Formulation And Evaluation of Polyherbal Anti-Inflammatory Gel

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Abstract- Nyctanthes arbor-tristis, commonly known as Parijat or Night-flowering Jasmine, is a medicinal plant widely used in traditional systems of medicine for the treatment of inflammatory disorders, fever, arthritis, and pain. The present study was aimed at the formulation and evaluation of a polyherbal anti-inflammatory gel containing ethanolic extract of Nyctanthes arbor-tristis leaves using Carbopol 934 as a gelling agent.

The leaves were collected, authenticated, shade dried, powdered, and extracted by maceration using ethanol: water (70:30 v/v) solvent system. Preliminary phytochemical screening confirmed the presence of flavonoids, alkaloids, tannins, glycosides, terpenoids, and phenolic compounds responsible for anti-inflammatory activity. Three gel formulations (F1, F2, and F3) were prepared using varying concentrations of Carbopol 934 and plant extract by the cold dispersion method. The formulations contained propylene glycol as humectant, Tween 80 as penetration enhancer, methyl paraben as preservative, sodium hydroxide as neutralizer, ethanol as co-solvent, and distilled water as vehicle.

The prepared formulations were evaluated for organoleptic characteristics, pH, viscosity, spreadability, extrudability, washability, homogeneity, drug content, skin irritancy, in vitro drug release, and stability studies. Among all formulations, F2 containing 1.5% Carbopol 934 and 5% extract showed optimum physicochemical properties with pH 6.8, viscosity 5120 cP, spreadability 35.6 g.cm/s, extrudability 94%, and drug content 97.8%. The formulation exhibited non-irritant behavior and satisfactory homogeneity. In vitro drug release studies using Franz diffusion cell demonstrated 93.8% cumulative drug release over 24 hours, comparable to the marketed formulation. Stability studies conducted as per ICH guidelines indicated good stability of the optimized formulation under both long-term and accelerated storage conditions.

Keywords: Nyctanthes arbor-tristis, Polyherbal gel, Anti-inflammatory activity, Carbopol 934, Topical drug delivery, Herbal formulation.

I.INTRODUCTION

Nyctanthes arbor-tristis, commonly known as Parijat, Harsingar, Night-flowering Jasmine, or Tree of Sorrow, is an important medicinal plant belonging to the family Oleaceae. The plant is widely distributed throughout India, Nepal, Bangladesh, and Southeast Asian countries. Among all parts of the plant, the leaves possess significant medicinal and pharmacological importance due to the presence of various bioactive phytochemicals such as flavonoids, alkaloids, glycosides, tannins, terpenoids, saponins, and phenolic compounds.

The leaves of Nyctanthes arbor-tristis are simple, opposite, rough, and dark green in color with a characteristic bitter taste. Traditionally, the leaves have been extensively used in Ayurveda, Siddha, Unani, and folk medicine systems for the treatment of fever, arthritis, rheumatism, sciatica, malaria, skin diseases, chronic cough, and inflammatory disorders. Leaf paste and decoctions are commonly employed as antipyretic, anti-inflammatory, anthelmintic, and laxative remedies in traditional medicine.

Scientific investigations have demonstrated that the leaves exhibit a wide range of pharmacological activities, including antioxidant, antimicrobial, antiviral, hepatoprotective, antidiabetic, anticancer, immunomodulatory, and anti-inflammatory effects. These therapeutic properties are mainly attributed to the presence of iridoid glycosides, flavonoids, oleanolic acid, ursolic acid, and other secondary

metabolites found in the leaf extracts. Researchers have also reported significant wound healing and analgesic activities of the leaves.

In phytochemical screening studies, Nyctanthes arbor-tristis leaves have shown the presence of important constituents such as tannins, alkaloids, glycosides, steroids, terpenoids, and phenolic compounds, which contribute to their medicinal value. Ethanolic, methanolic, aqueous, and hydroalcoholic extracts of the leaves are widely studied for their therapeutic efficacy and safety. Due to these pharmacological properties, the leaves are increasingly being explored in herbal formulations, gels, ointments, and pharmaceutical preparations.

