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DEVELOPMENT OF HERBAL TRANSDERMAL PATCH USING OCIMUM TENUIFLORUM (TULSI) LEAF EXTRACT

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Abstract:

This study focuses on the formulation and evaluation of a herbal transdermal patch using Ocimum tenuiflorum (Tulsi) leaf extract, a plant well known for its medicinal, pharmacological, and therapeutic properties. Tulsi has been widely used in traditional systems of medicine, such as Ayurveda, for its antimicrobial, anti-inflammatory, antioxidant, and adaptogenic activities. The objective of this research was to develop a transdermal drug delivery system (TDDS) incorporating Tulsi extract to provide controlled and sustained release of its active constituents through the skin. The ethanolic extract of Tulsi leaves was prepared by the Soxhlet extraction method and subjected to phytochemical screening, which confirmed the presence of bioactive compounds such as glycosides, tannins, steroids, and polyphenols. The transdermal patches were formulated with hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP) as polymers, polyethene glycol (PEG) as a plasticiser, and prepared by solvent evaporation. The prepared patches were evaluated for physicochemical parameters including appearance, thickness, moisture content, folding endurance, and weight uniformity. The patches were found to be smooth, flexible, and uniform, with an average thickness of 0.523 mm, moisture content of 3.54%, folding endurance of 85, and average weight of 0.412 g. These findings indicate that the formulated patches possess satisfactory mechanical and physical properties and support the feasibility of Tulsi extract as an active ingredient in transdermal drug delivery.

Keywords: *Ocimum tenuiflorum; Transdermal drug delivery system; Herbal transdermal patch; Phytochemical screening; Controlled drug release.*

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1. INTRODUCTION:

Tulsi (Ocimum tenuiflorum), commonly known as Holy Basil, is a highly revered plant in India, both culturally and medicinally. It belongs to the family Lamiaceae and is a small, aromatic shrub that typically grows up to one meter in height, with green or purple leaves depending on the variety, and small purple or white flowers.[1] The plant thrives in warm climates and requires moderate sunlight and well-drained soil; its strong fragrance and slightly spicy taste make it unique among herbs.[2]

Tulsi occupies a central place in traditional medicine, particularly in Ayurveda and Unani systems of holistic health, and is mentioned in the Charaka Samhita.[3] It is considered an adaptogen that helps the body adapt to stress, and because of its strong aroma and astringent taste it is regarded in Ayurveda as an 'elixir of life' believed to promote longevity.[4] Its leaves are rich in essential oils and compounds such as eugenol, which possess anti-inflammatory, antibacterial, and antioxidant properties, and it is commonly used to treat cough, cold, fever, and respiratory disorders, while also being credited with boosting immunity and reducing stress. The plant also contributes to environmental sustainability by purifying air and repelling insects naturally.[5,6]

Historically, Tulsi has been used therapeutically since 400-500 BC, with the earliest references found in the Rigveda (3500-1600 BC). It has been used in the management of cancer, oxidative stress, diabetes, infertility, and radiation exposure, as well as common cold, heart disease, stomach disorders, poisoning, convulsions, epilepsy, malaria, fever, bronchitis, and inflammatory conditions, and is accordingly also referred to as the "Extract of Life."[7]

1.1 Plant Profile

Belonging to the family Lamiaceae, *Ocimum tenuiflorum* L. is a fragrant herbaceous plant that grows up to approximately 18 inches in height and forms a small bush-like structure. It is commonly referred to as holy basil.

1.2 Varieties of Tulsi

Several varieties of Tulsi are recognized in Ayurveda, differing in appearance, taste, aroma, and medicinal use:

- Rama Tulsi (Green Tulsi): The most common variety, with bright green leaves and a mild, slightly sweet taste; widely used in herbal teas and home remedies for digestion, immunity, cough, and cold.[8]
- Krishna Tulsi (Shyama Tulsi): Dark purple or violet leaves with a stronger, more pungent flavour; considered more potent and used for respiratory problems, infections, and skin diseases owing to its antibacterial activity.
- Vana Tulsi (Wild Forest Tulsi): Grows naturally in forests, with light green leaves and a strong aroma; used to enhance stamina, immunity, and overall wellness.[9]
- Kapoor Tulsi: Known for fast growth and strong fragrance; mainly grown as an ornamental, insect-repellent, air-purifying plant, with additional medicinal use.[10]
- Amrita Tulsi: A hybrid variety of high medicinal value, combining benefits of other Tulsi types for immunity, stress reduction, and general health.
- Trittavu Tulsi: A variety common in South India, similar to Krishna Tulsi with minor differences in leaf shape and aroma, used in traditional remedies.[11]

