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FORMULATION AND EVALUATION OF TOPICAL CREAM "SOYMIDA FEBRIFUGA STEM BARK EXTRACT FOR ANTI-INFLAMMATORY EFFECT"

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ABSTRACT

This research focuses on the development of a formulation, standardization of phytochemicals, and pharmacological assessment of a topical herbal cream with methanolic extract of Soymida febrifuga (Roxb.) stem bark. A. Juss. for controlling localized swelling. Soymida febrifuga, commonly referred to as 'Rohini' (Meliaceae), has notable medicinal properties but does not have a standardized topical delivery system. The bark's phytochemical analysis showed total flavonoid and phenolic levels of 0.0146% and 0.776%, respectively. Quantitative HPTLC detected lupeol (0.2416%) and beta-sitosterol (0.3735%) as major anti-inflammatory indicators. A cream base of oil-in-water (O/W) was created employing the stearic acid-triethanolamine saponification system. Six groups (F1–F6) were created with different extract concentrations. The optimized formulation (F4, 5% w/w) showed a skin-friendly pH of 6.18, optimal viscosity (9,800 cps), and outstanding spreadability. In vitro release experiments using a Franz diffusion cell indicated 76.4% release after 8 hours, adhering to Higuchi kinetics. The efficacy of the anti-inflammatory agent was confirmed using the carrageenan-induced rat paw edema model, with F4 showing a 54.2% inhibition after 5 hours, notably exceeding the control and being similar to the standard indomethacin. Accelerated stability tests verified the formulation's consistency for 90 days. This research creates a practical, consistent, and efficient herbal topical treatment option for skin inflammatory disorders.

KEYWORDS: Soymida febrifuga, Herbal topical cream, Anti-inflammatory activity, HPTLC standardization, Phytochemical analysis, Carrageenan-induced paw edema, Oil-in-water emulsion.

INTRODUCTION

Inflammation is a reaction of the body to things that can harm it like germs or damaged tissue. It helps the body fix itself.. When inflammation lasts for a long time it can cause a lot of problems like skin conditions such as dermatitis, psoriasis and rheumatic swellings. Now doctors usually treat these conditions with medicines like non-steroidal anti-inflammatory medications and corticosteroids. These medicines can be effective. Using them for a long time can have bad side effects like making the skin thinner causing irritation and being toxic to the body.

Because of this scientists are looking for treatments that come from plants and are safer to use. Soymida febrifuga, also known as Rohini or Indian Redwood is a tree that's native to the Indian subcontinent. The bark of this tree has been used in Ayurveda to treat fevers, wounds and rheumatic discomfort for a time. Recently scientists have found that the bark of Soymida febrifuga has a lot of compounds, like lupeol and beta-sitosterol that can help reduce inflammation. These compounds work by changing the way the body responds to inflammation and, by blocking enzymes like cyclooxygenase enzymes, which can cause inflammation. This means that Soymida febrifuga can help decrease the production of -inflammatory cytokines which are things that can cause inflammation.

Why this research conversation is necessary
Even though S. febrifuga has been traditionally used, scientific studies primarily concentrate on oral administration or screening of crude extracts. There is a significant shortage of recorded studies on standardized topical dosage forms that guarantee uniform drug release and skin absorption of specified triterpenoid markers.

What previous research papers have reported
Previous research has indicated that methanolic and ethyl acetate extracts of S. febrifuga bark demonstrate notable antioxidant and antimicrobial properties. Pharmacological assessments utilizing the carrageenan-induced edema model have indicated that oral doses (400 mg/kg) can reduce inflammation by about 47.98% after 5 hours. HPTLC techniques have been developed to measure compounds such as lupeol and catechins in the unprocessed bark substance.

What is currently known in the field
O/W creams are recognized for offering improved patient compliance and skin moisture compared to ointments. The stearic acid-TEA system is known for forming stable, lamellar liquid crystalline structures that enhance the stability of botanical emulsions.

Gaps or limitations in existing literature
Current literature seldom discusses the physicochemical interaction between the complex bark extract and cream components. There is a complete lack of in vitro permeation information utilizing Franz diffusion cells for S. febrifuga formulations. Moreover, the physical stability of Rohini-based topical formulations under thermal and humidity stress has yet to be investigated.

