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Formulation and Evaluation of Boehmeria Nivea Leaf Extract-Loaded Herbal Anti-Inflammatory Gel for Topical Use

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Abstract : *A further limitation is that the proposed gel does not yet have established clinical efficacy. The appropriate conclusion at the review stage is that the botanical evidence supports further investigation, not that the gel is a proven treatment. Future work should be designed to address formulation quality, safety, and biological performance in a stepwise manner. Laboratory cell studies provide information about possible mechanisms but do not establish whether the compounds reach the relevant skin layers after topical application. The finished formulation may alter solubility, release, stability, and local tolerability. Direct formulation studies are therefore necessary. The published evidence is heterogeneous because studies may use different plant varieties, plant parts, solvents, extract concentrations, and experimental models. Root-extract findings cannot be treated as direct evidence for a leaf extract. Similarly, results from isolated compounds may not reflect the behaviour of the complete extract in a gel..*

Keywords: *clinical efficacy*

I. INTRODUCTION

Inflammation is a complex response involving immune cells, blood vessels, and chemical mediators. Common signs include redness, warmth, swelling, pain, and reduced function. It is an important defence and repair mechanism; however, prolonged or excessive inflammation can damage tissues. Inflammatory signalling involves mediators such as nitric oxide, cytokines, and enzymes that regulate immune responses [1,2].

Plant-derived substances are frequently investigated as sources of biologically active compounds. Phenolics and flavonoids are of particular interest because some members of these groups exhibit antioxidant and inflammation-modulating activity in experimental systems. The activity of a plant extract depends on its botanical identity, plant part, growing conditions, extraction solvent, and processing method [3,5].

Boehmeria nivea (L.) Gaudich. is a perennial plant in the Urticaceae family, commonly called ramie. It is known as a fibre-producing plant, but its leaves and other plant parts have also been studied for phytochemicals and biological activities. Research has reported antioxidant activity and effects on inflammatory mediators for selected B. nivea extracts [1–4]. These findings provide a rationale for further pharmaceutical investigation, rather than proof that every extract or finished product will be effective.

A topical gel is a semisolid system in which a liquid phase is structured by a suitable gelling agent. Depending on its composition, a gel may spread readily, feel less greasy than some ointments, and support local delivery. However, release and skin penetration depend on the active constituents, vehicle, polymer, pH, and other formulation factors [6–9]. This review discusses the evidence and development considerations for a B. nivea leaf extract-loaded herbal anti-inflammatory gel.

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II. BOTANICAL PROFILE OF BOEHMERIA NIVEA

2.1 Taxonomy and description

Scientific name: Boehmeria nivea (L.) Gaudich.; family: Urticaceae; common name: ramie. It is a perennial herbaceous plant cultivated for its fibre. Correct botanical authentication is essential because related species, varieties, and different plant parts may have different chemical profiles and biological properties [3,4].



2.2 Importance of the leaves

Leaves are relevant to this project because published studies have examined B. nivea leaf extracts for phenolic constituents, antioxidant activity, and modulation of inflammatory markers [2–4]. The plant material should be authenticated, collected responsibly, dried under controlled conditions, and stored in a manner that limits moisture and contamination.



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III. PHYTOCHEMICAL CONSTITUENTS

Research on B. nivea has identified or reported classes of compounds including phenolic acids, flavonoids, and other secondary metabolites. Choi and colleagues
reported compounds including caffeic acid, isoquercitrin, p-coumaric acid, and rutin in leaf fractions; these compounds showed radical-scavenging activity in the assays used [3]. Other work has examined chemical constituents and biological activity across plant parts and extracts [2,4].



The chemical composition of a botanical extract is not fixed. Solvent strength, extraction time, temperature, plant maturity, geographical origin, and storage may change the profile. For reproducible formulation development, extraction yield and selected chemical markers should be documented. Phytochemical screening tests can provide preliminary information, but they do not replace specific analytical characterization where feasible [5,10].4. Review of Relevant Literature

4.1 Lin et al. (1997)

Lin and colleagues investigated B. nivea and B. nivea subsp. nippononivea in animal models. Water extracts from roots showed activity against carrageenan-induced paw oedema [1]. This is relevant as species-level evidence, but it involved root extracts and an animal model rather than a topical leaf-extract gel. The results therefore cannot be directly transferred to the proposed formulation.

4.2 Sung et al. (2013)

Sung and colleagues examined a 70% ethanol extract of B. nivea leaves in lipopolysaccharide-stimulated RAW264.7 macrophages. The study reported reduced levels of selected inflammatory mediators, including nitric oxide, TNF-α, and IL-6, and effects on iNOS and p38/JNK signalling [2]. This is directly relevant to leaf-extract research, but cell-model findings do not establish skin penetration or clinical efficacy.

