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RESEARCH ARTICLE

Development and Physicochemical Evaluation of Jaggery-Based Polyherbal Lozenges

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Abstract: Oropharyngeal infections and pharyngitis are widespread clinical challenges which are frequently treated with synthetic medicated lozenges, which may present issues regarding chemical additives and adverse reactions. Natural alternatives employing traditional therapeutic agents offer a sustainable and biocompatible approach. This research work focuses on the formulation and characterization of jaggery-based lozenges containing a synergistic blend of Haritaki (*Terminalia chebula*), Cinnamon (*Cinnamomum zeylanicum*), Vacha (*Acorus calamus*), Turmeric (*Curcuma longa*), Black Pepper (*Piper nigrum*), and Clove (*Syzygium aromaticum*). Utilizing a precise molding technique, four distinct formulations (F1–F4) were developed within a demulcent matrix of jaggery and sucrose. Physicochemical evaluation shows that the formulations maintain optimal mechanical strength, with hardness values ranging from 8.20 ± 0.26 to 9.63 ± 0.25 kg/cm² and friability significantly below the 1% threshold. The disintegration time in a simulated oral environment (pH 6.8) is established between 16 and 17 minutes, facilitating a sustained release of phytochemicals. Antimicrobial analysis via the cup-plate method shows that the polyherbal variant (F4) produces a maximum zone of inhibition (22 ± 0.5 mm), indicating robust efficacy against oropharyngeal pathogens. Stability data over a 30-day period confirm the maintenance of structural integrity and chemical consistency. These results show that the polyherbal jaggery lozenge as a viable, patient-friendly delivery system for the localized treatment of throat-related ailments.

Keywords: Herbal lozenges; Jaggery; Demulcent; Antimicrobial inhibition; Polyherbal delivery; Pharyngitis therapy.

1. Introduction

Oropharyngeal inflammation, commonly occuring as pharyngitis, is a health concern characterized by painful deglutition, mucosal irritation, and localized infection [1]. The anatomical positioning of the throat makes it susceptible to various viral and bacterial pathogens, necessitating therapeutic interventions that provide prolonged contact with the laryngopharyngeal mucosa [2]. Lozenges are utilized as an ideal oral dosage form for this purpose, as they facilitate a slow dissolution rate, ensuring the active constituents remain in the oral cavity for extended durations to exert their local anesthetic, antiseptic, and anti-inflammatory effects [3].

The transition from synthetic chemical agents to plant-based therapeutics is driven by the need to mitigate antimicrobial resistance and avoid the side effects associated with artificial preservatives [4]. Herbal constituents such as Haritaki are valued for their astringent properties and high tannin content, which aid in tissue contraction and infection control [5]. Cinnamon and Clove contribute potent antiseptic and analgesic actions, primarily through volatile oils like cinnamaldehyde and eugenol [6]. Vacha acts as a traditional expectorant, assisting in the clearance of mucus, while Turmeric provides a broad-spectrum anti-inflammatory response through curcuminoids [7]. Black pepper, rich in piperine, serves as a bio-enhancer, potentially increasing the bioavailability and efficacy of the co-administered phytochemicals [8].

The selection of a base material is critical in lozenge formulation. Jaggery, a non-centrifugal sugar derived from *Saccharum officinarum*, offers a superior alternative to refined sucrose due to its inherent demulcent properties, which provide a protective coating over irritated mucosal layers [9]. While individual herbs have been studied for respiratory health, the combination of these six specific botanicals into a cohesive jaggery-based matrix represents an advancement in natural drug delivery systems [10]. This research indicates the parameters for formulating and evaluating these polyherbal lozenges to provide a scientifically validated natural alternative for oropharyngeal care.

