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Formulation and Evaluation of Herbal Nasal Balm.

Vishakha[1], Uday Thakur[1], Samriti Naik[2]
[1]*Student, Abhilashi College of Pharmacy, Ner Chowk, Mandi, H.P1*
[2]*Assistant Professor, Abhilashi College of Pharmacy, Ner Chowk, Mandi, H.P2*
Corresponding Author: Vishakha

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ABSTRACT:
Herbal nasal balm is a semi solid preparation which is formulated with the help of natural ingredients or herbs which have less side effects. The main aim to provide relief from nasal decongestion, cold and some other respiratory issues. It is the natural alternative to the synthetic decongestants products which may cause irritation and also have side effects. This study examines the formulation and assessment of a nasal balm that includes active ingredients like menthol, eucalyptus oil, camphor, and Tulsi extract, combined with a base of beeswax and coconut oil. The formulated balm was evaluated through various method such as pH, organoleptic properties, homogeneity, spreadability, viscosity, washability, phase separation, and skin irritation test. The evaluation results shows that the formulation was stable, smooth, and safe for use on the skin, with no indications of irritation or separation. The herbal components demonstrated soothing, decongestant, and antimicrobial properties. Therefore, this herbal nasal balm presents a viable and safe alternative to synthetic nasal products.

Keywords: Herbal Nasal Balm, Natural Decongestant, Cold Balm, Breathe Easy Balm.

I. INTRODUCTION:

HerbalPlants: The phrase “medicinal plant” encompasses a variety of plants utilized in herbalism, also known as "herbology" or "herbal medicine." This practice involves using plants for health-related purposes and studying their applications. The term “herb” originates from the Latin word “herba” and the Old French “herbe” Today, “herb” refers to any part of a plant, including fruits, seeds, stems, bark, flowers, leaves, stigmas, and roots, as well as non-woody plants. Previously, this term was limited to non-woody plants, including those from trees and shrubs. These medicinal plants are also employed as food, flavouring, medicine, perfume, and in specific spiritual practices[1].

India is a veritable gold mine of historically accurate and extensively used herbal medicine knowledge due to which various methods such as botanical,chemical,spectroscopical andbiological methods are now used to estimate the active constituents present in crude drug[2].
These approaches can be used to quantify a specific chemical or agroup of active substances,such as alkaloids,flavonoids or polyphenolic components,whenever possible[3].
Throughout history, people have relied on nature to meet their basic needs, utilizing it for medicines, shelter, food, fragrances, clothing, flavours, fertilizers, and transportation. For a significant portion of the global population, medicinal plants play a crucial role in healthcare, particularly in developing countries where herbal medicine has a long-standing tradition. Both industrialized and developing nations are increasingly acknowledging and promoting the medicinal and economic benefits of these plants[4].

Difference Between Herbal and Conventional Drugs: In contrast to clearly defined synthetic pharmaceuticals, herbal medicines show several notable distinctions, including:
1)The active ingredients are often not identified
2) Although standardization, stability, and quality control can be achieved, they are challenging
3) There can be issues with the availability and quality of raw materials
4) Well-designed double-blind clinical and toxicological research to establish their effectiveness and safety is uncommon
5)Their empirical application in traditional medicine is a significant feature
6)They have a broad range of therapeutic applications and are appropriate for long-term treatment
7) While adverse side effects appear to be less common with herbal medicines, well-controlled randomized trials have shown they can occur
8)They are typically more affordable than synthetic medications[5].

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Regulation and Safety of Herbal Medications:

The common belief that herbal medicines are completely safe and devoid of side effects is misleading. Many plants contain numerous compounds, some of which can be highly toxic, including certain anticancer drugs made from plants, digitalis, pyrrolizidine alkaloids, ephedrine, and phorbol esters. While adverse effects from herbal medications tend to occur less frequently when used correctly compared to synthetic drugs, well-controlled clinical trials have demonstrated that these side effects do indeed occur[6,7].

