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Formulation and Evaluation of Herbal Nasal Spray for the Management of Sinusitis and Rhinitis

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Abstract : *Sinusitis and rhinitis are common conditions that affect the nasal cavity and upper respiratory tract. They may produce symptoms such as nasal congestion, sneezing, excessive nasal discharge, facial pressure and difficulty breathing through the nose. Conventional management depends on the cause and severity of the condition and may include saline preparations, antihistamines and intranasal corticosteroids. In recent years, medicinal plants have attracted research interest because they contain various phytochemicals with potential biological activities.*

The present review examines the proposed development of a herbal nasal spray containing Tulsi (Ocimum tenuiflorum L.) and Eucalyptus (Eucalyptus globulus Labill.) as plant-derived ingredients for research into nasal symptom management. It discusses the nature of sinusitis and rhinitis, the relevant properties of the selected plants, formulation considerations, preparation approaches and quality evaluation tests. Important evaluation parameters include appearance, pH, viscosity, spray pattern, delivered-dose uniformity, microbial quality and stability. Particular attention is given to the safety of essential oils and the requirements of preparations intended for nasal administration.

Published research suggests that some medicinal plant preparations may have potential in managing allergic rhinitis, although the quality of evidence varies between products [1]. Evidence supporting saline nasal irrigation in chronic rhinosinusitis is more established [2]. Therefore, the proposed Tulsi–Eucalyptus formulation should be considered an experimental preparation until its quality, safety and clinical effectiveness have been demonstrated.

Keywords: Herbal nasal spray, sinusitis, rhinitis, Tulsi, Eucalyptus, nasal drug delivery, formulation, evaluation, medicinal plants.

I. INTRODUCTION

The nose is the first major part of the respiratory tract through which inhaled air passes. Its internal lining helps filter airborne particles, regulate the temperature and humidity of inhaled air, and protect the respiratory system. Mucus and cilia work together to trap and remove unwanted particles from the nasal cavity.

Inflammation of the nasal passages may interfere with these protective functions and cause discomfort. Rhinitis refers to inflammation of the nasal mucosa, whereas sinusitis involves inflammation of the paranasal sinuses. Because the two conditions frequently occur together, the term rhinosinusitis is also widely used.

Rhinitis may be allergic or non-allergic. Allergic rhinitis develops when the immune system reacts to substances such as pollen, dust mites or animal allergens. Non-allergic rhinitis may be associated with environmental irritants, infections and other triggers. Sinusitis may develop following a respiratory infection or in association with persistent inflammation of the nasal and sinus lining.

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The symptoms of these disorders can affect sleep, concentration, daily activities and overall quality of life. Their management depends on the underlying cause. Current clinical guidance supports saline nasal irrigation and, when appropriate, intranasal corticosteroids for symptom relief in chronic rhinosinusitis [2,3].

A nasal spray is a dosage form designed to deliver liquid as droplets into the nasal cavity. Depending on its composition, it may be used to provide moisture, deliver a medicinal substance or support local treatment. The performance of a nasal spray depends on both the formulation and the device used to administer it.

Medicinal plants are being investigated as potential sources of pharmaceutical ingredients. Tulsi and Eucalyptus are relevant to this area of research because their leaves contain different phytochemicals that have been studied for biological activities. Nevertheless, the presence of such compounds does not establish that a particular herbal nasal spray will treat sinusitis or rhinitis.

The scientific development of a herbal nasal spray therefore requires a clear formulation strategy, standardized raw materials, appropriate quality testing and adequate safety assessment. This review considers these requirements in relation to a proposed Tulsi–Eucalyptus preparation.

II. AIM AND OBJECTIVES

2.1 Aim

To review the scientific principles involved in formulating and evaluating a herbal nasal spray containing Tulsi and Eucalyptus for the potential management of symptoms associated with sinusitis and rhinitis.