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2. Materials and Methods

2.1. Collection and Authentication of Plant Materials

The primary herbal components, including the fruits of *Terminalia chebula*, barks of *Cinnamomum zeylanicum*, rhizomes of *Acorus calamus*, rhizomes of *Curcuma longa*, peppercorns of *Piper nigrum*, and flower buds of *Syzygium aromaticum*, were procured from authenticated botanical sources. The base materials, consisting of high-purity jaggery and pharmaceutical-grade sucrose, were selected for their consistency and binding properties. Peppermint oil (*Mentha piperita*) was utilized as a flavoring and cooling agent. All ingredients were verified for their organoleptic and purity standards prior to use, following established pharmacognostic protocols [11].

2.2. Processing and Pulverization

Each herbal ingredient was subjected to systematic processing to ensure uniformity and the preservation of bioactive constituents [10].

2.2.1. Haritaki and Cinnamon Processing

The Haritaki fruits were decorticated to remove the hard inner seed, as the medicinal value is concentrated in the pericarp. The separated pericarp was dried and pulverized using a mechanical grinder in short bursts to prevent thermal degradation of tannins. Similarly, the dried inner bark of Cinnamon was manually sorted to remove debris and ground into a fine powder. Both powders were screened through pharmaceutical Sieve No. 80 to ensure a particle size distribution suitable for a smooth mouthfeel in the final dosage form [2, 5].

2.2.2. Vacha, Clove, and Black Pepper Processing

The aromatic rhizomes of Vacha and the volatile oil-rich buds of Clove were processed using controlled pulses in a pulverizer to avoid the evaporation of essential oils such as eugenol [8]. Black pepper was ground to break the tough outer pericarp, releasing the alkaloid piperine. These pulverized materials were immediately transferred to amber-colored, airtight glass containers to protect them from photo-oxidation and atmospheric humidity until the formulation stage [7].

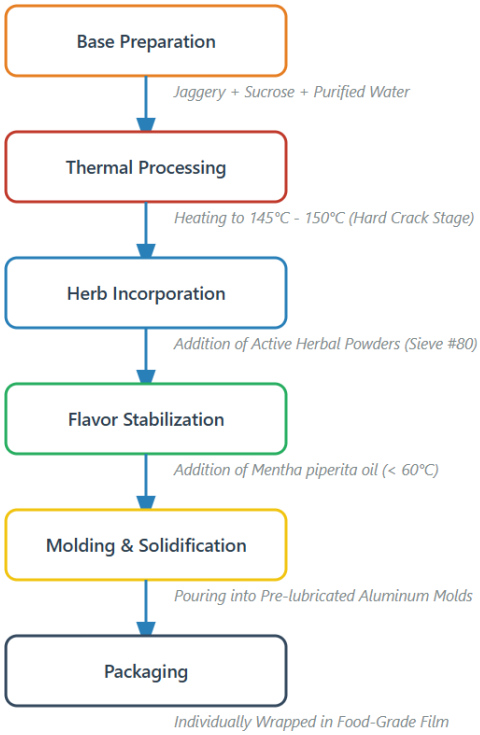

Figure 1. Stepwise Manufacturing Process of Herbal Lozenges

2.3. Formulation Design and Composition

Four distinct formulations were developed to evaluate the individual and synergistic effects of the botanical agents. The qualitative and quantitative composition of the herbal lozenges is summarized in Table 1.

Table 1. Quantitative Composition of Jaggery-Based Herbal Lozenges (Per Unit)

Ingredient	F1 (g)	F2 (g)	F3 (g)	F4 (g)	Functional Role
Haritaki Powder	0.50	-	-	0.25	Active (Astringent)
Cinnamon Powder	-	0.50	-	0.25	Active (Antiseptic)
Vacha Powder	-	-	0.50	0.25	Active (Expectorant)
Clove Powder	0.15	0.15	0.15	0.15	Local Anesthetic
Black Pepper Powder	0.10	0.10	0.10	0.10	Bio-enhancer
Turmeric Powder	0.05	0.05	0.05	0.05	Anti-inflammatory
Jaggery Base	1.00	1.00	1.00	1.00	Demulcent Matrix
Refined Sucrose	0.40	0.40	0.40	0.40	Hardening Agent
Peppermint Oil	Q.S.	Q.S.	Q.S.	Q.S.	Flavor/Coolant
Purified Water	Q.S.	Q.S.	Q.S.	Q.S.	Solvent