1.3 Traditional Uses and Medicinal Properties

Different parts of the Tulsi plant are used in Ayurveda and Siddha medicine for the prevention and treatment of common ailments such as cold, headache, cough, flu, earache, fever, colic pain, sore throat, bronchitis, asthma, hepatic disorders, malaria, snake bite and scorpion sting, flatulence, migraine, fatigue, skin disease, wounds, insomnia, arthritis, digestive disorders, night blindness, diarrhoea, and influenza. Its leaves are believed to benefit nerve function and memory, and chewing the leaves is traditionally used to treat mouth ulcers and infections.[12]

Reported medicinal properties include:

- Antimicrobial activity against skin, throat, and respiratory infections.
- Antiviral activity useful in managing cold and flu.
- Anti-inflammatory activity beneficial in arthritis and related disorders.
- Antioxidant activity that protects the body from free-radical damage.
- Immunostimulant activity that helps the body resist infection and disease.
- Adaptogenic activity that helps the body cope with stress and anxiety.[13]
- Antidiabetic activity through regulation of blood glucose levels.
- Mucolytic/expectorant activity useful in cough, bronchitis, and asthma.
- Cardioprotective activity through lowering of cholesterol and improved circulation.[14]

1.4 Pharmacological Properties of Ocimum tenuiflorum

Activity	Mechanism / Effect
Antimicrobial activity	Tulsi exhibits broad-spectrum antimicrobial activity against bacteria, fungi, and viruses. Eugenol and other essential oils disrupt microbial membranes and inhibit biofilm formation. These properties support its use in oral-care products and topical antiseptic formulations.[15]
Anti-inflammatory activity	Suppresses pro-inflammatory mediators (prostaglandins, leukotrienes, TNF-α, interleukins) and inhibits COX-2/LOX pathways, similar to NSAIDs; ursolic acid contributes to reduced tissue inflammation.
Antioxidant activity	Phenolic compounds and flavonoids neutralize free radicals and enhance endogenous antioxidant enzymes (SOD, catalase, glutathione peroxidase), protecting against cellular ageing and degenerative disease.
Adaptogenic (anti-stress) activity	Regulates the hypothalamic-pituitary-adrenal (HPA) axis, reduces cortisol, and balances dopamine and serotonin, potentially improving cognitive function and reducing anxiety.
Immunomodulatory activity	Increases activity of T-helper cells, NK cells, and macrophages, enhances antibody production, and helps control excessive immune responses.[16]
Antidiabetic activity	Enhances insulin secretion and sensitivity, reduces hepatic glucose production, and lowers oxidative stress linked to diabetic complications.
Cardioprotective activity	Lowers LDL and triglycerides while raising HDL, prevents lipid oxidation, and improves endothelial function and blood pressure.
Hepatoprotective activity	Enhances detoxifying enzymes (cytochrome P450, glutathione-S-transferase) and reduces hepatic lipid peroxidation, supporting liver regeneration.
Anticancer activity	Induces apoptosis in abnormal cells, inhibits angiogenesis, and prevents carcinogen-induced DNA damage; ursolic and rosmarinic acid suppress tumour growth and metastasis.
Analgesic activity	Inhibits prostaglandin-mediated pain signalling both peripherally and centrally; useful in headache, muscle, and joint pain.
Antipyretic activity	Acts on the hypothalamus to regulate body temperature and reduces pyrogen production.
Respiratory protective activity	Acts as a bronchodilator and expectorant, and its antimicrobial/anti-inflammatory action helps in asthma, bronchitis, sinusitis, and chronic cough.

1.5 Phytochemicals in Ocimum tenuiflorum

Plant part	Phytochemicals present
Leaf	Flavonoids, alkaloids, saponins, tannins, phenols, anthocyanins, terpenoids, steroids
Stem	Phenols, saponins, flavonoids, triterpenoids, tannins
Whole plant	Flavonoids, alkaloids, saponins, tannins, phenols, anthocyanins, triterpenoids

