal patch, Ehretialaevis, KhanduChakka Powder, Wound healing

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ABSTRACT

Transdermal drug delivery systems (TDDS) represent a novel and non-invasive approach to administering therapeutic agents systemically through intact skin. Unlike conventional dosage forms such as oral tablets or injections, TDDS bypass the gastrointestinal tract and hepatic first-pass metabolism, thus improving the bioavailability of drugs. Additionally, these systems offer controlled and sustained drug release, which contributes to maintaining steady plasma drug concentrations over extended periods. This leads to improved therapeutic efficacy and reduced dosing frequency, ultimately enhancing patient compliance and comfort. In recent years, there has been a growing interest in the use of herbal agents in TDDS due to their broad spectrum of pharmacological activities, lower toxicity profiles, and holistic approach to healing. Herbal drugs are rich in phytochemicals like flavonoids, alkaloids, tannins, and terpenoids, which possess antioxidant, anti-inflammatory, antimicrobial, and wound-healing properties. Incorporating such bioactives into transdermal systems provides a unique opportunity to deliver them directly to affected tissues or into systemic circulation in a controlled and efficient manner. This review highlights the fundamental principles of TDDS, including mechanisms of skin permeation, selection of polymers and permeation enhancers, and various evaluation techniques to ensure patch performance. TDDS could pave the way for innovative, plant-based therapeutic strategies in modern wound care management.

Introduction

The transdermal route has increasingly gained attention as a non-invasive, patient-friendly, and effective alternative for delivering therapeutic agents directly into systemic circulation. Compared to traditional oral or parenteral drug administration, transdermal drug delivery systems (TDDS) offer numerous advantages, including bypassing the hepatic first-pass metabolism, minimizing gastrointestinal degradation, and providing a controlled and sustained drug release over extended periods. This not only helps maintain steady plasma drug concentrations but also reduces dosing frequency, enhances therapeutic efficacy, and improves overall patient compliance. Additionally, the transdermal route reduces the likelihood of systemic side effects and improves the safety profile of many drugs. [1-2]

In parallel, the resurgence of interest in herbal medicine has led researchers to explore novel ways of delivering plant-based therapeutics using advanced delivery platforms such as TDDS. Herbal agents, derived from medicinal plants, are rich in bioactive compounds such as flavonoids, alkaloids, tannins, saponins, and essential oils, many of which possess potent antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties. These pharmacological activities make herbal substances particularly attractive for treating skin disorders, wounds, and even systemic conditions when delivered transdermally. Moreover, the natural origin, biocompatibility, and lower toxicity of herbal agents further support their integration into modern delivery systems. [3-4]

The synergy between traditional herbal knowledge and modern pharmaceutical technology, such as TDDS, opens new frontiers for safe, effective, and patient-friendly treatment strategies. Harnessing the full potential of herbal agents in transdermal systems could revolutionize the way both acute and chronic conditions are managed in the future. [5]

Transdermal Drug Delivery System (TDDS): Overview

A transdermal patch is a medicated adhesive device designed to be applied to the surface of the skin, allowing for the controlled and sustained release of therapeutic agents into systemic circulation over an extended period. This innovative dosage form represents a significant advancement in drug delivery technology, particularly for chronic and long-term treatment regimens. The patch system is composed of a backing layer, a drug-containing matrix or reservoir, a rate-controlling membrane (in some designs), and an adhesive layer that ensures close contact with the skin. [6-7]

One of the most significant advantages of transdermal drug delivery systems (TDDS) is the avoidance of first-pass hepatic metabolism, which can degrade many drugs when administered orally, thus improving the bioavailability of active compounds. Additionally, TDDS enhances patient

compliance by offering a painless, non-invasive route that reduces the need for multiple daily doses or injectable therapies. The delivery system is particularly beneficial for drugs that require steady plasma concentrations, as it provides a consistent therapeutic level, avoiding peaks and troughs commonly associated with conventional dosing.The drug permeates the skin primarily via passive diffusion, passing through the stratum corneum and entering the dermal capillary network. From there, it reaches the systemic circulation and is transported to its target site. The rate of drug release is regulated by the formulation matrix and the design of the patch, allowing for customized delivery profiles tailored to the pharmacokinetic needs of different drugs. TDDS is especially suitable for potent drugs with narrow therapeutic windows, where precise dosing is crucial. [8-9]