2.2 Objectives

1. To describe the causes and major symptoms of sinusitis and rhinitis.
2. To review research on medicinal plants relevant to nasal and respiratory health.
3. To discuss the potential role of Tulsi and Eucalyptus in herbal formulation research.
4. To explain the essential components and general development process of a nasal spray.
5. To describe the pharmaceutical evaluation parameters required for a nasal formulation.
6. To examine safety concerns, formulation limitations and future research opportunities.

III. OVERVIEW OF SINUSITIS AND RHINITIS

3.1 Sinusitis

Sinusitis is an inflammatory condition affecting the paranasal sinuses, which are air-containing spaces located around the nasal cavity. Inflammation may interfere with normal mucus drainage and produce pressure or discomfort.

Common symptoms include:

- Nasal blockage or congestion.
- Thick nasal discharge.
- Facial pain or pressure.
- Reduced sense of smell.
- Headache or a feeling of fullness around the face.

Acute sinusitis commonly develops in association with a viral respiratory infection. Chronic rhinosinusitis involves persistent inflammation and requires appropriate clinical assessment rather than treatment based on symptoms alone.

3.2 Rhinitis

Rhinitis is inflammation of the mucous membrane lining the nose. It may occur following exposure to allergens, irritants or infectious agents.

The main symptoms include sneezing, a runny nose, itching and nasal obstruction. Allergic rhinitis may also be accompanied by watery eyes and itching around the eyes.

In allergic rhinitis, the immune response to an allergen contributes to the release of inflammatory mediators, including histamine. These processes produce symptoms such as itching, sneezing and increased nasal secretions [4].

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3.3 Difference Between Sinusitis and Rhinitis

Feature	Sinusitis	Rhinitis
Main area affected	Paranasal sinuses, often with nasal inflammation	Nasal mucosa
Common symptoms	Facial pressure, nasal discharge, congestion	Sneezing, itching, runny nose, congestion
Common contributing factors	Viral infections and persistent inflammation	Allergens, irritants and infections
Treatment approach	Depends on cause and duration; may include saline irrigation and other prescribed treatment	Depends on cause; may include allergen avoidance, antihistamines or nasal corticosteroids

3.4 Need for Research into Herbal Nasal Preparations

The interest in herbal formulations has increased because plants contain diverse natural compounds that can be investigated for pharmaceutical use. However, an ingredient traditionally used for respiratory complaints cannot automatically be considered effective or safe for nasal administration.

A suitable herbal nasal formulation must demonstrate acceptable physical properties, consistent dosing, appropriate microbial quality and local tissue compatibility. It must also be evaluated for its intended purpose using appropriate scientific methods.

V. REVIEW OF LITERATURE

A review of existing research helps identify what is already known about medicinal plants, nasal drug delivery and the management of sinonasal conditions. The studies discussed below provide scientific background for developing the proposed formulation. They do not establish the efficacy of the specific Tulsi–Eucalyptus nasal spray.

4.1 Medicinal plants in allergic rhinitis

Lim et al. (2024) published a systematic review and meta-analysis examining medicinal plants used for allergic rhinitis. The authors included 29 randomized controlled trials involving 1,879 participants. Some analyses suggested improvements in nasal symptoms, but the certainty of evidence varied, and the authors concluded that clear evidence of benefit remained limited. They recommended better-designed studies and improved reporting of herbal preparations [1].

This study supports further investigation of medicinal plants but also highlights the need to evaluate each herbal preparation separately. The results cannot be directly applied to a newly developed Tulsi–Eucalyptus nasal spray.

4.2 Nasal irrigation in chronic rhinosinusitis

Park et al. (2022) developed an evidence-based clinical practice guideline for nasal irrigation in adults with chronic rhinosinusitis. Their recommendations support saline nasal irrigation as a useful method for improving symptoms and removing mucus and other material from the nasal cavity [2].

PubMed

This research is relevant to nasal formulation development because it demonstrates the importance of the delivery method and the properties of the administered solution. However, nasal irrigation is different from a metered nasal spray, and its clinical evidence should not be interpreted as proof of efficacy for herbal sprays.

