

PREPARATION AND EVALUATION OF POLYHERBAL LOZENGES FOR THE TREATMENT OF COUGH

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ABSTRACT

Herbal lozenges are solid dosage forms meant to dissolve gradually in the mouth, providing localized therapeutic effects in the oral cavity and throat. This review highlights the formulation and creation of herbal lozenges that incorporate natural ingredients like liquorice (*Glycyrrhiza glabra*), ginger (*Zingiber officinale*), peppermint (*Mentha piperita*), and tulsi (*Ocimum sanctum*), all of which are recognized for their anti-inflammatory, antimicrobial, expectorant, and soothing properties. Lozenges present multiple benefits, including ease of use, extended contact of the medication with throat tissues, enhanced patient adherence, and the capacity to mask unpleasant tastes of the drugs. The study also examines the categorization of lozenges, their benefits and drawbacks, and the function of various excipients such as sucrose, liquid glucose, acacia gum, and citric acid in the formulation process. Herbal extracts were prepared using the maceration method to obtain active phytoconstituents, which were then incorporated into a sugar-based lozenge formulation through extraction techniques. The prepared herbal lozenges provide a natural and effective approach for relieving cough, sore throat, and mild respiratory discomfort while minimizing the side effects associated with synthetic medications. Thus, herbal lozenges represent a promising alternative dosage form for the management of throat and respiratory conditions.

KEYWORDS: Polyherbal Lozenges, Herbal Formulation, Cough Treatment, Antitussive Activity, Throat Soothing, Oral Dosage Form.

INTRODUCTION

Lozenges are small, flavored tablets intended to dissolve gradually in the mouth. They are frequently utilized to alleviate symptoms related to sore throat, cough, and dry mouth. Additionally, lozenges can serve to deliver medication directly to the throat or mouth, making them a favored option for individuals who experience difficulty swallowing pills or capsules.^[1]

Lozenges are generally consumed by placing one tablet in the mouth and allowing it to dissolve slowly over a period of several minutes. They should not be chewed or swallowed whole. It is crucial to adhere to the dosage instructions provided by the manufacturer or your healthcare provider to prevent overuse or potential side effects.^[1] Herbal lozenges are solid medications employed to address mouth and throat conditions, releasing active therapeutic ingredients gradually as they dissolve on the tongue. They are particularly effective for treating coughs, sore throats, and mild respiratory issues when applied locally.^[2] Lozenges are beneficial for patients who are unable to swallow solid oral dosage forms, as well as for medications designed to be released slowly to maintain a consistent level of the drug in the oral cavity or to coat the throat tissues in a solution of the drug. Drugs commonly included in analgesic lozenges and anesthetics comprise antimicrobials, antiseptics, antitussives, aromatics, astringents, corticosteroids, decongestants, and demulcents.^[3]

CLASSIFICATION OF LOZENGES

Lozenges can be classified into various classes based on various methods like:

According to the site of action: Local effect

Ex. Antiseptics, Decongestants.

Systemic effect Ex. Vitamins, Nicotine.

According to texture and composition

Chewy or caramel based medicated lozenges

These are the dosage form in which medicament is incorporated into a caramel base which is chewed instead of being dissolved in mouth. Most formulations are based on the glycerinated gelatine suppository formula which consists of glycerine, gelatine, and water. These lozenges are often highly fruit flavoured and may have a slightly acidic taste to cover the acrid taste of the glycerine.^[3]

Compressed tablet lozenges

When the active ingredient is heat sensitive, it may be prepared by compression. The granulation method is similar to that used for any compressed tablet. These tablets differ from conventional tablets in terms of organoleptic property, non-disintegrating characteristics and slower dissolution profiles.^[4]

Soft lozenges

They are either meant for chewing or for slow drug release in mouth. They can be made from PEG 1000 or 1450, chocolate or sugar-acacia base while some soft candy formulations can also contain acacia and silica gel. Acacia is used to provide texture and smoothness and silica gel is used as a suspending agent to avoid settling of materials to the bottom of the Mold cavity during the cooling. The formulation requires heating process at about 50 0C, hence is only suitable to heat resistant ingredients.^[4]

Hard lozenges

These are mixtures of sugar and other carbohydrates in an amorphous (non crystalline) or glassy state. They can also be regarded as solid syrups of sugars. The moisture content and weight of hard can lozenge should be in between, 0.5 - 1.5% and 1.5-4.5 g respectively. These should undergo also want uniform dissolution or erosion over 5 10 min., and they should not disintegrate. Disadvantage: The temperature required for their preparation is high hence heat labile materials cannot be prepared.^[3]

MATERIALS AND METHODS

Materials Liquorice: It is the root of *Glycyrrhiza glabra* (Family: Leguminosae) from which a sweet flavour can be extracted. The liquorice plant is a herbaceous perennial legume native to southern Europe and parts of Asia, such as India. It is also known as mulethi in India and is widely used in Ayurvedic system of medicine for various ailment related to respiratory system. Used as Expectorant and Demulcent. These properties are due to the presence of Glycyrrhenic acid.^[11]



Figure no.1: Liquorice.

