IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

"A Novel Perspective on Pediatric Herbal Lozenges as Natural Throat-Acting Delivery Systems"

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Abstract

Herbal lozenges represent a safe, natural, and child-friendly dosage form designed to deliver phytotherapeutic agents locally to the oral cavity and throat. Their slow-dissolving matrix prolongs mucosal contact time, enabling sustained release of bioactive constituents and offering demulcent, antimicrobial, anti-inflammatory, and antioxidant actions beneficial for pediatric respiratory and oral conditions. Formulations commonly incorporate botanicals such as *Glycyrrhiza glabra*, *Piper longum*, ginger, turmeric, and guava leaf, supported by evidence demonstrating symptomatic relief in cough, sore throat, and mild irritation. Pediatric-specific formulation strategies include appropriate dose adjustment, optimized size and hardness, taste masking of bitter herbal extracts, and selection of safe excipients to ensure palatability and minimize choking risk. Techniques such as melting-molding, heating-congealing, and non-heat methods enable preparation of both hard and soft lozenges while preserving thermolabile constituents. Evaluation parameters—hardness, dissolution time, microbial safety, and palatability ensure quality and acceptability for children. Despite limited large-scale pediatric trials, herbal lozenges remain a promising natural alternative when carefully standardized, formulated, and administered within age-appropriate guidelines.

Keywords - Herbal lozenges; Pediatric formulation; Demulcent action; Phytotherapeutics; Throat relief; Controlled dissolution, etc.

1. INTRODUCTION

Herbal lozenges have emerged as an effective, natural, and patient-friendly solid oral dosage form designed to deliver phytoconstituents locally to the throat and oral cavity, offering soothing, antimicrobial, anti-inflammatory, and mucosal-protective effects. Their growing clinical relevance is supported by evidence from systematic investigations on herbal medicines for respiratory ailments, where strong therapeutic benefits have been documented for herbal actives commonly incorporated in lozenge formulations, such as *Andrographis paniculata*, ivy, thyme, and *Pelargonium sidoides* [1]. Reviews specific to herbal lozenges highlight that these formulations slowly dissolve in the mouth, increasing residence time and improving local bioavailability while bypassing first-pass metabolism, making them suitable for conditions like sore throat, cough, oral irritation, and mucosal inflammation [2,3].

Formulation studies demonstrate that herbs such as liquorice (*Glycyrrhiza glabra*), *Piper longum*, ginger, turmeric, betel leaf, and guava leaf provide significant antimicrobial, demulcent, antioxidant, and anti-ulcer activities, justifying their inclusion in lozenge systems for both respiratory and oral ulcer management [4–6]. Technologically, herbal lozenges present formulation challenges including taste masking of bitter extracts, achieving optimal hardness and disintegration, ensuring stability, and maintaining consistency across batches due to variability in herbal raw materials [3]. Modern development approaches such as Quality-by-Design (QbD) and Design of Experiments (DoE) have been successfully applied to optimize critical material and process parameters, improving product uniformity and performance [7].

Furthermore, therapeutic adaptations of traditional herbal preparations into lozenge forms have demonstrated compliance with standard quality control requirements, reinforcing their suitability as convenient unit dosage forms [8]. Additional investigations into polyherbal lozenges using in vitro antimicrobial assays and computational studies support their potential efficacy in throat infections and oral microbial control [9]. Despite these promising findings, the field still faces limitations, including insufficient large-scale clinical trials, lack of robust placebo-controlled studies, and challenges in standardizing herbal extract quality, which collectively restrict the full therapeutic validation of herbal lozenges [1, 3, and 10]. Therefore, expanding high-quality evidence and refining formulation strategies remain essential for advancing herbal lozenges as scientifically validated, safe, and effective natural therapeutic options for respiratory and oral health.

