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Research Article

Formulation and evaluation of anti-inflammatory topical polyherbal gel

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Abstract

NSAIDs are widely used to treat inflammation, but their long-term use can increase the risk of cardiovascular problems. This has led to growing interest in natural products that offer anti-inflammatory benefits with fewer side effects. The present study aimed to develop a polyherbal gel containing hydroalcoholic extracts of *Berberis aristata* root, *Rubia cordifolia* root, and *Boswellia serrata* gum, using Carbopol 934 and propylene glycol. A 3^2 factorial design was applied, considering polymer and penetration enhancer concentrations as variables, while viscosity and drug release served as responses. Nine formulations were prepared, and the optimised gel was selected through a desirability-based overlay plot. The final formulation showed a viscosity of 39,568 m. Pas and contained 0.48 mg berberine, 0.42 mg rubiadin, and 0.51 mg AKBA. In vivo and histopathology results indicated strong anti-inflammatory activity.

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INTRODUCTION

Traditional medicinal systems continue to play a significant role in global healthcare, with nearly three-fourths of the world's population depending on plants and plant-derived products for treatment. Many Indian medicinal plants are known for their diverse phytochemicals, which contribute to various pharmacological effects. Although opioids and NSAIDs are commonly used to manage inflammation, their use is often limited due to adverse reactions such as irritation, redness, and itching. This has encouraged the search for safer, plant-based alternatives.

Reports from the literature indicate that numerous plants across the plant kingdom possess anti-inflammatory properties. Well-known species such as *Acacia nilotica*, *Withania somnifera*, *Glycyrrhiza glabra*, *Boswellia serrata*, *Phyllanthus amarus*, and *Eclipta alba* contain flavonoids and have been studied for their anti-inflammatory potential.

The present study focuses on *Cynodon dactylon*, *Cassia tora*, and *Cassia alata*, which are rich in flavonoids and other bioactive constituents linked to anti-inflammatory effects. The work includes evaluating the activity of each extract individually, as well as in combination, to determine whether they exhibit a synergistic response when formulated together.

Gels were selected as the dosage form for topical application due to their ease of use, extended contact time with the skin, and lower risk of side effects compared to other topical or oral formulations. Traditionally, *Cassia tora* and *Cassia alata* have been used for their therapeutic benefits, including anti-inflammatory activity.

❖ Applications of Anti-Inflammatory Topical Polyherbal Gels.

♦ Management of Local Inflammation.

- Polyherbal gels are commonly used to ease various localised inflammatory symptoms, including:
- Redness.
- Swelling or oedema.
- Warmth and discomfort at the affected area.
- Mild to moderate inflammation of the skin, muscles, or soft tissues.

❖ Advantages

- Synergistic action: Multiple herbs act on different pathways, boosting the anti-inflammatory effect.
- Fewer side effects: Plant-based ingredients are generally safer than synthetic NSAIDs.
- Good patient acceptability: Gels are non-greasy, quick-absorbing, and soothing.
- Better penetration: Carbopol and propylene glycol enhance skin absorption of herbal actives.
- Targeted relief: Acts directly on the inflamed area, reducing the need for oral drugs.
- Lower dose needed: Combined herbs provide effective action at reduced concentrations.
- Improved stability: Gel base protects herbal compounds from light and oxidation.
- Cost-effective: Uses easily available medicinal plants, making the formulation economical.

❖ Disadvantages.

- Variability in extract quality: The number of active compounds in plants can differ between batches, affecting consistency.
- Stability issues: Some herbal extracts degrade with light, heat, or microbes and may need preservatives.
- Risk of irritation: Even natural ingredients can trigger allergic reactions in sensitive users.
- Limited penetration: Gels mostly work on surface tissues and may not reach deeper inflammation.
- Odor and color concerns: Certain plant extracts may have strong smells or noticeable color.
- Shorter shelf life: Herbal gels may deteriorate faster without proper stabilisers.

Limited clinical evidence: Many herbal ingredients still lack extensive clinical trial data.

❖ EXPERIMENTAL

Collection of Plant Material: The leaves of Cassia tora and Cassia alata were collected from Hingna, MIDC area of Nagpur, while the aerial part of Cynodon dactylon was obtained from a medicinal plant garden.

Preparation of Extract: Fresh plant materials were dried in a hot-air oven at 40°C to prevent loss of active constituents. The dried leaves and aerial parts were coarsely powdered and stored in airtight containers. Powders of *Cassia alata* (185 g), *Cassia tora* (100 g), and *Cynodon dactylon* (125 g) were first defatted using petroleum ether (60–80°C) in a Soxhlet extractor, followed by methanol extraction. The extracts were concentrated, solvents recovered, and residues stored in a desiccator until use.

Preparation of Polyherbal Gel: Methanolic extracts of *Cassia tora*, *Cassia alata*, and *Cynodon dactylon* were incorporated into a gel base prepared with 1% Carbopol-940. Individual extract gels and a combined polyherbal gel were formulated. A diclofenac sodium gel was prepared using the same procedure to serve as a reference.

❖ METHOD OF PREPARATION

Step 1 — **Gel Base:** Carbopol was dispersed in distilled water with continuous stirring and allowed to hydrate. Glycerin and propylene glycol were then mixed in.

Step 2 — **Herbal Phase:** The plant extracts were dissolved in a small volume of water or propylene glycol, depending on their solubility, and filtered if needed.

