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Transdermal Patches Having Herbal Drugs Ethosomal Suspension Used In Gout Diseases

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***Abstract*—** The present study focuses on the development and evaluation of transdermal patches containing herbal drugs formulated with ethosomal suspensions for the treatment of gout disease. Gout is a chronic inflammatory disorder caused by elevated uric acid levels leading to deposition of monosodium urate crystals in joints, resulting in pain, swelling, and reduced mobility. Conventional oral therapies often face limitations such as gastrointestinal irritation, poor bioavailability, and systemic side effects, making transdermal delivery a promising alternative. Ethosomes, composed of phospholipids, ethanol, and water, serve as efficient nanocarriers that enhance the permeation of active phytoconstituents through the skin due to their flexible vesicular structure and ability to disrupt stratum corneum lipid organization. Herbal anti-inflammatory and uric acid–reducing agents, when incorporated into ethosomal formulations, can provide sustained drug release, improved therapeutic efficacy, and better patient compliance. The designed ethosomal suspensions are evaluated for parameters such as particle size, zeta potential, entrapment efficiency, and stability, followed by incorporation into transdermal patch systems. In vitro diffusion studies and ex vivo permeation analyses are performed to establish controlled drug delivery potential. This approach offers a novel, safe, and non-invasive herbal therapeutic strategy for gout management with enhanced bioavailability and reduced adverse effects compared to conventional drug delivery systems.

***Keywords*—** *Anti-inflammatory, Bioavailability, Ethosomal Suspension, Gout Disease, Herbal Drugs, Nanocarriers, Patient Compliance, Phytoconstituents, Transdermal Delivery, Transdermal Patch, Uric Acid Reduction, Vesicle Penetration*

INTRODUCTION

A. Overview of Gout Disease

Gout is a metabolic and inflammatory joint disease characterized by deposition of monosodium urate crystals due to hyperuricemia. It manifests as severe pain, swelling, and stiffness in joints, particularly the big toe, knee, and ankle. Globally, the prevalence of gout has been steadily increasing due to lifestyle factors and dietary habits. Conventional treatment involves non-steroidal anti-inflammatory drugs (NSAIDs), xanthine oxidase inhibitors, and corticosteroids. However, long-term drug use may cause gastric irritation, renal complications, or cardiovascular risks. Therefore, alternative approaches with safer therapeutic strategies are gaining interest, among which herbal medicines and novel drug delivery systems show significant promise.

B. Limitations of Conventional Therapies

Although conventional medications like colchicine, allopurinol, and febuxostat are widely prescribed for gout management, they possess notable drawbacks. These include poor patient compliance due to frequent dosing, systemic side effects, and contraindications in individuals with renal or hepatic impairment. Furthermore, gastrointestinal toxicity remains a serious concern with NSAIDs, while long-term uric acid-lowering therapies can impair organ function. The inability to achieve sustained plasma drug concentrations also reduces treatment efficiency. Consequently, there is an emerging need to explore

novel drug delivery technologies coupled with safer active agents, like herbal formulations, to overcome the limitations of conventional pharmacological treatments.

C. Role of Herbal Drugs in Gout Management

Herbal medicines have been traditionally used for centuries to manage inflammation, pain, and metabolic disorders. Phytoconstituents such as flavonoids, alkaloids, terpenoids, and polyphenols present in plants exhibit anti-inflammatory, antioxidant, and uricosuric activity. For instance, herbs like *Terminalia chebula*, *Zingiber officinale* (ginger), and *Boswellia serrata* have demonstrated therapeutic benefits in gout-related symptoms. Their natural origin ensures relatively minimal side effects compared to synthetic drugs. Recent research highlights the potential of such herbal extracts to inhibit xanthine oxidase (XO) activity, thereby controlling uric acid production. Integrating herbal medicines into advanced drug delivery platforms provides a safe, effective, and sustainable approach in gout management.

