

# FORMULATION, DEVELOPMENT AND EVALUATION OF HERBAL ORAL SPRAY FOR SORE THROAT

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## Abstract:

A common upper respiratory disease is a sore throat or pharyngitis, which causes pain. Some people may feel discomfort or have trouble swallowing, or experience swelling in the throat due to inflammation. Natural herbs can be used to create remedies for sore throats because they are safe and effective. The goal of this study was to develop and assess an herbal throat spray for the safe and effective management of sore throats.

The herbal throat spray included natural ingredients such as Tulsi, turmeric, and ginger, mixed equally in a 1:1 ratio. It also contained propyl paraben and methyl paraben in a 10:1 ratio to preserve the formulation. Additionally, four different batches of the herbal throat spray were made, incorporating clove, Mentha, and honey to create various combinations.

All batches showed that the ingredients in batch 1, clove and Mentha, provided the best overall results. This batch had a stable brownish color and a pH of 6.7, both suitable for oral use. The evaporation time was 1 minute and 35 seconds, which indicated a stable spray. The viscosity was measured at 2.64 poise, showing it could spray smoothly, and the droplet size of 0.155 microns was appropriate for delivering to the throat. The spray angle was 5 degrees, and the circular spray pattern with a uniform volume of 0.11 ml allowed for effective and consistent delivery.

Based on the physicochemical evaluations and spray performance testing for batch 1, it was selected as the best formulation.

## Keywords:

Herbal throat spray, Sore throat, Pharyngitis, Tulsi, Turmeric, Physicochemical evaluation

## 1. Introduction:

Sore throat is a common health problem that affects both adults and children. Viral or bacterial infections, allergies, environmental pollution, or irritation of the throat mucosa are the common causes of sore throat. Pain, dryness, irritation and difficulty in swallowing are the commonly associated symptoms of a sore throat. Side effects associated with prolonged use of synthetic drugs include drug resistance, allergic reactions, and gastrointestinal problems. [1]Herbal medicines have been widely used in traditional systems of medicine for treatment of various diseases due to their therapeutic properties and less side effects. Herbal medicines have antimicrobial, anti-inflammatory, antioxidant and soothing properties that are useful in managing throat infections. Herbal formulations are more popular as natural remedies to synthetic medicines. [2]

Oral sprays are a convenient drug delivery system in the treatment of throat infections. Thus, the active ingredients are delivered exactly where there is infection in the throat and so fast symptom relief can be achieved. They are easy to administer, carry, and ensure appropriate dosage, thereby improving patient compliance. Ad-

vantages of herbal oral spray over conventional formulations The herbal oral spray has several benefits compared to the conventional formulations. They are more harmless, have fewer side effects, and reduce the use of antibiotics, thereby alleviating the threat of antimicrobial resistance. In addition, the spray dosage form is characterized by fast action since the drug gets into the infected throat tissues directly. [3]

