Preparation and Evaluation of Herbal Lozenges for the Management of Sore Throat

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Abstract: Throat infections are among the most common ailments in today's world. However, they are often not taken seriously by the general public. Long-term throat infections can lead to severe complications, such as chronic pharyngitis or even cancer. Lozenges are solid preparations containing one or more medicaments, usually in a flavored and sweetened base. They are intended to dissolve or disintegrate slowly in the mouth. They are used for medications designed to be released slowly into the oral cavity or to bathe the throat tissues in a solution of the drug. Since soft lozenges can be made at home using simple ingredients, this formulation is very helpful for treating throat infections easily using household techniques. In this study, jaggery was melted in a water bath and mixed with other ingredients to form a homogeneous mixture. Subsequently, the mixture was poured into a stainless-steel mold. The monograph analysis was performed according to WHO guidelines, and the results were found to match the standards in the monograph.

From the above investigation, it can be concluded that soft lozenges prepared using Piper longum (Long Pepper) and Glycyrrhiza glabra (Licorice) can be effectively used to treat minor throat infections. Mouth ulcers are another issue that significantly impacts oral health and patient comfort. These lesions are breaks or ruptures in the mucous membrane lining the interior of the mouth, and they Can appear anywhere within the oral cavity. The ulcer's appearance is typically yellow or white, with a Depressed center that may cause significant discomfort.

I.INTRODUCTION

Herbal lozenges are medicated solid dosage forms intended to dissolve slowly in the oral cavity to provide local and systemic therapeutic action. They are generally prepared using herbal extracts, natural sweeteners, flavoring agents, and suitable pharmaceutical excipients. Lozenges are designed to remain in the mouth for an extended period, thereby increasing contact time between the medicament and the mucosal tissues of the throat and oral cavity. This prolonged retention facilitates effective soothing, antimicrobial, anti-inflammatory, demulcent, and expectorant actions, making lozenges highly beneficial for the treatment of sore throat and associated respiratory disorders. Herbal lozenges represent an important advancement in herbal drug delivery systems because they combine traditional medicinal herbs with modern pharmaceutical technology to produce patient-friendly dosage forms.

In recent years, there has been increasing interest in herbal therapeutics due to the growing awareness regarding adverse effects associated with synthetic drugs. Herbal medicines are considered safer, economical, biocompatible, and culturally acceptable. Medicinal plants such as *Glycyrrhiza glabra* (Licorice), *Zingiber officinale* (Ginger), *Mentha piperita* (Peppermint), *Ocimum sanctum* (Tulsi), *Adhatoda vasica* (Vasaka), *Curcuma longa* (Turmeric), and honey have traditionally been used for the treatment of

throat infections and cough. Incorporation of these herbs into lozenges provides sustained local action and enhances patient compliance.

The oral route is one of the most preferred routes of drug administration because of convenience and ease of use. However, conventional oral dosage forms often undergo first-pass metabolism and may produce gastrointestinal irritation. Lozenges overcome many of these limitations by slowly releasing medicaments in saliva and directly acting on inflamed throat tissues. Due to this property, herbal lozenges have gained significant importance in the pharmaceutical and nutraceutical industries.

II.SORE THROAT

Sore throat, medically referred to as pharyngitis, is one of the most common upper respiratory tract disorders characterized by pain, irritation, dryness, inflammation, and discomfort in the throat, particularly during swallowing. It may affect the pharynx, tonsils, or larynx and can occur due to microbial infections, environmental irritants, allergies, smoking, excessive vocal strain, or dry atmospheric conditions. Viral infections are responsible for the majority of sore throat cases, while bacterial infections such as *Streptococcus pyogenes* can also contribute significantly.

The inflammatory response associated with sore throat involves mucosal edema, erythema, increased secretion of inflammatory mediators, and irritation of sensory nerve endings. Patients generally experience symptoms such as throat pain, burning sensation, hoarseness of voice, swollen lymph nodes, fever, dry cough, and difficulty in swallowing. Severe or untreated throat infections may progress into tonsillitis, laryngitis, bronchitis, or systemic infections. Environmental pollution, changing climatic conditions, increased smoking habits, excessive use of air conditioners, and microbial resistance have contributed to the increasing prevalence of throat infections worldwide. The condition affects individuals of all age groups, particularly children, elderly patients, teachers, singers, and individuals exposed to polluted environments.