1.6 Transdermal Drug Delivery Systems

Transdermal patches are drug-containing adhesive preparations designed to transport a predetermined amount of medication through the skin and into the bloodstream. TDDS are pharmaceutical formulations developed to administer medications across the skin barrier, enabling systemic drug absorption.[17] The FDA first approved a transdermal patch product in 1981, and current systems on the market deliver drugs such as nicotine (smoking cessation), fentanyl (chronic pain), clonidine and nitro-glycerine (cardiovascular disease), and scopolamine (motion sickness). Various permeation enhancers can be incorporated to achieve a predictable drug absorption profile, and different designs - vapour patches, membrane-moderated systems, matrix (drug-in-adhesive) systems, and single- or multi-layer drug-in-adhesive systems - use different mechanisms to regulate the rate of drug release.[18]

1.6.1 Advantages of Transdermal Drug Delivery

- Avoids gastrointestinal absorption problems associated with the drug.
- Improves patient compliance and convenience.
- Allows rapid termination of therapy in case of toxicity, as the patch can simply be removed.
- Enables self-medication.
- Reduces dosing frequency and maintains therapeutic levels for 1-7 days, offering a long duration of action.
- Provides a constant plasma drug level, similar to an intravenous infusion.
- Serves as an alternative to oral delivery for patients who have difficulty taking medication orally.[19,20]

1.6.2 Drug Absorption Mechanism of Transdermal Patches

Transdermal patches provide controlled drug release, allowing the medication to diffuse through the stratum corneum and enter systemic circulation primarily via passive diffusion. [21] The drug then diffuses through the deeper epidermis and dermis, enters the dermal blood capillaries, and is distributed throughout the body via systemic circulation to exert its therapeutic effect.[22]

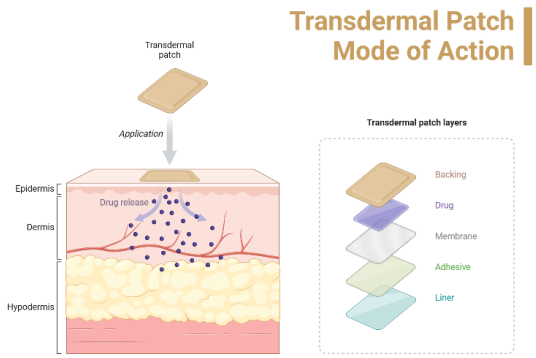


Figure1: Drug Absorption Mechanism of Transdermal Patches

1.6.3 Main Components of a Transdermal Patch

- Liner - protects the patch during storage and is removed prior to use.
- Adhesive - holds the patch layers together and adheres the patch to the skin.
- Membrane - controls drug release from multi-layer patches; also acts as a permeation enhancer.
- Drug reservoir maintained in close contact with the release liner
- Backing layer - protects the patch from the external environment.[23]

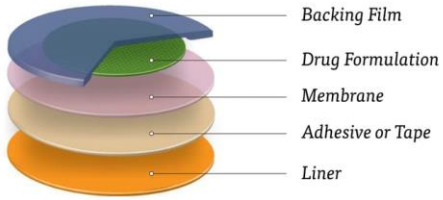


Figure2: Components used in Transdermal Patch

1.6.4 Types of Transdermal Patches

a) Single-layer patches: The drug is mixed directly into the adhesive layer, which both attaches the patch to the skin and releases the drug through the epidermis. The patch is covered by a backing layer on one side and a release liner on the other.

b) Multi-layer patches: Multi-layer patches incorporate both rapid- and controlled-release drug layers. The rate of drug release is regulated by membrane permeability and diffusion processes.[23]

c) Reservoir-type patches: The drug is held as a liquid or gel in a separate reservoir compartment between the backing layer and a rate-controlling membrane; the drug diffuses from the reservoir through the membrane and adhesive layer into the skin.[24]

d) Matrix-type patches: The drug is uniformly dispersed within a solid or semi-solid polymer matrix that forms the body of the patch; there is no separate reservoir or controlling membrane, making these patches simpler, thinner, and less prone to leakage.

e) Vapour patches: A newer patch type in which the adhesive layer also releases vapour, commonly essential oils, for up to 6 hours; used for decongestion, improving sleep quality, and reducing cigarette craving.

2. METHODOLOGICAL APPROACH:

2.1 Collection of Plant Material

Mature Tulsi leaves were gathered from the campus premises, thoroughly cleaned, and dried under shade conditions. The dried leaves were subsequently pulverised into a fine powder for further extraction studies.[25]

2.2 Materials Used in Patch Formulation

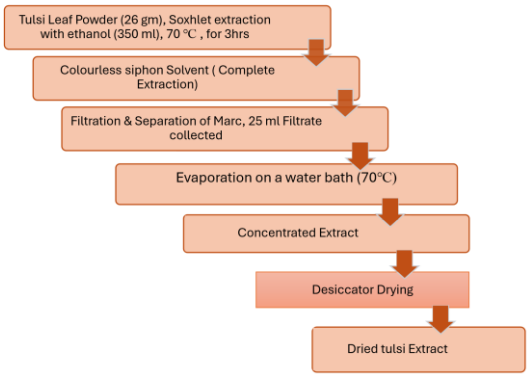
Tulsi extract served as the active ingredient; all additional components used were formulation excipients, as listed in Table 2.

