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FORMULATION AND EVALUATION OF HERBAL NASAL SPRAY FOR THE TREATMENT OF NASAL CONGESTION

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ABSTRACT

The study aims to find out the effectiveness of the combination of Herbal drug for the treatment of Nasal Congestion. Traditional medical systems around the world have a long history of using plant-based treatments for nasal congestion. Plants have therapeutic potential, especially in respiratory health, according to ethnopharmacological knowledge. The main focus of this study is to formulate and evaluate nasal decongestant spray using natural components such as *Ocimum tenuiflorum, Allium cepa, Eucalyptus globules, Piper longum*, Menthol, Camphor, Lemon grass oil for the treatment of allergic rhinitis and nasal congestion. Camphor and Menthol work together to alleviate congestion in the nasal passages and alleviate allergy symptoms. Due to seasonal variations, environmental, psychological, immunological, and idiopathic factors, congestion is highly prevalent across all age groups. The microbe's virulence and the immune system of the individual determine how long the symptoms last. Determining the etiology of congestion is frequently difficult.

Keywords: Herbal Nasal spray, Nasal Congestion

INTRODUCTION:

Congestion is frequently a sign of allergies or a cold. Both prescription and over-the-counter nasal sprays are available. They also come in two different container types: pump bottles and pressurized canisters. Medications can be administered systemically or locally using nasal sprays. Medications can be administered systemically or locally in the nasal canals using nasal sprays. Locally, they are used to treat ailments like allergic rhinitis and congestion of the nose **[1]**.

Plants with medicinal properties are being used as traditional medicine from times immemorial. The extract obtained from the leaves, stem and roots of various medicinal plants have been employed as a natural remedy in curing various ailments and diseases. Even though many of the plant based products have been replaced by synthetic chemicals, the safety and efficacy of Ayurvedic products has set standards **[2]**.

Herbal medicine has been practiced for thousands of years. Effective inhaler therapy is essential in today's world. Novel biomolecules derived from natural sources should be investigated in order to provide novel therapy options **[3]**.

Nasal sprays can deliver medication systemically or locally into the nasal canals. They are used locally to treat conditions such as allergic rhinitis and nasal congestion. Nasal sprays are liquid medications that are sprayed into the nose. They aid to reduce acute congestion or stuffiness in the nose **[4]**. Presently, a variety of formulations, such as nasal spray, nasal drop, nasal powder, nasal gels, and nasal insert, are utilized to deliver medications through the nasal channel. Drugs can be administered non-invasively through the nose in spray dosage form, which results in a quick beginning of effect. The nasal spray dosage form has a high degree of patient compliance because of its affordability, mobility, and ease of self-administration. Thus, nasal medication administration **[5]**.

Nasal decongestants are the most commonly purchased over-the-counter drugs. They can be taken orally or applied directly to the nose in the form of drops or sprays. These preparations are most commonly used to relieve symptoms of viral infections (nasal obstruction, vomiting, increased nasal secretion, difficulty breathing, etc.), but it is critical to inform users about the type of preparation, the active ingredient, and the proper dosage regimen. Considering their availability and the widespread implementation of safety measures, these

preparations can result in various prolonged conditions and complications (medicaments rhinitis). Also, an increasing number of allergens, in many parts of the world, and climate change, cause allergic manifestations, so the users decide on the solubility and purchase of drops or sprays without consultation with a physician or pharmacist. Because of the persistent symptoms with sporadic intervals of relief, nasal drops/sprays are increasingly being utilized for extended periods of time, sometimes even years. However, it is important to note that many products have age-related restrictions, and some are contraindicated in children under the age of two, pregnant women, and those with thyroid gland ailments, cardiovascular diseases, or prostate difficulties.

For ages, ethnomedicinal knowledge has directed the usage of herbs with purported anti-inflammatory, antibacterial, and decongestant effects to relieve respiratory distress. These traditions, documented through ethnobotanical research, serve as a historical foundation for understanding how different plant species have been utilized to treat colds, sinusitis, and other respiratory illnesses.

Even though these treatments are widely used, incorporating this age-old knowledge into contemporary evidence-based therapy requires rigorous validation. By examining the bioactive compounds in these historically used plants, modern pharmacology enables us to demonstrate the ways in which they offer medicinal advantages **[6-9]**.

Plants like *Ocimum tenuiflorum*, *Allium cepa,* eucalyptus, Piper longum, Menthol, Camphor, Lemon grass oil are known to contain bioactive compounds each with properties beneficial for respiratory health.

