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Research Article

FORMULATION AND EVALUATION OF HERBAL LOZENGES

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Abstract:

Pain, irritation, and difficulty swallowing are the hallmarks of sore throat, a common condition linked to upper respiratory tract infections. The need for safer alternatives is highlighted by the fact that conventional therapies. The need for safer alternatives is highlighted by the fact that conventional therapies, such as antibiotics and anti-inflammatory medications, are frequently linked to side effects, microbial resistance, and higher costs. The natural origin, safety, and therapeutic effectiveness of herbal medicines have drawn a lot of attention.

Using specific medicinal plants – such as Glycyrrhiza glabra, Zingiber officinale, Mentha piperita, Ocimum sanctum, clove oil, and honey – known for their anti-inflammatory, anti-microbial, demulcent, and calming qualities, the current study attempts to create and assess herbal lozenges to guarantee uniformity, stability, and palatability.

Along with organoleptic quantities, the formulated lozenges were assessed for physicochemical parameters such as weight variation, hardness, friability, thickness, drug content uniformity, and dissolution time. The prepared formulations showed satisfactory quality attributes and complied with pharmacopeial standards, according to the results.

According to the study's findings, herbal lozenges can be used to treat sore throats and related conditions in a safe, efficient, and patient-friendly manner. They also provide longer – lasting therapeutic action and better patient compliance.

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INTRODUCTION:

Lozenges are solid oral dosage forms that deliver the active ingredients straight to the oral cavity and throat by **slowly** dissolving in the mouth. They are particularly helpful in treating minor oral infections, cough, hoarseness, and sore throats. Lozenges increase the medication's therapeutic efficacy by prolonging its contact time with the afflicted tissues. Lozenges are well-liked by both young and old patients because of their delicious flavor and simplicity of use. Herbal lozenges combine the advantages of lozenge dosage forms with the therapeutic benefits of medicinal plants. Numerous herbal remedies, including *Glycyrrhiza glabra* (liquorice), *Zingiber officinale* (ginger), *Mentha piperita* (peppermint), *Ocimum sanctum* (tulsi), clove oil, and honey, have been shown to have anti-inflammatory, antimicrobial, calming, expectorant, and demulcent effects, making them good choices for lozenge formulation.¹ To ensure palatability, stability, uniformity, and therapeutic efficacy, herbal ingredients, sweeteners, binders, and flavoring agents are carefully chosen during the formulation of herbal lozenges. It is equally important to evaluate the formulated lozenges in order to determine their performance, safety, and quality. To guarantee that the product satisfies pharmacopeial and quality standards, parameters like weight variation, hardness, friability, thickness, drug content uniformity, disintegration or dissolution time, and organoleptic properties are crucial. The current project focuses on creating and testing herbal lozenges with specific herbal ingredients to treat cough and throat irritation. The goal of the project is to create an herbal lozenge formulation that is affordable, efficient, and patient-friendly while also assessing its physicochemical characteristics to guarantee consistency and quality.²

Herbal remedies have been used for centuries to prevent and treat a wide range of illnesses, and they are an essential component of traditional healthcare systems. Due to their natural origin, safety, affordability, and improved patient acceptance, herbal formulations have seen a resurgence of interest in recent years on a global scale. The World Health Organization (WHO) reports that many people worldwide rely on herbal remedies for their basic medical needs.³

MATERIALS & METHODOLOGY:**Materials**

Sr no.	Ingredients	Role
1	Liquorice (<i>Glycyrrhiza glabra</i>)	Expectorant

2	Ginger extract (<i>Zingiber officinale</i>)	Anti-inflammatory, throat soothing
3	Tulsi extract (<i>Ocimum sanctum</i>)	Antimicrobial, antitussive
4	Sucrose	Main lozenge base
5	Liquid glucose	Prevents crystallization, improves texture
6	Gelatin	Binding agent, provides firmness
7	Honey	Natural sweetener, soothing effect
8	Peppermint oil	Flavor, cooling sensation
9	Water	Vehicle