2.4. Preparation of the Lozenge Matrix

The demulcent base was prepared using a hard-boiled candy technique as described in previous literature [10, 12]. Refined sugar and grated jaggery were dissolved in purified water to create a concentrated syrup. This mixture was heated to a temperature range of 145°C to 150°C under continuous mechanical stirring to reach the desired "hard-crack" stage. Once the temperature stabilized, the heat was reduced, and the specific herbal powders were incorporated to ensure uniform dispersion. Peppermint oil was added at the final stage (below 60°C) to minimize the loss of volatile menthol constituents. The viscous mass was poured into pre-lubricated aluminum molds and allowed to solidify at room temperature.

2.5. Physicochemical Evaluation Protocols

2.5.1. Dimensional and Weight Uniformity

The dimensional consistency (length, width, and thickness) of ten randomly selected lozenges from each batch was determined using digital Vernier calipers. Weight variation was assessed by weighing twenty individual units using an analytical balance, and the mean weight ± SD was calculated to ensure compliance with Indian Pharmacopoeia (IP) standards [2, 11].

2.5.2. Hardness and Friability

The mechanical strength was quantified using a Pfizer-type hardness tester. Three units from each batch were tested, and the force required to induce fracture was recorded in kg/cm². Friability was determined by subjecting ten pre-weighed lozenges to 100 rotations at 25 rpm in a Roche friabilator. The percentage weight loss was calculated, with a limit of less than 1% established as the acceptable threshold for mechanical durability [3, 4].

2.5.3. In-vitro Disintegration and pH Analysis

Disintegration testing was conducted using an IP-standard apparatus. One unit was placed in each tube of the basket assembly, using 900 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C to simulate oral conditions [3, 12]. For pH evaluation, a 1% w/v solution of the crushed lozenge was prepared in distilled water, and the surface pH was measured using a calibrated digital pH meter to ensure non-irritancy to the oral mucosa [12].

2.5.4. Determination of Moisture Content

To prevent microbial proliferation and maintain structural integrity, the moisture content was determined using the gravimetric method. Samples were weighed (W1) and dried in a hot air oven at 60°C until a constant weight (W2) was achieved. The percentage moisture loss was calculated to verify stability [12].

2.6. Antimicrobial Activity

The antimicrobial efficacy of the formulations was evaluated against a broad microbial challenge using the agar well diffusion technique [1, 5]. Sterile nutrient agar plates were inoculated with a microbial suspension. Wells of 8 mm diameter were created using a sterile cork borer, and 100 µL of the dissolved lozenge solution was introduced. Following incubation at 37°C for 24 hours, the zones of inhibition were measured in millimeters.

2.7. Mucosal Irritancy Test

To ensure safety without human exposure, an acute oral mucosal irritation study was designed using a rabbit model, adhering to OECD guidelines [13]. The polyherbal extract was applied to the oral mucosa of New Zealand White rabbits for a specified duration. The site was monitored for signs of erythema or edema, and the irritation index was calculated to confirm biocompatibility.

2.8. Stability Test

Long-term stability was monitored over a 30-day period under controlled environmental conditions (25°C ± 2°C / 60% ± 5% RH). Samples were periodically withdrawn and evaluated for changes in organoleptic characteristics, hardness, pH, and moisture content to establish a preliminary shelf life [12, 14].

3. Results

3.1. Organoleptic Characterization

The formulated herbal lozenges (F1–F4) exhibited physical characteristics consistent with high-quality oral dosage forms. The coloration varied from yellowish-brown to dark brown, primarily influenced by the concentrations of Haritaki and jaggery. All units maintained a uniform oval shape with a smooth mouthfeel, devoid of grittiness. The taste profiles ranged from sweet and astringent (F1) to pungent and spicy (F4), with the latter providing a notable cooling sensation due to the peppermint oil and clove content.

