

FORMULATION AND EVALUTION OF HERBAL LOZENGES

Corresponding Author: Dr. Dasari Nirmala¹

¹Department of Pharmaceutics, Malla Reddy College of Pharmacy, Dhulapally, Secunderabad, Telangana, 500100 (Affiliated to Osmania University)

Authors: Nalusani Sahithi ², Akshayareddypalla ², Palaparthi Anilsmitha ², Nenavanth Sandhya ², Narla Bhanuprasad ².

²Department of Pharmacy, Malla Reddy College of Pharmacy, Dhulapally, Secunderabad, Telangana, 500100 (Affiliated to Osmania University)

sahithireddynalusani@gmail.com

akshayareddypalla790@gmail.com

palaparthismitha@gmail.com

sandhyanavath883@gmail.com

narlabhanuyadav123@gmail.com

ABSTRACT

Cough is a common respiratory symptom that can significantly affect the quality of life when persistent or severe. Conventional antitussive medications, while effective, are often associated with side effects and limited patient compliance. Herbal remedies, on the other hand, offer a safer and more natural alternative due to their soothing and therapeutic properties. This study focuses on the formulation and evaluation of herbal lozenges, aiming to provide a convenient and patient-friendly dosage form for cough management.

The research involved the selection of suitable herbal ingredients known for their cough-suppressing effects, such as Glycyrrhiza glabra (Licorice), Trachyspermum ammi (Ajwain) and Zingiber officinale (Ginger). Herbal extracts were incorporated into lozenges using the heating and congealing method, along with appropriate excipients to ensure proper consistency and stability. Multiple formulations were prepared and evaluated for physicochemical parameters, including hardness, friability, weight variation, and disintegration time.

The results indicated that all formulations met pharmacopeial limits and demonstrated satisfactory mechanical strength and uniformity. The herbal lozenges showed controlled behavior and good stability under selected conditions. Overall, the study concludes that herbal lozenges can be successfully formulated using natural ingredients and may serve as a safe, effective, and patient-friendly dosage form for the management of throat irritation and cough.

Keywords: Zingiber officinale, Glycyrrhiza glabra, Trachyspermum ammi, herbal lozenges, antitussive therapy, controlled-release dosage forms, formulation optimization, stability studies

INTRODUCTION

Lozenges are a widely used solid oral dosage form for the management of cough and throat irritation, particularly in conditions affecting the upper respiratory tract. Their therapeutic effectiveness is largely due to their slow dissolution in the oral cavity, which allows continuous release of active constituents and prolonged contact with the oral and pharyngeal mucosa. This localized delivery enhances symptom relief at the site of irritation while minimizing gastrointestinal involvement and systemic side effects. Owing to their ease of administration and palatability, lozenges are well accepted by patients across different age groups.

The performance of lozenges depends on formulation design, manufacturing method, and selection of excipients, which collectively influence dissolution rate, stability, and patient acceptability. Depending on composition, lozenges may provide sustained or relatively rapid relief and may act locally or through limited absorption across the oral mucosa. In recent years, herbal lozenges have gained attention due to their favorable safety profile and compatibility with traditional medicinal practices. Natural bases such as jaggery, sucrose, and honey are commonly employed to improve taste, mouthfeel, and gradual dissolution.

Medicinal herbs further enhance therapeutic efficacy. Ginger helps reduce inflammation and throat irritation, liquorice provides demulcent and expectorant effects, and ajwain contributes bronchodilatory and antimicrobial actions. Peppermint oil offers a cooling sensation that calms the cough reflex. When properly formulated, herbal lozenges represent an effective, patient-friendly approach for cough management.

INGREDIENTS

Jaggery

Jaggery was used as a natural sweetening and binding agent in the lozenge formulation. It improves taste and mouthfeel, thereby enhancing patient acceptability. Due to its hygroscopic nature, jaggery helps retain moisture and prevents excessive hardness or brittleness of the lozenges. Its slow solubility supports gradual dissolution in the oral cavity, allowing

prolonged contact with the throat. Traditionally, jaggery has been associated with relief from throat discomfort, making it suitable for respiratory formulations.