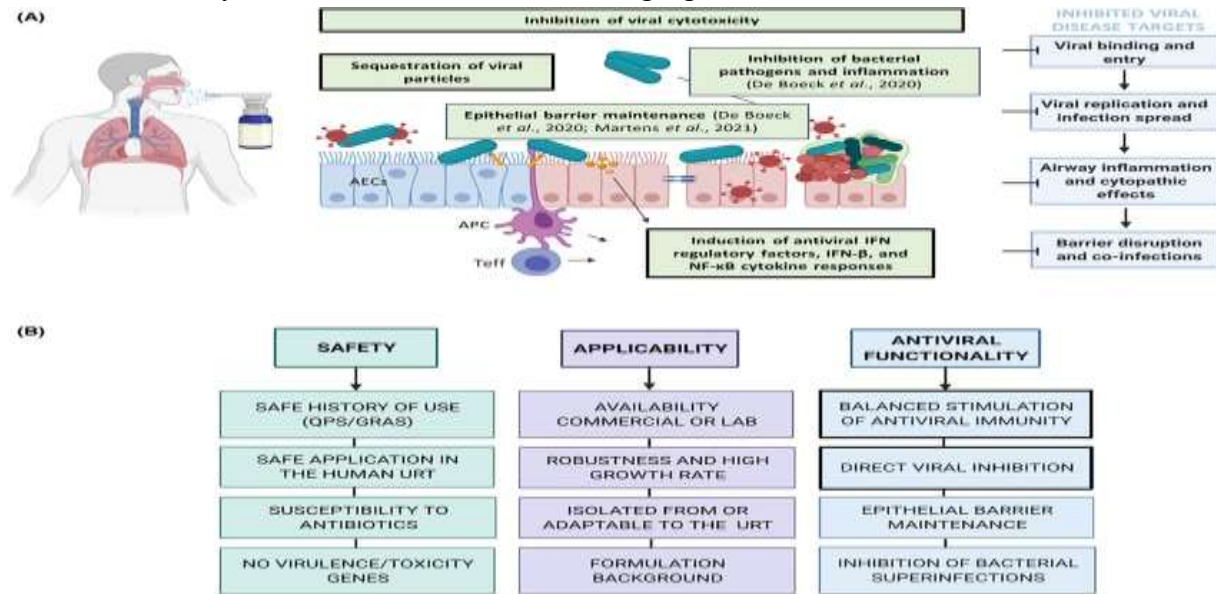


FIG-

URE 1: [A] Mechanisms through which topically applied beneficial lactobacilli can act against respiratory viral disease [4]

**SYMPTOMS** [5]:

1. Painful sore or lesion in the mouth.
2. Burning sensation with swelling or redness in the affected area,
3. Difficulty in eating, drinking or speaking..
4. Fever, swollen lymph nodes.

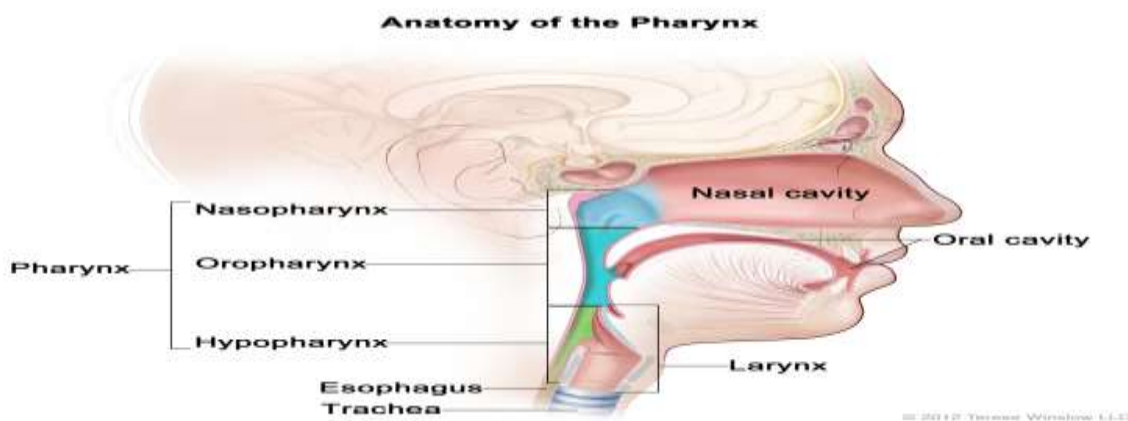


Fig.2 throat cavity [6]

**1.1 Advantages of oral spray over the other dosage form drug delivery systems [7]:**








1. The oral method of delivery is also very helpful to individuals who have difficulties in swallowing pills or capsules and it is cost effective in that, a smaller dosage is required.
2. It's possible that faster absorption will lead to rapid commencement of effect.
3. Patient compliance for disabled bedridden patients, travelers, and busy people who do not have access to a water source.