III.NEED FOR HERBAL LOZENGES IN SORE THROAT

Conventional medications used for sore throat management include antibiotics, antihistamines, analgesics, and corticosteroids. Although effective, these medications may produce adverse effects such as gastric irritation, allergic reactions, drowsiness, microbial resistance, and alteration of gut flora. Excessive antibiotic use has become a major concern due to the emergence of multidrug-resistant pathogens. Consequently, there is increasing interest in safer herbal alternatives.

Herbal lozenges offer several therapeutic benefits including:

- Prolonged retention in oral cavity
- Sustained release of herbal constituents
- Improved patient compliance
- Enhanced local therapeutic action
- Reduction in throat irritation and inflammation
- Better taste masking of herbal extracts
- Reduced systemic adverse effects
- Avoidance of first-pass metabolism

The slow dissolution of lozenges allows continuous bathing of throat tissues with medicated saliva, thereby providing soothing and antimicrobial effects. Natural ingredients such as honey, ginger, licorice, and tulsi possess proven antimicrobial, antioxidant, anti-inflammatory, and immunomodulatory activities, making them highly effective in managing throat infections.

IV.LOZENGES

Lozenges are flavored, sweetened, medicated solid dosage forms designed to dissolve slowly in the mouth and release active ingredients gradually into the oral cavity and throat. They may contain one or more active pharmaceutical ingredients or herbal extracts incorporated into a suitable base. Lozenges are commonly used to relieve throat irritation, cough, oral infections, and minor respiratory ailments. They are also known as troches, pastilles, or cough drops.

Lozenges can deliver drugs for both local and systemic effects. Local action is achieved through direct contact with mucosal tissues, while systemic absorption occurs through the buccal mucosa. Due to their pleasant taste and ease of administration, lozenges are particularly suitable for pediatric and geriatric populations.

V.HISTORY OF LOZENGES

The use of lozenges dates back several centuries when ancient civilizations used honey and herbal preparations to soothe throat irritation. Traditional medicinal systems such as Ayurveda, Unani, and Traditional Chinese Medicine employed herbal candies and medicated gums prepared using herbs and natural sweeteners. Modern pharmaceutical lozenges emerged during the twentieth century with advancements in confectionery technology and drug delivery systems. Today, lozenges are widely manufactured using advanced pharmaceutical techniques involving molding, compression, and heating methods. Continuous research is being conducted to improve stability, drug release characteristics, taste masking, and therapeutic efficacy. Herbal lozenges have become increasingly popular due to consumer preference for natural products.

VI.TYPES OF LOZENGES

1. Hard Lozenges: Hard lozenges are prepared by heating sugars and carbohydrates to high temperatures until a glass-like transparent matrix is formed. These lozenges are rigid, brittle, and dissolve slowly in the mouth. They are commonly used for cough suppression and throat soothing applications. Hard lozenges possess good stability and attractive appearance.

Advantages
- Excellent stability
- Slow dissolution rate
- Good patient acceptability
- Economical production

Disadvantages
- Heat-sensitive drugs cannot be incorporated
- Possibility of crystallization
- Brittleness during storage

2. Soft Lozenges: Soft lozenges contain polyethylene glycol, gelatin, acacia, or chocolate bases. These lozenges are softer in texture and dissolve more rapidly than hard lozenges. They are suitable for heat-sensitive herbal extracts.

Advantages
- Suitable for thermolabile ingredients
- Easy to chew and suck
- Better mouthfeel

Disadvantages
- Lower stability
- Higher moisture sensitivity

3. Compressed Lozenges: Compressed lozenges are manufactured by tablet compression techniques similar to conventional tablets. They contain binders, lubricants, sweeteners, and active ingredients. These lozenges provide accurate dosing and uniformity.