II.LITERATURE REVIEW

Srivastava *et al.* (2014)
Srivastava and colleagues evaluated the anti-inflammatory activity of Nyctanthes arbor-tristis leaf extract in carrageenan-induced rat paw edema model. The ethanolic extract at 400 mg/kg showed significant reduction in paw edema comparable to standard diclofenac sodium. The study confirmed the presence of oleanolic acid as a major anti-inflammatory constituent responsible for inhibiting cyclooxygenase (COX) enzyme activity. The authors suggested Nyctanthes arbor-tristis as a promising candidate for anti-inflammatory drug development.

Patel and Parmar (2016)
Patel and Parmar formulated a herbal gel using Carbopol 934 as the gelling agent and evaluated it for topical anti-inflammatory activity. The gel containing 2% Carbopol 934 showed optimal rheological properties with a pH of 6.5 to 7.0 compatible with skin. Spreadability, viscosity, and drug release studies confirmed that the formulation was suitable for topical application. The penetration enhancer Tween 80 significantly increased drug permeation across excised rat skin.

Kumar *et al.* (2017)
Kumar and co-workers prepared polyherbal gels combining extracts of Azadirachta indica, Curcuma longa, and Withania somnifera for anti-inflammatory and wound healing activity. The gel formulations were evaluated for physicochemical parameters and in vivo activity. Results showed that the polyherbal combination produced superior anti-inflammatory activity compared to individual plant extracts, demonstrating the value of synergistic herbal combinations. Carbopol 934 at 1.5% was found optimal for gel consistency and drug release.

Jadhav *et al.* (2018)
Jadhav and colleagues investigated the phytochemical profile of Nyctanthes arbor-tristis and its role in modulating inflammatory mediators. High-performance liquid chromatography (HPLC) analysis identified nyctanthoside, beta-sitosterol, and oleanolic acid as major biomarkers. The study demonstrated that these compounds inhibit NF-kB activation and reduce TNF-alpha and IL-6 production in macrophages, providing a molecular basis for the observed anti-inflammatory activity.

III.AIM AND OBJECTIVES

Aim :
To formulate and evaluate a polyherbal anti-inflammatory gel using ethanolic extract of Nyctanthes arbor-tristis leaves with Carbopol 934 as gelling agent, targeting safe and effective topical anti-inflammatory activity.

Objectives :
To collect and authenticate Nyctanthes arbor-tristis leaves and prepare their ethanolic extract using 70:30 ethanol: water solvent system.
To perform preliminary phytochemical screening of the prepared extract for identification of active phytoconstituents.
To select appropriate excipients (Carbopol 934, propylene glycol, Tween 80, methyl paraben, sodium hydroxide, ethanol, distilled water) and prepare three gel formulations (F1, F2, F3) with varying concentrations.
To evaluate the prepared polyherbal anti-inflammatory gel formulations for physicochemical parameters: appearance, colour, odour, consistency, pH, viscosity, spreadability, extrudability, washability, and homogeneity.
To determine the drug content uniformity of all three formulations.
To assess skin irritancy and safety of the formulated gels through patch test.
To perform in vitro drug release studies using Franz diffusion cell and study the release kinetics.

To carry out stability studies of the optimized formulation as per ICH guidelines.
To compare the optimized formulation with a marketed anti-inflammatory gel.
To develop an herbal topical preparation with minimal side effects compared to synthetic anti-inflammatory formulations.

IV.PLAN OF WORK

- Collection and authentication of plant materials
- Drying and powdering of collected plant materials
- Preparation of herbal extracts by suitable extraction method
- Phytochemical screening of prepared extracts
- Selection of suitable excipients for gel formulation
- Preparation of polyherbal gel formulation
- Optimization of gel formulation batches
- Evaluation of formulated gel for physical parameters.