Herbal Agents in TDDS

Herbal compounds have long been employed in traditional medicine systems across the globe in various formulations such as pastes, oils, poultices, and decoctions, especially for the treatment of wounds, burns, and dermatological conditions. Their natural origin, broad pharmacological spectrum, and generally low toxicity make them attractive candidates for incorporation into modern drug delivery systems. The integration of herbal agents into transdermal drug delivery systems (TDDS) represents a significant advancement, enabling more targeted, controlled, and effective delivery of phytoconstituents. This fusion of traditional knowledge with contemporary pharmaceutical technology opens new avenues for enhancing the therapeutic efficacy of herbal remedies. [10-11]

Among promising herbal candidates, Ehretialaevis, a plant from the Boraginaceae family, has garnered attention for its potent anti-inflammatory, antimicrobial, and wound-healing properties. It is traditionally used in Indian medicine for treating skin infections, cuts, and wounds. The plant contains a rich profile of bioactive compounds, including flavonoids, phenolic compounds, and triterpenoids, which are known to promote fibroblast proliferation, epithelial regeneration, and collagen synthesis—all essential phases of wound healing. Extracts of Ehretialaevis, particularly in aqueous or hydro-alcoholic form, can be effectively incorporated into polymeric transdermal patches for enhanced delivery and prolonged therapeutic action. [12-13]

Another noteworthy agent is KhanduChakka Powder, a traditional, indigenous remedy used in Ayurvedic and tribal medicine. Though lesser-known in scientific literature, it is reputed for its antiseptic, drying, and skin-regenerating properties. Despite anecdotal efficacy, KhanduChakka Powder still requires systematic pharmacognostical and pharmacological validation. Incorporating it into TDDS platforms offers a novel approach for delivering its active constituents in a sterile, sustained, and targeted manner—potentially transforming it into a

standardized phytopharmaceutical for wound care (Figure 1). [14-15]

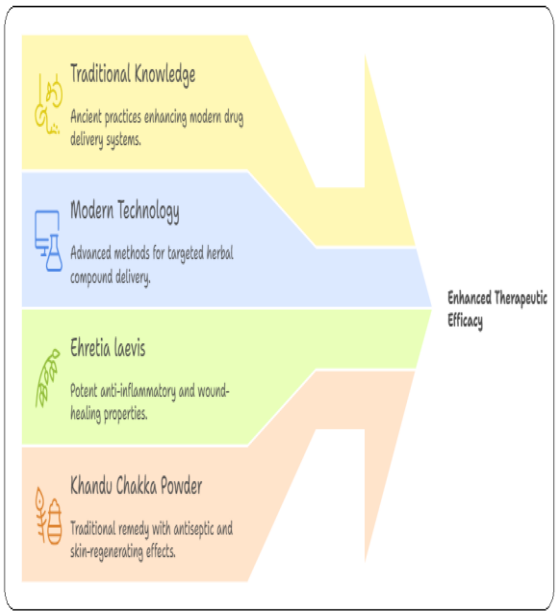

Figure 1: Fusion of Tradition & Innovation

Methods of Formulation of Herbal TDDS

The solvent casting method is the most widely used and effective technique for preparing transdermal patches, particularly those incorporating herbal extracts. This method allows for uniform dispersion of active ingredients within a polymeric matrix, ensuring controlled and sustained drug release through the skin (Table 1). [16]

Steps involved in this method are as follows:

Polymer Dissolution: Appropriate film-forming polymers such as hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP), or ethyl cellulose (EC) are selected based on their mechanical strength, compatibility with the drug, and desired release profile. These polymers are dissolved in suitable solvents like ethanol, water, or a hydroalcoholic mixture to form a clear, uniform solution.