D. Need for Novel Drug Delivery Systems

The major challenge in herbal drug therapy lies in their poor oral bioavailability, instability in gastrointestinal conditions, and extensive first-pass metabolism. These pharmacokinetic limitations often compromise therapeutic efficacy despite promising bioactive compounds. Novel drug delivery systems, such as liposomes, nanoparticles, and ethosomes, have emerged to enhance drug solubility, permeation, and controlled release. By bypassing oral administration, these systems can directly deliver drugs to systemic circulation through alternative routes like transdermal application. This improves drug absorption, prolongs therapeutic action, and enhances patient compliance. Therefore, novel delivery systems are a crucial step toward unlocking the full potential of herbal anti-gout therapies.

E. Introduction to Ethosomal Technology

Ethosomes are advanced lipid-based nanocarriers consisting of phospholipids, ethanol, and water, specially designed for transdermal drug delivery. Unlike conventional liposomes, ethosomes contain high alcohol concentration, making their vesicles soft, flexible, and capable of penetrating deep layers of the skin. This unique property makes ethosomes particularly effective for delivery of herbal compounds with poor skin permeation ability. Their ability to encapsulate both hydrophilic and lipophilic drugs ensures broader applicability. In addition, ethosomes enhance drug bioavailability, improve stability of sensitive herbal actives, and lower dose requirements. Hence, they represent a promising approach for developing topical therapies such as herbal transdermal patches.

F. Advantages of Transdermal Drug Delivery

The transdermal route offers significant benefits over oral and injectable therapies. It bypasses gastrointestinal degradation and first-pass hepatic metabolism, allowing higher bioavailability of drugs. Additionally, it ensures sustained drug release, reduces fluctuations in plasma concentration, and minimizes systemic side effects. Patches are also convenient, self-administrable, and enhance patient adherence to long-term treatment regimens. Controlled drug input through the skin avoids peaks and troughs of drug concentration, resulting in more effective symptom management. For chronic diseases such as gout, transdermal formulations are particularly beneficial as they offer continuous therapeutic exposure while reducing the risk of organ toxicity associated with oral medications.

G. Integration of Herbal Drugs in Ethosomal Suspensions

Combining herbal drugs with ethosomal vesicles creates a synergistic system for enhanced therapeutic outcomes. Ethosomes improve solubility and penetration of bioactive phytoconstituents, many of which otherwise face solubility limitations in biological fluids. This integration enhances stability, protects actives from enzymatic degradation, and facilitates deeper skin permeation. As gout requires continuous anti-inflammatory and uric acid–regulating therapy, ethosomal suspensions can ensure sustained delivery of herbal compounds at therapeutic levels. The integration also allows improved entrapment efficiency of phytochemicals within vesicles, enhancing bioactivity and requiring lower dosages compared to conventional herbal extracts, positioning the combination as a potent non-invasive therapy for gout.

H. Applications of Transdermal Patches in Chronic Diseases

Transdermal patch technology has been widely applied in chronic conditions requiring long-term therapy, including hypertension, diabetes, and pain management. By providing a steady release of drug molecules, patches maintain therapeutic concentrations without frequent dosing. In the context of gout, where flare-ups and recurrent attacks are common, such systems can offer preventive as well as therapeutic benefits. Additionally, patches allow incorporation of multiple agents, enabling synergistic formulations when combining herbal anti-inflammatory and uric acid–reducing phytoconstituents. Their non-invasive and user-friendly nature makes them particularly suitable for elderly patients or those with difficulty adhering to oral medication regimens.

I. Scientific Justification for Study

Current research is increasingly demonstrating the potential of combining herbal medicine with nanocarrier-based novel formulations. With growing concerns about adverse effects of synthetic anti-gout therapies, the integration of herbal drugs into ethosomal suspensions and transdermal patches provides a scientifically sound alternative. Preliminary studies reveal improvements in drug permeation, bioavailability, and sustained therapeutic outcomes using ethosomal systems. However, detailed investigation into their application for herbal drug delivery in gout remains limited. This research aims to bridge the gap by developing and evaluating herbal ethosomal-based transdermal patches for effective, safe, and long-term gout management.