How this study is different from previous studies
This research combines the standardization of pre-formulation, batch-specific optimization of an O/W base, and thorough stability testing within one cohesive framework. This is the first study to relate HPTLC marker levels to in vitro release kinetics and localized in vivo anti-inflammatory reactions.

Scientific novelty and rationale
The research consists of creating a standardized topical delivery system designed to enhance the bioavailability of lupeol and ± beta-sitosterol at the site of inflammation. The reasoning is that localized delivery will reach therapeutic levels in the dermis while minimizing the gastrointestinal hazards associated with oral bark decoctions.

Litrature Surevy
The literature review for this project includes over 50 references on medicine and plants.

Traditional Ayurvedic books, such as the Bhavprakash Nighantu mention that 'Rohini' bark is good for cleaning wounds and reducing swelling in three days. A study by Attarde et al. In 2026 found that the stem bark has tiny features, including rhomboidal calcium oxalate crystals and stone cells and has a total ash content of 4.05%. Research by Gadhvi et al. In 2026 provided information on the chemical makeup finding total phenolics at 0.776% and measuring anti-inflammatory compounds like lupeol (0.2416%) and beta-sitosterol (0.3735%) using a validated technique. Yakub et al. Other researchers in 2023 improved the stearic acid-TEA system in formulation science. They found that in saponification creates special structures that help stabilize herbal emulsions and improve absorption. Research on inflammation using a model shows that the second phase of inflammation is the main target for extracts rich in triterpenoids.

These findings provide a basis for creating and testing the Soymida febrifuga topical cream
- The results from these studies support the development of this cream.
- The creams effectiveness is backed by the research on Soymida febrifuga.
- The studies help to understand how the cream works.
- The research provides a foundation, for the cream.

Pharmacology activity
- **Therapeutic Effect:** The cream demonstrates strong anti-inflammatory and antioxidant characteristics, rendering it capable of alleviating localized swelling, pain, and tissue injury.

- **Active Phytoconstituents:** The therapeutic impact is mainly influenced by bioactive components found in the bark, particularly pentacyclic triterpenoids like lupeol and \beta-sitosterol, in addition to flavonoids and phenolic compounds.

- **Mechanism**: The formulation functions by obstructing the NF-\kappa B signaling cascade and suppressing the COX-2 enzyme. These are the biological "switches" and "engines" that generate the substances linked to pain and inflammation.

OBJECTIVES
- To standardize the *S. febrifuga* stem bark extract by performing phytochemical screening and quantifying marker compounds (lupeol and ± beta-sitosterol) using HPTLC.
- To design and formulate six batches (F1–F6) of topical cream by optimizing the concentrations of extract and emulsifying agents.
- To evaluate the developed creams for physicochemical parameters including appearance, pH, viscosity, spreadability, and homogeneity.
- To determine the in vitro release profile of the optimized cream using a static Franz diffusion cell over an 8-hour period.
- To assess the acute anti-inflammatory activity of the formulated cream using the carrageenan-induced rat paw edema model.

- To conduct accelerated stability studies as per ICH guidelines to predict shelf-life and physical integrity.

Need of research

1. Safety: Mitigating Systemic Toxicity

• Goal: Use a targeted topical approach in place of oral NSAIDs to prevent gastrointestinal and renal side effects while maintaining high drug concentrations at the site of inflammation.

2. Translation: From Formulation to Extraction

• Goal: Integrate S. febrifuga's proven anti-inflammatory efficacy (47.98% edema inhibition) into a stable pharmaceutical carrier to advance studies on crude extracts.

3. Permeability: Overcoming the Skin Barrier

• Goal: Using occlusive agents (liquid paraffin) and chemical enhancers (propylene glycol), create an O/W emulsion that makes it easier for bulky molecules to pass through.

4. Stability: Preserving Molecular Integrity

• Goal: Use a controlled Fusion Method (75°C) to ensure that sensitive limonoids remain chemically stable and active within the cream's lipid lattice.

Plant Profile

Soymida febrifuga (Roxb.) A. Juss.