Table 2: Ingredients used in the formulation of the herbal transdermal patch

Ingredient	Function
Plant extract (Tulsi)	Active ingredient (antioxidant, anti-inflammatory, antifungal properties)
HPMC	Matrix-forming polymer that retains the active ingredient and excipients within the patch
Polyvinylpyrrolidone (PVP)	Solubilizer and adhesive
Ethanol	Solvent, preservative, and penetration enhancer
Methyl cellulose	Stabilizer and thickening agent
Polyethene glycol (PEG)	Plasticizer

HPMC was chosen for its excellent film-forming ability, biocompatibility, and controlled-release behaviour; upon hydration, it swells into a gel-like matrix whose viscosity grade governs the rate of drug diffusion, and it additionally imparts flexibility, tensile strength, and stability to the patch.[26] PVP was included for its film-forming, drug-release-regulating, and penetration-enhancing properties, and for its stabilising action in the casting solution; it is biocompatible, non-toxic, and FDA-recognized as safe. PEG (as PEG 400) was used as a plasticizer to improve the flexibility and mechanical properties of the film and to act as a permeation enhancer, while also being water-soluble, biocompatible, and FDA-approved.[27]

2.3 Extraction Method (Soxhlet Extraction)



2.4 Phytochemical Screening

The ethanolic extract of Tulsi was screened for the presence of alkaloids, glycosides, phenols, saponins, tannins, and steroids using standard qualitative tests (Table 3).

Table 3. Qualitative analysis of Plant Constituents

Test for	Methodology	Observation (positive)
Alkaloids	1 mL extract + 1 mL Wagner's reagent	Reddish-brown precipitate
Glycosides	1 mL extract + picric acid	Yellowish colour
Phenols	1 mL extract + 4 drops ferric chloride	Blackish colour
Saponins	5 mL extract, shaken vigorously	Foamy layer
Tannins	5 mL extract + few drops 1% ferric chloride	Greenish yellow precipitate
Steroids	2 mL extract + 2 mL chloroform + 2 mL sulphuric acid	Chloroform layer red, acid layer green

2.5 Formulation of Transdermal Patch (Solvent Evaporation Method)

Preparation of backing membrane: Backing films were prepared by dissolving 4 g of HPMC in 100 mL distilled water, followed by the addition of glycerine as a plasticiser. The solution was cast into glass moulds and dried at 60°C for 6 hours in a hot-air oven.[28]

Preparation of casting solution: After dissolving methyl cellulose and PVP in ethanol while stirring constantly, PEG was added as a plasticising agent. To create a homogenous mixture, the tulsi extract was added gradually and stirred for around 45 minutes. After casting the resultant solution onto prefabricated backing membranes in glass Petri plates, it was dried for six hours at 60°C in a hot-air oven. The transdermal films were carefully removed from the molds after drying and kept for later assessment.[29]

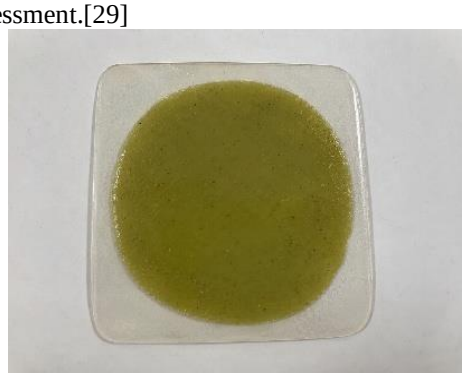


Figure 3: Development of Transdermal Herbal Patch

2.6 Transdermal Patch Characterisation

a) Physical appearance: Colour, clarity, and smoothness of the formulated patches were visually examined.

b) Moisture content: Films were individually weighed, stored in a desiccator containing calcium carbonate at room temperature for 24 hours, and reweighed at intervals until a constant weight was obtained. Moisture content (%) was calculated as [(initial weight - final weight) / initial weight] × 100.