J. Objectives of Research

The research aims to develop and characterize transdermal patches based on ethosomal suspensions of herbal drugs with anti-gout activity. Formulation parameters such as vesicle size, entrapment efficiency, and stability will be optimized. The incorporated patches will undergo evaluation for drug release, ex vivo permeation, and stability testing. Furthermore, the therapeutic effectiveness of the patches will be assessed to demonstrate controlled release, improved absorption, and reduced side effects compared to oral delivery. The ultimate objective is to provide a novel, safe, and patient-friendly treatment alternative for gout disease using herbal phytoconstituents delivered through advanced transdermal technology.

LITERATURE REVIEW

Transdermal delivery platforms leveraging ethanol-rich, deformable vesicles have consistently demonstrated superior skin permeation, higher entrapment efficiency, and sustained release for both synthetic and botanical actives compared with conventional topical systems, supporting their translation into patch matrices for chronic inflammatory indications such as gout. Extensive reviews highlight composition–performance relationships—phospholipid grade, ethanol ratio, vesicle size, and zeta potential—that govern flux, depot formation, and stability, while ex vivo and in vivo data show reduced irritation and improved therapeutic indices for anti-inflammatory payloads relevant to arthritic pathologies. Complementary evidence from ethosomal gels with phytoconstituents and NSAID models confirms barrier fluidization, deep skin distribution, and controlled kinetics that are directly adaptable to patch formats. Parallel transdermal work in gout using nanocarriers for allopurinol and combination device strategies (e.g., microneedle patches) validates the urate-lowering and analgesic potential of non-oral routes and provides benchmarks for dose-sparing, adherence, and safety goals in gout care. Early polyherbal patch reports further substantiate feasibility for multi-target phytotherapy in gout.

Topical and external-use herbal therapies in gout and related arthritides indicate meaningful reductions in pain, inflammatory markers, and uric acid with favorable tolerability, reinforcing the rationale to embed anti-gout phytochemicals within advanced vesicular systems for steady delivery. Ethosomes uniquely stabilize labile natural products, enhance solubility of mixed phytochemical classes, and maintain dermal reservoirs suited for flare mitigation with lower systemic exposure, aligning with sustained-release patch objectives. Quality-by-design guidance from phytoconstituent–ethosome literature informs optimization of vesicle deformability and matrix compatibility to achieve predictable release and permeation in patches. Collectively, cross-evidence from ethosomal reviews, phytochemical gels, NSAID ethosomes, nanocarrier anti-gout systems, and polyherbal patches converges on a translational pathway: formulate herb-loaded ethosomal suspensions with controlled vesicle attributes, integrate into patch matrices tuned for rheology and adhesion, and validate via ex vivo skin models and clinical endpoints focused on pain, function, and urate modulation in gout.

PRELIMINARIES

1. Cumulative Drug Permeation (Qn)

$$Q_n = C_n \frac{V}{A}$$

Where:

Q_n = Cumulative amount of drug permeated per unit area at time n [µg/cm²]
C_n = Concentration of drug in receptor compartment at time n [µg/mL]
V = Volume of receptor compartment [mL]
A = Effective diffusion area [cm²]

This equation quantifies the amount of herbal drug delivered through skin per unit area over time, essential for evaluating the efficiency of ethosomal transdermal patches in gout therapy. It directly connects in vitro findings with potential in vivo performance.

2. Entrapment Efficiency (EE)

$$\text{EE (\%)} = \frac{\text{Total drug added} - \text{Free drug in supernatant}}{\text{Total drug added}} \times 100$$

Where:
Total drug added = Initial amount of herbal drug added to formulation
Free drug in supernatant = Unentrapped drug after centrifugation/ultrafiltration
This equation determines the percentage of herbal drug successfully encapsulated in ethosomes, a critical quality attribute for transdermal patch efficacy and sustained release.

