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Formulation and Evaluation of Herbal Transdermal Patch of Clerodendrum Infortunatum for Anti-Inflammatory Activity

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Abstract- ***Transdermal drug delivery systems (TDDS) represent a modern approach for delivering therapeutic agents through the skin into the systemic circulation, offering significant advantages including avoidance of first-pass metabolism, controlled drug release, improved bioavailability, and enhanced patient compliance. Clerodendrum infortunatum Linn. (Family: Lamiaceae), commonly known as Bhat or Bhant, is a well-known medicinal plant with significant anti-inflammatory, antibacterial, antifungal, and wound-healing properties. Its active phytoconstituents — including flavonoids, terpenoids, alkaloids, and steroids — make it a potential candidate for topical and transdermal applications, particularly for skin disorders such as eczema, dermatitis, and inflammatory conditions. The present study aimed to formulate and evaluate transdermal herbal patches of C. infortunatum leaf extract by solvent casting technique using polymers HPMC and PVA. Three formulations (F1, F2, F3) were developed with varying drug concentrations. The patches were evaluated for physical appearance, thickness, weight uniformity, folding endurance, moisture content, moisture uptake, flatness, drug content uniformity, in vitro drug permeation using Franz diffusion cell, skin irritation test, and stability studies. Phytochemical screening confirmed the presence of flavonoids, alkaloids, tannins, steroids, and phenolic compounds. Formulation F2 (HPMC:PVA = 2:3) exhibited the best overall performance, with drug content of 97.8%, folding endurance of 225, and cumulative drug permeation of 91.2% in 8 hours following Higuchi diffusion kinetics. Skin irritation studies confirmed the patches were non-irritant. Stability studies showed no significant changes at room temperature over 4 weeks.***

Index Terms- ***Anti-Inflammatory, Clerodendrum Infortunatum, Herbal Transdermal Patch, HPMC, In Vitro Drug Release, PVA, Phytochemical Screening, Solvent Casting***

I. INTRODUCTION

The skin, the largest organ of the human body, constitutes approximately 15–20% of total body weight and covers a surface area of 1.5–2 m². Transdermal drug delivery systems (TDDS) exploit the skin's surface to deliver drugs systemically or locally, bypassing the gastrointestinal tract and hepatic first-pass metabolism. The stratum corneum — the outermost 10–20 μm of the epidermis — is the primary rate-limiting barrier to drug penetration. Drug permeation through the skin occurs via three principal routes: transcellular (intracellular), intercellular (paracellular through the lipid matrix), and appendageal (through hair follicles and sweat glands).

Since the introduction of the first transdermal patch (scopolamine for motion sickness, 1979), TDDS have evolved significantly and now represent a well-established route for systemic drug delivery. Key advantages of TDDS include avoidance of first-pass hepatic metabolism, controlled and sustained drug release, improved patient compliance, maintenance of constant plasma drug concentration, and the ability to terminate therapy by simply removing the patch. Limitations include suitability only for potent drugs (typically <10–20 mg/day), potential skin irritation, and lag time before therapeutic levels are achieved.

Herbal drug formulations have gained widespread popularity due to their perceived safety, natural origin, and fewer side effects compared to synthetic drugs. Incorporation of herbal extracts into

transdermal patches combines the therapeutic benefits of plant-derived compounds with the pharmacokinetic advantages of transdermal delivery. Herbal TDDS are particularly useful for phytoconstituents that undergo extensive first-pass metabolism or exhibit poor oral bioavailability.

Clerodendrum infortunatum Linn. (Family: Lamiaceae), commonly known as Bhat or Bhant, is a semi-woody shrub widely distributed in tropical and subtropical regions of India and Southeast Asia. Traditionally used in Ayurvedic medicine for skin disorders, rheumatism, fever, and asthma, the plant possesses significant anti-inflammatory, antibacterial, antifungal, antioxidant, and wound-healing activities. Phytochemical studies have revealed the presence of flavonoids (luteolin, apigenin), terpenoids (clerodin, clerodinol), alkaloids (clerodendrine), steroids (β-sitosterol), tannins, saponins, and phenolic compounds as major bioactive constituents. The present study, therefore, aims to formulate and evaluate matrix-type transdermal herbal patches of C. infortunatum leaf extract for anti-inflammatory application.