Herbal medicines have been associated with two types of side effects. The first type is intrinsic to the herbal drugs themselves, primarily involving predictable toxicity, excessive use, and interactions with conventional medications, much like modern medicines. As a result, there have been numerous reports of allergic reactions linked to herbal drugs. Conversely, most side effects associated with herbal products are extrinsic to their formulation and arise from various manufacturing issues, including plant misidentification, lack of standardization, inadequate manufacturing practices, contamination, substitution and adulteration of plants, and improper preparation or dosing[8,9].

Relationship between Ayurveda and modern medicines:

Ayurveda, a prominent traditional medical system in India, has contributed significantly to the development of treatments for chronic illnesses. Nearly 2,500 years ago, Hippocrates stated, "Let food be your medicine and medicine be your food."[10]

Integrating the strengths of traditional knowledge systems like Ayurveda with the significant capabilities of combinatorial sciences and High Throughput Screening can lead to the creation of structure-activity libraries. Ayurvedic knowledge and its experiential database can offer new functional leads that minimize time, cost, and toxicity—three primary challenges in drug development. These records are particularly valuable because these remedies have been trialed on people for thousands of years. There are ongoing efforts to establish a pharacoepidemiological evidence base to ensure the safety and application of Ayurvedic medicines. Furthermore, the Council for Scientific and Industrial Research (CSIR) is currently working on the development of standardized herbal formulations as part of the New Millennium Indian Technology Leadership Initiative (NMITLI)[11].

Benefits of Herbal Medicine:

1)Herbal medicines have a long-standing history of use, leading to greater tolerance and acceptance among patients.
2) Medicinal plants provide a renewable resource, offering hope for sustainable, cost-effective medicines for the growing global population.
3) In developing countries like India, the availability of medicinal plants is not an issue, thanks to their rich agricultural, climatic, cultural, and ethnic diversity.
4)The extensive and generally trouble-free use of herbal medicines suggests their safety and effectiveness.
5)Worldwide, herbal medicine has contributed many of the most powerful treatments to the vast array of drugs used in modern medicine, both in their natural state and as refined chemicals forming the basis for contemporary pharmaceuticals[12].

Drawbacks of Herbal Medicines:

1) Not suitable for immediate medical treatment
2) Poor standardization and absence of quality criteria
3) Insufficient scientific evidence[13].

Herbal Nasal Balm: In recent years, herbal balms have become increasingly popular due to a growing public interest in natural, safe, and affordable topical treatments, along with concerns about antimicrobial resistance linked to synthetic antiseptics. Research has shown that phytochemicals like terpenoids, phenolics, flavonoids, and alkaloids can work together to enhance antimicrobial and wound-healing effects in multicomponent herbal formulations, making these balms an effective way to deliver these bioactive compounds[14,15]. For centuries, various traditional medicine systems worldwide, such as Ayurveda, Siddha, and Traditional Chinese Medicine, have utilized herbal topical preparations to treat skin infections, wounds, inflammation, and pain. These systems include many plant-based balms and ointments made from botanical extracts, essential oils, and natural resins used externally for healing and antiseptic purposes[16].

PURPOSES OF THIS STUDY:

1. Alleviate nasal congestion: By administering decongestant substances directly to the nasal passages, it reduces swelling and clears obstructions.
2. Facilitate breathing: Offers immediate relief from a blocked nose, enhancing breathing ease, particularly during colds and allergies.

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3. Soothe and moisturize nasal tissues: Often includes ingredients that alleviate irritation of the mucous membranes.
4. Ensure effective medication delivery: Provides accurate delivery of components like menthol, camphor, or essential oils for the best outcomes.
5. Enhance sleep quality: By reducing congestion, it contributes to improved sleep, especially for those who suffer from nasal blockages at night[17].

ADVANTAGES OF HERBAL BALM

1.Use of Herbal Formula- Prepared using natural herbs,making it and skin friendly
2.Calming sensation
3. Reduce risk of reactions[18].