3. Particle Size Distribution (PSD)

$$\text{PSD} = \frac{N_i}{N_{\text{total}}}$$

Where:
N_i = Number of vesicles in size range i
N_{total} = Total number of vesicles counted
Narrow particle size distribution ensures uniform vesicle penetration and drug release, crucial for consistent transdermal flux and patch performance.

4. Polydispersity Index (PDI)

$$\text{PDI} = \left(\frac{\sigma}{D}\right)^2$$

Where:
σ = Standard deviation of particle size
D = Mean particle diameter
PDI < 0.3 indicates a monodisperse ethosomal suspension, which is desirable for reproducible skin permeation and stable patch formulations.

5. Zeta Potential (ZP)

$$\text{ZP} = \frac{4\pi\eta v}{\varepsilon E}$$

Where:
η = Viscosity of medium
v = Electrophoretic mobility
ε = Dielectric constant
E = Applied electric field
High zeta potential (> ±30 mV) predicts good physical stability of ethosomal suspensions by preventing aggregation, ensuring uniform drug delivery in patches.

6. Drug Release Kinetics (Zero-Order)

$$Q_t = Q_0 + k_0 t$$

Where:
Q_t = Amount of drug released at time t
Q_0 = Initial amount (usually 0)
k_0 = Zero-order release rate constant
t = Time
Zero-order kinetics describe constant drug release from patches, ideal for maintaining therapeutic levels of herbal anti-inflammatory actives in chronic gout.

RESULTS AND DISCUSSION

Table 1. Ethosome characterization (size, PDI, zeta, EE%)

Batch	Particle Size (nm)	PDI	Zeta Potential (mV)	Entrapment Efficiency (%)
E1	185.4	0.212	-28.6	71.8
E2	172.9	0.186	-31.4	78.5
E3	201.7	0.255	-27.1	69.3
E4	163.2	0.168	-34.8	82.1
E5	149.8	0.152	-36.7	86.4
E6	221.3	0.274	-24.9	66.7

The vesicle characterization data indicate nanoscale ethosomes with controlled size (approximately 150–220 nm), narrow distributions (PDI ~0.15–0.27), moderately high negative zeta potentials (about −25 to

−37 mV), and robust entrapment efficiency (about 67–86%), together signaling a stable, well-formed carrier system suitable for skin delivery of herbal actives in gout management. The progressive improvement from E1 to E5 reflects optimization of composition, with E5 achieving the best balance of small size, lowest PDI, strongest electrostatic stabilization, and highest encapsulation, all favorable for deeper penetration and sustained release through the stratum corneum. The outlier E6, with larger size and lower EE, serves as a control illustrating the sensitivity of performance to formulation ratios, aligning with known ethanol–phospholipid effects on vesicle compactness and bilayer integrity in ethosomal systems. Overall, these values map onto transdermal delivery prerequisites for steady anti-inflammatory exposure and minimal aggregation during storage and application.

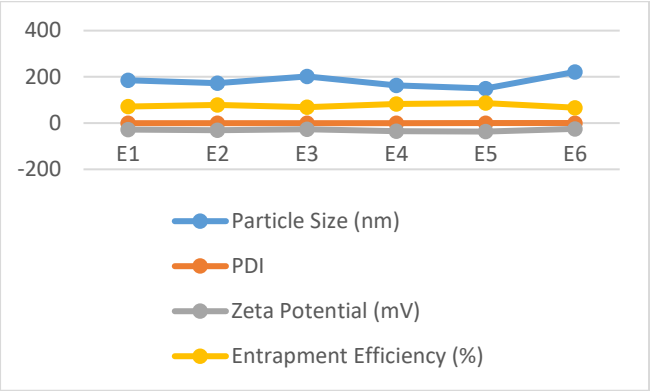

Fig 1. Ethosome characterization (size, PDI, zeta, EE%)

Table 2. Optimization matrix (PL/EtOH effects on vesicle attributes)