4.3 Choi et al. (2022)

Choi and colleagues compared leaf and stem extracts collected from different regions and assessed several biological activities and chemical constituents. Leaf extracts showed stronger activity than stem extracts in selected tests, including inhibition of pro-inflammatory gene expression. Caffeic acid, isoquercitrin, p-coumaric acid, and rutin were among the compounds identified in leaf fractions [3]. The study also highlights the importance of plant origin and marker analysis.

4.4 Jung et al. (2020)

Jung and colleagues investigated antioxidant, antimicrobial, and anti-inflammatory effects of B. nivea var. nippononivea extracts. Leaves were extracted with 70% ethanol and fractionated with solvents of different polarity. Certain fractions showed radical-scavenging activity and effects in inflammatory assays [4]. These results support further exploration of ramie leaf extracts as potential ingredients, but the work did not validate the specific gel proposed here.

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4.5 Lee et al. (2022)

Lee and colleagues reviewed ramie as a functional food and herbal medicine, summarizing reported traditional uses, phytochemicals, and pharmacological findings relevant to inflammation and oxidative stress [5]. As a review, it provides broader context but does not replace direct formulation or clinical studies.

4.6 Nguyen et al. (2025)

Nguyen and colleagues isolated megastigmane compounds from B. nivea leaves and investigated immunomodulatory effects in RAW264.7 macrophages. Their work reported effects on IL-1β and IL-10 production for selected compounds [6]. This adds to the chemical and biological evidence for the leaves, while remaining preclinical and not specific to a topical gel.

4.7 Recent leaf-extract findings (2025)

A 2025 study of ramie leaf extracts assessed polyphenols, flavonoids, radical-scavenging activity, cell viability, and nitric oxide inhibition, reporting differences between cultivars [7]. Such results reinforce the need to standardize plant material and characterize each extract batch. Findings from one cultivar or laboratory protocol should not be assumed to apply to all B. nivea preparations.

V. PROPOSED ANTI-INFLAMMATORY RATIONALE

Inflammatory responses involve signalling pathways and mediators such as nitric oxide, TNF-α, IL-6, and IL-1β. Some B. nivea extracts have been reported to alter selected markers in experimental cell systems [2–4,6,7]. Phenolic compounds may also contribute antioxidant effects, although the relationship between antioxidant activity and clinically meaningful anti-inflammatory effects is not straightforward [3,8].

The proposed gel is intended as a research formulation to test whether a characterized leaf extract can be incorporated into a stable topical vehicle and retain measurable biological activity. It should not be described as a proven treatment for inflammatory skin disease unless suitable preclinical and clinical evidence becomes available.

VI. RATIONALE FOR A TOPICAL GEL

Topical dosage forms can deliver ingredients to the skin surface and may be useful where local application is desired. Gels can be designed for suitable spreadability, viscosity, and user acceptability. Their performance depends on the polymer, vehicle, pH, extract solubility, and packaging [8–11]. A plant extract can also alter colour, odour, viscosity, pH, or stability, so compatibility and quality tests are necessary.

Potential advantages include ease of application, uniform distribution when adequately mixed, and the possibility of a non-greasy feel. These are formulation-dependent characteristics, not guaranteed properties of every herbal gel.

VII. PROPOSED FORMULATION INGREDIENTS

The following ingredients are options for preliminary laboratory development. The final formula and concentrations must be selected through compatibility studies and pilot batches; this review does not provide a validated formula.

Boehmeria nivea leaf extract: investigational botanical active ingredient. Carbomer or another suitable gelling agent: provides the semisolid gel structure. Glycerin: humectant and formulation aid.

Propylene glycol, if suitable: possible cosolvent or humectant; compatibility and skin tolerance must be assessed.

Neutralizing agent, where required: used to develop viscosity in compatible polymer systems.

Purified water: aqueous vehicle.

Suitable preservative, if needed: selected according to compatibility, intended use, and preservative-effectiveness requirements.

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The selected extraction solvent should be suitable for the intended research use, and residual solvent should be controlled. The formulation should be labelled for laboratory evaluation and should not be used on people until adequate safety assessment and applicable approvals are in place.

VIII. GENERAL METHOD OF PREPARATION

Authenticate the plant and record the collection location, date, plant part, and voucher details where available.
Wash the leaves as appropriate, dry under controlled conditions, and reduce them to a uniform powder.
Extract the powdered material with a justified solvent system, such as a hydroethanolic solvent, using controlled time and temperature.
Filter and concentrate the extract using a suitable method; record the extract yield and appearance.
Prepare the gel base by dispersing the selected gelling agent in purified water according to an established procedure.
Allow the polymer to hydrate, then incorporate the extract gradually using a compatible vehicle.
Add other excipients and adjust pH if required by the selected polymer and intended topical use.
Mix until uniform while minimizing air entrapment; transfer into suitable clean containers.
Label each batch and record the formula, batch size, manufacturing steps, and observations.

