Formulation and Evaluation of Polyherbal Lozenges

Madhurani Gulab Khedekar[1], Madhavi Bindu[2], Sayali Deshmukh[3]
[1]Student, J.S.P.M's Rajarshi Shahu College of Pharmacy & Research, Tathwade, Pune
[2]Professor, J.S.P.M's Rajarshi Shahu College of Pharmacy & Research, Tathwade, Pune
[3]Student, J.S.P.M's Rajarshi Shahu College of Pharmacy & Research, Tathwade, Pune

Corresponding Author:-
Madhurani Gulab Khedekar
Email ID : madhurani777khedekar@gamil.com

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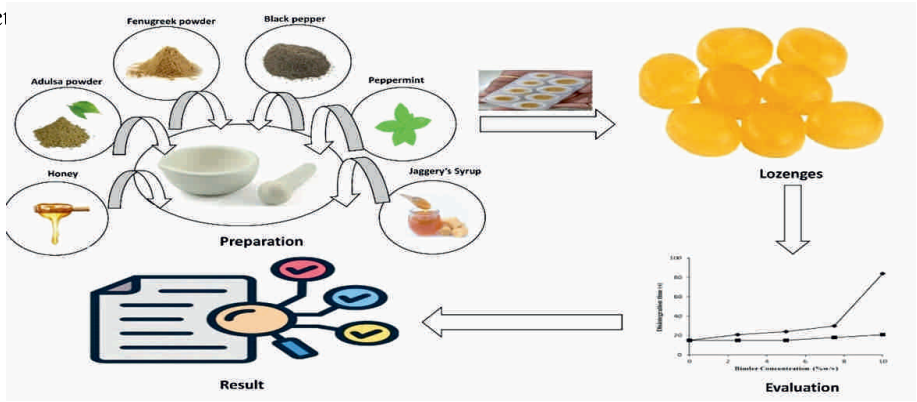
Abstract

The present study aimed to formulate and evaluate polyherbal lozenges for the management of cough and throat irritation using natural ingredients. Jaggery was selected as the primary base due to its soothing properties and natural sweetness, making the formulation potentially suitable even for diabetic patients. Lozenges were prepared by the fusion method incorporating a synergistic blend of herbal powders of peppermint (*Mentha piperita*), fenugreek (*Trigonella foenum-graecum*), adulsa (*Adhatoda vasica*), and black pepper (*Piper nigrum*)—all of which are well documented for their therapeutic benefits in respiratory disorders. Excipients such as honey, lemon juice, acacia, and carboxymethyl cellulose (CMC) were employed to enhance palatability and improve the physical properties of the lozenges. The prepared formulations were evaluated for weight variation, hardness, friability, disintegration, dissolution, stability, and organoleptic acceptability. The results indicated that the lozenges were physically stable, within acceptable limits for all quality control parameters, and exhibited favourable sensory attributes. In conclusion, the formulated polyherbal lozenges demonstrate potential as a safe, effective, and natural alternative for alleviating cough and throat discomfort, warranting further clinical investigation.

Keywords: Polyherbal lozenges, Herbal formulation, Jaggery base, Fusion method, Cough relief, Respiratory health.

Graphical abstract



Introduction:

Lozenges are solid, flavoured, medicated dosage forms intended to be dissolved slowly in the oral cavity for localized or systemic therapeutic effects[(1)]. Lozenges, commonly referred to as *troches* or *pastilles*, are solid dosage forms designed for slow dissolution in the oral cavity. They are particularly beneficial in the treatment of conditions affecting the mouth and throat, such as sore throat, cough, and oral infections. Lozenges are typically placed in the buccal cavity (between the cheek and gums), where they gradually dissolve, providing sustained drug release for approximately 30 minutes. Traditionally, lozenges have been formulated to relieve minor throat pain and discomfort, incorporating agents such as topical anaesthetics, antibacterial compounds, or soothing substances. Most commercial lozenges consist of a hard candy base, usually prepared from a mixture of sugar and syrup, and often include binding agents such as acacia to improve texture, stability, and therapeutic effectiveness[(2)].

Respiratory ailments such as cough, sore throat, and throat infections are prevalent indicators of several underlying conditions, creating a steady demand for effective therapeutic solutions. In recent years, the shift toward natural and herbal remedies has gained momentum, driven by consumer concerns regarding the adverse effects of synthetic drugs and an increasing focus on holistic wellness[(3,4)]. The global market for natural remedies for cold, cough, and sore throat was valued at USD 5.2 billion in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 6.1%, reaching USD 8.9 billion by 2032, positioning polyherbal lozenges as a significant growth driver in this segment[(5)].