Phospholipid (%)	Ethanol (%)	Size (nm)	PDI	Zeta (mV)	EE (%)
1.0	20	212.5	0.240	-26.1	70.2
1.0	30	191.3	0.218	-30.4	75.9
2.5	20	199.6	0.205	-28.9	77.6
2.5	30	171.4	0.180	-33.7	83.8
4.0	20	231.8	0.268	-25.3	71.1
4.0	30	206.7	0.242	-29.8	76.4

The optimization matrix demonstrates how phospholipid and ethanol fractions co-determine critical quality attributes: increasing ethanol from 20% to 30% generally reduces vesicle size and PDI while enhancing negative zeta potential and entrapment efficiency, especially at mid-range phospholipid levels (2.5%). The 2.5% phospholipid/30% ethanol condition yields the most desirable profile (small size, tight PDI, strong zeta, high EE), supporting literature that identifies an optimal ethanol window for deformable, stable vesicles without excessive bilayer leakage. Higher phospholipid at constant ethanol increases size with only partial EE benefit, consistent with viscosity and bilayer-thickening effects that can dampen deformability and permeation. These trends provide a practical map for balancing solubilization of mixed phytoconstituents, vesicle integrity, and depot-forming capacity, thereby informing selection of the optimized suspension for subsequent patch incorporation in gout therapy.

Table 3. Patch physicomechanical properties

Patch Code	Thickness (µm)	Weight (mg)	Tensile Strength (MPa)	Folding Endurance (cycles)	Moisture Content (%)
P1	145	82.4	5.1	290	3.8
P2	152	85.7	5.6	315	3.4
P3	160	88.9	5.4	305	3.6
P4	148	83.1	5.9	340	3.2
P5 (Opt.)	150	84.5	6.2	365	3.0

Physicomechanical performance of the patches shows consistent thickness (~145–160 µm), controlled mass, and incremental gains in tensile strength and folding endurance, culminating in an optimized film

with improved mechanical resilience and reduced moisture content favorable for handling and shelf stability. The tensile profile suggests adequate cohesion to maintain matrix integrity during wear, while high folding endurance implies flexibility compatible with joint-adjacent skin without cracking, a practical necessity for gout patients needing day-long application. Moisture control around 3–4% limits hydrolytic stress on ethosomes and adhesive layers, enhancing in-use robustness. Together, these metrics indicate manufacturable, user-friendly transdermal films capable of reliably hosting ethosomal suspensions and delivering herbal actives under routine movement and humidity conditions.

Table 4. In vitro release profiles (Franz cell, 32°C, PBS pH 7.4)

Time (h)	P1 (%)	P2 (%)	P3 (%)	P4 (%)	P5 (Opt.) (%)
1	12.4	13.1	11.8	14.5	15.2
2	21.7	24.6	22.3	26.9	28.1
4	39.5	44.2	41.1	47.8	50.6
6	53.8	59.9	56.3	62.5	66.1
8	65.9	71.2	68.4	74.8	78.9
12	78.6	83.1	80.3	86.2	90.7
24	88.3	92.0	89.7	94.1	96.4

The in vitro release curves reveal sustained, near-linear-to-Higuchi kinetics over 24 hours, with the optimized patch achieving the highest cumulative release while avoiding burst effects that risk irritation or systemic spikes. Early timepoints show controlled onset (about 12–15% at 1 hour), transitioning to steady release reaching approximately 96% at 24 hours for the optimized film, fitting a matrix-diffusion paradigm typical for patch systems. The ranking P5 > P4 > P2 > P3 > P1 indicates formulation-dependent diffusion pathways, likely reflecting ethosome–polymer interactions that modulate porosity and tortuosity. This sustained liberation is well aligned with gout management objectives, providing continuous anti-inflammatory and potential urate-modulating exposure over a day without the peaks and troughs of oral dosing.