Ginger: Comprised of *Zingiber officinale* (Family: Zinziberaceae) rhizomes that have been scraped to remove the brown outer skin and sun-dried. Oleoresin, the primary compound in ginger, has expectorant, carminative, and fragrant qualities. Fresh ginger contains an active ingredient called gingerol, which is typically found as yellow, strong oil with a spicy-sweet. Adrak is an additional name for ginger.^[14]



Figure no.2: Ginger.

Tulsi: Tulsi, also known as holy basil, is an herb that has been traditionally used in Ayurvedic medicine for its various health benefits. It is known for its anti-inflammatory, anti-bacterial, and anti-viral properties, which makes it a popular ingredient in herbal remedies for coughs, colds, and other respiratory ailments.^[1]



Figure no.3: Tulsi.

Mentha piperita; Mentha piperita contains menthol, which exhibits antimicrobial, anti-inflammatory, soothing, and cooling effects.

Effective against oral pathogens and relieves throat irritation and cough.

- Family: Lamiaceae
- Active constituents: Menthol, menthone
- Pharmacological actions:

Cooling & soothing effect

Mild local anesthetic

Antimicrobial

- Role in formulation: Relieves throat irritation and provides freshness



Figure no. 4: Mentha piperita.

Table 1: Quantities For 100 Tablets^[15]

S.NO	INGREDIENTS	QUANTITY	PROPERTIES
1	Ginger Extract	6.69g	Anti-inflammatory
2	Liquorice Extract	2.3g	Demulcent
3	Mentha Piperita Extract	2g	Cooling Agent
4	Tulsi Extract	3.3g	Antimicrobial, Immune booster
5	Sucrose	55g	Sweetening Agent
6	Liquid Glucose	27.5g	Binder, Prevent Crystallization
7	Acacia	2.5g	Emulsifier
8	Citric Acid	0.55g	Flavouring Agent

Table 2: Quantities For 15 Tablets.^[15]

S.NO	INGREDIENTS	QUANTITY	PROPERTIES
1	Ginger Extract	1.00g	Anti-inflammatory
2	Liquorice Extract	0.35g	Demulcent
3	Mentha Piperita Extract	0.30g	Cooling Agent
4	Tulsi Extract	0.50g	Antimicrobial, Immune booster
5	Sucrose	8.25g	Sweetening Agent
6	Liquid Glucose	4.13g	Binder, Prevent Crystallization
7	Acacia	0.38g	Emulsifier
8	Citric Acid	0.08g	Flavouring Agent

Procedure for Extracts by Maceration Method

Preparation of Mentha piperita Extract

The dried leaves of Mentha piperita were powdered separately. Required quantity of the powder was soaked in hydroalcoholic solvent (Ethanol: Water) in a conical flask. The mixture was kept for 48–72 hours with occasional shaking for proper extraction. After maceration, the extract was filtered using filter paper and concentrated on a water bath to obtain a semisolid extract.

Preparation of Ocimum sanctum (Tulsi) Extract

The dried leaves of Ocimum sanctum were cleaned, shade dried, and powdered. The powder was soaked in hydroalcoholic solvent and kept for maceration with occasional shaking. The mixture was then filtered and the filtrate was concentrated using a water bath to obtain Tulsi extract.

Preparation of Glycyrrhiza glabra (Liquorice) Extract

The dried roots of Glycyrrhiza glabra were powdered and subjected to maceration using hydroalcoholic solvent. The mixture was allowed to stand for 48–72 hours with intermittent shaking. After filtration, the extract was concentrated to obtain a thick liquorice extract.

Preparation of Zingiber officinale (Ginger) Extract

The dried rhizomes of Zingiber officinale were powdered and soaked in hydroalcoholic solvent for maceration. The mixture was shaken occasionally to improve extraction efficiency. The extract was filtered and concentrated on a water bath to obtain ginger extract.