Table 2. Organoleptic Properties of Herbal Lozenge Formulations

Parameter	F1	F2	F3	F4
Color	Yellowish-Brown	Dark Brown	Yellowish-Brown	Dark Brown
Texture	Smooth	Smooth	Smooth	Smooth
Odor	Characteristic	Aromatic	Pungent	Strongly Aromatic
Taste	Sweet-Astringent	Sweet-Spicy	Sweet-Bitter	Sweet-Pungent

3.2. Physicochemical Metrics and Weight Uniformity

Dimensional analysis confirmed the precision of the molding technique, with all batches exhibiting a mean length of 15.0 ± 0.15 mm and width of 10.0 ± 0.12 mm. The weight variation results indicated that all formulations were within the permissible limits defined by the Indian Pharmacopoeia.

Table 3. Physical Parameters and Weight Variation (Mean ± SD, n=10)

Formulation	Mean Weight (g)	Thickness (mm)	Weight Deviation (%)	Result
F1	2.23 ± 0.04	13.0 ± 0.17	< 2.0	Passed
F2	2.20 ± 0.02	13.0 ± 0.11	< 1.5	Passed
F3	2.25 ± 0.05	13.0 ± 0.08	< 2.5	Passed
F4	2.44 ± 0.03	13.0 ± 0.19	< 1.2	Passed

3.3. Hardness and Friability

Mechanical testing demonstrated that the polyherbal matrix (F4) possessed the highest structural durability. Hardness values for all formulations were found to be above 8.0 kg/cm², ensuring resistance to breakage during transport. Friability remained significantly below the 1% threshold for all batches, confirming the effectiveness of the sugar-jaggery binding matrix.

Table 4. Mechanical Strength and Friability Data

Formulation	Hardness (kg/cm²)	Friability (%)
F1	8.60 ± 0.36	0.49
F2	8.20 ± 0.26	0.41
F3	8.67 ± 0.21	0.45
F4	9.63 ± 0.25	0.49

(Mean ± SD, n= 3 values)

3.4. Disintegration Dynamics and Surface pH

The disintegration time in simulated salivary fluid (pH 6.8) ranged from 16:35 ± 0.05 to 16:55 ± 0.08 minutes. This slow erosion rate is conducive to localized therapy. The pH of a 1% w/v solution was found to be near-neutral (6.60–6.70), suggesting high biocompatibility with the oral mucosa.

