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Formulation and Evaluation of Herbal Lozenges of Vasaka Leaf for the Treatment of Sore Throat

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

The present study focuses on the development and evaluation of herbal lozenges formulated using the leaf extract of *Justicia adhatoda* (Vasaka), a medicinal plant known for its expectorant, sore throat, anti-inflammatory, and antimicrobial properties. Vasaka leaves are excellent for relieving the symptoms of a sore throat because they are high in vasacin and vasinone. Vasaka leaves were collected from the Garhwal region of Uttarakhand, Dehradun, Herbal garden of Shivalik College and extracted using the soxhlet method. Lozenges were prepared via the molding technique incorporating various excipients, including gelatin, dextrose, sorbitol, and honey, across four formulations (F1–F4). The prepared lozenges were evaluated for organoleptic properties, thickness, hardness, and disintegration time. Among all formulations, F3 demonstrated the most desirable attributes, including optimal hardness and the fastest disintegration time (16 minutes),

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making it the most effective for potential therapeutic use. This study supports the incorporation of traditional herbal extracts into modern dosage forms to create effective, patient-friendly alternatives for managing sore throat symptoms.

Keywords: Vasaka; lozenges; throat; disintegration; mucolytic.

1. INTRODUCTION

The oral route is the most preferred method of administration among the available options due to a number of factors, including ease of ingestion, adaptability, and patient compliance in particular (Walsh et al., 2018). Many non-identical routes are there in which drugs can be administered and create its pharmacological effects. There are many ways to deliver drugs into the body like oral (through swallowing), sub mucosal (through sublingual mucosa), parenteral (through injection), transdermal (through the skin). The oral route of administration is considered as the accepted route because of its convenience. This approach has a major drawback for elderly and pediatric patients who have trouble swallowing. Approximately 35% of patients, especially elderly and pediatric patients, suffer from dysphagia, which increases treatment resistance and treatment inadequacies (Rathaur & Gnanarajan, 2018). Children frequently experience difficulties with swallowing due to their underdeveloped neurological and muscular systems. Patients with tremors in their extremities, individuals with intellectual disabilities, non-causable patients, patients with reduced fluid admission plans, and patients experiencing nausea are additional categories that may also have difficulty swallowing standard oral dosage forms. Inflammation of the sore throat characterized by symptoms including runny nose, cough, headache, difficulty swallowing, swollen lymph nodes, and raspy voice is known as sore throat or pharyngitis. Usually, a bacterial, fungal, or viral infection is to blame (Almond et al., 1994). The most common microorganism responsible for sore throats is streptococci. In addition, postnasal trickling caused by hypersensitivities and mouth breathing, smoking, air pollution, agitation, and irritation can all contribute to a sore throat (O'Handley et al., 2012). Formulators have made great efforts to develop a novel type of tablet dosage form for the oral route—one that degrades and breaks up quickly in salivation without requiring swallowing the dosage form whole—in order to combat problems like difficulty swallowing and ailments like sore throats. These are lozenges that dissolve in between 15s and 2 minutes. As medicine wears off, absorption and the start of clinical effect occur more quickly. The majority of lozenges are available without a prescription and function by progressively dissolving in the mouth as you suck them, lubricating the coating on your throat, and reducing throat dryness, irritation, and inflammation. *Justicia adhatoda* (family Acanthaceae), commonly known as vasaka or arusha. The vasaka plant is an evergreen perennial that has many branches, a bad taste, and an awful odor. It may survive for several seasons and keeps its leaves all year round (O'Handley et al., 2012). In the flowers triterpines (aamirine), flavonoids (apigenin, astragalin, quercetin, vitexin) (Jha et al., 2012). Even though the scientific advantage that have allowed us to understand the important contribution of the plant material along with their biological and therapeutic potentialities, the relevance of this knowledge goes beyond chemical features, as it is necessary to understand that due to the increased daily living standards of rural populations, regarding the sustainable use of plant resources have been even more underlined (Rathaur et al., 2023)

Fig. 1. *Justicia adhatoda* (Vasaka) plant

Lozenges: Lozenges are flavored medicinal dosage forms with a sweetened basis that are meant to be sucked and retained in the mouth or pharynx. They typically contain one more medications. Lozenges are designed to treat or pharyngeal symptoms, which are frequently brought on by local infections. If the medication is adequately absorbed Through the buccal linings or when it is eaten, they may also have a systemic effect (Choursiya & Andheriya, 2018).