Sucrose

Sucrose served as a sweetening and bulking agent in the formulation. It contributes to the structural strength and smooth texture of lozenges while masking the bitter taste of herbal ingredients. Sucrose dissolves slowly in saliva, supporting sustained release of active constituents and prolonged soothing action on the throat mucosa.

Ginger (*Zingiber officinale*)

Ginger was incorporated for its well-recognized role in relieving throat and respiratory irritation. Its bioactive components help reduce inflammation and provide warmth, which supports comfort and mucus clearance. Ginger also contributes to flavor enhancement and supports immune response in respiratory conditions.

Liquorice (*Glycyrrhiza glabra*)

Liquorice was included due to its demulcent and expectorant properties. It helps soothe irritated mucosal surfaces by forming a protective layer over the throat and assists in loosening thick mucus. Its mild sweetness improves palatability while enhancing overall therapeutic effectiveness.

Honey

Honey was used as a natural sweetener and soothing agent. It helps coat the throat mucosa, reducing dryness and irritation associated with cough. Its viscous nature supports gradual dissolution, while its mild antimicrobial action contributes to respiratory comfort.

Ajwain (*Trachyspermum ammi*)

Ajwain was selected for its bronchodilatory and antispasmodic properties. It aids in relieving congestion, loosening mucus, and calming the cough reflex. Its antimicrobial action supports throat health in respiratory discomfort.

Peppermint Oil (*Mentha piperita*)

Peppermint oil was incorporated to provide a cooling sensation and mild local anesthetic effect. It helps reduce throat irritation and suppress coughing while improving aroma and taste of the lozenges.

Corn Starch

Corn starch functioned as a binder and stabilizing agent. It improved mechanical strength, moisture control, and uniform distribution of ingredients, ensuring smooth dissolution and formulation stability.

Lemon

Lemon was added primarily for flavor enhancement and salivation stimulation. It's refreshing taste improves acceptability and supports prolonged throat contact during lozenge use.

Hydroxypropyl Methylcellulose (HPMC)

HPMC was used as a binder and release-modifying polymer. It enhanced hardness, shape uniformity, moisture control, and controlled dissolution by forming a gel layer in contact with saliva.

Need of Study

Although herbal remedies are widely used and increasingly studied, few studies have properly developed and tested herbal lozenges with optimized formulas. Most previous studies have focused on single herbs or crude plant extracts without serious formulation work or complete testing. We designed this project to fill this gap by developing herbal lozenges containing ginger, licorice, and ajwain and testing different bases and ingredients to achieve the best performance.

MATERIALS AND METHODS**Materials and Ingredients**

All plant materials (ginger powder, licorice powder, ajwain powder, and peppermint oil) were obtained from certified suppliers and authenticated according to official pharmacy standards. Jaggery was obtained from local agricultural suppliers. Pharmaceutical-grade sucrose, corn syrup, and HPMC K4M met the United States Pharmacopeial standards. Citric acid and purified water (prepared by reverse osmosis and deionization) were used in all preparations.

Formulation

We developed two formulations by testing different sweeteners and polymers. Formulation F1 used jaggery and honey as the base with herbal ingredients to test whether simple ingredients could work well. Formulation F2 combined jaggery, sucrose, and corn syrup with

HPMC as a structure-building polymer to improve strength and extend the duration of lozenge dissolution. Table 1 shows the exact amounts of each ingredient.

Ingredient	F1 WEIGHT(g)	F2 WEIGHT(g)	Purpose
Jaggery (powdered)	18.45 g	14.65 g	Sweetener/binder
sucrose (powdered)	-	5.27 g	Hard candy base
corn syrup	-	3.81 g	Prevents crystallization
Honey	4.92 g	1.76 g	Soothing (reduced)
Ginger powder	1.84 g	1.17 g	Antitussive
Liquorice powder	1.84 g	1.17 g	Demulcent
Ajwain powder	2.46 g	1.76 g	Bronchodilator, Expectorant,
Peppermint oil	2 drops	3 drops	Flavor
HPMC	-	0.29 g	Binder & hardness
Citric acid	0.49 g	0.12 g	Preservation (acidic nature)
Purified water	qs	qs	Dissolution

Table:1 Formulation of Herbal Lozenges

PROCEDURE

Step 1: Preparation of Raw Materials

1. Accurately weigh all ingredients.
2. Lightly grease lozenge moulds with liquid paraffin or glycerin.

Step 2: Preparation of Sugar Syrup

1. Transfer purified water into a heavy-bottomed beaker.
2. Add sucrose, powdered jaggery, and corn syrup.
3. Heat gently with continuous stirring until all solids dissolve completely.
4. Stop stirring once the solution starts boiling.