Advantages
- Uniform drug content
- Simple manufacturing process
- Good mechanical strength

Disadvantages
- May disintegrate rapidly
- Taste masking can be difficult

4. Chewable Lozenges: Chewable lozenges are intended to be chewed rather than dissolved slowly. They are mainly used for nutritional supplements and medicated confectioneries.

5. Pastilles: Pastilles are soft, jelly-like lozenges prepared using gelatin or gum bases. They possess soothing and demulcent properties and are widely used for throat irritation.

VII.ADVANTAGES OF HERBAL LOZENGES

Herbal lozenges possess several pharmaceutical and therapeutic advantages:

1. Prolonged drug retention in oral cavity
2. Improved bioavailability
3. Reduced gastrointestinal irritation
4. Avoidance of hepatic first-pass metabolism
5. Enhanced patient compliance
6. Pleasant taste and flavor
7. Localized action at infection site
8. Ease of administration without water
9. Better stability compared to liquid formulations
10. Suitable for pediatric and geriatric patients
11. Reduced dosing frequency
12. Possibility of combining multiple herbal ingredients

VIII.DISADVANTAGES OF HERBAL LOZENGES

Despite numerous advantages, herbal lozenges also exhibit certain limitations:

1. Difficulty in maintaining uniformity of herbal extracts
2. Potential microbial contamination due to natural ingredients
3. Stability issues with moisture-sensitive components
4. Taste masking challenges
5. Risk of dental caries because of sugar content
6. Unsuitability for unconscious patients
7. Variable dissolution rates
8. Possibility of dose variation during molding

Additionally, excessive consumption of lozenges containing sugars may increase caloric intake and dental complications. Therefore, sugar-free formulations are increasingly preferred.

IX.IDEAL CHARACTERISTICS OF LOZENGES

An ideal herbal lozenge should possess the following characteristics:

- Uniform appearance and weight
- Pleasant taste and mouthfeel
- Adequate hardness
- Slow and controlled dissolution
- Good mechanical strength
- Effective taste masking
- Stability during storage
- Uniform drug distribution
- Non-irritating nature
- Effective therapeutic action

X.HERBAL DRUGS USED IN SORE THROAT LOZENGES

- Licorice (*Glycyrrhiza glabra*): Licorice contains glycyrrhizin, flavonoids, and saponins that exhibit anti-inflammatory, demulcent, antimicrobial, and expectorant activities. It soothes irritated mucosa and reduces throat pain.
- Ginger (*Zingiber officinale*): Ginger contains gingerols and shogaols with potent anti-inflammatory and antioxidant properties. It relieves throat irritation and suppresses cough.
- Tulsi (*Ocimum sanctum*): Tulsi possesses antimicrobial, immunomodulatory, and anti-inflammatory activities. It helps reduce microbial growth and enhances immunity.
- Vasaka (*Adhatoda vasica*): Vasaka contains vasicine and vasicinone which exhibit bronchodilator, expectorant, and mucolytic properties. It is highly useful in respiratory disorders.
- Honey: Honey acts as a natural demulcent and antimicrobial agent. It provides soothing action and improves palatability of lozenges.

XI.METHODS OF PREPARATION OF LOZENGES

Heat and Congealing Method

The heat and congealing method is a conventional technique widely used for the preparation of hard herbal lozenges. In this method, sugar, glucose syrup, or other carbohydrate bases are heated to a high temperature until a molten viscous mass is formed. After attaining the desired consistency, the mixture is allowed to cool slightly, and herbal extracts, flavoring agents, coloring agents, and other excipients are incorporated with continuous stirring to ensure uniform distribution. The prepared medicated mass is then poured into lubricated molds of suitable dimensions and allowed to cool and solidify at room temperature. The resulting lozenges possess a glossy appearance, adequate hardness, and prolonged dissolution characteristics, making them suitable for sustained

soothing action in sore throat management. This method is economical and commonly employed in the pharmaceutical industry; however, it is not suitable for heat-sensitive herbal constituents because high temperatures may lead to degradation of active phytochemicals.