Plant Profile:

1. *Ocimum tenuiflorum*

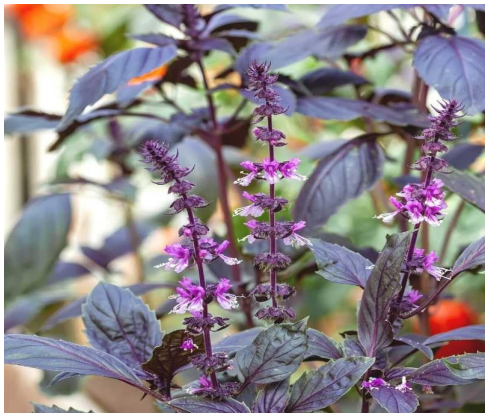

Figure 1: Leaves of *Ocimum tenuiflorum*

Ocimum tenuiflorum L., an annual herb with at least 150 variations, is a member of the mint family. Due to their alleged therapeutic properties, at least two varieties of *Ocimum tenuiflorum*, also called *Ocimum sanctum*, Tulsi, or Holy Basil from the Lamiaceae family, have been referred to as the "Queen of plants" and the "mother medicine of nature." The plant is an erect, herbaceous, much-branched, softly hairy annual. The

leaves are elliptic-oblong, acute or obtuse, entire or serrate, pubescent on both sides, and minutely gland-dotted; the flowers are in close whorled racemes, purplish or crimson **[10]**.

The nutritional and pharmacological properties of the whole herb in its natural form, as it has been traditionally used, result from synergistic interactions of many different active phytochemicals.

The leaves of Ocimum sanctum reported to be a rich source of volatile oil containing eugenol (71%) and methyl eugenol (20%) content. The volatile oil also consists of carvacrol and sesquiterpine hydrocarbon caryophyllene. The other chemical constituents present are phenolics, flavonoids, terpenoids and fattyacids. Two flavonoids orientin and andvicenin from aqueous leaf extract of Ocimum sanctum hav been isolated .Ursolic acid, apigenin, luteolin, apigenin-7 O-glucuronide, luteolin-7-O glucuronide, orientin and molludistin have also been isolated from the leaf extract **[11]**.

2. *Allium cepa*

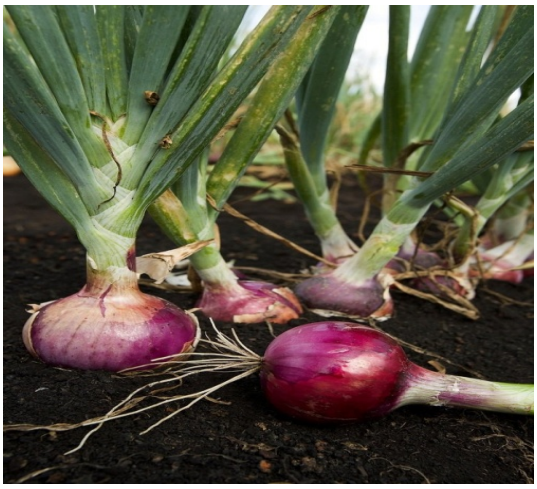

Figure 2: Bulbs of *Allium cepa*

Allium cepa is one of the most common bulb of the Alliaceae family usually known as onion which is extensively cultivated vegetable in the world. Phytoconstituents of *Allium cepa* contain sugar, water, Protein, Carbohydrate, Minerals, Fiber, Vitamins, Fat, and they also contain various secondary metabolites like Flavonoids (Quercetin, Kaempferol, Anthocyanins) compound, and Volatile and non-volatile organosulfur compound and sterols, Saponins **[12]**.

3. *Eucalyptus globules*

Figure 3: Leaves of *Eucalyptus globules*

The blooming tree *Eucalyptus globulus* is a member of the Myrtaceae family. More than 300 of the 900 species and subspecies that make up this group have volatile oil in their leaves. They are abundant in bioactive compounds including eucalyptol (1,8-cineole), which has unique medicinal qualities. The second biggest genus after acacia, these towering, evergreen trees are indigenous to Australia and Tasmania **[13]**. Eucalyptus from the Myrtaceae family is known and used in folk medicine for a number of different ailments and health problems. The plant or essential oil has been used for treatments such as rhinitis, bronchial infection, or to reduce fever **[14]**.

4. *Piper longum*

Figure 4: Seeds of *Piper longum*

Long pepper or Pippali (*Piper longum* Linn.L; family Piperaceae) is a very important medicinal plant. It is indigenous to South-India and Western Ghats of India, and is cultivated in hotter parts of India mainly Orissa, Kerala and Central to North Eastern Himalayas. It is being used from thousands of years in various traditional medicinal practices such as Ayurveda, Unani etc. Piper *longum* also shows various pharmacological activities such as antifungal, insecticidal, antimicrobial, antiamoebic, antidiabetic, antioxidant, anti-cancerous and effect on respiratory system.[15] Pippali is a powerful stimulant for both respiratory and digestive systems and showed a reviving effect on lungs. Pippali enhances the bioavailability of other drugs also. The biochemical basis of this enhanced drug bioavailability is through the interaction of the active ingredient piperine with enzymatic drug biotransforming reactions **[15]**.