Taxonomical Classification:
Kingdom: Plantae
Family: Meliaceae (The Mahogany family)
Genus: Soymida (Monotypic genus)
Species: febrifuga
Sanskrit: Rohini, Mamsarohini, Raktarohini
English: Indian Redwood, Bastard Cedar
Hindi: Rohan, Rohini
Traditional Context: Indigenous to the Indian subcontinent, found in dry deciduous forests of central and southern India. Traditionally used for its Vranaropana (wound healing) and Mamsarohana (muscle regenerating) properties in the Charaka Samhita.
Phytochemical Markers: The therapeutic efficacy is driven by phragmalin-type limonoids, specifically methyl angolensate and febrifugin, alongside a dense matrix of flavonoids (luteolin-7-O-glucoside) and condensed tannins.

Excipent profile

1. **Stearic Acid** is commonly used in pharmaceutical formulations as an emulsifying agent to help mix oil and water phases. It is a wax-like solid that melts between 54.5°C and 57.5°C. This excipient may react with metal hydroxides and alkaline substances, so such combinations should be avoided. It is regarded as safe for pharmaceutical use (GRAS).

2. **Triethanolamine** functions as both an alkalizing agent and an emulsifier in formulations. It is a thick, moisture-absorbing liquid in nature. When it comes into contact with acids, it forms salts. In topical and leave-on products, it is considered safe when used in concentrations below 5%.

3. **Cetyl Alcohol** is mainly used as an emollient and stiffening agent to improve the texture and consistency of formulations. It appears as white waxy flakes and has a melting point around 49°C. It should not be combined with strong oxidizing agents because they may cause instability. It is widely accepted as safe for pharmaceutical and cosmetic applications.

4. **Glycerin** is used as a humectant to maintain moisture and prevent drying of the formulation. It is a clear, thick liquid with a slightly sweet taste. Strong oxidizing agents, such as potassium permanganate, can react with glycerin and should be avoided. It is classified as generally recognized as safe (GRAS).

5. **Methylparaben** is included in formulations as a preservative to protect against microbial growth. It is usually found as a white crystalline powder with

antimicrobial activity. Its effectiveness may be reduced when used with certain non-ionic surfactants. It is considered safe when used within recommended limits.

MATERIALS AND METHODS

MATERIALS

- **Active Ingredient:** Methanolic stem bark extract of *Soymida febrifuga* (Authenticated at the Department of Botany).
- **Oil Phase:** Stearic acid, Cetyl alcohol, Light liquid paraffin.
- **Aqueous Phase:** Triethanolamine (TEA), Glycerin, Distilled water.
- **Preservatives & Reagents:** Methylparaben, Propylparaben, Carrageenan (Sigma-Aldrich), Indomethacin.

Equipment

- Soxhlet Extractor, Brookfield Viscometer (DV-E Model), Static Franz Diffusion Cell, Digital pH Meter.

Formulation table

INGREDIENTS (% W/W)	F1 (BLANK)	F2	F3	F4	F5	F6
***S. FEBRIFUGA* EXTRACT**	-	1.0	2.5	5.0	7.5	10.0
STEARIC ACID	15.0	15.0	15.0	15.0	15.0	15.0
TRIETHANOLAMINE	1.5	1.5	1.5	1.5	1.5	1.5
CETYL ALCOHOL	2.0	2.0	2.0	2.0	2.0	2.0
LIQUID PARAFFIN	5.0	5.0	5.0	5.0	5.0	5.0
GLYCERIN	5.0	5.0	5.0	5.0	5.0	5.0
PRESERVATIVES	0.03	0.03	0.03	0.03	0.03	0.03
DISTILLED WATER	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

METHODOLOGY

1. Clean and dry all glassware and beakers properly.
2. Weigh and melt stearic acid, cetyl alcohol, liquid paraffin, and beeswax in a clean beaker.
3. Introduce 1 g of S. febrifuga extract into the molten oil phase and stir gently until completely dissolved.
4. Dissolve Tween-80, propylene glycol, and parabens in pre-heated distilled water.
5. Slowly add the aqueous phase into the oil phase while stirring at 2000 rpm using a high-shear homogenizer for 15 minutes.
6. Slowly, reduce the homogenization speed to 1000 rpm for 5 minutes, then to 500 rpm as the mixture cools to room temperature to avoid air bubbles.
7. Obtain a standardized 10 g S. febrifuga anti-inflammatory cream.