4.3 Phytochemicals and biological activities of Tulsi

Bhattarai et al. (2024) reviewed the phytochemical constituents and biological activities of Ocimum tenuiflorum. Their review discussed compounds such as rosmarinic acid, ursolic acid, oleanolic acid and luteolin, along with reported antioxidant and anti-inflammatory activities [5].

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These findings indicate that Tulsi is a potential source of compounds for pharmaceutical research. Nevertheless, the concentration and composition of its constituents depend on the plant material and extraction process. Further studies are needed to determine whether a particular Tulsi extract is suitable for nasal administration.

4.4 Essential oils and rhinosinusitis

A systematic review published in 2025 examined essential oils used in the management of acute rhinosinusitis. The review identified five randomized controlled trials involving preparations such as cineole-containing products and other herbal combinations. Some products showed improvements in symptoms, although the preparations and study methods differed [6].

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The findings provide background for investigating plant-derived volatile compounds in respiratory health. However, the studied products were administered in capsule form. Their results do not establish the safety or effectiveness of eucalyptus essential oil applied directly inside the nose.

4.5 Development of nasal dosage forms

Research on nasal dosage-form development emphasizes that a product must be assessed as a complete system consisting of the formulation and its delivery device. Important factors include delivered dose, spray pattern, droplet-size distribution, pH, viscosity, microbial quality and container performance [7].

These factors are particularly important when developing a herbal preparation because plant-derived materials may vary in composition and may introduce additional challenges related to solubility, stability and microbial contamination.

4.6 Research gap

The available literature demonstrates interest in medicinal plants for respiratory and inflammatory conditions. However, evidence relating to one extract, essential oil or dosage form cannot be generalized to another.

A specific gap remains in establishing the formulation characteristics, intranasal safety and clinical effectiveness of a standardized Tulsi–Eucalyptus nasal spray. Research should therefore focus on reproducibility, quality control, local tolerability and appropriate efficacy testing.

V. SELECTED HERBAL INGREDIENTS

5.1 Tulsi (Ocimum tenuiflorum L.)

Tulsi, commonly known as holy basil, belongs to the family Lamiaceae. Its leaves are used in traditional systems of medicine and have been investigated for their chemical constituents and biological properties.

Phytochemical constituents: Published research describes phenolic compounds, flavonoids, terpenes and other secondary metabolites in Tulsi. The precise composition depends on the plant variety and the method used to obtain the extract [5].

Research relevance: Certain Tulsi extracts and isolated compounds have demonstrated antioxidant or anti-inflammatory activity in experimental studies. These findings provide a basis for further investigation but do not demonstrate clinical effectiveness against sinusitis or rhinitis.

Proposed role: A suitably characterized Tulsi extract or distillate may be investigated as a plant-derived component of the proposed formulation.

5.2 Eucalyptus (Eucalyptus globulus Labill.)

Eucalyptus belongs to the family Myrtaceae. Its leaves are used to obtain essential oil containing volatile compounds. Depending on the species and preparation, these may include 1,8-cineole, also known as eucalyptol.

Phytochemical characteristics: Eucalyptus essential oil contains volatile constituents whose proportions vary with the plant source, extraction procedure and storage conditions.

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Research relevance: Certain standardized cineole-containing products have been investigated for respiratory symptoms. However, evidence from oral products cannot be transferred directly to a nasal preparation [6].

Proposed role: A suitable eucalyptus-derived ingredient may be considered for formulation research only after its identity, concentration, compatibility and safety for the intended route have been established.

Safety consideration: Essential oils are concentrated materials. Direct nasal application may cause irritation or other adverse effects. Eucalyptus oil should not be added to a water-based nasal spray without an appropriate formulation strategy and evidence supporting intranasal safety.