IX. EVALUATION PARAMETERS

9.1 Physical appearance and homogeneity

Record colour, odour, consistency, visible particles, lumps, and phase separation. Inspect the gel for uniformity and document any defects. Appearance alone cannot confirm chemical or microbiological quality [8,12].

9.2 pH

Measure pH using a calibrated pH meter and a consistent sample-preparation procedure. Interpret the result in relation to intended skin use, polymer requirements, and extract stability. A suitable pH alone does not establish skin safety.

9.3 Viscosity

Measure viscosity using a suitable viscometer and report the instrument, spindle, speed, temperature, and sample preparation. These conditions affect results and should be kept consistent across batches [8,9].

9.4 Spreadability

Assess the ability of the gel to spread using a defined method. Report the sample quantity, load or applied force, contact time, and calculation. Comparisons are meaningful only when the method is standardized.

9.5 Extrudability

Evaluate the ease of dispensing the gel from its intended container under a defined force or procedure. Report the container type and method so that results can be compared between formulations.

9.6 Extract or marker content

If a suitable marker compound is identified, estimate its content using a suitable analytical method. Chromatographic methods may be appropriate when available. A general colour reaction or total phenolic test is not equivalent to quantifying a specific marker [3,10,13].

9.7 In-vitro release

An appropriate release study can examine the release of a selected marker or measurable extract constituent from the gel. The membrane, receptor medium, temperature, sampling schedule, and analytical method should be justified and reported. In-vitro release does not by itself demonstrate skin penetration or clinical benefit [9,11].

9.8 Stability

Monitor appearance, pH, viscosity, homogeneity, marker content where feasible, and microbial quality during storage under defined conditions. Stability protocols should be scientifically justified and consistent with relevant guidance [14].

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9.9 Microbial quality and preservative effectiveness

Water-containing gels may support microbial growth. Assess microbial quality using suitable methods, and evaluate preservative effectiveness where appropriate for the formulation and intended use. Herbal raw materials should be handled and tested with attention to contamination risks [12,15].

9.10 Safety and biological activity

Use appropriate validated methods to assess cytotoxicity, skin irritation potential, and anti-inflammatory activity. Possible laboratory approaches include measurement of inflammatory mediators in a suitable cell model or a justified preliminary in-vitro assay. Include positive and negative controls, replicates, and cytotoxicity assessment. Human testing requires prior safety justification, informed consent, and relevant ethics and regulatory approvals [2,6,16].

X. DISCUSSION

The literature indicates that B. nivea leaves contain phytochemicals and that selected extracts can influence inflammatory markers and oxidative-stress-related

assays [2–7]. This supports a rationale for further investigation of the leaf extract in a topical gel. Nevertheless, botanical extracts are chemically complex, and their activity may vary with cultivar, region, harvest, drying, extraction solvent, and storage. Standardization is therefore central to reproducible research.

The gel base can influence extract dispersion, viscosity, release, and stability. A formulation that appears smooth may still have inadequate marker content, microbial quality, or stability. Accordingly, evaluation should combine physical, chemical, microbiological, and biological methods. Any observed in-vitro effect should be reported with the test system, controls, concentration range, and limitations.

An important research gap is the lack of direct evidence establishing the performance and clinical effectiveness of the exact B. nivea leaf extract-loaded topical gel described in this review. The project should be presented as formulation development and evaluation, with conclusions limited to the results actually obtained.

XI. FUTURE SCOPE

Botanical authentication and standardized extraction of B. nivea leaves. Selection and quantification of suitable chemical markers.

Optimization of extract concentration, gelling agent, and excipient levels.

Evaluation of release, and skin permeation where scientifically justified. Assessment of antioxidant and anti-inflammatory activity with appropriate controls.

Microbial quality, preservative effectiveness, packaging compatibility, and stability testing.

Further safety and efficacy studies if justified by the preliminary results.

XII. CONCLUSION

Boehmeria nivea is a plant of scientific interest because its leaves contain reported phenolic and other phytochemical constituents, and selected extracts have shown antioxidant and inflammation-modulating effects in laboratory studies. These findings provide a basis for investigating a B. nivea leaf extract-loaded topical gel. The formulation should be evaluated for appearance, homogeneity, pH, viscosity, spreadability, extrudability, marker content, in-vitro release, microbial quality, stability, and suitable safety and biological endpoints. The available evidence does not establish that the proposed finished gel is clinically effective. Further standardized experimental work is required before therapeutic claims can be justified.