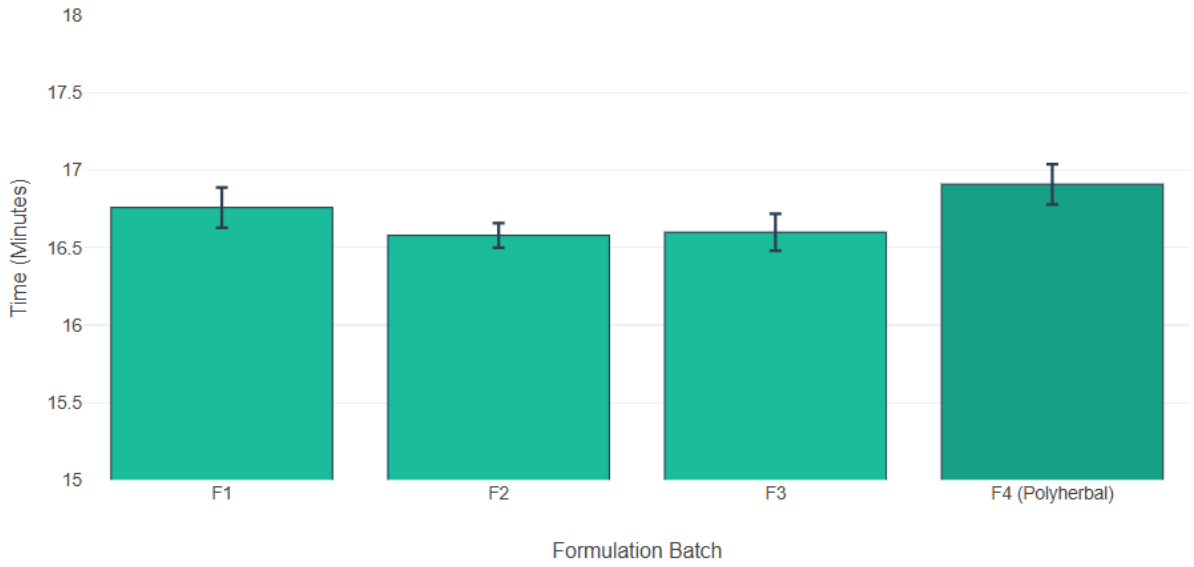

Figure 2. *In-vitro* Disintegration in Phosphate Buffer (pH 6.8) at 37°C

3.5. Moisture Content and Antimicrobial Inhibition

The moisture content was maintained between 0.63% and 0.73%, which is optimal for preventing microbial growth while maintaining a non-sticky texture. In the antimicrobial evaluation, the polyherbal formulation (F4) exhibited a superior zone of inhibition (22 ± 0.5 mm), significantly outperforming the single-herb variants.

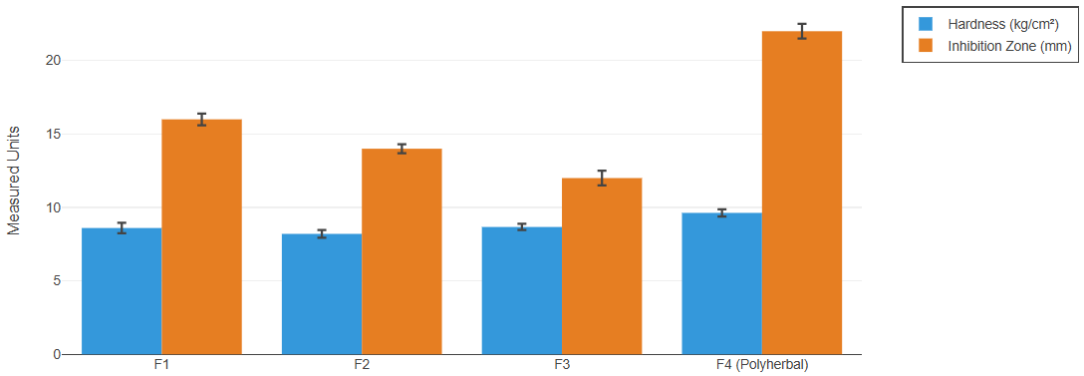

Figure 3. Correlation between Mechanical Hardness and Antimicrobial Zone of Inhibition across Formulations F1-F4

Table 5. Antimicrobial Efficacy and Moisture Analysis (Mean ± SD)

Formulation	Zone of Inhibition (mm)	Moisture Content (%)
F1	16.0 ± 0.4	0.63
F2	14.0 ± 0.3	0.73
F3	12.0 ± 0.5	0.64
F4	22.0 ± 0.5	0.66

3.6. Mucosal Irritancy Test

In the acute oral mucosal irritation study conducted on rabbits (Animal Ethical Committee Approval Number (AKRG/IAEC/2025/056), no clinical signs of inflammation, erythema, or ulceration were observed over a 72-hour period. The irritation index was calculated as 0.00, confirming that the herbal ingredients and the jaggery base are safe for localized oral application and do not induce adverse mucosal reactions.