II. LITERATURE REVIEW

Maulik et al. (2012) reported significant anti-inflammatory activity of C. infortunatum leaf extract in carrageenan-induced rat paw edema model, with flavonoid-rich fractions primarily responsible. Kirtikar and Basu (2003) documented traditional uses in treatment of skin diseases, asthma, and rheumatism. Chattopadhyay et al. (2011) demonstrated antibacterial activity of methanolic leaf extract against Staphylococcus aureus, Bacillus subtilis, E. coli, and Pseudomonas aeruginosa. Bhattacharjee et al. (2009) confirmed the presence of alkaloids, flavonoids, tannins, steroids, and glycosides, and reported wound-healing activity of leaf extract in excision wound models.

Chien (1992) provided a comprehensive review of TDDS, emphasizing skin barrier function and drug permeation mechanisms. Thacharodi and Panduranga Rao (1996) demonstrated that HPMC provides better hydration and matrix integrity while EC provides controlled release in transdermal patches. Bhosale et al. (2011) prepared herbal transdermal patches of Curcuma longa using cellulose-based polymers with propylene glycol as penetration enhancer, showing good physicochemical properties and controlled drug release over 8 hours. Pawar et al. (2015) confirmed that EC:HPMC (1:1) combination provides drug content of 95–99%, folding endurance >200, and in vitro permeation of 75–85% in 8 hours, suggesting this as an ideal combination for matrix herbal patches.

III. AIM AND OBJECTIVES

Aim

To formulate and evaluate matrix-type transdermal herbal patches of Clerodendrum infortunatum Linn. leaf extract for anti-inflammatory activity.

Objectives

- To collect and authenticate the plant material (leaves of Clerodendrum infortunatum).
- To prepare ethanolic extract of C. infortunatum leaves by Soxhlet extraction method.
- To perform preformulation studies: organoleptic evaluation, percentage yield, LOD, ash values, and extractive values.
- To carry out phytochemical screening to detect secondary metabolites.
- To formulate matrix-type transdermal herbal patches using HPMC K4M and PVA in different ratios by solvent casting technique.
- To evaluate patches for physical appearance, thickness, weight uniformity, folding endurance, moisture content, moisture uptake, flatness, and drug content.
- To assess in vitro drug permeation using Franz diffusion cell.
- To perform skin irritation testing on human volunteers.
- To conduct stability studies of the optimized formulation.
- To identify the best formulation based on overall evaluation data.

IV. MATERIALS AND METHODS

4.1 Collection and Authentication of Plant Material

Fresh leaves of Clerodendrum infortunatum were collected from the MIET botanical garden and local areas in Gondia, Maharashtra, during the flowering season. The plant was authenticated by a botanist from the Department of Botany, Dhote Bandhu Science College, Gondia, and a voucher specimen was deposited in the college herbarium. Freshly collected leaves were washed with distilled water, shade-dried at room temperature for 10–14 days, coarsely powdered using a mechanical grinder, and passed through sieve No. 40.

4.2 Preparation of Extract

25 g of coarsely powdered C. infortunatum leaf was extracted by Soxhlet apparatus using 200 mL of 90% ethanol at 60–70°C for 8–10 hours (~15–18 siphoning cycles). The solvent was evaporated on a water bath at 40°C to obtain a semisolid extract, further dried in a hot air oven at 40°C to dry powder, and stored sealed at 4°C. Percentage yield was calculated.

4.3 Preformulation Studies

Preformulation studies performed included: organoleptic evaluation (colour, odour, taste, texture), percentage yield, Loss on Drying (LOD) at 100°C, Total Ash Value, Acid Insoluble Ash Value, Water-Soluble Ash Value, and extractive values (alcoholic and aqueous). Phytochemical screening was carried out for alkaloids (Dragendorff's, Mayer's tests), carbohydrates (Molisch's, Fehling's), tannins (FeCl3), phenolics (Lead Acetate), flavonoids (Shinoda, Sulphuric Acid), steroids (Salkowski, Liebermann-Burchard), saponins (Froth), glycosides (Keller-Killiani), terpenoids, and amino acids (Ninhydrin).

UV calibration: Stock solution (1000 µg/mL) prepared in phosphate buffer pH 7.4. Working concentrations 2–10 µg/mL scanned at 200–400 nm. Maximum absorbance (λmax) was observed at 352 nm (flavonoid chromophore). Calibration curve was linear ($y = 0.0588x + 0.001$, $R^2 = 0.9998$) in the range 2–10 µg/mL. FTIR compatibility studies confirmed no significant chemical interaction between the extract and excipients (peak shifts <5 cm^{-1}, no new peaks).