Step 3: Concentration to Hard-Crack Stage (Critical Step)

1. Continue heating the syrup without stirring.
2. Monitor temperature using a thermometer.
3. Heat until the temperature reaches 145–150 °C (hard-crack stage).
4. Confirm hard-crack stage by cold-water test:
 - Drop a small amount into cold water.
 - Syrup should form brittle threads that snap immediately.

Step 4: Addition of Heat-Sensitive Ingredients

1. Remove the pan from heat immediately.
2. Allow temperature to reduce slightly.
3. Add the following ingredients quickly in sequence:
 - Ginger powder
 - Liquorice powder
 - Ajwain powder
 - HPMC
 - Citric acid
1. Mix gently but quickly to obtain a uniform mass.
2. Add honey and peppermint oil last after reducing temperature and mix briefly.

Step 5: Moulding of Lozenges

1. Immediately pour the molten mass into pre-lubricated lozenge moulds.
2. Avoid air entrapment during pouring.
3. Allow lozenges to cool and solidify at room temperature (25–30 °C).
4. Do not disturb moulds until complete solidification.



Fig:3 Moulding of Lozenges

Step 6: Drying of Lozenges

1. Remove lozenges carefully from moulds.
2. Place them on butter paper or a clean tray.
3. Air-dry for 24–48 hours in a dry environment.

Step 7: Packaging

1. Ensure lozenges are completely dry and cooled.
2. Individually wrap lozenges.
3. Place silica gel desiccant in the container.
4. Store in a cool, dry place away from sunlight.

Step 8: Storage Conditions

- Temperature: Below 30 °C
- Protection from light and moisture.

EVALUATION TESTS OF HERBAL LOZENGES

1. Organoleptic Evaluation

Ten lozenges were randomly selected from the prepared batch. Each lozenge was visually examined for color, shape, and surface texture. Odor was assessed by smelling the lozenges, and taste was evaluated carefully to determine palatability and throat-soothing sensation.

2. Weight Variation Test

Twenty lozenges were selected randomly and weighed individually using a calibrated digital balance. The average weight was calculated, and the percentage deviation of each lozenge from the mean weight was determined.

Formula:

$$\% \text{ Weight Deviation} = \frac{|\text{Individual Weight} - \text{Average Weight}|}{\text{Average weight}} \times 100$$

3. Thickness and Diameter

Ten lozenges were selected and their thickness and diameter were measured using a vernier caliper. The mean and standard deviation were calculated.

Formula:

$$\text{Mean} = \frac{\sum X}{n}$$

$$SD = \sqrt{\left[\frac{\sum (X - \bar{X})^2}{(n - 1)} \right]}$$

4. Hardness Test

Six lozenges were placed individually between the jaws of a hardness tester. Pressure was applied gradually until fracture occurred, and the breaking force was recorded.

5. Friability Test

Ten pre-weighed lozenges were placed in a Roche friabilator and rotated at 25 rpm for 4 minutes. The lozenges were then dedusted and reweighed.

Formula:

$$\% \text{ Friability} = \frac{(W^1 - W^2)}{W^1} \times 100$$

6. In-Vitro Disintegration Time

One lozenge was placed in a suitable medium maintained at $37 \pm 0.5^\circ\text{C}$, and the time required for complete dissolution was recorded.

7. Stability Studies

The lozenges were stored under specified temperature and humidity conditions and evaluated periodically.