MECHANISM OF ACTION

Anatomy and Physiology of the Nasal Cavity:

Researchers have become interested in the nasal route for systemic drug delivery due to the nasal mucosa's extensive vascularization and permeability[19].In both humans and various animals, the primary roles of the nasal cavity include breathing and sense of smell. Additionally, it serves a vital protective function by filtering, warming, and humidifying the inhaled air before it reaches the lower airways. The nasal cavity extends from the nasal vestibule to the nasopharynx, measuring about 12-14 cm in depth. In adult humans, the total surface area of the nasal cavity is approximately 150 cm^2, with a volume of around 15ml[20]. Each of the two nasal cavities can be divided into different sections: the nasal vestibule, inferior turbinate, middle turbinate, superior turbinate, olfactory region, frontal sinus, sphenoidal sinus, and the cribriform plate of the ethmoid bone. Additionally, it contains nasal-associated lymphoid tissue (NALT), primarily located in the nasopharynx. The mucous membrane lining the nasal cavity, along with hair-like structures, plays a crucial role in trapping inhaled particles and pathogens. Other essential functions of nasal structures include mucociliary clearance,immune responses, and the metabolism of endogenous substances[21]. The nasal cavity comprises two regions of mucous membrane: non-olfactory and olfactory epithelium. The non-olfactory area includes the nasal vestibule, covered by skin-like stratified squamous epithelium, while the respiratory region features airway epithelium rich in microvilli, providing a larger surface area for drug absorption and transport[22]. The nasal cavity is symmetrically divided by the middle septum into two halves, each opening at the nostrils and extending back to the nasopharynx. Both halves include four areas (nasal vestibule, atrium, respiratory region, and olfactory region) that are distinguished by their anatomical and histological features[23].

INTRODUCTION TO PLANTS:

1.Camphor:

Synonym: Kapur,Karpura.
Biological source: Cinnamomum camphora.
Family: Lauraceae.

Chemical Constituents: 1,8- cineole (4.3%), and D- camphor (51.3%) Alpha-terpineol.Camphor is a compound that can be used topically on the skin for pain relief and as an antiseptic. However, when ingested, camphor can quickly become toxic, particularly in the form of camphorated oil. It is also utilized in vaporizers to help relieve coughs, though lower concentrations of camphor are available in various over-the-counter medications.

Medicinal Applications:

Pain Relief: Camphor is commonly found in topical analgesics like creams and ointments to help ease pain and diminish inflammation.
Respiratory Assistance: It is included in decongestant balms and inhalation products to help relieve nasal congestion and facilitate breathing.
Pharmaceuticals: Camphor serves as a component in a range of pharmaceutical formulations, such as cough syrups, throat lozenges, and antimicrobial creams.
Uses:
1. Like menthol, camphor provides a soothing effect and has slight local anaesthetic qualities.
2. It helps alleviate bronchitis, asthma, chest congestion, and coughs associated with colds.
3. It improves blood flow and eases discomfort in muscles and joints.
4. This strong analgesic oil creates a cooling sensation to relieve pain and a warming sensation to promote circulation.

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5. It contains reliable anti-fungal and anti-inflammatory agents that help diminish pain and swelling[24].

2. Menthol:

Scientific Name: Hexahydro thymol.

Synonym: Mint extract, peppermint oil.

Biological Source: Mentha piperita.

Family: Labiatae.

Chemical Constituents: 40.7% of menthol, 23.4% of menthone, menthylacetate, 1,8cineolelimonine,betapinene, and beta-caryophllene.

Uses: Menthol possesses mild pain-relieving qualities and is commonly included in over-the-counter topical analgesics like creams, ointments, and balms to help ease minor discomfort. Additionally, it is found in some cough drops and throat sprays due to its soothing effect on the throat.