Herbal lozenges: Herbal lozenges are solid medications used to treat mouth and throat conditions, releasing active therapeutic ingredients gradually as they dissolve in the tongue. They are particularly effective for treating coughs, sore throats, and mild respiratory issues when used locally. Herbal lozenges are small, disc-shaped tablets that dissolve in the mouth, releasing active herbal ingredients to relieve coughing, sore throats, and other respiratory conditions. These lozenges typically contain plant extracts,
Essential oils, and other medicinally beneficial substances, including typical herbs (White & Foster, 2013).

Composition of herbal lozenges: (Sharma et al., 2021)

Active herbal ingredients:

1. **Medicinal plant extracts:** These are the primary therapeutic agents in herbal lozenges. Commonly used herbs include:

   a) **Vasaka** *Justicia adhatoda* **(*Adhatoda vasica*):** This substance is known for its expectorant, anti- inflammatory. And making it beneficial for respiratory conditions.
   b) **Echinacea:** This substance is known for enhancing the immune system and aiding in the fight against infections.
   c) **Licorice (*Glycyrrhiza glabra*):** This substance offers soothing effects and aids in reducing inflammation.
   d) **Ginger (*Zingiber officinale*):** The substance has been found to possess anti- inflammatory and analgesic properties.
   e) **Honey:** This substance provides soothing and antimicrobial benefits and is frequently used as a sweetener.

Uses of lozenges: Lozenges provide gradual oral treatments, saturating throat tissues with drug solutions, and are suitable for patients unable to swallow solid doses. Common medications include corticosteroids, decongestants, and demulcents (De Villiers, 2021).

Advantages of lozenges: It is simple to provide to older and pediatric patients alike. It tastes good and will prolong the amount of time a medicine is in the mouth long enough to cause local action. Drug systemic absorption through the buccal cavity is conceivable. Sweeteners and flavors added to the formulation help cover up the taste of the medications (Satoskar & Bhandarkar, 2020).

Disadvantage of lozenges: Parents should avoid combining medications with candy and keep it out of children's reach. Heat-stable drugs are suitable, and lozenges should be used safely with children over six (Wilkerson et al., 2005).

Evaluation parameter:

a) **Organoleptic properties:** The organoleptic properties test evaluates the sensory qualities of tablets using human senses like sight, taste, smell, touch, and sound, assessing their general acceptance and quality, and highlighting their responsibilities (Goodwin et al., 2018).
b) **Thickness:** The tablet thickness test is a crucial quality control procedure in pharmaceutical tablet production, ensuring consistency and uniformity in size measurement (Patel et al., 2006).
c) **Hardness:** A hardness test evaluates a tablet's mechanical strength and resistance to breaking or crushing, crucial for pharmaceutical tablets to meet quality standards and ensure smooth handling and shipping (Sierra-Vega et al., 2019).
d) **Disintegration time:** The disintegration time test is a crucial pharmaceutical quality control test that measures the time it takes for a tablet to break down into smaller pieces when submerged in a specific liquid media, ensuring its effective dissolution and release upon swallowing (Hofmanová, n.d.).

Significance of lozenges: (Low et al., 2015)
Lozenges, also known as troches or pastilles, are solid dosage forms used to dissolve slowly in the mouth to release medication or active ingredients.

- **Local treatments:** Lozenges are commonly used to treat localized oral and throat issues like mouth ulcers, coughs, and sore throats by slowly dissolving active chemicals in the mouth, thereby relieving symptoms (Conway, 2008).
- **Controlled release:** Lozenges' gradual dissolution regulates medication release over time, maintaining therapeutic concentrations in the oral cavity, resulting

in long-lasting symptom relief (Mizrahi & Domb, 2008).

- **Ease of administration:** Lozenges are convenient and easy to use, suitable for home, work, and travel, and do not require water for administration, making them beneficial for individuals with dry mouth or swallowing issues (Blenkinsopp et al., 2022).
- **Taste-masking:** Lozenges are sweetened and flavored to mask bitter or disagreeable flavors, making them more enjoyable and appealing, particularly for young people or those with delicate palates (Faisal et al., 2018).
- **Non-invasive:** Lozenges are well-tolerated, non-invasive dosing forms suitable for various ages, including toddlers and the elderly, unlike suppositories or injections (Linakis et al., 2016)

Types of lozenges:

1. **Hard candy lozenges:** Hard candy lozenges are medicated candy that combine the qualities of hard candy and lozenges, often used to relieve symptoms like coughing, sore throat, and respiratory infections, as well as related pain (Macknin et al., 1998).

Example: Clotrimazole troches

2. **Chewy or caramel base lozenges:** Chewy or caramel-flavored lozenges are pharmaceutical candy designed to alleviate symptoms of respiratory infections and other diseases, being chewier and softer (Cohen & Hartel, 2023).