Incorporation of Herbal Extract and Plasticizer: The selected herbal extract (e.g., Ehretialaevis or KhanduChakka Powder extract) is accurately weighed and incorporated into the polymer solution under continuous stirring to ensure homogeneity. Plasticizers such as polyethylene glycol 400 (PEG 400), propylene glycol, or glycerin are added to impart flexibility, elasticity, and smoothness to the final film.

Casting: The resulting homogeneous mixture is poured onto a flat, level surface such as a petri dish or glass plate. It is then spread evenly using a suitable casting knife or applicator to achieve a uniform thickness.

Drying: The cast solution is dried at controlled temperatures (typically 40–50°C) in a hot air oven or desiccator to evaporate the solvent completely and form a dry film.

Cutting and Storage: After drying, the film is carefully peeled off and cut into patches of desired dimensions. These patches are stored in air-tight, moisture-resistant containers to prevent degradation or loss of integrity.

This method is simple, cost-effective, and scalable for both laboratory and industrial settings, making it ideal for herbal transdermal patch formulation. [17-19]

Table 1: Steps Involved in the Solvent Casting Method for Herbal Transdermal Patch Formulation

Step	Description
Polymer Dissolution	Selection and dissolution of suitable film-forming polymers (e.g., HPMC, PVP, EC) in solvents like ethanol, water, or hydroalcoholic mixture.
Herbal Extract Addition	Accurate weighing and incorporation of herbal extract (e.g., *Ehretialaevis*, *KhanduChakka Powder*) into polymer solution with continuous stirring.
Addition of Plasticizer	Addition of plasticizers (e.g., PEG 400, propylene glycol, glycerin) to enhance flexibility, elasticity, and smooth texture of the patch.
Casting	Pouring of the homogeneous mixture onto a flat surface (e.g., petri dish/glass plate) and spreading uniformly using a casting knife or applicator.
Drying	Drying at controlled temperature (typically 40–50°C) to evaporate the solvent and form a stable, dry film.
Cutting	Peeling and cutting the dried film into patches of uniform size and shape.
Storage	Storing the patches in airtight, moisture-resistant containers to maintain integrity and prevent degradation.

Evaluation of Transdermal Patches

To ensure quality, stability, and therapeutic efficacy, patches must undergo rigorous evaluation (Table 2).

Table 2: Evaluation parameters for transdermal patches

Parameter	Test/Method
Physical appearance	Visual inspection for uniformity, transparency
Thickness	Micrometer screw gauge
Weight uniformity	Analytical balance
Folding endurance	Repeated folding until breakage
Moisture content	Desiccation method
Water vapor transmission rate	WVTR studies using desiccators
Drug content uniformity	Extraction followed by UV/HPLC analysis
In vitro release	Franz diffusion cell using synthetic/natural membranes
Skin irritation	Patch test on human volunteers or animal models (ethical approval needed)

To ensure the quality, performance, and safety of transdermal patches, several physicochemical and biological evaluation parameters must be assessed systematically. The physical appearance of the patches is examined visually to ensure uniformity in color, smoothness, flexibility, and absence of surface defects such as air bubbles or cracks, which could affect the

efficacy and patient acceptability of the dosage form. The thickness of the patch is measured using a micrometer screw gauge at different points, as uniform thickness is critical to maintain consistent drug loading and controlled release. [20-21]

Weight uniformity is evaluated by individually weighing multiple patches using an analytical balance. This test ensures dosage consistency and confirms that each patch contains the correct amount of drug and excipients. The folding endurance test determines the mechanical strength and flexibility of the patch by repeatedly folding it at the same point until it breaks. A high folding endurance value reflects good flexibility and resistance to mechanical stress during application or wear.