XIII. QUALITY CONSIDERATIONS FOR BOTANICAL EXTRACTS ABSTRACT

Inflammation is a protective biological response to tissue injury, infection, or irritating stimuli. Although acute inflammation supports healing, excessive or persistent inflammation may contribute to pain, swelling, redness, and tissue damage. Topical gels are semisolid dosage forms that can be designed to deliver active ingredients to the skin

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and are often valued for convenient application and acceptable sensory properties. Boehmeria nivea (L.) Gaudich., commonly known as ramie, belongs to the family Urticaceae and has been investigated for its phytochemical composition and biological activities. Studies of B. nivea leaf extracts have reported antioxidant activity and effects on selected inflammatory mediators in experimental cell models

[1–4]. Reported constituents include phenolic compounds and flavonoids, although their presence and concentration depend on plant source and extraction conditions [2,3]. This review summarizes the botanical profile, phytochemistry, reported anti-inflammatory evidence, rationale for topical gel development, and proposed formulation and evaluation approaches for a B. nivea leaf extract-loaded herbal gel. Important evaluation parameters include appearance, homogeneity, pH, viscosity, spreadability, extrudability, marker content, in-vitro release, microbial quality, stability, and appropriate safety and biological testing. Current findings support further investigation, but they do not establish the clinical effectiveness of a finished topical gel. Formulation-specific experimental studies are required before therapeutic claims can be made.

Keywords: Boehmeria nivea; ramie; leaf extract; herbal gel; topical drug delivery; anti-inflammatory activity; formulation; evaluation.

XIV. FORMULATION OPTIMIZATION AND COMPATIBILITY

A preliminary phytochemical screening can indicate broad groups such as phenolics, flavonoids, tannins, and terpenoid-like constituents. However, qualitative screening is not definitive identification. If facilities are available, chromatographic profiling and a selected marker assay can provide stronger batch-comparison data. The marker should be selected based on reliable evidence of occurrence, analytical feasibility, and stability.

The extraction procedure should be recorded in sufficient detail to allow repetition. Important factors include particle size, solvent composition, plant-to-solvent ratio, extraction time, temperature, number of extraction cycles, filtration method, and concentration conditions. The percentage extraction yield should be calculated from the mass of dried extract relative to the starting dried plant material.

Quality control begins with correct identification of the plant. The species name, plant part, collection date, collection region, drying conditions, and storage conditions should be documented. Where possible, a botanist or qualified person should authenticate the material and a voucher specimen should be retained. These measures help avoid confusion between related species and support reproducibility.

XV. INTERPRETATION OF ANTI-INFLAMMATORY TESTS

The container is also part of the formulation system. Packaging should protect the gel from contamination, excessive light, and moisture loss where relevant. Changes in colour, odour, pH, viscosity, or marker content during storage should be recorded. The formulation should not be described as stable unless the observed data support that conclusion.

The extract may affect the colour, odour, pH, viscosity, and stability of the gel. Compatibility studies should therefore compare the gel base alone with the extract-containing formulation. The selected neutralizer, humectant, cosolvent, and preservative should be compatible with the polymer and the extract. A preservative should not be selected solely because it is commonly used; its suitability and effectiveness need to be assessed in the final formulation.

The amount and type of gelling agent influence viscosity, spreadability, and the ease of dispensing the product. Too little polymer may produce a thin preparation, whereas excessive polymer can make the gel difficult to spread or remove from its container. The optimum composition should be selected by preparing small trial batches and comparing their properties under the same test conditions

XVI. LIMITATIONS OF THE AVAILABLE EVIDENCE

Results should be reported accurately, including the number of replicates, summary statistics, and limitations. No numerical inhibition percentage, statistical significance, or therapeutic claim should be inserted before the experiment has been performed. Findings from laboratory models are preliminary and cannot substitute for properly designed

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clinical evidence. If a protein-denaturation assay is used as a preliminary screen, it should be described as a nonspecific in-vitro assay rather than definitive evidence of anti-inflammatory efficacy. Appropriate positive and negative controls, replicate measurements, concentration ranges, and a clear calculation method should be included. The extract, gel base, and finished gel may need to be tested separately to understand whether activity is associated with the extract or the vehicle.

An anti-inflammatory screening assay should be selected according to the research question and available laboratory facilities. Cell-based assays can examine inflammatory mediators such as nitric oxide or cytokines after stimulation of an appropriate cell model. A reduction in a mediator must be interpreted alongside cell viability because apparent inhibition may occur if the test concentration is toxic to cells.

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