4. Direct access to systemic circulation through the internal jugular vein bypasses drugs to the hepatic first pass metabolism to achieve high bioavailability.
5. Suitability for drugs or excipients that mildly and reversibly damages or irritates the mucosa.
6. Hospice from the administration and the ease of drug withdrawal.
7. Facility to add permeation enhancer/enzyme inhibitor or pH modifier in the formulation.
8. Versatility in designing as multidirectional or unidirectional release systems for local or systemic actions etc.

### 1.2 Disadvantages of Oral Sore Throat:

1. Pain and Discomfort. A sore throat is very painful especially when you swallow, talk or eat. This pain can really get in the way of your life.[8]
2. Difficulty in Eating and Drinking. When you have a throat you do not feel like eating or drinking. This can be bad for you because you might not get water and food which can be a big problem for kids and older people.[9]
3. Disturbed. Daily Activities. The pain and irritation from a throat can keep you awake at night and make it hard to do things during the day. This can make you feel tired and unhappy.[10]
4. Risk of Complications. If you do not take care of a throat it can lead to other problems like tonsillitis, ear infections or sinusitis.[11]
5. Recurrent or Chronic Conditions. If you keep getting throats it might be a sign of something else going on like acid reflux, allergies or postnasal drip which can be a big problem, for your health and a sore throat.[12]

### 2. Ingredient profile [13,14,15,16]: Table no.1

Feature	Tulsi	Turmeric	Ginger	Honey	Clove Oil	Mentha	Peppermint oil
<b>Synonym</b>	Holy Basil	Haldi	Zingiber	Madhu	Clove Oil	Mint	Peppermint
<b>Biological Source</b>	Leaves of <i>Ocimum sanctum</i>	Rhizome of <i>Curcuma longa</i>	Rhizome of <i>Zingiber officinale</i>	Bee product [ <i>Apis</i> spp.]	Bud oil of <i>Syzygium aromaticum</i>	Leaves of <i>Mentha</i> spp.	Oil of <i>Mentha piperita</i>
<b>Family</b>	Lamiaceae	Zingibera- ceae	Zingibera- ceae	Apidae	Myrtaceae	Lami- aceae	Lamiaceae
<b>Colour</b>	Green	Yellow	brown	Golden	yellow	Green	pale yellow
<b>Major Con- stituent</b>	Eugenol	Curcumin	Gingerol	Glucose, fructose	Eugenol	Menthol	Menthol
<b>Use in Sore Throat</b>	Relieves irritation	Reduces in- flammation	Soothes throat	Coats throat	Pain relief	Cooling effect	Relieves con- gestion
<b>Images</b>							

### 3. Aim:

To formulate, develop, and evaluate a **Herbal Oral Spray** using natural ingredients for the effective relief of sore throat.[17]

### 4. Objectives:

1. To formulate a herbal oral spray using suitable herbal ingredients.[18]
2. To evaluate the prepared formulation for physicochemical properties.[19]
3. To study the stability of the formulation.[20]
4. To determine the effectiveness of the spray for sore throat relief.[21]

### 5. EXPERIMENTAL WORK:

**Instruments used:** Table no. 2

Sr. No.	Equipment	Supplier [Industry Name with Location]
1	Digital Weighing Scale	Citizen Scales [India] Pvt. Ltd., Mumbai, India
2	Mortar and Pestle	Borosil Scientific Ltd., Mumbai, India
3	Water Bath	Remi Elektrotechnik Ltd., Mumbai, India
4	Burner [Laboratory Gas Burner]	Borosil Scientific Ltd., Mumbai, India
5	pH Meter	Eutech Instruments [Thermo Fisher Scientific], Singapore / India Division