Methodology**• Preparation of herbal extract process:**

1. The selected medicinal plant materials such as liquorice roots, ginger rhizomes, and tulsi leaves were collected, cleaned thoroughly to remove dirt and foreign matter, and shade dried at room temperature.³
2. The dried materials were coarsely powdered using a grinder.
3. The powdered drug was then subjected to aqueous extraction by maceration method.
4. Accurately weighed quantity of powdered drug was soaked in distilled water for 24–48 hours with occasional stirring.
5. After maceration, the extract was filtered through muslin cloth followed by whatman filter paper.⁴
6. The filtrate was concentrated on a water bath to obtain a thick extract, which was stored in an airtight container until further use.

• Preparation of herbal lozenges

1. The herbal lozenges were prepared by heating and congealing method. Initially, sucrose was dissolved in a measured quantity of purified water and heated gently to obtain a clear syrup.
2. Liquid glucose was then added to the syrup with continuous stirring to prevent crystallization.
3. Gelatin was soaked separately in warm water and added to the syrup mixture. The temperature was maintained at about 70–80°C.⁵
4. After achieving a uniform viscous mass, the herbal extracts were added slowly with constant stirring to ensure uniform distribution.
5. Honey and peppermint oil were added at the final stage. The molten mass was then poured into pre-lubricated lozenge moulds and allowed to cool at room temperature.
6. After solidification, the lozenges were removed from the moulds and stored in airtight containers.⁶

Formulation Table:

complete dissolution was recorded. This test indicates the rate at which the lozenge releases

Sr.No	Name of ingredients	F1	F2	F3	Function
1	Liquorice	2g	2g	1.5g	Expectorant
2	Ginger	1ml	1ml	1ml	Anti-inflammatory
3	Tulsi	1ml	1ml	1ml	Antimicrobial, antitussive
4	Sucrose	60g	50g	40g	Main lozenge base
5	Liquid glucose	15ml	15ml	10ml	Prevents crystallization
6	Gelatin	2g	2g	1g	Binding agent
7	Honey	5g	5g	3g	Natural sweetener
8	Peppermint oil	q.s	q.s	q.s	Flavor, cooling sensation
9	Purified water	q.s	q.s	q.s	Vehicle

the active ingredients.¹²

EVALUATION PARAMETER

- **Physical Appearance:**
The prepared herbal lozenges were examined visually for color, shape, surface texture, and presence of cracks or air bubbles. The lozenges were also evaluated for taste and mouthfeel.⁷
- **Weight Variation Test:**
Twenty lozenges were selected randomly and weighed individually using an analytical balance. The average weight was calculated and individual weights were compared with the average weight. The percentage deviation was calculated to ensure compliance with pharmacopoeia limits.⁸
- **Thickness Test:**
The thickness of ten lozenges was measured using a Vernier caliper. The mean thickness was calculated to ensure uniformity of the formulation.⁹
- **Hardness Test:**
The hardness of the lozenges was determined using a Monsanto hardness tester. The force required to break the lozenge was recorded and expressed in kg/cm². Adequate hardness ensures mechanical strength and slow dissolution.¹⁰
- **Friability Test:**
Friability was determined using a Roche friabilator. A pre-weighed sample of lozenges was rotated at 25 RPM for 4 minutes. After the test, lozenges were deducted and reweighed. The percentage weight loss was calculated. Friability should be less than 1%.¹¹
- **Dissolution Time:**
The dissolution time of lozenges was determined by placing one lozenge in simulated saliva solution at 37°C. The time taken for

- **pH Determination:**

The pH of the lozenge solution was determined by dissolving one lozenge in a specified volume of distilled water and measuring the pH using a digital pH meter. The pH should be near neutral to avoid throat irritation.¹³

RESULTS & DISCUSSION:

The physicochemical and organoleptic properties of the herbal lozenges made with specific medicinal plant extracts were satisfactory. Good patient acceptability was indicated by the formulations' consistent shape, smooth texture, and acceptable color, taste, and odor.