5. Menthol

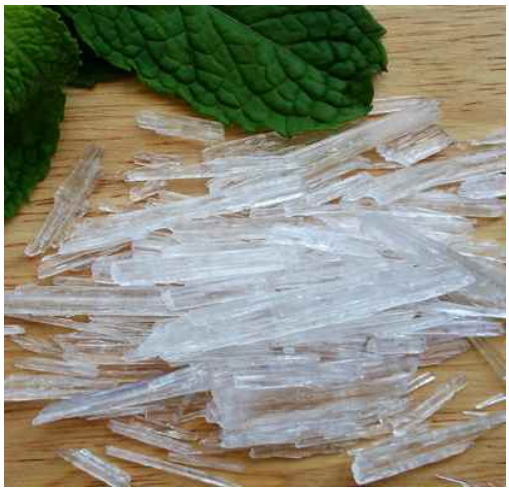

Figure 5: Menthol Crystals

The essential oils of *Mentha canadensis* L. (cornmint) and *M. piperita* L. (peppermint) contain a significant amount of menthol, a

cyclic monoterpene alcohol. Menthol, together with menthone, isomenthone, and other chemicals, gives plants, particularly those in the Mentha genus, a refreshing minty flavor and aroma. Aromatic herbs are the main source of monoterpenes like menthol. Together with other organic components of essential oils, they serve a variety of purposes as chemical messengers **[16]**.

6. Camphor

Figure 5: Camphor Solids

Camphor is a solid ketone, obtained from the volatile oil of *Cinnamomum camphora* (L.) Nees et Eber, belonging to family Lauraceae. Synthetic camphor, which is optically inactive, is prepared from turpentine and would probably have completely replaced the natural product. Camphor oil contains camphor, cineole, pinene, camphene, phellandrene, limonene, and diterpenes. Camphor is entirely a monoterpenic ketone. Its basic carbon framework is related to bofneol. Camphor is a natural product with many applications in traditional and modern medicines. Traditionally, camphor has been used as a cold remedy for the relief of chest congestion and the treatment of inflammation related diseases such as rheumatism, sprains, bronchitis, asthma and muscle pain **[17, 18]**.

7. Lemon grass oil


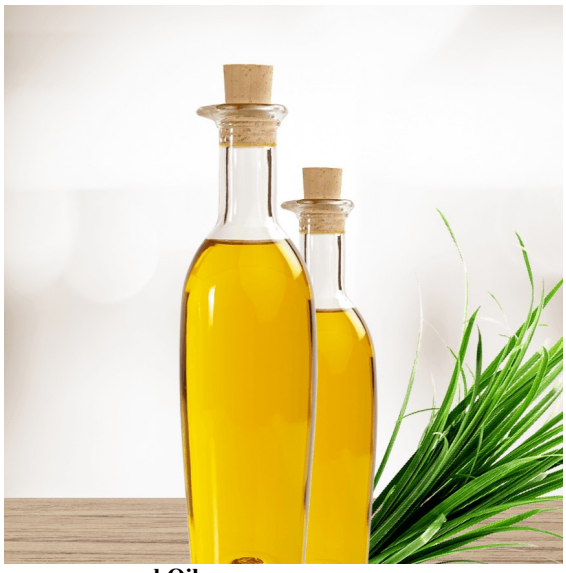

Figure 5: Leaves of Lemon grass and Oil

Cymbopogon citrates staff is popularly known as citronella grass or lemongrass. This species belongs to the Gramineae family, which comprises approximately 500 genus and 8,000 herb species. Lemon grass is a tufted perennial grass growing to a height of 1 meter with numerous stiff leafy stems arising from short rhizomatous roots. Lemongrass is a folk remedy for coughs, elephantiasis, flu, gingivitis, headache, leprosy, malaria, ophthalmic, pneumonia and vascular disorders. Studies have shown that the lemon grass has antibacterial and antifungal properties. Lemon grass contains active ingredients like myrcene, an antibacterial and pain reliever, citronellal, citronellol and geraniol. The essential oil consists of, mainly, citral a volatile oil with strong lemon fragrance **[19]**.