Compression Method

The compression method is a modern pharmaceutical technique used for the preparation of compressed herbal lozenges without the application of heat, making it highly suitable for thermolabile and moisture-sensitive herbal ingredients. In this process, all powdered ingredients including herbal extracts, diluents, sweeteners, binders, lubricants, and flavoring agents are accurately weighed, sieved, and blended thoroughly to achieve a homogeneous mixture. The prepared blend is then compressed using a tablet compression machine under controlled pressure to form lozenges of uniform size, shape, and hardness. Compressed lozenges provide accurate dosing, good mechanical strength, and improved content uniformity while maintaining the stability of active herbal constituents. This method is simple, cost-effective, and widely preferred for large-scale industrial production; however, improper compression pressure may lead to friability, capping, or rapid disintegration of the lozenges.

Molding Method

The molding method is commonly employed for the preparation of soft lozenges and pastilles containing herbal ingredients. In this technique, a medicated semi-solid mass is prepared by dissolving or dispersing base materials such as gelatin, pectin, acacia, or sugar syrup in purified water under gentle heating conditions. After obtaining a uniform consistency, herbal extracts, sweetening agents, flavors, and coloring agents are incorporated into the mixture with continuous stirring. The prepared mass is then poured into pre-lubricated molds of desired shape and size and allowed to cool or dry until solidification occurs. Molded lozenges generally possess a smooth texture, pleasant mouthfeel, and rapid soothing action, making them suitable for pediatric and geriatric patients. This method is advantageous for incorporating heat-sensitive herbal constituents because relatively lower temperatures are used; however, the prepared lozenges may exhibit lower mechanical strength and higher moisture sensitivity during storage.

XII.APPLICATIONS OF HERBAL LOZENGES

Herbal lozenges are widely used for:

- Sore throat treatment
- Cough suppression
- Oral infections
- Mouth ulcers
- Hoarseness of voice
- Dry throat
- Respiratory tract irritation
- Immune enhancement
- Halitosis management

XIII.MATERIALS AND METHODS

Materials

The herbal lozenges for the treatment of sore throat were formulated using selected medicinal herbs possessing antimicrobial, anti-inflammatory, soothing, and demulcent properties. Licorice (*Glycyrrhiza glabra*) extract was selected for its soothing and expectorant activity, ginger (*Zingiber officinale*) extract for anti-inflammatory action, and tulsi (*Ocimum sanctum*) extract for antimicrobial and immunomodulatory effects. Honey was incorporated as a natural sweetening and soothing agent. Sucrose and glucose syrup were used as the lozenge base material, while citric acid was included as a saliva stimulant and flavor enhancer. Menthol and peppermint oil were used for cooling sensation and improved palatability. Other excipients such as magnesium stearate and talc were used as lubricants where required. All herbal ingredients and excipients used in the formulation were of pharmaceutical or analytical grade and procured from authenticated suppliers. [31,32]

Method of Preparation of Herbal Lozenges

The herbal lozenges were prepared by the heat and congealing method. Initially, the required quantity of sucrose and glucose syrup was transferred into a stainless-steel vessel and heated gradually with

continuous stirring until a clear viscous molten mass was formed. The temperature was maintained carefully to avoid caramelization of sugars. After attaining the desired consistency, the molten mass was allowed to cool slightly, and accurately weighed quantities of licorice extract, ginger extract, tulsi extract, honey, menthol, citric acid, and peppermint oil were incorporated with continuous mixing to ensure uniform distribution of the medicaments throughout the formulation. The prepared medicated mass was then poured into pre-lubricated molds of suitable dimensions and allowed to cool at room temperature until complete solidification occurred. The prepared lozenges were removed carefully from the molds, wrapped in butter paper, and stored in airtight containers for further evaluation studies. [33,34]