5.3 Comparison of the selected plants

Parameter	Tulsi	Eucalyptus
Botanical name	Ocimum tenuiflorum L.	Eucalyptus globulus Labill.
Family	Lamiaceae	Myrtaceae
Plant material commonly studied	Leaves	Leaves
Important chemical groups	Phenolics, flavonoids and terpenes	Volatile terpenes
Research interest	Antioxidant and anti-inflammatory activities	Respiratory applications of selected preparations
Major development concern	Extract standardization	Volatility, solubility and local tolerability

VI. FORMULATION OF HERBAL NASAL SPRAY

A nasal spray is a liquid preparation administered into the nasal cavity through a spray pump or another suitable delivery device. The formulation should provide reproducible delivery and meet quality requirements appropriate to its intended use.

The composition depends on whether the product is designed as a solution, suspension or emulsion. The selected dosage form determines which excipients and evaluation methods are appropriate.

6.1 Proposed formulation components

Component	Intended function
Standardized Tulsi extract or distillate	Proposed plant-derived ingredient
Eucalyptus-derived ingredient	Proposed plant-derived ingredient, subject to safety assessment
Purified water	Aqueous vehicle
Glycerin	Humectant; may influence moisture retention and viscosity
Sodium chloride	Tonicity adjustment, if needed
Suitable buffer	pH control, if required
Suitable solubilizer or emulsifier	May be necessary for an oil-containing formulation
Preservative, if justified	Microbial control in an appropriate multidose product
Nasal spray container	Delivery of the formulation

This is a list of possible components, not a finalized formula. Their inclusion and concentration must be justified through experimental development.

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6.2 Important formulation considerations

Solubility: Water-based vehicles do not automatically dissolve essential oils. A suitable, validated approach is needed if an oil-containing preparation is pursued.

pH: The pH should be selected based on nasal tolerability, ingredient stability and compatibility.

Tonicity: Osmolality should be evaluated to help minimize discomfort caused by an unsuitable formulation.

Viscosity: Excessive viscosity may interfere with spray formation, while insufficient viscosity may influence retention and drainage.

Preservation: A multidose aqueous preparation may require an appropriate microbial-control strategy. Preservative selection must consider efficacy, compatibility and nasal safety.

Container compatibility: The packaging should be assessed for leakage, dose reproducibility, material compatibility and possible interactions with volatile ingredients.

VII. GENERAL METHOD OF PREPARATION

The following workflow describes the general development of an experimental formulation. It is not a validated preparation method for human use.

Step 1: Selection and authentication

Obtain suitable plant material from a reliable source and verify its botanical identity. Record the plant part, source, collection conditions and relevant quality information.

Step 2: Preparation of plant extract or distillate

Prepare the selected Tulsi material using a documented extraction or distillation procedure appropriate to the intended ingredient. Record the process conditions and yield.

Obtain the eucalyptus-derived ingredient separately and verify its identity and quality. A Tulsi aqueous distillate and a eucalyptus essential oil are chemically different materials and require different handling.

Step 3: Preliminary characterization

Assess the plant-derived ingredients for relevant physical and chemical properties. Where feasible, identify marker compounds or establish suitable specifications to support batch consistency.

Step 4: Development of the vehicle

Select a vehicle and appropriate excipients according to the intended dosage form. Assess pH, tonicity, viscosity and compatibility.

Step 5: Incorporation of ingredients

Incorporate the plant-derived ingredients using a suitable formulation process. If eucalyptus oil is used, its dispersion or solubilization must be demonstrated rather than assumed.

Step 6: Homogeneity and physical assessment

Examine the preparation for visible particles, separation, precipitation and other changes. Determine whether the system behaves as a solution, suspension or emulsion.

Step 7: Filling and packaging

Select an appropriate spray container and establish a controlled filling process. The manufacturing conditions must support the required microbiological quality.

Step 8: Evaluation

Carry out suitable physicochemical, microbiological, device-performance and stability tests before considering further biological or clinical investigation.

VIII. EVALUATION PARAMETERS

The quality of a nasal spray cannot be established through appearance and pH alone. The formulation and its delivery device must be assessed together [7,8].