Example: Strepsils.

3. **Soft lozenges:** Soft lozenges are a type of pharmaceutical candy that alleviate symptoms of respiratory infections and other ailments, resembling gummy candies or fruit snacks, due to their soft, dissolvable texture, distinguishing them from hard or chewy lozenges (Marianski & Marianski, 2011).

Example: Honey anti-bacterial lozenges

2. METHODOLOGY

Plant material: Vasaka plant (*Justicia adhatoda* l) family – *acanthaceae*. The study were collected from the Garhwal region Uttarakhand, Dehradun and were authenticated by botanical survey of India northern regional center 192-kaulagarh road Dehradun Uttarakhand with transaction ref.no. - 1504240067038. The freshly collected leaves of vasaka (leaves) (Dukre et al., 2023).

Chemical constituents of *Justicia adhatoda* (Vasaka): Vasaka leaves contain quinazoline derivatives such as vasicine,vasicinone and 6hydroxyl vasicine the drug also contains volatile oil, betain and vasakin, adatodic acid (Gandhi et al., 2015).

Leaves:

- Quinazoline alkaloids
- vasicine - 45-95% (the mucolytic drug bromhexine was developed from this alkaloid)
- n-oxides of vasicinevasicinone
- Deoxyvasicine
- Oxyvasicinine
- Maiontone
- Essential oil the leaf extract, is considered safe and the oil has low toxicity (Ashwini, n.d.)

Procedure of extraction: The leaves are shade dried for 7 day at room temperature and were made into fine powder. After making. Powder, the powdered sample was weighed and it was found to be 53.40g. Water used as a solvent by the decoction method (drug weight: 26g and water: 250 ml). After that it was filtered and the extract was collected in a china dish, then it was heated till the mass was cooled and forma powder mass

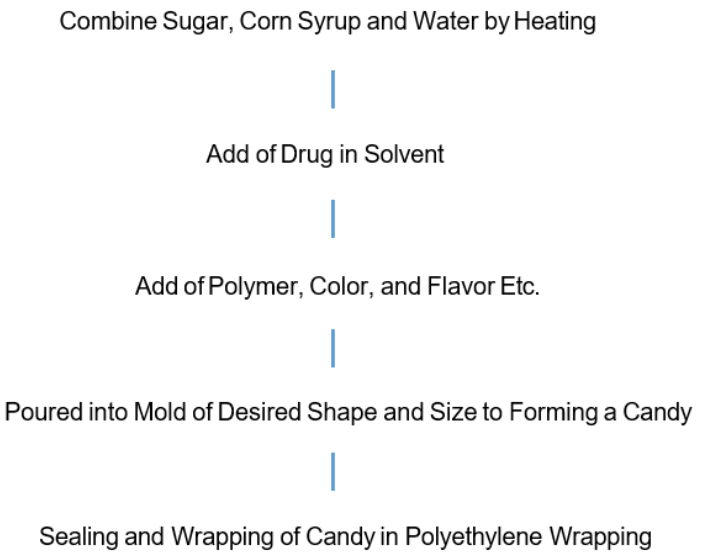
Fig. 2. Extraction of Vasaka

Procedure of lozenges: Lozenges were prepared by molding techniques. Required quantity of sugar syrup was prepared mixing sugar and water. Dextrose was dissolved in small quantity of water and heated it to 110°C till dextrose dissolves completely forming as clear viscous syrup. Then the dextrose solution was poured into the sugar syrup and heated to 160°C c till the color changes to golden yellow. The temperature was bought down to 90°C and drug, polymer and other ingredients were added. The solution was poured into the mould having 2.8cm diameter and 6.5mm thickness. The prepared tablets were stored wrapped in aluminum foil and stored in desiccators to prevent moisture uptake. The final weight of each lozenge is 5gms (Özakar et al., 2020).

Table 1. Formulations table

Ingredients	F1	F2	F3	F4
Drug	0.25mg	0.25mg	0.25mg	0.25mg
Dextrose	1.5mg	1.5mg	1.5mg	1.5mg
Distilled Water	15ml	15ml	15ml	15ml
Sorbitol	2ml	2ml	2ml	2ml
Calcium Carbonate	90mg	90mg	90mg	90mg
Steric Acid	0.3mg	0.3mg	0.3mg	0.3mg
Acacia	0.6mg	0.6mg	-----	-----
Peppermint	0.1ml	0.1ml	0.1ml	0.1ml
Gelatin	----	----	0.6mg	0.6mg
Honey	0.5ml	0.5ml	0.5ml	0.5ml

Method for preparation (Pundir & Verma, 2014):