Polyherbal lozenges have emerged as an effective and convenient dosage form for throat infections, offering the

combined therapeutic benefits of multiple natural ingredients. In the present study, lozenges were formulated using Adulsa (*Adhatoda vasica*), Fenugreek (*Trigonella foenum-graecum*), Jaggery syrup, Peppermint (*Mentha piperita*), Black pepper (*Piper nigrum*), and Honey. Each ingredient contributes distinct pharmacological effects: Adulsa acts as an antimicrobial and anti-inflammatory agent, easing breathing and reducing mucus; Fenugreek provides mucilaginous protection to soothe irritation; Jaggery syrup serves as a demulcent and mild expectorant, while also enhancing palatability; Peppermint delivers menthol, which produces cooling, analgesic, and mild antiseptic effects; Black pepper improves bioavailability and adds antimicrobial action; and Honey provides natural antimicrobial, healing, and throat-soothing properties.

The synergistic action of these components is expected to reduce inflammation, fight microbial infection, and alleviate throat irritation, while also enhancing patient compliance due to their natural origin and palatable taste. Additionally, as a natural and palatable option, the lozenges improve patient compliance and reduce dependency on synthetic medications, promoting safer action . Thus, the primary aim of the present research was to formulate and evaluate polyherbal lozenges incorporating these medicinal plant extracts for their potential antimicrobial and throat-soothing effects.

Materials

Acacia, honey, jaggery, lemon juice, carboxymethyl cellulose (CMC), peppermint (*Mentha piperita*), and black pepper (*Piper nigrum*) were procured from Manakarnika Aushadhalay and Smart Chemist, Pune. Fenugreek (*Trigonella foenum-graecum*) seeds and adulsa (*Adhatoda vasica*) leaves were obtained from institute. The fenugreek pods and adulsa leaves were carefully dried under controlled conditions, powdered separately using a grinder, and passed through a 120-mesh sieve to obtain a fine, uniform powder suitable for formulation.(Table 1)

Table 1. Formulation table of lozenges

Sr. No	Ingredients	Quantity
1	Fenugreek powder	0.1gm (100mg)
2	Adulsa Powder	0.1gm (100mg)
3	Jaggery	8 gm (8000mg)
4	Lemon	0.05 gm (50mg)
5	Accacia	1 gm (1000mg)
6	Peppermint	0.1 gm (100mg)
7	Carboxymethyl cellulose	0.15 gm (150mg)
8	Honey	0.5 gm (500mg)
9	Black Papper	0.0550 (mg)

Methodology

Manufacturing procedure

1) All powdered ingredients like fenugreek powder, adulsa powder, black pepper, and peppermint were collected.
2) The powdered ingredients were passed through a sieve to obtain fine and uniform particles.
3) Each component was accurately weighed according to the formulation table.
4) Jaggery was liquefied by melting over a medium flame.
5) The measured powders were gradually added to the molten jaggery with continuous stirring.
6) The required quantity of honey, flavouring agent, and colouring agent was incorporated while maintaining constant stirring, and moulds were kept ready.
7) The homogeneous mixture obtained was poured into moulds to form lozenges.
8) The lozenges were allowed to solidify at room temperature and subsequently refrigerated for 1–2 days for proper setting.
9) After solidification, the lozenges were demoulded, wrapped in aluminium foil, and stored in plastic bags.[7]
10) Finally, the lozenges were dried appropriately and packaged for further use.(Figure 1)

Figure 1. Formulated Polyherbal Lozenges

Evaluation of prepared lozenges

1) Organoleptic properties: The organoleptic properties of the prepared lozenges were evaluated to assess their sensory characteristics, including colour, shape, surface texture, taste, and odor. These evaluations were conducted using human senses (sight, taste, smell, and touch) to determine general acceptability, patient compliance, and overall quality of the formulation. Observations were recorded systematically, and any deviations from the desired characteristics were noted to ensure the lozenges met standard organoleptic criteria[8].

2) Diameter and thickness: The thickness of the prepared lozenges was measured as a critical quality control parameter to ensure consistency and uniformity in size. A vernier caliper or micrometer was used to measure the thickness of randomly selected lozenges, and the average value was calculated[9] .