1. Respiratory advantages: The cooling effect of menthol can alleviate nasal congestion, making it a popular ingredient in certain cough syrups and inhalers. It provides a refreshing sensation and can improve respiratory function.

2.Topical uses: Menthol is commonly included in topical products for its skin-cooling properties. It appears in items like muscle rubs and patches designed to relieve pain in muscles and joints.

3. acts as a counterirritant and provides a soothing, slight pain-relieving effect by activating cold receptors.

4. Used for migraine headaches.

5. Treats cough and throat soreness.

6. Serves as a decongestant for chest and sinus issues[25].

3.Coconut oil:

Synonym: Nariyal tail, courage oil.

Biological Source: Cocos nucifera.

Family: Palmae.

Chemical Constituents: caprylic acid, lauric acid, Fatty acids include, myristic acid, triglycerides, phospholipids, squalene.

Uses:

1. It may reduce discomfort.
2. Numerous studies indicate that virgin coconut oil possesses anti-inflammatory qualities because of its elevated lauric acid content.
3. Consequently, coconut oil is an excellent choice for alleviating muscle and joint soreness, especially post-exercise.
4. It is also utilized for promoting growth in preterm infants and treating eczema[26].

4. Tulsi:

Synonyms: Holy basil, Tulasei, Tulsi, Tulasi.

Biological Source: Tulsi consists of the fresh and dried leaves of Ocimum species like Ocimum santum L. and Ocimum basilicum L. etc.

Family: Lamiaceae.

Chemical constituents-Eugenol,methyl eugenol, linalool.Tulsioffers numerous health benefits and is often taken as an herbal tea, dietary supplement, or extract. It is also commonly utilized in traditional Ayurvedic treatments.

Uses:

1.ANTIOXIDANT:The polyphenol rosmarinic acid found in Tulsi serves as a strong antioxidant, safeguarding bodily cells against damage caused by free radicals. Excessive oxidation in the body can lead to cell harm, and this acid helps prevent that.

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2.ANTIFUNGAL:Research indicates that the compounds linalool and methyl chavicol extracted from Tulsi essential oil exhibit antifungal properties against dermatophytes isolated from clinical settings.

3.ANTIBACTERIAL:Tulsi contains antibacterial agents such as carvacrol and terpene, along with the sesquiterpene B-caryophyllene, which serve similar functions. This constituent, recognized as an FDA-approved food additive, plays a role in protecting the body from illness-inducing bacteria.

4.ANTI-INFLAMMATORY: Beyond its antioxidant capabilities, rosmarinic acid also provides anti-inflammatory benefits. Another compound, pegenin, contributes similarly. However, the primary anti-inflammatory agent in Tulsi is eugenol, which also helps regulate blood sugar levels by enhancing pancreatic beta cell function and insulin secretion.

5.ANTI-MICROBIAL ACTIVITY:Tulsi demonstrates antibacterial, antifungal, and antiviral properties, effectively hindering the growth of pathogens like E. coli, B. anthracis, and M. tuberculosis. Its antitubercular efficacy is one-tenth that of streptomycin and one-fourth that of isoniazid. Preparations containing Tulsi extracts have been shown to significantly shorten the duration of illness and alleviate clinical symptoms and biochemical markers in patients suffering from viral hepatitis and encephalitis.

6.ANTI-STRESS: Studies have shown that the leaves of O. sanctum exhibit antistress properties in rabbits[27].

5. Beeswax:

Scientific name: Cera alba.

Synonym: Yellow wax.

Biological source: Apis mellifera.

Family: Apidae**.**

Chemical components: Myricylpalmitate (80%), free cerotic acid (15%), melissic acid, cerolein.

Uses:

1. Acts as an antibacterial and antifungal agent.
2. Exhibits anti-inflammatory and anti-allergic effects.
3. Primarily used as an emulsifier, stiffening agent, and mild skin adhesive.
4. Helps to alleviate stress and encourage relaxation.
5. Provides pain relief[28].

6.Eucalyptus oil:

Synonym: River red gum, lemon-scented gum, and blue gum.