Fig. 1. Lozenges

Advantages of Herbal Lozenges

1. **Sustained Local Drug Release**
   Herbal lozenges dissolve slowly in the oral cavity, increasing residence time and allowing prolonged local action on the throat and oral mucosa, which enhances therapeutic effectiveness in cough, sore throat, and irritation [2, 3].
2. **Improved Bioavailability & No First-Pass Metabolism**
   Since the drug is released directly into the oral cavity, lozenges bypass hepatic first-pass metabolism, improving bioavailability of herbal actives and allowing lower doses compared to oral syrups or tablets [2].
3. **Multiple Pharmacological Benefits from Herbal Actives**
   Herbs used in lozenges such as liquorice, *Piper longum*, ginger, turmeric, betel leaf, guava leaf, and ivy/thyme provide antimicrobial, anti-inflammatory, antioxidant, demulcent, and mucosal-protective actions [1,4–6].
4. **Patient-Friendly Form & Better Compliance**
   Lozenges are easy to administer, convenient for children and elderly patients, portable, and preferred due to pleasant taste, making them ideal for repeated use during throat discomfort [3, 8].
5. **QbD-Based Optimization Possible**
   Applying QbD and DoE ensures consistent product quality, predictable disintegration time, stability, and batch-to-batch reproducibility, enhancing pharmaceutical acceptability and regulatory compliance [7].
6. **Useful for Both Respiratory and Oral Conditions**
   Studies support their effectiveness not only for cough and cold but also for mouth ulcers and oral inflammation, providing a broader therapeutic scope compared to conventional lozenges [5, 6].

Disadvantages of Herbal Lozenges

1. **Variability in Herbal Raw Material Quality**
   Herbal extracts show batch-to-batch phytochemical variation, making it difficult to maintain consistent potency and quality in lozenge formulation [3, 10].
2. **Taste Masking Challenges**
   many herbal extracts have bitter, pungent, or astringent tastes. Effective masking with sweeteners, flavors, and bases like is malt is technically challenging and affects overall acceptability [3].
3. **Limited Robust Clinical Evidence**
   despite promising results, large-scale, placebo-controlled clinical trials for herbal lozenges are scarce. Reviews highlight insufficient evidence for herbs like ivy and *Pelargonium* due to methodological limitations [1, 10].
4. **Stability Issues**
   Moisture sensitivity, degradation of herbal actives, and challenges in achieving uniform hardness and disintegration can compromise product stability if not carefully optimized [3, 7].
5. **Regulatory & Standardization Constraints**
   Regulatory frameworks for herbal products vary widely across regions. Lack of standardized monographs for many herbal ingredients complicates approval and quality assurance [3, 10].

6. **Sugar Content in Some Lozenges**
   Some formulations may contain sugars, increasing the risk of dental caries, making them unsuitable for diabetic patients unless sugar-free bases are used [3].

2. Components of Lozenges

1. Active herbal ingredients
2. Base or matrix-forming agents
3. Sweeteners
4. Binding agents
5. Flavors and cooling agents
6. Colorants
7. Lubricants / anti-sticking agents
8. Stabilizers and preservatives

Active herbal ingredients

Herbal lozenges primarily contain active herbal ingredients, which provide therapeutic effects such as anti-inflammatory, antimicrobial, demulcent, antioxidant, antitussive, and mucosal-healing actions. Commonly used botanicals include *Glycyrrhiza glabra* (liquorice), *Piper longum*, ginger, turmeric, guava leaf, betel leaf, and ivy, thyme, and *Pelargonium sidoides*. These herbs are selected for their proven benefits in relieving cough, sore throat, oral ulcers, and respiratory discomfort, making them essential functional components of the formulation.

Base or matrix-forming agents

The base or matrix-forming agents provide the structural framework of the lozenge and control its hardness, stability, and dissolution behavior. Traditional hard lozenges use sucrose and liquid glucose, whereas modern formulations often employ is malt or sugar-free polyols such as sorbitol and mannitol. These bases not only determine the lozenge texture but also influence mouth feel and the slow-release characteristics that are crucial for sustained local therapeutic action.

Sweeteners

To make the formulation palatable, sweeteners are added. These help mask the bitterness or pungency of herbal extracts. Conventional sweeteners such as sucrose are widely used, while sugar-free alternatives like is malt, mannitol, sorbitol, and natural sweeteners such as honey are preferred in herbal and health-oriented lozenges. Besides sweetening, they also contribute to bulk and stability.

Binding agents

Binding agents are incorporated to ensure cohesive blending of herbal extracts with the base. Natural gums like acacia, along with gelatin and honey, act as binders that improve hardness, structural integrity, and uniform distribution of the active constituents throughout the lozenge mass.

Flavors and cooling agents

Such as peppermint, menthol, lemon, and fruit essences are essential for improving organoleptic properties. Menthol and peppermint also provide an added soothing and cooling effect on the throat, enhancing patient comfort and acceptability.