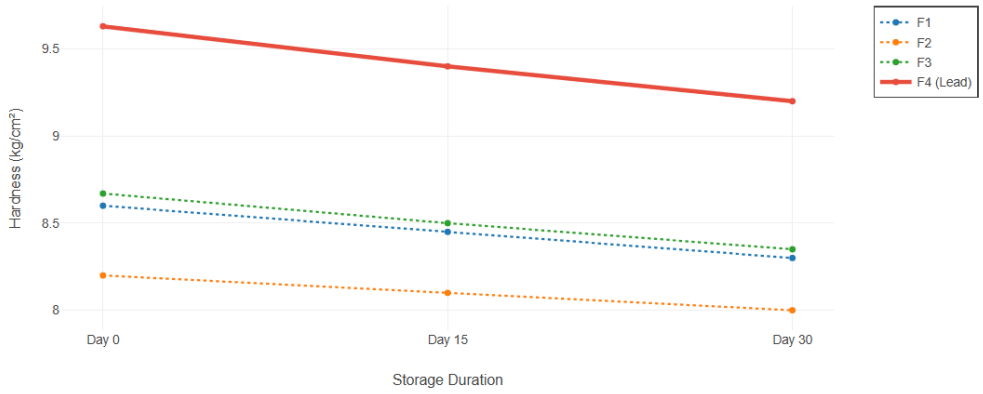

Figure 4. Mean Hardness (kg/cm²) over 30 days under controlled conditions (25°C/60% RH).

3.7. Stability Studies

Stability studies showed that the jaggery-based lozenges are resistant to syneresis (moisture exudation) and graining (sugar crystallization) under standard storage conditions. The near-neutral pH values further validate the selection of jaggery over more acidic synthetic bases, reducing the risk of dental erosion or mucosal irritation during prolonged use.

4. Discussion

The development of a stable and effective herbal lozenge requires a balance between botanical potency and mechanical stability. This research work successfully combined six bioactive herbs into a demulcent jaggery-sugar matrix. The use of jaggery proved advantageous not only for its sweetening properties but also for its ability to form a protective film over the oropharyngeal mucosa, which assists in alleviating the "scratchy" sensation associated with pharyngitis [9]. The significant increase in the zone of inhibition observed in the polyherbal formulation (F4) compared to F1–F3 indicates a synergistic interaction between the phytochemical constituents. Haritaki's tannins likely interact with bacterial cell wall proteins, while the eugenol from Clove and cinnamaldehyde from Cinnamon provide rapid antiseptic action [6, 14]. The inclusion of piperine from Black Pepper acts as a critical bio-enhancer, likely facilitating the penetration of these compounds into the microbial biofilm [8]. Mechanically, the high hardness (9.63 ± 0.25 kg/cm²) of F4 suggests that the high concentration of herbal powders acts as a reinforcing filler within the crystalline sugar-jaggery matrix, without compromising the disintegration time. The disintegration values (approx. 17 min) align with clinical requirements for lozenges, ensuring the active ingredients maintain a therapeutic concentration in the saliva for a duration sufficient to neutralize local pathogens [2, 10, 12].

5. Conclusion

This research work showed jaggery-based polyherbal lozenges as a safe and effective vehicle for the treatment of oropharyngeal infections. The optimized formulation (F4), containing a blend of Haritaki, Cinnamon, Vacha, Turmeric, Black Pepper, and Clove, achieved superior antimicrobial efficacy and mechanical durability compared to single-herb formulations. The use of natural

demulcents like jaggery improves patient comfort by providing immediate symptomatic relief. Stability and animal safety studies confirm the feasibility of this dosage form for large-scale production as a natural alternative to synthetic throat lozenges.

Compliance with ethical standards

Acknowledgements

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Conflict of interest statement

The authors declare that they have no potential conflicts of interest or competing interests with respect to the research, authorship, and/or publication of this manuscript. No financial support or products from any third-party institutions influenced the outcome of this study.

Statement of ethical approval

The experimental protocol was reviewed and approved (AKRG/IAEC/2025/056) by the Institutional Animal Ethics Committee (IAEC) of the institute and was conducted in strict accordance with the guidelines of the Committee for Control and Supervision of Experiments on Animals (CCSEA), formerly known as CPCSEA, Government of India. All procedures were performed under appropriate ethical oversight to ensure animal welfare.

Statement of informed consent

The present research work does not contain any studies performed on human subjects by any of the authors. Therefore, the statement of informed consent is not applicable to this study

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