The prepared lozenges' weight variation was found to be within acceptable pharmacopeial limits, indicating dosage uniformity. While friability values were less than 1%, indicating sufficient resistance to abrasion, hardness values showed enough mechanical strength to endure handling without breaking. The consistent thickness measurements showed that the lozenges were uniformly compressed or molded.

The active herbal ingredients were uniformly distributed throughout the formulations, with values falling within acceptable bounds, according to drug content uniformity studies. Long-term contact with the oral mucosa for improved therapeutic effect was ensured by the in vitro dissolution studies, which demonstrated a gradual and consistent release of active ingredients over a period of 5–10 minutes.

According to organoleptic analysis, the bitter taste of herbal extracts was successfully covered up by the addition of flavorings and sweeteners, improving their palatability. According to stability studies, there were no appreciable changes in the formulations' performance or physical appearance under the specified storage conditions.

Overall, the optimized formulation met standard evaluation criteria and showed desirable quality attributes, suggesting that it is a suitable herbal lozenge for treating sore throats.

DISCUSSION:

Lozenges were selected for this project because they dissolve slowly in the mouth, releasing the medicament directly to the site of infection and providing a soothing effect (demulcent action). The oral route remains the most preferred method for drug administration; however, for local throat infections, a dosage form that offers prolonged contact time with the pharyngeal mucosa is superior. The goal of the current study was to create and assess herbal lozenges using specific medicinal plant extracts that have been shown to be effective in treating minor oral infections, coughs, and sore throats. Because herbal lozenges can prolong drug contact time in the oral cavity, provide localized action, and improve patient compliance particularly in pediatric and geriatric populations they were selected as an appropriate dosage form.

CONCLUSION & SUMMARY:

Conclusion

The present study successfully demonstrates the potential of poly herbal lozenges as an effective dosage form for the management of sore throat. The following conclusions can be drawn from the experimental work:

Feasibility: The heating and congealing method is a viable, cost-effective technique for preparing herbal lozenges with reproducible characteristics.

Quality Control: The formulated lozenges met all standard official requirements regarding hardness, friability, weight variation, and stability.

Patient Compliance: The formulation achieved acceptable taste masking and organoleptic properties, addressing the common challenge of palatability in herbal medicines.

Efficacy: The preliminary evaluation suggests that the formulation possesses significant antimicrobial potential suitable for treating minor oropharyngeal infections.

The present study successfully demonstrates the development and evaluation of poly-herbal lozenges as a therapeutic alternative for the management of sore throat and minor oropharyngeal infections. By integrating traditional herbal knowledge with modern pharmaceutical technology, this research provides a standardized approach to a traditionally empirical field.

The following comprehensive conclusions are drawn from the experimental work:

Key Findings Summary

Methodological Viability: The heating and congealing method proved to be an ideal manufacturing pathway. It is not only cost-effective and easy to scale, but it also ensures the uniform distribution of herbal extracts, yielding lozenges with consistent, reproducible physical characteristics.

Pharmaceutical Integrity: The formulation successfully passed rigorous quality control parameters. Specifically, the lozenges maintained optimal hardness to ensure slow dissolution in the oral cavity, low friability for durability during transport, and high weight uniformity, meeting all official pharmacopeial standards.

Organoleptic Success: One of the primary hurdles in herbal medicine bitter or astringent taste was effectively overcome. Through strategic sweetening and flavoring, the lozenges achieved high patient compliance scores, making them a viable option for both pediatric and geriatric populations.

Therapeutic Potential: Preliminary antimicrobial evaluations confirmed that the phytochemical constituents remain active post-formulation. The lozenges provide a sustained release of herbal actives directly to the site of infection, offering a localized treatment that minimizes systemic side effects.

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