List of Ingredients and Their Uses

Sr. No.	Ingredient	Quantity (F2)	Role in Formulatio
1	Nyctanthes extract	5% w/w	Active anti-inflammatory agent
2	Carbopol 934	1.5% w/w	Gelling agent, viscosity builder
3	Propylene glycol	5% w/w	Humectant, co-solvent, penetration enhance
4	Tween 80 (Phospholipid)	1% w/w	Penetration enhancer, surfactant
5	Methyl paraben	0.1% w/w	Preservative, antimicrobial agent
6	Sodium hydroxide (10% soln.)	q.s.	pH adjuster, Carbopol neutralizer
7	Ethanol	10% w/w	Co-solvent, extraction medium
8	Distilled water	q.s. to 100%	Aqueous vehicle/base
9	Rose water	2 ml	Act As Perfume

V.MATERIALS AND METHODS

Collection and Authentication of Plant Material
Nyctanthes arbor-tristis leaves were collected from the local region during the flowering season (September–November). The plant was authenticated by a recognized botanist and a voucher specimen was deposited in the herbarium of the institution. The collected leaves were thoroughly washed with running tap water followed by distilled water to remove dust, dirt, and microbial contaminants.

Preparation of Dried Nyctanthes Leaves Powder
Step 1: Wash fresh Nyctanthes arbor-tristis leaves thoroughly with tap water and then distilled water.

Step 2: Shade-dry the washed leaves at room temperature (25°C) for 10–14 days until completely dry.

Step 3: Confirm complete dryness by checking crispness and absence of moisture.

Step 4: Coarsely powder the dried leaves using a mechanical grinder.

Step 5: Pass the powder through sieve No. 40 to obtain uniform coarse powder.

Step 6: Store the dried powder in an airtight container away from light and moisture.

Preparation of Polyherbal Anti Inflammatory Gel (Gupta *et al.,* 2019).
The gel was prepared by the cold dispersion method. Three formulations (F1, F2, F3) were prepared using different concentrations of Carbopol 934 (1%, 1.5%, 2%) and Nyctanthes extract (3%, 5%, 7%). The method is described below for batch F2:
Step 1: Accurately weigh all ingredients as per the formulation table.

Step 2: Dissolve methyl paraben (0.1 g) in ethanol (10 mL) to prepare a clear solution.

Step 3: Disperse Carbopol 934 (1.5 g) in 70 mL distilled water slowly with continuous stirring.

Step 4: Dissolve the Nyctanthes extract (5 g) in ethanol: water (70:30) and add propylene glycol (5 mL). Mix well.

Step 5: Add Tween 80 (1 g) to the extract solution and stir until homogeneous.

Step 6: Add the methyl paraben–ethanol solution to the extract-propylene glycol-Tween 80 mixture.

Step 7: Slowly add the above solution to the swollen Carbopol 934 dispersion with constant stirring.

Step 8: Neutralize with 10% NaOH solution (added dropwise) until the pH reaches 6.5–7.0 and a clear gel forms.

Step 9: Add rose water for good fragrance

Step 10: Make up the volume to 100 g with distilled water and mix thoroughly using a mechanical stirrer at 200 rpm for 15 minutes.

Step 11 : Transfer to suitable airtight containers and label appropriately.

VI.EVALUATION PARAMETERS

Organoleptic Evaluation: Visual inspection for colour, odour, texture, appearance, and consistency.
pH Determination: 1 g of gel dispersed in 10 mL distilled water; pH measured by digital pH meter.
Viscosity: Measured using Brookfield viscometer (spindle No. 4) at 20 rpm, 25°C.
Spreadability: Between glass slides under defined weight; measured as time taken for 5 cm separation.
Extrudability: Percentage of gel extruded from crimped aluminium tube under defined pressure.
Washability: Applied to skin; observed for ease of removal with water.
Homogeneity: Visual inspection after thorough mixing; absence of lumps or aggregates.
Drug Content: Spectrophotometric determination of oleanolic acid at 254 nm.
Skin Irritancy (Patch Test): Applied to 1 cm² area on forearm for 24 h; observed for redness/irritation.
In Vitro Drug Release: Franz diffusion cell; cellulose membrane; PBS pH 7.4; samples at 1, 2, 4, 6, 8, 12, 24 h.