**Material used:** Table no.3

SR.NO	Material	Supplier [Industry Name with Location]
1	Tulsi [ <i>Ocimum sanctum</i> ]	Local Ayurvedic raw material supplier / Herbal drug store
2	Ginger [ <i>Zingiber officinale</i> ]	Local herbal supplier / Crude drug market
3	Turmeric [ <i>Curcuma longa</i> ]	Ayurvedic raw material supplier / Herbal wholesaler
4	Honey	Dabur India Ltd., Ghaziabad, India
5	Clove Oil	Essential oil supplier / Pharmaceutical raw material supplier
6	Mentha [Peppermint Oil]	Essential oil supplier / Pharmaceutical raw material supplier
7	Methyl Paraben	Loba Chemie Pvt. Ltd., Mumbai, India
8	Propyl Paraben	S.D. Fine-Chem Ltd., Mumbai, India

**Different batches of herbal oral spray formulation:** Table no. 4

Ingredients	F1	F2	F3	F4
Tulsi	50ml	50ml	50ml	50ml
Ginger	50ml	50ml	50ml	50ml
Turmeric	50ml	50ml	50ml	50ml

Honey	-	10ml	10ml	10ml
Clove oil	10ml	15ml	-	-
Mentha	10ml	-	-	15ml
Methyl paraben	10ml	10ml	10ml	10ml
Propyl paraben	1ml	1ml	1ml	1ml

### 5.1 Appearance

The color of the spray solution was checked by looking at it.

Method: The formulation was observed against dark backgrounds to check clarity, color, presence of particles and uniformity.

Significance: Appearance is an important quality parameter. A clear and uniform solution means the formulation components are properly dissolved and physically stable. Any cloudiness, precipitation or color change may indicate instability or degradation of ingredients. [22,23].

### 5.2 pH Measurement

The pH of the spray formulation was measured using a pH meter.

Method:

- The pH meter was calibrated using buffer solutions (pH 4.0 and pH 7.0).
- The electrode was rinsed with distilled water before measurement.
- The pH of the formulation was recorded.

Significance: affects drug stability solubility, irritation potential and preservative efficacy. Maintaining a pH ensures formulation stability and patient comfort. [23,24].

### 5.3 Evaporation (Drying) Time

Evaporation time is the time required for the sprayed formulation to dry after application.

Method: The formulation was sprayed onto a clean glass slide. The time required for complete drying was measured using a stopwatch.

Significance: Drying time affects convenience, drug residence time and film formation. Slow drying may reduce compliance while very rapid drying may affect uniform deposition. [22].

### 5.4 Spray Pattern

Spray pattern evaluation determines the distribution characteristics of the spray.

Method:

- The formulation was sprayed onto -sensitive paper.
- The distance between nozzle and target surface was kept 5 cm).
- Sprays were tested in both horizontal orientations.

Measurements:

D<sub>max</sub> – Maximum diameter of spray pattern

D<sub>min</sub> – Minimum diameter of spray pattern

Diameter Ratio = D<sub>max</sub> / D<sub>min</sub>

Significance: Spray pattern analysis provides information about spray symmetry, uniformity and reproducibility. A diameter ratio close to unity indicates uniform spray distribution. [25,23].

### 5.5 Spray Angle

Spray angle represents the degree of dispersion of the spray plume.

Method:

- The spray was actuated horizontally onto paper.
- The distance between nozzle and paper (l) was kept constant (10 cm).
- The radius of spray deposition (r) was measured.

Calculation:  $\theta = 2 \tan^{-1} (r / l)$

Significance: Spray angle affects surface coverage and deposition efficiency.[26]

### 5.6 Volume per Spray

Volume per spray determines the consistency of dose delivery.

Method:

- The container was weighed before spraying (W<sub>o</sub>).
- The container was weighed after spraying (W<sub>t</sub>).

Calculation:  $V_s = (W_o - W_t) / \rho$

Significance: This parameter ensures dose accuracy, reproducibility and uniform drug delivery.[25,24]

### 5.7 Viscosity

Viscosity of the spray solution was determined using an Ostwald viscometer.

Method:

- The formulation was filled into the viscometer.
- Flow time between two fixed points was recorded.
- Measurements were repeated three times at constant temperature.