Colorant

To improve visual appeal, **colorants** may be added. Herbal lozenges typically use natural colorants such as caramel or plant-based extracts to maintain a natural product profile while enhancing aesthetic value.

Lubricants and anti-sticking agents

During manufacturing, lubricants and anti-sticking agents such as magnesium stearate, talc, and cornstarch are used to prevent sticking to molds and processing equipment. These agents support smooth production and consistent quality output.

Stabilizers and preservatives

Finally, stabilizers and preservatives are incorporated to maintain the chemical stability and shelf-life of the product. Antioxidants like ascorbic acid protect sensitive herbal constituents from oxidative degradation, while moisture-regulating agents prevent softening, cracking, or microbial contamination, ensuring long-term product integrity.

3. Mechanism of Herbal Lozenges

Herbal lozenges exert their therapeutic effect through a multi-step mechanism involving saliva activation, controlled dissolution, mucosal adhesion, and localized pharmacological action. When the lozenge is placed in the mouth, it begins to dissolve gradually, stimulating salivary flow, which is essential for activating and solubilizing the herbal constituents embedded in the matrix. This increased salivation not only enhances patient comfort but also helps disperse the extract evenly across the oral cavity, forming a hydrating and soothing protective film over irritated mucosal surfaces, thereby providing an immediate demulcent effect (11). As the matrix continues to erode, bioactive phytoconstituents such as polyphenols, flavonoids, alkaloids, saponins, terpenoids, and essential oils are released in a controlled and sustained manner, maintaining prolonged local contact with the oral and pharyngeal tissues.

This sustained release allows the active compounds to exert targeted antimicrobial effects against pathogens commonly associated with throat infections, while simultaneously providing anti-inflammatory, analgesic, antioxidant, and mucosal-protective activity, which collectively reduce pain, dryness, irritation, edema, and microbial load (13). Furthermore, many herbal ingredients and excipients like pectin, acacia, mucilage-containing botanicals, and glycyrrhizin demonstrate natural mucoadhesive properties, enabling the softened lozenge matrix to adhere to the oral mucosa, thereby extending the residence time of the actives at the therapeutic site and improving bioavailability without requiring systemic absorption (16).

This bioadhesion forms a thin interactive layer that prolongs exposure to the herbal compounds and enhances their functional benefits. In addition, the combination of demulcent activity, mucosal coating, and gradual release influences mucosal drug transport, allowing diffusion of actives into the superficial mucosal layers where they modulate inflammatory mediators, support epithelial repair, reduce oxidative stress, and sometimes promote mild expectorant effects by increasing mucus hydration and reducing viscosity. Altogether, this integrated mechanism creates a synergistic therapeutic effect, wherein antimicrobial, anti-inflammatory, antioxidant, demulcent, and expectorant actions work harmoniously to alleviate conditions such as cough, sore throat, oral ulcers, mucosal dryness, and respiratory irritation, demonstrating the comprehensive functional capability of herbal lozenges as effective localized delivery systems (19).

4. Formulation considerations for Pediatric use of Herbal Lozenges

Designing herbal lozenges intended for children requires tailored decisions at every stage from selection and standardization of botanicals through to final packaging and caregiver instructions because children differ from adults in dose requirements, taste sensitivity, swallowing ability, metabolic capacity, and safety tolerances. The following points elaborate the major formulation, safety and clinical considerations that should guide development of pediatric lozenges.

Target age groups, dosage form appropriateness and choking risk

Lozenges are inherently intended to dissolve slowly in the mouth. This can create a choking or aspiration hazard in very young children. Therefore, clearly define the target pediatric age band(s) (e.g., 2–5 yrs, 6–12 yrs, adolescents). Many regulatory authorities and pediatric safety guidelines advise avoiding lozenges in toddlers and children who cannot reliably hold a lozenge and let it dissolve (commonly under ~4–5 years) for younger children consider alternative dosage forms (syrups, orally dispersible films, or mucosal sprays, dissolvable strips) instead. Size, shape and hardness must be optimized to minimize choking risk: smaller diameter, rounded edges, and relatively fast but controlled dissolution times for younger children help reduce risk. During development, perform age-appropriate human factors testing or observational acceptability studies with caregiver supervision.