c) Thickness of patch: The thickness of each patch was measured using a vernier caliper (patch thickness tester) at three different positions per patch, for accuracy.[22]

d) Folding endurance: Each patch was repeatedly folded at the same point until it broke; the number of folds required was recorded as the folding endurance.

e) Weight uniformity: Patches were dried at 60°C for 4 hours, and samples of a specified area were cut from different regions of each patch and weighed on a digital balance to obtain the average weight.[11]

3. RESULT AND DISCUSSION:

The Soxhlet extraction of *Ocimum tenuiflorum* (Tulsi) leaves yielded an extractive value of 3.7% w/w, indicating effective recovery of phytoconstituents. Qualitative phytochemical analysis of the ethanolic extract revealed the presence of alkaloids, cardiac glycosides, steroids, tannins, and polyphenols, whereas saponins were absent. The occurrence of these bioactive constituents supports the well-documented antioxidant, anti-inflammatory, and antimicrobial properties of Tulsi.

The formulated transdermal patches exhibited desirable physicochemical characteristics, appearing translucent, light green in colour, smooth, and flexible. The average moisture content was 3.54%, suggesting low residual moisture and good storage stability. Patch thickness was found to be 0.523 mm with minimal variation, indicating uniform film casting and drying. Folding endurance studies demonstrated an average value of 85 folds, reflecting adequate mechanical strength and flexibility to withstand repeated handling without rupture. In addition, the average patch weight was 0.412 g, with negligible variation among samples, confirming uniform distribution of the herbal extract and excipients throughout the matrix.

Overall, the prepared Tulsi-loaded transdermal patches showed satisfactory phytochemical and physicochemical properties, indicating their potential suitability as a stable and effective transdermal drug delivery system.

The physicochemical evaluation indicates that the HPMC-PVP matrix, plasticized with PEG, produced a herbal transdermal patch with acceptable mechanical integrity. The folding endurance value (85) and uniform thickness (0.523 mm) reflect good film flexibility and casting consistency, properties attributed in the literature to the film-forming and plasticizing roles of HPMC, PVP, and PEG, respectively. Weight uniformity across samples further supports homogeneous dispersion of the Tulsi extract within the polymer matrix during the solvent-evaporation casting process. Taken together with the confirmed presence of glycosides, steroids, tannins, and polyphenols - phytoconstituents associated with the antioxidant, anti-inflammatory, and antimicrobial activity of Tulsi - these results support the feasibility of incorporating Tulsi extract into a matrix-type transdermal patch as a herbal alternative or adjunct to synthetic transdermal formulations.

Table 4: Phytochemical screening of Tulsi extract (+ moderately present, ++ actively present, – absent)

S. No.	Test for	Observation
1	Alkaloids	+
2	Cardiac glycosides	++
3	Saponins	–
4	Steroids	+
5	Tannins	+
6	Polyphenols	++

Table 5: Physical characteristics of the prepared patches

S. No.	Physical characteristic	Result
1	Appearance	Smooth uniform patch
2	Colour	Light Green
3	Clarity	Translucent
4	Flexibility	Good

Table 6: Moisture content of the prepared patches

S. No.	Moisture content (%)
1	3.56
2	3.57
3	3.47
4	3.56
Average	3.54

Table 7: Thickness of the prepared patches

S. No.	Thickness (mm)
1	0.525
2	0.524
3	0.525
4	0.520
Average	0.523

Table 8: Folding endurance of the prepared patches

S. No.	Folding endurance
1	83
2	82
3	87
4	90
Average	85

Table 9: Weight uniformity of the prepared patches

S. No.	Weight (g)
1	0.410
2	0.415
3	0.413
4	0.410
Average	0.412

4. CONCLUSION:

Transdermal patches containing Ocimum tenuiflorum (Tulsi) extract were successfully developed using a polymer matrix of hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP), plasticized with polyethylene glycol (PEG) to improve flexibility and adhesion, and prepared by the solvent evaporation (casting) method. The prepared patches were smooth, uniform, and flexible, with consistent thickness, an acceptable moisture content, good folding endurance, and uniform weight, indicating satisfactory physical and mechanical quality and proper distribution of the extract and polymers. These findings suggest that Tulsi extract can be effectively incorporated into transdermal patches with good physicochemical properties, supporting its potential as a convenient, controlled, and sustained-release route for delivering herbal actives through the skin. Further pharmacokinetic and pharmacodynamic evaluations are required to confirm the safety, permeation behaviour, and therapeutic efficacy of Tulsi-based transdermal delivery.

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