3) Uniformity of weight: Weight variation of the prepared lozenges was assessed to ensure uniformity of dosage. Twenty lozenges were randomly selected from the batch and weighed individually using a digital balance. The average weight and standard deviation of the 20 lozenges were calculated. According to official pharmacopeial guidelines, the batch passes the weight variation test if not more than two individual lozenges deviate beyond the acceptable range of 90–110% of the average weight. Calculation was done by using the following formula[10].

$$\text{Average Weight} = \frac{\text{Weight of Lozenges}}{20}$$

$$\text{Weight Variation} = \frac{\text{Individual weight - Average Weight}}{\text{Average Weight}} 100$$

4) Measurement of pH: The pH of the prepared lozenges was determined to assess their acidity or alkalinity. A 1% w/v solution was prepared by dissolving 1 g of the lozenge in 100 mL of distilled water. The pH of the resulting solution was measured using a calibrated laboratory pH meter, which operates on a scale of 1 to 14[11].

5) Friability test: Friability testing was conducted to assess the mechanical durability of the prepared lozenges during handling, packaging, and transportation. A pre-weighed sample of lozenges was placed in a friabilator, which rotates the tablets with a baffle for a fixed duration, simulating stress conditions. After the test, the lozenges were removed, and any broken or chipped pieces were noted[12]. The percentage weight loss was calculated using the formula:

$$\text{Friability (\%)} = \frac{\text{Initial Weight - Final Weight}}{\text{Initial Weight}} 100$$

6) Hardness: The mechanical strength of the prepared lozenges was assessed using a Monsanto hardness tester. A representative sample of lozenges was tested, and the force required to break each lozenge was recorded. The average hardness was calculated and expressed in kg/cm^2[13].

7) Disintegration test: Disintegration time refers to the time required for a lozenge to completely break down into smaller particles in a specified medium. The disintegration test was performed using a standard disintegration test apparatus. The lozenges were tested in phosphate buffer (pH 6.8) maintained at 37 °C, and the time taken for complete disintegration was recorded [14].

8) Dissolution test: Dissolution time is a critical parameter for herbal lozenges, as it influences the release of active constituents and the overall therapeutic efficacy of the product. Factors such as lozenge size and shape, type and quantity of excipients, and storage conditions can affect dissolution. In this study, the dissolution time was determined by placing a lozenge in a beaker containing water maintained at a specified temperature and observing the time required for the lozenge to completely dissolve. The results provide insight into the formulation's performance and its ability to deliver active ingredients efficiently. The acceptable dissolution time is product-specific and ensures timely onset of therapeutic action[15].

Result and Discussion

The formulated polyherbal lozenges were successfully evaluated for their physical characteristics and in vitro performance parameters.

Organoleptic characteristics: The polyherbal lozenges were evaluated for their physical and organoleptic characteristics. The lozenges exhibited a brownish-yellow colour, oval shape, and smooth, glassy surface (Figure 1). They possessed a mildly aromatic odour and a pleasant sweet taste, indicating good palatability and patient acceptability[16].

Diameter and Thickness: The average diameter and thickness of the lozenges were found to be 1.4 cm and 0.905 cm, respectively, indicating uniformity in size and shape [17].

Uniformity of weight: The average weight of the lozenges was found to be 1.31 g, indicating good uniformity within the acceptable limits [18].

Measurement of pH: The pH of the formulation was found to be 6.0, which is close to neutral and thereby minimizes the risk of oral mucosal irritation [19].

Friability test: The friability of the prepared lozenges was found to be 0.55%, which is well within the acceptable limit of not more than 1%, indicating good mechanical resistance. [20].

Hardness: The hardness of the lozenges was found to be 4 kg/cm^2. This value reflects satisfactory mechanical strength, ensuring the dosage form can endure routine handling, packaging, and transport without risk of fracture.[21].

Disintegration Test: The lozenges exhibited a rapid disintegration time of 1.2 minutes, ensuring quick onset of action and patient compliance [22].

Dissolution Test: The lozenges demonstrated a dissolution time of eight minutes, which is critical for the rapid release and absorption of the active herbal constituents, thereby ensuring effective therapeutic performance [23].

Conclusion

The present study successfully developed and evaluated polyherbal lozenges incorporating fenugreek, adulsa, jaggery, and honey for the management of throat infections. The formulation demonstrated desirable physical properties, including uniform weight, appropriate hardness, low friability, and satisfactory disintegration and dissolution

times. Preliminary phytochemical analysis confirmed the presence of bioactive compounds such as flavonoids, tannins, and saponins, which are likely contributors to the therapeutic potential of the formulation.While the findings suggest that the lozenges are safe, palatable, and promising as a natural remedy for cough and throat irritation, the study was limited by the lack of quantitative antimicrobial evaluation and detailed stability profiling. Future work should therefore focus on comprehensive phytochemical quantification, antimicrobial efficacy testing, and long-term stability studies to strengthen the scientific validity and clinical relevance of this formulation.

Source of Support: Nil

Conflict of Interest: Nil

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