Significance: Viscosity affects sprayability, atomization, droplet formation and spray angle.[22]

### 5.8 Droplet Size

Method: The formulation was sprayed onto a clean glass slide. Droplets were observed under a microscope. Diameters of droplets were measured using a micrometer.

Significance: Droplet size influences deposition characteristics spreading behavior and absorption efficiency. [23,26]

## 6. RESULT:

### 6.1. Appearance:

The F1 and F2 formulations both showed a brownish yellow color, which may be due to the natural colour of clove oil combined with other components. F3 showed a brown color, which is the typical natural colour of honey. Similarly, the F4 formulation also appeared brown, indicating that the colour of honey dominated the final appearance of the preparation, as found according to IP 2026.

### 6.2 PH:

The pH values of all formulations were found to be slightly acidic, ranging from 6.1 to 6.7. The F1 formulation had a pH of 6.7, F2 formulation showed a pH of 6.3, while F3 formulation had a pH of 6.1. The F4 formulation showed a pH of 6.5. These pH values are suitable for throat formulations because a mildly acidic environment is generally acceptable and safe for oral use, as found according to IP 2026.

### 6.3. Evaporation time:

The evaporation time varied among the formulations. The F1 formulation showed an evaporation time of 1 minute 35 seconds, while F2 required 1 minute 55 seconds. The F3 had evaporation time of 2 minutes 10 seconds, which may be due to the higher viscosity and sticky nature of honey. In contrast, the F4 formulation showed evaporation time of 1 minute 3 seconds, indicating faster drying after spraying, as found according to IP 2026.

### 6.4. Spray pattern:

The spray pattern differed depending on the formulation composition. The F1 formulation produced a circular spray pattern, which is generally considered uniform and effective for throat sprays. The F2 and F4 formulations produced an oblong spray pattern, while the F3 formulation showed an irregular spray pattern, indicating less uniform dispersion, as found according to IP 2026.

### 6.5. Spray angle:

The F1 formulation showed a spray angle of 5°, while F2 had 6°. F3 formulation had the spray angle of 3°, indicating a narrower spray spread. The F4 formulation showed the spray angle of 7°, suggesting a wider distribution of spray droplets, as found according to IP 2026.

### 6.6. Volume of each spray:

The volume delivered in each spray ranged from 0.09 ml to 0.13 ml. The F4 formulation delivered [0.13 ml] per spray, while F2 delivered 0.12 ml. The F1 formulation produced 0.11 ml per spray. The F3 formulation had the spray volume [0.09 ml], as found according to IP 2026

### 6.7. Viscosity:

The viscosity values ranged between 2.64 and 2.93 poise. F3 showed the viscosity [2.93 poise] because honey is naturally thick. The F2 formulation had viscosity [2.89 poise]. The F4 formulation showed viscosity [2.71 poise], while the F1 viscosity [2.64 poise], indicating a slightly thinner consistency, as found according to IP 2026.

### 6.8. Droplet size:

The F1 formulation produced droplets of 0.155 µm, The F2 formulation showed a droplet size of 0.133 µm, while F4 produced droplets of 0.127 µm. F3 formulation showed the droplet size [0.084 µm], which may help in better dispersion of the spray in the throat area, as found according to IP 2026.

**TABULAR RESULT OF ALL EVALUATION TEST : Table no. 5**

PARAMETERS	FORMULATIONS			
	CLOVE+MENTHA	CLOVE+HONEY	HONEY	MENTHA+HONEY
APPRERANCE [COLOUR]	BROWNISH YEL LOW	BROWNISH YEL LOW	BROWN	BROWN
PH	ACIDIC 6.7	ACIDIC 6.3	ACIDIC 6.1	ACIDIC 6.5
EVAPORATION TIME[MIN]	1 MIN 35 SEC	1 MIN 55 SEC	2MIN10 SEC	1 MIN 3 SEC
VISCOSITY [POISE]	2.64	2.89	2.93	2.71
DROPLETSIZE[UM]	0.155	0.133	0.084	0.127
VOLUM OFEACH SPRAY[ML]	0.11ML	0.12ML	0.09ML	0.13ML
SPRAY PATTEERN	Circular	oblong	irregular	oblong
SPRAY ANGLE [DEGREES]	5	6	3	7