RESULTS

1. Organoleptic Evaluation

TABLE:2 Observations

Parameter	F1	F2
Color	dark, slightly non-uniform	Uniform brown
Shape	Acceptable	Uniform and well-defined
Surface texture	Slight roughness	Smooth and glossy
Odor	Mild peppermint	Pleasant peppermint



Fig:3.1 herbal lozenges (f1)



Fig:3.2 herbal lozenges(f2)

2. TABLE:3 Weight Variation Test

Formulation	Average weight (g)	Maximum deviation (%)	Acceptance criteria
F1	3.12 g	±4.4%	±3.0
F2	3.01 g	±1.6%	±3.0

Sample Calculation (F2)

$$\% \text{ Deviation} = \frac{\{3.05 - 3.01\}}{\{3.01\}} \times 100 = 1.33\%$$

3. TABLE:4 Thickness and Diameter

Parameter	F1 (Mean ± SD)	F2 (Mean ± SD)
Thickness (mm)	5.4 ± 0.28	5.1 ± 0.12
Diameter (mm)	16.8 ± 0.42	16.5 ± 0.18

4. TABLE:5 Hardness Test

Formulation	Hardness (kg/cm ²)	Acceptance criteria
F1	3.2 ± 0.3	4–8 kg/cm ²
F2	6.8 ± 0.4	4–8 kg/cm ²

5.TABLE:6 In-Vitro Disintegration Time

Formulation	Disintegration time (min)
F1	5.2
F2	15.6

6. Friability Test**TABLE:7 Observed Values**

Formulation	Initial weight (g)	Final weight (g)	Friability (%)	Acceptance criteria
F1	30.00	29.55	1.50	±1.0%
F2	30.00	29.85	0.50	±1.0%

Calculation (F2)

$$\% \text{ Friability} = \frac{\{30.00 - 29.85\}}{\{30.0\}} \times 100 = 0.50\%$$

7. TABLE:8 Stability Studies (Accelerated Conditions)

Formulation	Storage Condition	Duration	Physical Appearance	Hardness	Drug Content
F1	25°C ± 2°C	30 days	Slight stickiness	Decreased	Slight decrease
F1	40°C ± 2°C	30 days	Softening observed	Decreased	Decreased
F2	25°C ± 2°C	30 days	No change	Stable	Stable
F2	40°C ± 2°C	30 days	Slight softening	Acceptable	Within limits

DICUSSION

The comparative evaluation of herbal lozenge formulations demonstrated clear differences in quality attributes and performance. Organoleptic analysis showed that formulation F2 exhibited uniform colour, smooth surface, and pleasant odor, indicating better homogeneity and improved patient acceptability compared to F1. Weight variation results confirmed

compliance with pharmacopeial limits for both formulations; however, F2 showed lower deviation, suggesting improved flow and uniform mixing during manufacture. Dimensional measurements revealed reduced variability in thickness and diameter for F2, reflecting consistent molding and structural uniformity. Hardness testing indicated that F2 achieved values within the acceptable range, providing adequate mechanical strength for handling and controlled dissolution, while F1 was comparatively softer. This was further supported by disintegration studies, where F2 demonstrated prolonged disintegration time, allowing sustained release of herbal actives in the oral cavity. Friability and stability studies confirmed superior mechanical integrity and storage stability of F2. Overall, formulation F2 showed enhanced physicochemical properties and stability, making it more suitable for herbal lozenge development.

CONCLUSION

In conclusion, the present study successfully formulated and evaluated herbal lozenges using natural ingredients such as jaggery, sucrose, corn syrup, honey, ginger powder, liquorice powder, ajwain powder, peppermint oil, corn starch, lemon, and hydroxypropyl methylcellulose (HPMC). These ingredients are well known for their antitussive, demulcent, anti-inflammatory, and soothing properties, making the formulation effective in relieving cough and throat irritation while improving patient acceptability.

The prepared herbal lozenges showed satisfactory physicochemical characteristics, including uniform appearance, acceptable hardness, low friability, controlled disintegration time, and good stability. Among the formulations, F2 exhibited better overall performance due to improved mechanical strength and controlled behavior. Overall, the study confirms that herbal lozenges formulated with natural ingredients can serve as a safe, effective, and patient-friendly alternative to conventional preparations.

This study demonstrates that careful formulation design can produce effective herbal medicines of pharmaceutical quality. The polyherbal approach, which combines multiple beneficial herbs, provides a solid foundation for developing cough medicines that are both effective and safe for diverse patient populations.

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