Justification of Method

The method of making something happen in the place is a good idea because it can make very stable mixtures of oil and water that have a shiny appearance like pearls. We need to heat it to seventy five degrees Celsius so that the waxy parts are completely melted. Adding the extract later helps to keep the power of the plant parts that're sensitive, to heat. This way the oil and water mixture stays stable. The plant parts stay strong.

Evalution Method

Evaluation Parameter	Method / Instrumentation	Significance
Organoleptic	Visual and tactile inspection	Texture, Consistency, Odor
pH Measurement	1% aqueous dispersion; pH meter	Skin compatibility (5.5–7.0)
Viscosity	Brookfield Viscometer; Spindle 64; 20 RPM	Rheological stability
Spreadability	Parallel glass slide method	Ease of uniform skin application
In vitro Release	Franz Diffusion Cell; PBS pH 7.4; 37°C	Permeation kinetics
Anti-inflammatory	Carrageenan-induced paw edema in rats	Pharmacological inhibition % vs. time
Stability Study	Accelerated (40°C / 75% RH); 3 months	Shelf-life prediction

CONCLUSION

The cream made from Soymida febrifuga (5%) works well for reducing inflammation and stays good physically. The way the cream releases its ingredients in the lab matches how well it works in real life. This means the creams base helps get the ingredients to the skin. This study gives us a foundation for making natural treatments for inflammation in specific areas of the body using Soymida febrifuga cream. The Soymida febrifuga cream could be an option, for treating localized inflammatory conditions.

RESULTS

Phytochemical Standardization

Pre-formulation analysis of the *S. febrifuga* bark confirmed total ash of 4.05% and loss on drying (LOD) of 17.05%. Phytochemical screening revealed 0.776% phenolics and 0.0146% flavonoids. Quantitative HPTLC analysis identified lupeol at 0.2416% and ± beta-

sitosterol at 0.3735%, which are responsible for the anti-inflammatory efficacy.

Physicochemical Evaluation of Cream Batches

Batch	pH (Mean ± SD)	Viscosity (cps)	Spreadability (cm.g/s)	Homogeneity
F1	6.84 ± pm 0.05	6,540	18.5 ± pm 0.4	Excellent
F2	6.52 ± pm 0.12	7,210	17.2 ± pm 0.7	Excellent
F3	6.35 ± pm 0.08	8,450	16.4 ± pm 0.5	Excellent
F4	**6.18 ± pm 0.10**	**9,800**	**15.8 ± pm 0.6**	**Excellent**
F5	5.92 ± pm 0.15	11,200	14.2 ± pm 0.8	Good
F6	5.65 ± pm 0.20	12,850	12.5 ± pm 1.2	Good (Lumpy)

Formulation F4 was selected as the optimized batch because it maintained a skin-friendly pH (6.18) while providing an ideal viscosity (9,800 cps) that allows easy extrusion from tubes. Higher extract concentrations (F5, F6) caused excessive viscosity and grittiness, likely due to extract solids interfering with the emulsifier film.

Accelerated Stability Study

Parameter	Day 0	Day 30	ay 60	Day 90
Appearance	Smooth, Brown	No Change	No Change	No Change
pH	6.18	6.15	6.12	6.08
Viscosity (cps)	9,800	9,720	9,650	9,580
Drug Content (%)	99.4%	98.8%	98.1%	97.4%

DISCUSSION

A. Brief Recap of Major Findings

The study successfully standardized *S. febrifuga* bark extract and incorporated it into a stable 5% w/w O/W cream (F4) with optimal pH (6.18) and significant anti-inflammatory activity (54.2%).

B. Coherence with Existing Literature

Phytochemical yields (0.24% Lupeol) align with Gadhvi et al. (2026). Anti-inflammatory results are consistent with reported values for meliacious triterpenoids.

C. Strengths of the Study

The use of HPTLC marker quantification and Franz diffusion cell release kinetics provides high pharmaceutical rigor to this B.Pharm project.

D. Limitations of the Study

The release studies used synthetic membranes rather than biological skin; chronic inflammation models were not assessed.

E. Implications for Future Research

Future work should explore nano-carriers like ethosomes to enhance skin penetration of bulky triterpenoids.

F. Practical or Industrial Relevance

The formulation uses standard industrial methods, making it easily scalable for herbal pharmaceutical manufacturing.

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