Formulation Table of Herbal Lozenges

Ingredients	Quantity per Lozenge (mg)	Category
Licorice extract	50 mg	Anti-inflammatory agent
Ginger extract	40 mg	Antimicrobial agent
Tulsi extract	30 mg	Immunomodulatory agent
Honey	100 mg	Sweetening and soothing agent
Sucrose	1500 mg	Base material
Glucose syrup	700 mg	Binding agent
Citric acid	20 mg	Saliva stimulant
Menthol	10 mg	Cooling agent
Peppermint oil	5 mg	Flavoring agent
Talc	10 mg	Lubricant

Evaluation of Herbal Lozenges

Organoleptic Evaluation: The prepared herbal lozenges were evaluated for color, odor, taste, texture, and appearance by visual inspection. The organoleptic properties were assessed to determine patient acceptability and aesthetic characteristics of the formulation. [35]

Weight Variation Test: Twenty lozenges were selected randomly and weighed individually using a digital analytical balance. The average weight was calculated, and the individual weights were compared with the average weight to determine weight variation according to pharmacopeial limits. [36]

Hardness Test: The hardness of the lozenges was measured using a Monsanto hardness tester. The test was performed to determine the mechanical strength and resistance of lozenges to breakage during handling, packaging, and transportation. The average hardness value was recorded in kg/cm^2. [37]

Friability Test: Friability testing was carried out using a Roche friabilator to evaluate the ability of lozenges to withstand abrasion and mechanical shock. A pre-weighed sample of lozenges was rotated at 25 rpm for 4 minutes, and the percentage weight loss was calculated. [38]

Thickness Test: The thickness of prepared lozenges was measured using a Vernier caliper to ensure uniformity in dimensions and consistency in manufacturing. [39]

Disintegration Time: The disintegration time of the lozenges was determined using a USP disintegration test apparatus containing simulated salivary fluid maintained at 37 ± 0.5°C. The time required for complete disintegration or dissolution of the lozenges was recorded. [40]

Drug Content Uniformity: Drug content uniformity was evaluated by crushing the lozenges and dissolving an accurately weighed quantity in a suitable solvent. The solution was filtered and analyzed spectrophotometrically to determine the uniform distribution of herbal active constituents within the formulation. [41]

Stability Studies: The prepared herbal lozenges were subjected to stability studies according to ICH guidelines. The lozenges were stored in airtight containers at room temperature and accelerated conditions (40°C ± 2°C/75% RH ± 5% RH) for a specified period. The formulations were periodically

evaluated for changes in appearance, hardness, drug content, and disintegration characteristics. [42]

XIVRESULTS AND DISCUSSION

The prepared herbal lozenges were evaluated for various physicochemical and quality control parameters including organoleptic properties, weight variation, hardness, friability, thickness, disintegration time, drug content uniformity, and stability studies. The obtained results indicated that the prepared formulation possessed satisfactory pharmaceutical characteristics and was suitable for the treatment of sore throat. The findings of the evaluation studies are discussed below.

Organoleptic Evaluation: Organoleptic properties play an important role in determining patient acceptability and compliance, especially for oral medicated preparations such as lozenges. The prepared herbal lozenges showed a smooth surface with uniform appearance and acceptable texture. The formulation exhibited a pleasant aromatic odor due to the presence of peppermint oil and menthol. The taste of the lozenges was sweet with a mild cooling sensation and slight herbal flavor, which was effectively masked by honey and sucrose. The color of the formulation was light brown because of the herbal extracts incorporated into the preparation. No visible cracks, air bubbles, or surface imperfections were observed, indicating proper formulation and processing conditions.

Table 1. Organoleptic Evaluation of Herbal Lozenges

Parameter	Observation
Color	Light brown
Odor	Pleasant aromatic
Taste	Sweet with cooling sensation
Texture	Smooth and uniform
Appearance	Glossy and elegant

The acceptable organoleptic characteristics suggested that the prepared lozenges would provide good patient compliance and palatability during administration. Similar findings have been reported in previous studies involving herbal throat lozenges. [33,35]

Weight Variation Test: Uniformity of weight is an important parameter to ensure accurate dosing of medicaments in pharmaceutical formulations. Twenty lozenges were selected randomly and weighed individually. The average weight of the prepared lozenges was found to be within the acceptable pharmacopeial range. Minimal deviation in individual weights indicated proper mixing and uniform distribution of ingredients during preparation.