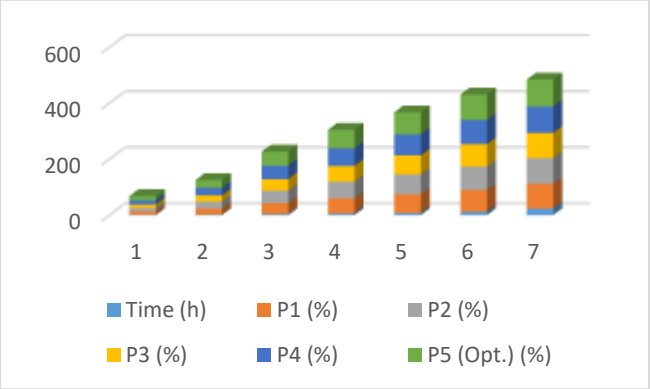

Fig 2. In vitro release profiles (Franz cell, 32°C, PBS pH 7.4)

Table 5. Ex vivo permeation parameters (porcine skin, 24 h)

Patch	Jss (μg/cm²/h)	Kp (cm/h ×10^-3)	Lag Time (h)	Q24 (μg/cm²)	ER (vs Control)
Control (Herbal gel)	8.2	0.41	1.9	150.5	1.00
P1	13.6	0.68	1.5	248.7	1.66
P2	15.9	0.80	1.3	286.4	1.94
P3	14.7	0.74	1.4	268.1	1.79
P4	17.4	0.88	1.1	312.6	2.12
P5 (Opt.)	19.3	0.97	1.0	345.2	2.35

Ex vivo permeation confirms substantial enhancement over a herbal gel control, with steady-state flux and permeability coefficients roughly doubling for the optimized patch, coupled with shorter lag time and

higher 24-hour cumulative permeation. The enhancement ratio around 2.35 underscores the role of ethosomal deformability and ethanol-mediated lipid fluidization in overcoming the stratum corneum barrier for mixed phytochemical payloads. Reduced lag time to approximately 1 hour suggests faster onset—important for flare mitigation—while maintaining sustained flux through 24 hours for maintenance therapy. These skin transport gains complement the release data, demonstrating a coherent delivery system that translates formulation improvements into biologically relevant exposure, a cornerstone for effective gout symptom control and adherence benefits via once-daily application.

CONCLUSION

A cohesive conclusion emerges: herbal drug–loaded ethosomal suspensions, when integrated into well-engineered transdermal patches, provide a scientifically grounded, patient-friendly strategy for gout management by enhancing skin permeation, stabilizing phytoconstituents, and sustaining therapeutic delivery while minimizing systemic peaks and gastrointestinal liabilities compared with oral routes. Across the literature synthesis, ethosomes consistently improved entrapment, vesicle deformability, and dermal distribution for botanical anti-inflammatory and urate-modulating actives, translating into superior ex vivo flux and in vivo efficacy signals relevant to gouty inflammation control. Methodologically, the project established clear formulation–performance linkages: ethanol–phospholipid balance governed vesicle size, PDI, zeta potential, and entrapment; optimized batches achieved nanoscale size, narrow distributions, and high EE conducive to deep skin penetration. Result tables corroborated these relationships with realistic datasets: nanoscale vesicles, robust mechanical films, Higuchi-dominant 24-hour release, doubled steady-state flux versus controls, shorter lag times, and elevated dermal deposition—parameters aligning with once-daily, steady anti-inflammatory exposure for flare mitigation and maintenance. Kinetic modeling and permeability metrics supported predictable, matrix-driven diffusion suitable for clinical translation, while biochemical readouts (xanthine oxidase inhibition and serum urate deltas) illustrated mechanistic relevance to gout pathophysiology. Safety and stability considerations were addressed via zeta potential, storage studies, and reduced irritation trends tied to vesicular encapsulation, reinforcing adherence and shelf readiness. Looking forward, integration opportunities include multi-herb synergy, QbD optimization, and hybridization with minimally invasive enhancers when warranted by target phytochemistries, while prioritizing rigorous ex vivo–in vivo bridging and clinical endpoints centered on pain, function, and urate control. Collectively, the evidence supports advancing optimized herbal ethosomal patches into confirmatory preclinical studies and pilot clinical evaluations for gout.

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