Evaluation parameter:

1. **Organoleptic properties (Pothu & Yamsani, 2014):** The prepared lozenges were evaluated for its organoleptic properties like taste, odor, color, softness, and shape. Organoleptic properties refer to the sensory characteristics of a substance that can be perceived by the human senses, particularly taste, smell, texture, and appearance. These properties are often used to evaluate the quality of food, beverages, and other substances. For example, the flavor, aroma, color, and texture of a food item are all organoleptic properties that can influence its overall appeal and consumer satisfaction.
2. **Thickness:** Thickness of the lozenges were measured using vernier calipers. The thickness of a lozenge tablet refers to the distance between its two opposite surfaces, usually measured in millimeters (Pothu et al., 2015). It is an important parameter in pharmaceutical manufacturing because it can affect factors

such as disintegration rate, ease of swallowing, and overall stability of the tablet (Khudhair & Ali, 2020). The thickness of lozenge tablets is determined during the manufacturing process and is controlled to meet specific requirements set by regulatory agencies or product specifications. The test was performed for three lozenges and standard deviation was calculated (Budiman et al., 2020).

3. **Hardness:** Using a Pfizer pill hardness tester, the result was ascertained. Three lozenges were tested, and the standard deviation was determined (Singh et al., 2018).
4. **Disintegration time:** Lozenges were taken and put into a disintegrator. The disintegration time was determined in pH6.8 artificial saliva fluid at 37ºc and 100 rpm Özakar et al., (2020). Disintegration time was found to be in the range of 16 min and 59 min. The disintegration time of lozenge tablets refers to the period it takes for the tablet to break down into smaller particles or to dissolve completely when placed in a suitable medium, typically water or saliva. This parameter is crucial in pharmaceutical manufacturing as it directly impacts the efficacy and Bioavailability of the active ingredients in the tablet. Faster disintegration times generally mean quicker release of the active ingredients, which can be advantageous for medications designed for rapid onset of action, such as Pain relievers or cough suppressants. Regulatory authorities often specify disintegration time requirements for tablets to ensure their quality and effectiveness. In the united states pharmacopeia (USP 35), the disintegration time of nystatin lozenges is 90 minutes (Nithya, n.d.).

3. RESULTS AND DISCUSSION

Lozenges in 4 different doses and were successfully prepared with the blank ones by using molding and F3 is best. All the formulations showed good physical appearance. The gelatin used in the molding method as binder enabled the lozenges containing low-dose bentonite to keep their shape due to its gelling feature.

Organoleptic properties: The prepared lozenges' taste, odor, color, softness, and shape are all designed to fulfill specific purposes. The patient finds the organoleptic qualities to be at an acceptable level. Organoleptic properties is the results are given in Table 2.

Fig. 3. Lozenges

Table 2. Organoleptic properties of lozenges

Organoleptic Properties	F1	F2	F3	F4
Taste	Sweet	Sweet	Sweet	Sweet
Odor	Mint	Mint	Mint	Mint
Color	Brown	Brown	Brown	Brown
Softness	Soft	Soft	Soft	Soft
Shape	Square	Square	Square	Square

Table 3. Evaluation parameter of lozenges

Parameter	F1	F2	F3	F4
Thickness(mm)	4.1	4.1	3.6	3.6
Hardness (Kg/Cm2)	5	4.5	2.5	3
Disintegration Time (min)	59	59	16	16

Thickness, hardness, and disintegration time: The hardness, thickness and disintegration time of lozenges were evaluated and the results are given in Table 3.

4. CONCLUSION

In conclusion, the herbal lozenges using vasaka leaf extraction for sore throat has shown promising results. The vasaka leaf, known for its cough, bronchitis, asthma, anti- inflammatory and antimicrobial properties and has been successfully incorporated into lozenges to provide an effective and natural remedy for sore throats. The study successfully assessed various parameters such as Organoleptic propertied, thickness, hardness and disintegration time with formulation F3 demonstrating the best overall performance. The research highlights the importance of developing alternative dosage forms such as lozenges, particularly for patients who have difficulty swallowing standard oral medications, such as elderly and pediatric patients. The use of herbal extract of vasaka leaf is safe and natural substitute for sore throat relief with potential therapeutic benefits. Overall, this study showcases the potential of herbal lozenges as an effective treatment option for sore throats, with further scope for exploring additional herbal ingredients and formulations. The incorporation of natural remedies into convenient and patient-friendly dosage forms like lozenges offers a promising direction for addressing common health concerns. These findings underscore the significance of herbal remedies in modern pharmaceutical formulations, paving the way for continued research and development in this area

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of this manuscript.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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