Stability Studies: ICH guidelines: 25°C/60% RH (long-term) and 40°C/75% RH (accelerated) for 3 months

VII.RESULTS AND DISCUSSION

Organoleptic and Physicochemical Evaluation

Parameter	F1	F2	F2	F2
Colour	Light green	Pale green	Dark green	White/colourless
Odour	Characteristic herbal	Characteristic herbal	Characteristic herbal	Slight
Appearance	Clear, smooth	Clear, smooth	Slightly turbid	Clear
Consistency	Good	Excellent	Slightly stiff	Good
pH	6.4 ± 0.08	6.8 ± 0.05	7.1 ± 0.07	6.5 ± 0.06
Viscosity (cP)	3820 ± 45	5120 ± 38	7250 ± 62	5000 ± 50
Spreadability (g.cm/s)	28.4 ± 1.2	35.6 ± 0.9	22.8 ± 1.5	34.2 ± 1.1
Extrudability (%)	88 ± 2.1	94 ± 1.8	81 ± 2.5	92 ± 2.0
Washability	Easily washable	Easily washable	Easily washable	Easily washable
Homogeneity	Homogeneous	Homogeneous	Homogeneous	Homogeneous
Drug Content (%)	92.4 ± 1.2	97.8 ± 0.8	96.1 ± 1.1	–
Skin Irritancy	Non-irritant	Non-irritant	Non-irritant	Non-irritant

Drug Release Studies (Cumulative % Drug Released)

Time (h)	F1 (%)	F2 (%)	F3 (%)	Marketed (%)
1	12.4 ± 0.6	15.8 ± 0.5	10.2 ± 0.7	16.5 ± 0.6
2	22.6 ± 0.8	27.4 ± 0.7	18.5 ± 0.9	28.2 ± 0.8
4	38.4 ± 1.1	46.2 ± 0.9	32.8 ± 1.2	47.8 ± 1.0

6	52.5 ± 1.3	61.8 ± 1.1	44.6 ± 1.5	63.4 ± 1.2
8	64.8 ± 1.5	74.5 ± 1.2	55.2 ± 1.6	76.2 ± 1.4
12	76.2 ± 1.7	85.4 ± 1.4	65.8 ± 1.8	87.1 ± 1.5
24	84.5 ± 2.0	93.8 ± 1.6	74.2 ± 2.1	94.5 ± 1.8

Stability Study Results :

Parameter	Initial	25°C/60% RH (3 months)	40°C/75% RH (1 month)
Appearance	Pale green, clear	Pale green, clear	Slight colour deepening
pH	6.8 ± 0.05	6.7 ± 0.06	6.6 ± 0.08
Viscosity (cP)	5120 ± 38	5080 ± 42	5010 ± 55
Drug Content (%)	97.8 ± 0.8	96.9 ± 1.0	95.4 ± 1.3
Microbial Growth	Absent	Absent	Absent
Phase Separation	None	None	None

VIII.CONCLUSION

The present study on 'Formulation and Evaluation of Polyherbal Anti-Inflammatory Gel' was successfully completed. The ethanolic extract of Nyctanthes arbor-tristis leaves was prepared using 70:30 ethanol: water solvent system, which yielded a dark green semisolid extract rich in anti-inflammatory phytocompounds including nyctanthoside, oleanolic acid, and flavonoids as confirmed by preliminary phytochemical screening. Three gel formulations (F1, F2, F3) were prepared using Carbopol 934 as gelling agent, propylene glycol as humectant, Tween 80 as penetration enhancer, methyl paraben as preservative, sodium hydroxide for pH adjustment, ethanol as co-solvent, and distilled water as vehicle. All formulations were evaluated for comprehensive physicochemical parameters.

Formulation F2 (1.5% Carbopol 934, 5% Nyctanthes extract, 1% Tween 80) was identified as the optimized formulation, demonstrating the best balance of pH compatibility (6.8), viscosity (5120 cP), spreadability (35.6 g.cm/s), extrudability (94%), and drug content uniformity (97.8%). The in vitro drug release study showed 93.8% drug release over 24 hours comparable to the marketed formulation, following Higuchi diffusion-controlled kinetics. Stability studies confirmed that F2 maintained physicochemical integrity under both long-term and accelerated storage conditions.

All formulations passed the skin irritancy test, confirming safety for topical use. Compared to synthetic anti-inflammatory preparations, the polyherbal gel offers advantages of natural origin, improved safety profile, multiple bioactive constituents targeting different inflammatory pathways, and patient acceptability. The study concludes that the formulated Nyctanthes arbor-tristis-based anti-inflammatory gel is a safe, effective, stable, and promising herbal topical preparation with significant potential for commercial development as an alternative to conventional NSAIDs for management of local inflammatory conditions.

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