The moisture content of the patch is measured using the desiccation method, which involves drying the patch and calculating the loss of weight due to moisture evaporation. This is essential to prevent microbial growth and to maintain formulation stability. Additionally, the water vapor transmission rate (WVTR) is determined by placing the patch over a desiccator and measuring the rate of moisture absorption. This helps evaluate the patch's permeability and its ability to maintain a moist wound environment—an important consideration in wound healing.

To confirm the uniform distribution of the drug, the drug content uniformity test is performed by extracting the drug from a known area of the patch using suitable solvents and quantifying it through UV-Visible spectrophotometry or high-performance liquid chromatography (HPLC). The in vitro drug release study is conducted using a Franz diffusion cell, where the patch is placed on a membrane (synthetic or natural), and the drug permeation into the receptor compartment is measured over time. This simulates how the drug will diffuse through the skin and allows for the calculation of release kinetics.

Lastly, the skin irritation test is carried out by applying the patch to the skin of human volunteers or animal models, observing the area for signs of erythema, itching, or edema. This test is crucial for ensuring the biocompatibility and safety of the patch, especially when using herbal extracts that may contain multiple active components. All tests involving human or animal models must be conducted following ethical guidelines and require prior institutional approval.

Together, these evaluation parameters form a comprehensive quality assessment framework, helping ensure the transdermal patch is safe, effective, and suitable for clinical or commercial use. [22-24]

Role of TDDS in Wound Healing

The use of transdermal drug delivery systems (TDDS) for wound healing offers several distinct advantages, particularly when combined with herbal bioactives (Figure 2). One of the primary benefits of TDDS is the controlled and sustained release of herbal actives, which ensures prolonged contact of the therapeutic agent with

the wound site. This extended exposure enhances the local therapeutic action, leading to faster and more effective healing. Additionally, transdermal patches act as physical barriers, protecting the wound from microbial invasion and reducing the risk of secondary infections. [25-26]

Moreover, these systems help maintain a moist environment, which is widely recognized as conducive to optimal wound healing, as it facilitates cellular migration, angiogenesis, and the removal of necrotic tissue. The incorporation of anti-inflammatory herbal agents further aids in reducing local inflammation, swelling, and pain, while also promoting tissue regeneration through stimulation of fibroblast proliferation and collagen synthesis.Another important advantage of using herbal TDDS is the avoidance of systemic side effects, as the localized delivery minimizes systemic absorption and toxicity. This also reduces the need for frequent applications or oral medications, improving patient compliance. Herbal agents like Ehretialaevis, known for their antimicrobial and wound-healing properties, when delivered through transdermal systems, offer a promising and targeted approach to wound management, significantly enhancing therapeutic outcomes in a natural and patient-friendly manner. [27-28]

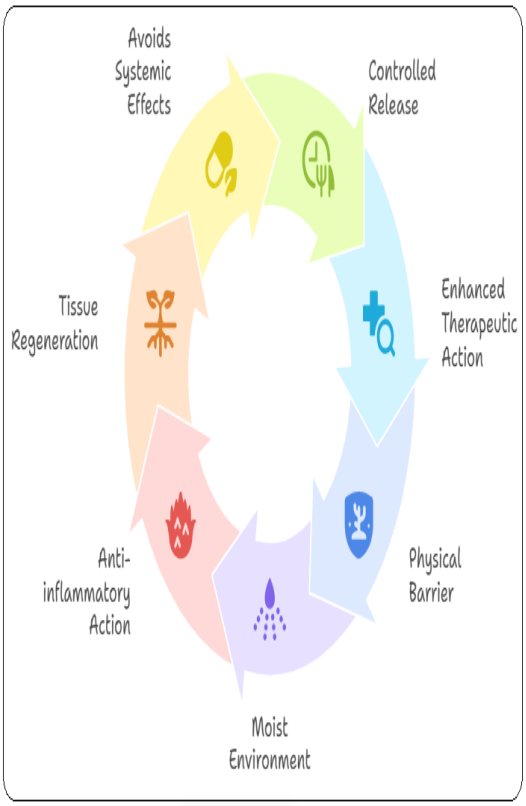

Figure 2: Cycle of Herbal TDDS in Wound Healing

Novel Perspectives and Challenges

The development of herbal-based transdermal drug delivery systems (TDDS) represents a highly innovative and interdisciplinary advancement in pharmaceutical sciences. The utilization of underexplored herbal agents, such as KhanduChakka Powder, offers a novel direction for pharmacognostic research. Traditionally used in local and tribal medicine for wound healing and skin ailments, this formulation holds untapped therapeutic potential that merits detailed scientific investigation. Exploring such lesser-known botanicals can lead to the discovery of new bioactive compounds with significant