Biological Source: Eucalyptus globules.

Family: Myrtaceae.

Chemical Components: 1,8 cineole, alpha-pinene, p-cymene, alpha-terpineol, limonene.

Applications:

1.Anti-Microbial Activity.
2.Anti-Fungal Activity.
3. Anti-Viral Activity.
4.Anti-Inflamatory Activity.
5.Anti-Bacterial Activity.
6.Antiseptic[29].

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II. Methods and Materials:

Equipment:

Sr. No.	Equipment
1	Beaker and Measuring cylinder
2	Clevenger Apparatus,Heating metal
3	Mortar and pestle
4	Digital pH meter
5	Weighing balance

Materials:

Sr. No.	Ingredients
1	Camphor
2	Menthol
3	Coconut Oil
4	Tulsi
5	Bees Wax
6	Eucalyptus oil

Preparation Formula Of Herbal Nasal Balm:

Sr. No.	Ingredients	Quantity	Medicinal Uses
1	Camphor	2g	Relives cough
2	Menthol	1ml	Counter Irritant
3	Coconut Oil	4ml	Solvent
4	Tulsi	1ml	Antimicrobial activity
5	Bees Wax	2g	Base
6	Eucalyptus oil	0.5ml	Nasal Decongestant

Methodology:

1. Methodology:

1)Collection of herbs: The plant materials such as Tulsi (Ocimum sanctum) leaves and menthol were collected from Local forests / Balh valley or near college. The plant material was identified.

2)Washing and Drying: Wash the plant material with water and provide shade drying for 2 weeks.

3)Extraction: 1. Menthol leaves -Steam distillation is a primary method for extracting essential oils due to its cost-effectiveness and popularity. This technique is conducted at low temperatures, allowing for the efficient separation of non-volatile and non-water-soluble substances below the boiling points of various components. Extraction of mint oil from Mentha arvensis using a conventional 2-L steam distillation setup. The start of the distillation process was marked by the first drop of essential oil collected in a Florentine separator. After turning off the electric power, the mint oil was gathered at the conclusion of each distillation. The amounts of corn mint oils were measured using an analytical balance, and the oil yield was calculated as grams of oil per 100 grams of dried Japanese corn mint shoots. The term "content" generally refers to the quantity of essential oil in 100 grams of biomass, while "concentration" denotes the percentage of individual constituents within the total oil. The total yields of various components were determined from the essential oil yield and the concentration of each component. The yield of menthol ranged from 74% to 79% at an extraction temperature of 35 to 40 ºC[30].

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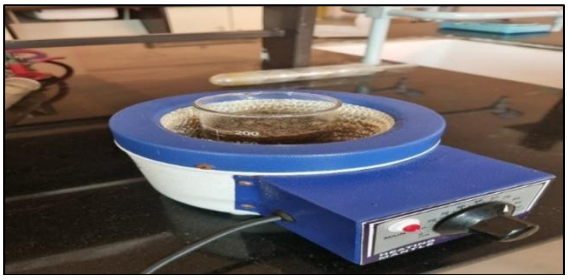
2.Tulsi – Extraction of Tulsi by using solvent extraction method, take 20g Tulsi leaves and dissolved it in 100 ml water and heat it until it becomeconcentrate[31].



Base Preparation: Beeswax was melted in a beaker at a temperature between 60 and 70°C until fully liquefied. Then Coconut oil was added and mixed with glass rod.

Incorporating Active Ingredients: Once the mixture had partially cooled,0.5mleucalyptus oil and2g camphor were added in specific proportions, carefully stirring to maintain an even distribution: 1ml mint oil, and 1mlTulsi.

Cooling and Packaging: The sterilized jar was filled with the heated mixture, which was allowed to cool at room temperature until it solidified[31].