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8.1 Organoleptic properties

Examine and record the colour, odour and general appearance of the formulation. Look for visible particles, precipitation, phase separation or changes during storage.

Odour alone cannot confirm the identity, quality or safety of a herbal ingredient.

8.2 pH determination

Measure the pH using a calibrated pH meter and a suitable procedure. Record the observed value and compare it with the predetermined specification for the formulation.

The acceptable pH should be justified according to the intended route, ingredient compatibility and stability data.

8.3 Clarity and homogeneity

Examine the formulation for visible particulate matter and uniformity.

A solution should meet its appropriate clarity requirements. A suspension or emulsion must instead be evaluated using suitable criteria for uniformity, particle characteristics or phase stability.

8.4 Viscosity

Determine viscosity using a suitable viscometer. Record the temperature and measurement conditions because these can influence the results.

Viscosity can affect the spray pattern, delivered dose, drainage and retention of the formulation.

8.5 Spray pattern

Assess the shape and consistency of the spray produced by the device under standardized conditions. Record any irregularity, dripping or formation of a continuous liquid stream.

A reproducible spray pattern helps demonstrate consistent device performance.

8.6 Delivered-dose uniformity

Determine the amount of formulation delivered per actuation using an appropriate method. Evaluate variability across repeated actuations and, where necessary, at different stages of container use.

The test should follow a predefined protocol with suitable acceptance criteria.

8.7 Droplet-size distribution

Determine droplet-size distribution using an appropriate, validated analytical technique. Parameters may include D10, D50 and D90, depending on the method and product design.

Droplet characteristics affect nasal deposition and are important in assessing the performance of the delivery system [7,8].

8.8 Osmolality

Measure osmolality when relevant to the formulation. The results help characterize the solution and assess whether its properties are appropriate for the intended nasal use.

8.9 Microbiological quality

Evaluate the formulation according to applicable pharmaceutical microbiological requirements. Testing should address relevant microbial limits and specified microorganisms.

If a preservative is included, its effectiveness should be established using an appropriate method. Sterility requirements must be determined from the applicable product classification and regulatory standards rather than assumed for every nasal spray.

8.10 Stability studies

Conduct stability studies under appropriate conditions and for a justified period. Monitor relevant characteristics, including:

- Appearance and phase separation.
- pH and viscosity.
- Chemical marker content, where applicable.
- Delivered dose and spray performance.
- Microbiological quality.

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- Container and closure integrity.
- Stability results are required before assigning a justified shelf life.

8.11 Safety and local tolerability

The formulation requires an appropriate safety assessment before administration to humans. This is particularly important when concentrated essential oils are involved.

Assessment should consider nasal irritation, tissue compatibility, potential allergic reactions and the possibility of harmful effects from repeated exposure.

8.12 Biological activity

Potential anti-inflammatory or antimicrobial effects may be investigated using appropriate validated laboratory methods.

Results should include relevant controls, replicate measurements and suitable statistical analysis. Any observed activity should be interpreted in the context of the model used.

Laboratory activity alone does not prove that the formulation improves symptoms in patients.

IX. DISCUSSION

The development of a herbal nasal spray involves several linked scientific questions: whether the selected ingredients are appropriate for the intended purpose, whether they can be formulated into a stable product, whether the device delivers a reproducible dose and whether the resulting preparation is safe for nasal administration.

Tulsi is of interest because published research has identified numerous phytochemicals and reported biological activities in its extracts [5]. Eucalyptus-derived products have also been investigated for respiratory applications, although the route of administration and composition differ between preparations [6].

These findings provide a scientific rationale for further research, but they do not establish that combining the two ingredients will produce a beneficial effect. Interactions between ingredients may influence solubility, stability, chemical composition and local tolerability.

A major challenge is the variability of botanical raw materials. Plant species, growing conditions, harvesting and extraction methods can influence the final chemical composition. Standardization is therefore important if different batches are to be compared reliably.