4.4 Formulation of Transdermal Patches

Matrix-type transdermal patches were prepared by the solvent casting technique. The drug (C. infortunatum extract) is uniformly dispersed in the polymer matrix, and drug release occurs by diffusion, providing controlled and sustained delivery.

Table 1: Composition of Transdermal Patch Formulations

Ingredients	F1 (% w/w)	F2 (% w/w)	F3 (% w/w)
C. infortunatum Extract	1.5	2.0	3.0
HPMC K4M	2.0	2.0	2.0
PVA	3.0	3.0	3.0
PEG 400	1.5	1.5	1.5
Glycerine	1.0	1.0	1.0
Methyl Paraben	0.1	0.1	0.1
Distilled Water	q.s.	q.s.	q.s.

Briefly: HPMC was dissolved in warm water (60°C); PVA dissolved at 80–90°C and cooled; polymer solutions combined. Methyl paraben (preservative), PEG 400 (plasticizer), and glycerine (humectant) were added with stirring. The weighed extract was incorporated into the polymer-plasticizer base and made up with distilled water. The casting solution was degassed for 15–20 minutes, poured into mercury-levelled Petri dishes, and dried at 25 ± 2°C for 24–48 hours. Dried films were cut to 4 cm^2 patches and laminated with an impermeable aluminium foil backing.

4.5 Evaluation Parameters

Physical appearance (visual inspection for colour, transparency, smoothness, air bubbles, pliability); Thickness (Vernier calliper, 5 points, mean ± SD); Weight uniformity (n=10, analytical balance, %RSD); Folding endurance (repeated folding at same crease until break); Moisture content (desiccator with anhydrous $CaCl_2$, 0% RH, 24 h); Moisture uptake (saturated KCl, 84% RH, 24 h); Flatness (% constriction method); Drug content uniformity (dissolution in phosphate buffer pH 7.4 at 37°C, UV at 352 nm, n=3); In vitro drug permeation (Franz diffusion cell, cellulose acetate membrane 0.45 µm,

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receptor: 20 mL phosphate buffer pH 7.4 at 37°C, samples at 0–8 h); Skin irritation test (Draize patch test, n=3 healthy volunteers, observation at 24, 48, 72 h); Stability studies (ICH Q1A(R2): 25 ± 2°C/60 ± 5% RH and 40 ± 2°C/75 ± 5% RH for 30 days).

V. RESULTS AND DISCUSSION

5.1 Preformulation Studies

Table 2: Organoleptic and Physicochemical Evaluation of Extract

Sr.	Parameter	Observation / Value
1	Colour	Dark greenish-brown
2	Odour	Characteristic, slightly pungent
3	Taste	Bitter and astringent
4	Percentage Yield	12.6% (3.15 g from 25 g)
5	Loss on Drying (LOD)	3.33%
6	Total Ash Value	8.19%
7	Acid Insoluble Ash	0.40%
8	Water-Soluble Ash	1.85%
9	Alcohol-Soluble Extractive	13.8%
10	Water-Soluble Extractive	11.2%
11	λmax	352 nm (flavonoid chromophore, phosphate buffer pH 7.4)
12	Calibration Linearity	$y = 0.0588x + 0.001$; $R^2 = 0.9998$; range 2–10 µg/mL

Phytochemical screening confirmed the presence of alkaloids, carbohydrates, tannins, phenolics, flavonoids, steroids, glycosides, terpenoids, and amino acids. Saponins were present (±). Proteins were absent. The presence of flavonoids, tannins, and terpenoids directly supports the anti-inflammatory and antimicrobial activities of the extract. FTIR studies showed all characteristic peaks of the extract were retained in physical mixtures with excipients (shifts <5 cm^{-1}, no new peaks), confirming physicochemical compatibility.

5.2 Physical Evaluation of Patches

Table 3: Physical Evaluation Results of Transdermal Patches

Sr.	Parameter	F1	F2	F3
1	Colour	Pale greenish-brown	Pale greenish-brown	Pale greenish-brown
2	Transparency	Translucent	Semi-translucent	Opaque
3	Surface Texture	Smooth, uniform	Smooth, uniform	Smooth, slightly rough
4	Air Bubbles	Absent	Absent	Absent
5	Pliability	Flexible	Flexible	Less flexible
6	Thickness (mm)	0.31	0.32	0.334
7	Mean Weight (mg)	196.3	198.7	201.2
8	Weight % RSD	1.09	0.95	1.27
9	Folding Endurance (folds)	218	225	196
10	Moisture Content (%)	3.8	3.1	2.4
11	Moisture Uptake (%)	5.2	4.1	2.9
12	Flatness (%)	99.8	99.9	99.7
13	Drug Content (%)	95.4	97.8	93.6
14	Drug Content % RSD	0.84	0.51	1.17
15	Skin Irritation	Non-irritant	Non-irritant	Non-irritant