EVALUATION OF PREPARED HERBAL FORMULATION:

PHYSICAL PARAMETERS:

1.Organoleptic evaluation-

Sr. No.	Characteristic	Appearance
1	Colour	CreamyWhite
2	Odour	Mild, light strong
3	Consistency	Semi-solid
4	Texture	Smooth

Clarity and colour were assessed visually against a white background, and the odour was evaluated through smell.

2.PH Test: Take the PH paper and placed in the sample of herbal nasal balm and the compare the PH paper with the standard values.

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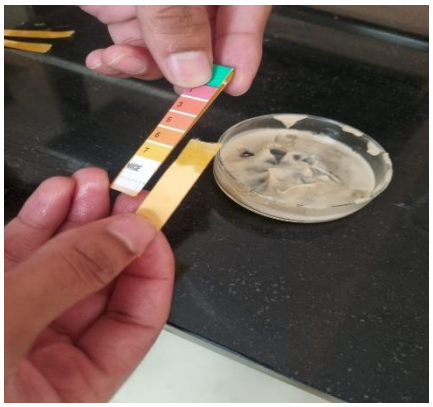

3.Phase Separation: The balm was placed in a suitable wide-mouth container for storage. After 24 hours, any separation between the oil phase and aqueous phase was observed.

4.Spradability: Two glass slides of standard size were used, with the herbal balm formulation applied to one slide. The second slide was then placed on top of the gel, sandwiching it between the two slides over a distance of 7.5 cm. A weight of 100 g was placed on the upper slide to uniformly compress the gel into a thin layer. After removing the weight, any excess gel on the slides was scraped off. The slides were then secured on a stand to prevent any disturbance, allowing only the upper slide to move freely under the applied weight.

$S = M \times L / T$

where S = Spreadability, M = Weight tied to upper slide, L = Length moved, T = Time (sec).

5.Washability: Washability refers to the ease with which the balm can be removed from the skin using water or mild soap. Products with high wax content may adhere more strongly, which makes washability a key factor for user convenience. Effective washability helps avoid residue buildup and lowers the chances of pore blockage or irritation[33**].**

6.Homogeneity: Homogeneity guarantees consistent distribution of essential oils, extracts, and excipients within the formulation. Both visual and microscopic inspections verify the lack of clumps, separation, or aggregated particles. An even texture and colour signify effective mixing, which directly affects dosing accuracy and therapeutic reliability[34].

7.Skin irritation test: In this the small amount ofbalm applied on the skin to observe the irritation, redness, itching on the skin. Testing for skin irritation is crucial to ensure dermatological safety, particularly because essential oils such as clove oil, camphor, and peppermint can be irritating in high concentrations. Patch tests conducted on human volunteers or approved animal models evaluate symptoms like redness, itching, burning, or inflammation. An effectively formulated balm should cause little to no irritation, making it appropriate for frequent topical application[35].

III. Result:

The herbal nasal balm made from natural components like menthol, eucalyptus oil, Tulsi extract, camphor, beeswax, and coconut oil exhibited suitable physicochemical characteristics. It had a smooth texture, remained stable, and was easy to apply**.**The PH of the formulation was found to be 7 which is suitable and safe for skin. No phase separation was noted, suggesting that the formulation is stable. The spreadability assessment indicated that the balm can be applied easily without the need for excessive pressure.The balm was easily washable, suggesting that it promotes good adherence by patients.The formulationshow good homogeneity without any visible lumps.There were no indications of irritation noted during the skin irritation test, demonstrating that the formulation is safe for use on the skin.

IV. Conclusion:

This study shows successfully formulated herbal nasal balm incorporating the natural

ingredients such as menthol,eucalyptus oil, Tulsi extract, camphor, beeswax, and coconut oil. The evaluation test of the formulated nasal balm shows the good physical properties including good spreadability,washability and the neutral PH indicating suitability for nasal use and it represents the effective nasal decongestant. The development of herbal nasal balm shows the growing interest in traditional medicinal plants and in natural alternative to the synthetic nasal preparation with less side effects.

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