pharmacological value. When combined with modern TDDS technology, these traditional remedies can be transformed into standardized, effective, and user-friendly dosage forms. This convergence of ethnomedicinal knowledge and pharmaceutical innovation exemplifies a unique and holistic approach to drug development, particularly relevant in the context of plant-based and personalized medicine. [29-31]

Despite its promise, the development of herbal transdermal systems also presents several technical and regulatory challenges. One of the foremost issues is the standardization of herbal extracts, as variations in plant sources, harvesting methods, and extraction procedures can affect consistency and efficacy. Furthermore, enhancing skin permeation for large molecular weight phytoconstituents remains a significant barrier, often requiring the use of penetration enhancers or nanoformulation strategies. Stability concerns, such as moisture sensitivity and microbial contamination, must also be addressed through appropriate formulation techniques and packaging solutions. Lastly, for clinical translation, these systems must undergo rigorous safety and efficacy evaluations, followed by regulatory approvals and clinical trials. Meeting these challenges will be crucial in establishing herbal TDDS as reliable, scientifically validated therapeutic alternatives in mainstream healthcare. [32-34]

Innovation Potential, Challenges, and Patent Status

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In terms of current patent status, there has been growing interest in protecting intellectual property around herbal-based transdermal patches. Numerous patents have been filed and granted for transdermal systems incorporating well-known herbs such as Aloe vera, Curcuma longa, Neem, and Centellaasiatica. However, novel combinations, such as those involving underutilized agents like Ehretialaevis or KhanduChakka Powder, are largely unexplored and remain open for intellectual property claims. This offers significant opportunity for researchers and institutions to file process, composition, or method-of-use patents based on innovative herbal TDDS formulations. A successful patent application would require scientific data supporting novelty, therapeutic advantage, and formulation stability. As the global demand for plant-based therapeutics continues to rise, securing patent rights in this domain could enhance commercial value, research funding prospects, and market competitiveness. [39-40]

Conclusion

The integration of herbal agents into transdermal drug delivery systems (TDDS) represents a forward-looking approach in the development of modern therapeutics, particularly in the areas of wound healing and systemic disease management. Herbal medicines have been utilized for centuries in traditional healing practices and are known for their wide range of pharmacological actions, including anti-inflammatory, antimicrobial, antioxidant, and tissue-regenerating properties. When delivered through the transdermal route, these bioactive compounds can exert their therapeutic effects in a controlled and sustained manner, directly at the site of action or systemically, without undergoing degradation in the gastrointestinal tract or liver.

Plants such as Ehretialaevis have demonstrated significant wound-healing potential owing to the presence of phytoconstituents like flavonoids, saponins, and phenolic compounds that promote cellular regeneration and reduce inflammation. Likewise, traditional herbal remedies like KhanduChakka Powder, though lesser-known in modern pharmacology, are rooted in ethnomedicinal practices and show great promise for cutaneous applications.

However, despite their potential, herbal-based TDDS formulations face several challenges that must be addressed to ensure their successful translation from lab to clinic. These include the need for comprehensive pharmacological evaluation to confirm efficacy, standardization

of herbal extracts to ensure consistency, development of stable formulations, and rigorous clinical validation to establish safety and therapeutic outcomes in humans. Bridging traditional knowledge with modern pharmaceutical technology through standardized TDDS platforms could pave the way for safe, effective, and accessible plant-based therapies in contemporary medicine.

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