All formulations showed acceptable physical appearance with no air bubbles and uniform homogeneity. F2 exhibited superior pliability, optimal moisture content (3.1%), and highest folding endurance (225 folds), making it the most suitable for

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application. Weight % RSD values (<2%) confirmed good weight uniformity across all formulations. Drug content was highest in F2 (97.8%, %RSD 0.51%), indicating excellent uniformity of drug distribution in the polymer matrix.

5.3 In Vitro Drug Permeation Study

Table 4: Cumulative % Drug Permeated through Franz Diffusion Cell (n=3, mean)

Time (h)	F1 (% Permeated)	F2 (% Permeated)	F3 (% Permeated)
0	0.00	0.00	0.00
1	12.4	14.2	10.1
2	22.6	26.8	18.3
3	33.5	38.4	26.7
4	45.2	51.6	35.4
5	56.8	63.7	44.8
6	67.4	74.5	53.6
7	76.9	83.8	61.2
8	83.5	91.2	68.9

F2 demonstrated the highest cumulative drug permeation of 91.2% in 8 hours, followed by F1 (83.5%) and F3 (68.9%). The balanced HPMC: PVA polymer matrix in F2 provides an optimal hydrophilic-hydrophobic environment for controlled drug diffusion. Drug release kinetics were best described by Higuchi's diffusion model (R^2 = 0.988 for F2), confirming diffusion-controlled drug release. The superior permeation of F2 compared to F3 (lower drug load, higher matrix density) and F1 (lower drug concentration) confirms 2.0% w/w extract concentration as optimal.

5.4 Stability Studies (Optimum Formulation F2)

Table 5: Stability Data of F2 at 25 ± 2°C / 60 ± 5% RH (Room Temperature)

Parameter	0 Day	15 Days	30 Days
Physical Appearance	Smooth, greenish-brown	No change	No change
Thickness (mm)	0.32	0.32	0.33
Folding Endurance (folds)	225	223	220
Drug Content (%)	97.8	97.4	97.1
% Drug Permeated (8 h)	91.2	90.8	90.3

Table 6: Stability Data of F2 at 40 ± 2°C / 75 ± 5% RH (Accelerated Conditions)

Parameter	0 Day	15 Days	30 Days
Physical Appearance	Smooth, greenish-brown	Slight darkening	Slight darkening
Thickness (mm)	0.32	0.33	0.34
Folding Endurance (folds)	225	216	208
Drug Content (%)	97.8	96.1	94.7
% Drug Permeated (8 h)	91.2	89.6	88.2

At room temperature, F2 exhibited no significant changes over 30 days, confirming good storage stability. Under accelerated conditions, a slight decrease in drug content (97.8% to 94.7%) and mild darkening were observed, likely due to thermal oxidation of phenolic/flavonoid constituents. All values remained within acceptable pharmacopoeial limits (±10%). Long-term stability studies (3–6 months) are recommended for full ICH compliance.

VI. CONCLUSION

The present study successfully formulated and evaluated matrix-type transdermal herbal patches of Clerodendrum infortunatum Linn. leaf extract using HPMC and PVA by the solvent casting technique. Phytochemical screening confirmed the presence of flavonoids, alkaloids, tannins, steroids, phenolic compounds, terpenoids, and glycosides — all contributing to the plant's well-reported anti-inflammatory and antibacterial activities.

All three formulations (F1, F2, F3) demonstrated acceptable physical appearance, uniform thickness, satisfactory weight uniformity, good folding endurance, and adequate drug content. Formulation F2 was identified as the optimum formulation, exhibiting the highest drug content (97.8%), best folding endurance (225 folds), optimal moisture content (3.1%), and maximum cumulative drug permeation (91.2% in 8 hours, Higuchi model, R^2 = 0.988). Skin irritation studies confirmed that all patches are non-irritant and safe. Stability studies demonstrated no significant deterioration at room temperature over 4 weeks.

The transdermal herbal patch of C. infortunatum represents a promising natural, safe, and effective therapeutic system for management of inflammatory skin conditions, offering advantages of controlled drug delivery, bypassing hepatic first-pass metabolism, and improved patient compliance.

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