Step 3 — **Mixing:** The herbal solution was slowly blended into the gel base with gentle stirring to prevent foam formation.

Step 4 — **Preservatives:** Methyl and propyl parabens were dissolved in warm water or PG and added to the mixture.
Step 5 — **Final Adjustment:** pH was adjusted to 5.5–6.5 using triethanolamine (TEA) until the gel set. The final gel was mixed uniformly and filled into the appropriate containers.

❖ **MATERIALS REQUIRED ACTIVE HERBAL EXTRACTS:**

♦ **Active Herbal Extracts:**

- Aloe vera gel.
- Turmeric extract (Curcumin)
- Green tea extract.
- Liquorice extract.

♦ **Gel Base Ingredients:**

- Carbopol 940 / 934 (gelling polymer).
- Triethanolamine (TEA) – neutraliser.
- Glycerin (moisturiser)
- Propylene glycol (penetration enhancer)
- Distilled water.
- Preservatives: Methyl paraben, Propyl paraben

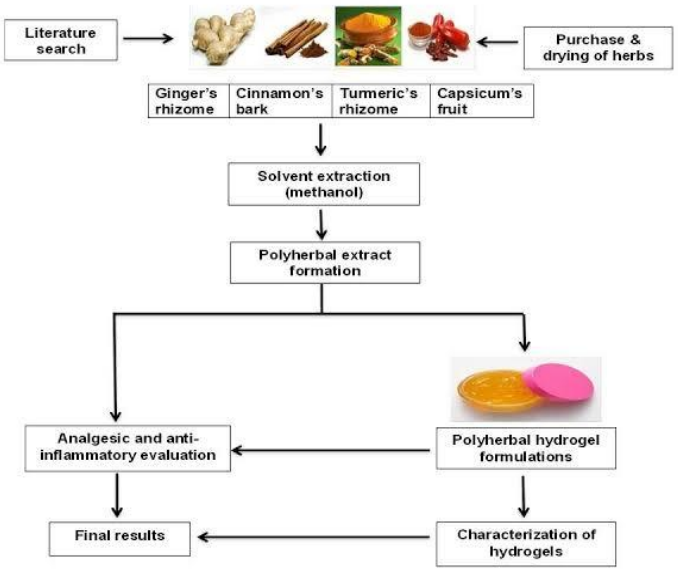
❖ **FORMULATION COMPOSITION.**

The gel was prepared with 1% Carbopol 940, 5% glycerin, 10% propylene glycol, 2% each of Herbal Extracts A and B, and 1% Herbal Extract C (optional). Preservatives included 0.2% methyl paraben and 0.05% propyl paraben. Triethanolamine adjusted the pH to 5.5–6.5, and water was added to make 100%.

Evaluation

1. **pH:** The pH of each gel and the polyherbal gel was checked using a digital pH meter.
2. **Appearance and Homogeneity:** All formulations were examined visually for colour, consistency, and uniformity.
3. **Viscosity:** Gel viscosity was determined using a Brookfield viscometer (Model RVTDV II) at 100 rpm with spindle no. 6.
4. **Spreadability:** One gram of gel was placed between two glass plates, and the spread diameter after one minute under a 125 g weight was recorded.
5. **Skin irritation studies:** Wistar rats (150–200 g) with shaved skin were treated with the gel once daily for seven days. The treated area was inspected for redness and swelling.
6. **Extrudability:** Gels were filled into collapsible tubes, and the percentage of gel expelled after applying pressure was calculated to assess ease of extrusion.
7. **Stability study:** Formulations were tested for stability according to ICH guidelines.
8. Primary Dermal Irritation Index (PDIIThe gels were classified as irritating or non-irritating based on skin reactions

Selected Bioactivities of Polyherbal Extracts



❖ **Mechanism of Anti-Inflammatory Action of Herbal Constituents.**

Herbal compounds reduce inflammation by inhibiting COX-1/COX-2 and LOX pathways, modulating pro-inflammatory cytokines (TNF-α, IL-1β, IL-6), scavenging free radicals, stabilising cell membranes, and decreasing nitric oxide (NO) production.

❖ **Future Research Directions.**

- AI-based prediction of synergistic herb combinations.
- 3D-printed personalised herbal gels.
- Metabolomics for detailed extract profiling
- Microbiome-friendly formulations.
- Long-term safety and post-market surveillance.

❖ **Market & Industrial Relevance.**

- Increasing demand for natural, clean-label anti-inflammatory topicals.
- Commercialisation Barrier:

Raw material variability, scale-up difficulties intellectual property issues.

♦ **Safety Evaluation**

❖ **Skin irritation tests.**

- Dermal sensitisation studies.
- Patch test on a volunteer.
- Limits for heavy metals and microbial contamination.

❖ **Challenges in Polyherbal Topical Formulations.**

- Standardisation issues and plant quality variability.
- Interactions among multiple phytochemicals.
- Difficulty in maintaining consistent formulations.
- Regulatory hurdles.

CONCLUSION

The study showed that polyherbal gels made from methanolic extracts of *Cassia tora*, *Cassia alata*, and *Cynodon dactylon* exhibited significant anti-inflammatory activity, comparable to standard diclofenac gel. Phytochemical analysis revealed glycosides, carbohydrates, flavonoids, steroids, and resins, which may inhibit prostaglandin and bradykinin formation. The combination gel demonstrated a synergistic effect, making it more effective than individual extracts for treating local inflammation.

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