### 7. SUMMARY AND CONCLUSION:

The prepared formulation is a herbal oral throat spray containing common natural ingredients ingredient are Tulsi, turmeric, ginger in 1:1 proportion & Propyl Paraben: Methyl Paraben. Also in 10:1 Proportion in all batches.

In the 1<sup>st</sup> formulation clove [analgesic and local aesthetics], Mentha [cooling effect] were added. In this 2<sup>nd</sup> batch clove [analgesic and local aesthetics], & honey [demulcent and antibacterial] were added. In 3<sup>rd</sup> batch only honey [demulcent and antibacterial] was added. In 4<sup>th</sup> batch Mentha [cooling effect] & honey [demulcent and antibacterial] were added.

Based on physiochemical evaluation & spray, performance studies:

- Appearance of 1<sup>st</sup> batch showed brownish-yellow colours that indicate stable formulation as compare to another batch brownish-yellow, brown, brown respectively.
- PH value of 1st batch is 6.7 that are suitable for oral use as compare to batch 6.3, 6.1,6.5 respectively.
- Evaporation time of 1<sup>st</sup> batch 1 min 35 sec. that indicates stable performance as compared to batch 1 min 55 sec, 2 min 10 sec, 1 min 3 sec respectively.
- Viscosity of 1st batch 2.04 poise that suitable for spraying that ensure smooth flow as compare to another batch 2.89, 2.93, 2.71 respectively.
- Droplet size of 1st batch is 0.155 UM which responsible for proper distribution in the throat as compare to other batches 0.133, 0.084, 0.127 UM respectively.

- Batch 1st shows 5-degree angle indicate proper spray dispersion as compared to another batch 6, 3, 7 respectively.
- Volume of each spray of batch 0.11 ml that ensure dose uniformity as compose to 1<sup>st</sup> batch 0.12, 0.09, 0.13 respectively.
- Spray pattern of 1<sup>st</sup> batch showed circular pattern that indicate uniform spray pattern & better performance as compare to another batch shows irregular or oblong.

on the basis of all evaluation test the performance like appearance.ph, viscosity, F. T, droplet size, volume of each spray & spray pattern is better & safer than other batch so, batch 1<sup>st</sup> is optimized.

## **8. FUTURE SCOPE:**

- Clinical Testing on Patients: Test the spray, on sore throat patients to confirm its safety and effectiveness.
- Stability Testing-Check how long our herbal spray remains safe and effective under storage conditions like heat, humidity and room temperature.
- Microbial Testing-We need to test our spray against common throat infection bacteria to prove that it really works against them.
- Safety Studies-Lets conduct toxicity studies to make sure our spray is completely safe for people to use every day.
- Use of Natural Preservatives-We should replace preservatives with natural preservatives to make our herbal spray fully herbal.
- Improve Taste and Flavour-We can modify the flavour to make it more pleasant, especially for children and elderly patients who will be using our spray.
- Long-Term Use Study-We should study the effects of using our spray repeatedly to confirm that there are no side effects.
- Comparison with Market Products-..Lets compare our herbal spray with other throat sprays available in the market to see what advantages it has.
- Large-Scale Production-We need to develop methods for manufacturing our spray on a big scale so that many people can use it.
- Packaging Improvement-We should improve the design of our spray bottle for dose control and easy use.
- Application for Other Conditions-We can study using our spray for mouth ulcers, cough, tonsillitis and minor oral infections to see if it helps with these conditions too.
- Special Formulations-We can develop versions of our spray like sugar-free or child-friendly ones to make it more suitable, for different people.

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