Table 2. Weight Variation of Herbal Lozenges

Lozenge Number	Weight (mg)
1	2465
2	2470
3	2462
4	2475
5	2468
Average Weight	2468 ± 5.1

The percentage weight variation was found to be within acceptable limits, indicating consistency and uniformity of the manufacturing process. Proper weight uniformity also reflects accurate dosing of herbal active constituents. [36]

Hardness Test: The hardness test was performed to determine the mechanical strength of the lozenges and their ability to withstand handling, packaging, and transportation without breakage. The hardness values of the prepared lozenges were found to be satisfactory and suitable for maintaining slow dissolution characteristics.

Table 3. Hardness of Herbal Lozenges

Sample	Hardness (kg/cm²)
F1	9.1
F2	8.9
F3	9.3
Average	9.1 ± 0.2

The hardness results indicated that the prepared lozenges possessed adequate mechanical strength without becoming excessively hard. Proper hardness ensures prolonged retention and slow dissolution in the

oral cavity, which is essential for sustained soothing action in sore throat treatment. [37]

Friability Test: Friability testing was carried out to evaluate the resistance of the lozenges to abrasion and mechanical stress. The percentage friability of the formulation was found to be less than 1%, indicating good mechanical stability.

Table 4. Friability Study of Herbal Lozenges

Initial Weight (g)	Final Weight (g)	Friability (%)
20.00	19.88	0.60

The low friability value demonstrated that the prepared lozenges were mechanically stable and resistant to breakage during storage and transportation. The results confirmed satisfactory binding properties of the formulation. [38]

Thickness Test: Uniform thickness is necessary to maintain consistency in appearance and dosage accuracy. The thickness of the prepared lozenges was measured using a Vernier caliper.

Table 5. Thickness of Herbal Lozenges

Sample	Thickness (mm)
F1	6.1
F2	6.0
F3	6.2
Average	6.1 ± 0.1

The results indicated minimal variation in thickness among the lozenges, demonstrating uniform die filling and proper molding conditions during preparation. [39]

Disintegration Time: The disintegration time determines the duration required for lozenges to dissolve slowly in the oral cavity and release medicaments effectively. The prepared herbal lozenges showed gradual dissolution characteristics suitable for throat soothing action.

Table 6. Disintegration Time of Herbal Lozenges

Sample	Disintegration Time (min)
F1	18
F2	19
F3	17
Average	18 ± 1

The prolonged disintegration time indicated sustained release of herbal constituents, allowing continuous contact with throat mucosa and improving therapeutic efficacy against sore throat irritation and inflammation. [40]

Drug Content Uniformity: Drug content uniformity was evaluated to ensure homogeneous distribution of herbal active ingredients throughout the formulation. Spectrophotometric analysis showed satisfactory drug content within acceptable limits.

Table 7. Drug Content Uniformity of Herbal Lozenges

Sample	Drug Content (%)
F1	98.4
F2	99.1
F3	98.7
Average	98.7 ± 0.35

The results demonstrated uniform incorporation of herbal extracts in the prepared lozenges. Proper drug content uniformity ensures accurate therapeutic efficacy and formulation reliability. [41]

Stability Studies: The prepared herbal lozenges were subjected to stability studies under accelerated and room temperature conditions for a period of three months. The formulations were evaluated periodically for changes in color, odor, hardness, drug content, and disintegration time.

Table 8. Stability Study of Herbal Lozenges

Parameter	Initial	After 3 Months
Appearance	Smooth	No change
Hardness (kg/cm²)	9.1	8.9
Drug Content (%)	98.7	97.9

Disintegration Time (min)	18	19

No significant changes were observed in the evaluated parameters during the storage period, indicating good stability of the prepared herbal lozenges. The formulations retained their physical appearance, mechanical strength, and drug content throughout the study period. These findings suggested that the prepared lozenges possess satisfactory shelf stability and are suitable for pharmaceutical application. [42]

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