MATERIALS AND METHODS

Procurement and identification

The raw drugs *Ocimum tenuiflorum leaves, Allium cepa bulbs, Eucalyptus globules* were collected from botanical garden of JES College of Pharmacy, Nandurbar and get authenticated by Botany department of Jijamata Science college, Nandurbar. *Piper longum,* Menthol, Camphor, Lemon grass oil were collected from the local area market and Plant materials were authenticated by the experts of the field.

Chemicals required

Sodium Benzoate, Glycerine, Proplyene glycol were purchase from Scientific Science. India.

Preparation of aqueous extractions

The **Preparation of aqueous extractions** is prepared according the standard guidelines of

IP. Initially the fresh juices of *Ocimum tenuiflorum leaves, Allium cepa bulbs, Eucalyptus globules* Leaves were prepared and taken in equal quantity. The decoction of *Piper longum* is prepared. The juices and decoction were taken in RB flask of distillation chamber.

Method of preparation of spray solution

The spray solution consisted of co-solvents and a permeation enhancer. All ingredients, except for the extract like Menthol, Camphor, Lemon grass oil, were combined in a solvent system of ethyl alcohol and Proplyene glycol at room temperature, using a magnetic stirrer set to 500 rpm for thorough mixing. During mixing add Sodium Benzoate, Glycerine. Once a uniform solution was achieved the extract was added and stirred at the same speed until it became homogeneous. Finally, the solution volume was adjusted by adding more ethanol to ensure the desired drug release with each spray, and the mixture was then transferred into a spray bottle **(Table 1)**. The salinity of Nasal spray is maintained. Then the prepared solution is calibrated according to the IP standards. The prepared spray is filtered through bio phasic filter paper **[20]**.

Table 1: Composition and formulation of spray solution

Sr. No	Name of Herbs/ Ingredients	Roll of Ingredients	Quantity
01	*Ocimum tenuiflorum*	Antimicrobial and anti-inflammatory	2 ml
02	*Allium cepa*	Allergic rhinitis and Nasal congestion	2 ml
03	*Eucalyptus globulus*	Decongestant	2 ml
04	*Piper longum*	Enhance the effectiveness of other ingredients.	1 ml
05	Menthol	Improved airflow	0.76 gm
06	Camphor	Relieve nasal congestion	1 gm
07	Lemon grass oil	Antibacterial	2.5 ml
08	Sodium Benzoate	Preservative	0.015 ml
09	Glycerine	Humectant	3.4 ml
10	Proplyene glycol	Solvent	3.5 ml
11	Ethyl alcohol	Analytical Solvent	QS to make 20 ml

Physicochemical evaluation

The prepared batches were optimized on following parameters for standardization of herbal spray **(Table 2)**.

pH value

A digital pH meter was used to measure the formulations' pH.

Viscosity

The viscosity of mechanical spray was determined using an Ostwald Viscometer. The solution was put into the viscometer,

suctioned into the upper reservoir, and then emptied into the lower reservoir via gravity. The time required for the liquid to pass between two engraved markers, one above and one below the upper reservoir, is measured.

Evaporation time

Evaporation time is the time required to evaporate the solvents after spraying the formulation and leaving behind only therapeutic drug. The drying time was noted after spraying the formulation on white paper at an average room of temperature 32ºC-34ºC.

Spray pattern

Spray pattern was obtained by spraying the liquid on light color paper. The formulation was sprayed on a fixed white paper from the distance of 2-3 cm and diameters and the spraying pattern of the spots were measured.

Table: 2: Evaluation Parameter

Sr. No	Parameter	Result
01	pH value	07
02	Visual appearance and color	Clear and pale yellow
03	Viscosity	15.6±0.15
04	Spray pattern	Spherical and uniform
05	Stability	Stable for 2 months
06	Sterility	Sterile and free from contamination of microorganism

DISCUSSION:

The nasal administration technique is the most ideal system for both local and systemic medication delivery since it avoids first-pass metabolism and inhibits drug degradation by enzymatic/chemical processes. Ayurvedic classics also emphasize the nasal method of delivery. Nasal mucosa is well-supplied with blood and has a vast surface area, making it an ideal place for medication absorption. The results of this study show the potential benefits of herbal nasal decongestant beads, including distinct advantages and areas for improvement. The nasal beads exhibit good regularity and controlled release, indicating a possible long-term solution. While these formulations show promise, further research and development is required to improve their efficacy, stability, and economic feasibility.

CONCLUSION:

Nasal Spray is a unique preparation derived out of poly herbal mixtures. The distillate and nasal spray showed the presence of effective phyto – constituents. These components acts as Anti-inflammatory, antimicrobial effects. With further research and development, the product could offer a safer, more holistic, and more effective alternative to synthetic nasal decongestants, ultimately benefiting

consumers seeking natural remedies for nasal congestion.

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