Method of Preparation

1. Required quantities of sucrose and liquid glucose were heated at 110°C to prepare the syrup base.
2. Acacia was added as a binder with continuous stirring.
3. Prepared herbal extracts of Mentha piperita, Ocimum sanctum, Glycyrrhiza glabra, and Zingiber officinale were added to the syrup base.
4. The temperature was maintained at 75°C during mixing to prevent degradation of herbal constituents.
5. Citric acid was added for flavour enhancement.
6. The mixture was stirred continuously until a uniform mass was obtained.
7. The prepared mass was poured into lubricated mould and allowed to cool at room temperature.
8. After solidification, the lozenges were removed from the mould and stored in airtight containers.

EVALUATION PARAMETERS OF HERBAL LOZENGES TABLET**Appearance**

The lozenges are examined visually for color, shape, uniformity, and absence of cracks or air bubbles. A good lozenge should have a smooth surface and uniform appearance.

Weight Variation

Twenty lozenges are individually weighed and the average weight is calculated. Each lozenge weight should be within the acceptable pharmacopoeia limits to ensure uniform drug distribution.

Hardness Test

Hardness determines the mechanical strength of lozenges. It is measured using a hardness tester to ensure that the lozenges are strong enough to withstand handling and packaging but still dissolve slowly in the mouth.

Thickness

The thickness of the lozenges is measured using a Vernier caliper or micrometer screw gauge to ensure uniformity in size.

Friability Test

Friability evaluates the ability of lozenges to resist abrasion during handling, transportation, and packaging. It is tested using a friabilator, and the weight loss should generally be less than 1%.

Disintegration/ Dissolution Time

Since lozenges are designed to dissolve slowly in the mouth, the dissolution time is evaluated in simulated saliva or water to determine the time required for complete dissolution.

Drug Content Uniformity

This test ensures that each lozenge contains the required amount of active herbal constituents. The content is analyzed using suitable analytical methods.

pH Determination

The pH of the dissolved lozenge solution is measured to ensure it is suitable for oral mucosa and does not cause irritation.

Moisture Content

Moisture content is determined to ensure stability and prevent microbial growth or stickiness of the lozenges.

Organoleptic Evaluation

The taste, flavor, mouth feel, and overall acceptability are evaluated by sensory analysis because palatability is important for lozenge dosage forms.

RESULT

The herbal lozenges were successfully prepared using extracts of liquorice (*Glycyrrhiza glabra*), ginger (*Zingiber officinale*), tulsi (*Ocimum sanctum*) and Peppermint (*mentha piperita*) with sucrose as the sweetening agent and liquid glucose as a binder. The prepared lozenges showed a uniform shape, smooth surface, and acceptable color and flavor.

Evaluation parameters such as weight variation, hardness, and thickness were found to be within acceptable limits, indicating uniformity in the formulation. The lozenges exhibited good mechanical strength with minimal friability and dissolved slowly in the mouth, ensuring prolonged contact of the active ingredients with the throat tissues. Organoleptic evaluation indicated a pleasant taste due to the presence of honey and citric acid, which helped in masking the herbal taste. Overall, the formulation demonstrated satisfactory physicochemical properties and was suitable for use as a throat- soothing herbal preparation.

S.NO	Evaluation Parameters	Method/Instrument Used	Observation
1	Appearance	Visual inspection	Smooth surface, uniform color & no cracks
2	Weight variation	Weighing 15 lozenges using digital balance	With in acceptable pharmacopoeia limits
3	Hardness test	Monsanto hardness tester	Adequate hardness ensuring mechanical strength
4	Thickness	Vernier caliper	Uniform thickness observed
5	Friability test	Roche friabilator	Weight loss less than 1%
7	Disintegration/ Dissolution time	Dissolution in stimulated saliva and wate	Slowly dissolved within 5-10 minutes
8	pH determination	pH meter	pH suitable for oral cavity (around 5-7)
9	Organoleptic evaluation	Sensory evaluation	Pleasant taste, acceptable flavor and mouth feel

CONCLUSION

These herbal ingredients possess natural anti-inflammatory, antimicrobial, and expectorant properties that help in relieving cough, sore throat, and minor respiratory discomfort. The prepared lozenges showed acceptable physical characteristics, stability, and patient-friendly organoleptic properties. Herbal lozenges offer several advantages such as ease of administration, prolonged drug action in the oral cavity, and improved patient compliance. Therefore, herbal lozenges can be considered a safe, effective, and natural alternative to conventional throat medications and may be useful in the management of throat irritation and cough.

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