Another challenge is the use of essential oils in aqueous nasal formulations. Their limited miscibility with water means that a suitable formulation strategy is needed. The resulting product must then be evaluated for uniformity, stability and safety; simply obtaining a visually uniform mixture is insufficient.

Existing clinical guidance provides support for saline nasal irrigation and appropriate intranasal therapy in chronic rhinosinusitis [2,3]. Research on medicinal plants for allergic rhinitis has produced mixed or uncertain results, highlighting the need for product-specific evidence [1].

Accordingly, the proposed Tulsi–Eucalyptus spray should be evaluated through a stepwise development programme. Initial work should establish ingredient quality and formulation feasibility. Subsequent studies should assess physicochemical properties, microbiological quality, device performance and stability. Suitable safety studies should precede any clinical investigation.

X. POTENTIAL ADVANTAGES OF THE RESEARCH APPROACH

1. Plant-derived ingredients: The project investigates botanical materials as possible sources of pharmaceutical constituents.
2. Local dosage form: Nasal delivery provides a way to study the administration of a formulation directly into the nasal cavity.
3. Measurable quality attributes: Parameters such as pH, viscosity, spray pattern and dose uniformity can be evaluated experimentally.
4. Standardization: The project can investigate how to improve the consistency of botanical raw materials.

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5. Further research opportunities: The formulation may provide a starting point for studying stability, compatibility and biological activity.

These are potential advantages of investigating the formulation. They should not be presented as established therapeutic benefits.

XI. LIMITATIONS AND SAFETY CONSIDERATIONS

- The proposed formulation has several limitations that must be addressed during development.
- Limited product-specific evidence: The available literature does not establish the clinical effectiveness of this particular Tulsi–Eucalyptus spray.
- Variability in plant materials: The composition of extracts and essential oils may differ between batches.
- Formulation challenges: Oil-containing preparations may require specialized methods to maintain uniformity.
- Microbial contamination: Aqueous botanical preparations require appropriate controls during preparation, filling and storage.
- Local irritation: Some ingredients may cause burning, irritation or allergic reactions.
- Uncertain shelf life: Stability cannot be assumed without experimental data.
- Need for appropriate controls: Biological studies require relevant controls and validated methods.
- Limits of laboratory findings: In-vitro results cannot independently establish clinical benefit.
- The proposed formula should not be used as a homemade nasal treatment or administered to people before appropriate quality and safety requirements have been met.

XII. FUTURE SCOPE

1. Further work may focus on the following areas:
2. Authentication and standardization of Tulsi and Eucalyptus raw materials.
3. Characterization of relevant phytochemical constituents.
4. Screening of suitable formulation approaches.
5. Optimization of pH, tonicity, viscosity and physical stability.
6. Evaluation of spray pattern, droplet-size distribution and delivered-dose uniformity.
7. Investigation of microbial quality and preservative effectiveness, where applicable.
8. Assessment of local tolerability and nasal tissue compatibility.
9. Laboratory studies of selected biological activities.
10. Comparative studies against an appropriate vehicle or control.
11. Well-designed clinical studies, if justified by preliminary safety and quality findings.

These steps would help determine whether the proposed formulation is suitable for further pharmaceutical development.

XIII. CONCLUSION

Sinusitis and rhinitis are common conditions that can cause nasal obstruction, discharge, sneezing and facial discomfort. Their management depends on the underlying cause and may involve established treatments such as saline preparations, antihistamines or intranasal corticosteroids.

Tulsi and Eucalyptus are of interest in pharmaceutical research because their constituents have been investigated for different biological activities. However, their presence in a formulation does not establish that the resulting nasal spray is effective or safe.

The development of a Tulsi–Eucalyptus nasal spray requires standardized ingredients, suitable formulation design, reliable spray performance, microbial quality control, stability testing and appropriate safety assessment. Particular care is necessary when essential oils are considered for intranasal administration.

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In conclusion, the proposed formulation represents a research opportunity rather than an established treatment for sinusitis or rhinitis. Its potential value can only be determined through systematic experimental investigation and, where appropriate, well-designed clinical studies.

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