Dosing strategy and potency standardization

Pediatric dosing must be weight- or age-adjusted; therefore, lozenge strength and recommended frequency should be designed so caregivers can dose safely (e.g., mg/kg/day guidance). Prefer standardized extracts with clearly defined marker compounds to ensure predictable potency and avoid batch-to-batch variability. Use conservative dosing margins start with the lowest effective herbal concentration supported by preclinical/clinical evidence and safety data. If the active concentration in a single lozenge would be too high for small children, consider lower-strength pediatric lozenges or instruct dosing by age/weight with maximum daily counts. Establish robust content uniformity and assay methods for low-dose formulations to ensure accurate dosing.[12]

Excipients, selection for pediatric safety and acceptability

Excipients commonly used in adult lozenges may be inappropriate or require limits in children:

- **Sweeteners:** Xylitol, sorbitol and other polyols improve palatability and dental profile but may cause osmotic diarrhea at high doses in young children set maximum polyol content per lozenge and per day. Note that xylitol toxicity concerns relate primarily to dogs, but gastrointestinal tolerance in children must be considered. Non-nutritive sweeteners (sucralose, stevia) have different regulatory statuses by region; if used, document safety data for pediatric use.
- **Sugar vs. sugar-free:** Sucrose improves mouthfeel but increases caries risk. For frequent dosing, prefer sugar-free matrices (is malt, sorbitol) with attention to polyol tolerability.
- **Preservatives and solvents:** Avoid or limit preservatives and solvents that have pediatric restrictions (e.g., benzyl alcohol, certain parabens) and screen for excipient–herb interactions. Use low water-activity formulations and moisture-protective primary packaging to minimize need for preservatives.
- **Colorants and flavors:** Use only food-grade colors and natural flavorings with established pediatric safety; test for allergenicity and acceptability.[13]

Taste-masking and palatability

Children are more sensitive to bitter/astringent tastes. Effective taste-masking is critical for adherence: employ layered strategies such as flavor blends matched to age preferences, sweetness optimization, inclusion complexes (cyclodextrins) or microencapsulation of bitter extracts. Keep aroma and aftertaste pleasant but not overwhelming; conduct quantitative palatability testing (hedonic scales) in the intended pediatric cohorts (with ethical approvals) to refine formulations.

Matrix selection and dissolution profile for pediatric use

On basis of matrix type with pediatric factors in mind:

- **Fast-dissolving vs. sustained release:** For quick symptomatic relief in older children, a faster-dissolving soft lozenge may be preferred; for prolonged local therapy in older pediatric groups, a mucoadhesive slower-dissolving lozenge can be considered. For younger children, faster dissolution reduces risk of accidental ingestion while ensuring therapeutic exposure.
- **Texture and mouthfeel:** Soft lozenges (pectin/gelatin) are more palatable for some children but may have higher microbial risk; hardness must be controlled to avoid fragments that could be swallowed whole. Conduct in-mouth dissolution testing in simulated pediatric saliva when possible.[21]

Safety profiling of herbal actives in children

Thoroughly evaluate each botanical for pediatric safety: genotoxicity, developmental and reproductive toxicity, local irritation, allergenicity, and potential for herb drug interactions (particularly CYP or transporter effects that may alter pediatric drug metabolism). Some herbs commonly considered safe in adults may lack pediatric toxicology data in such cases either avoid those herbs for pediatric formulations or generate specific safety data. Maintain strict heavy metals, pesticide, and microbial controls.

Microbial safety and preservation strategy

Because children may store and handle lozenges differently (e.g., leaving them open, multiple handling), design low sugar or polyol matrices and robust packaging to limit re-contamination. If a soft lozenge with higher water activity is used, choose preservative systems with established pediatric safety, or alternatively use single-unit sealed blister packs to reduce contamination risk. Conduct preservative efficacy and microbial challenge tests per pediatric product expectations. [12,15]

Packaging, labeling and caregiver guidance

- **Child-resistant secondary packaging** is recommended to prevent accidental ingestion of multiple units. Primary packaging should be single-dose blister packs to maintain hygiene and limit moisture ingress.
- **Labeling** must include age bands, per-dose instructions, maximum daily dose, warnings about choking risk, allergen statements, and explicit instruction that younger children (specify age) should not be given lozenges and should be supervised. Provide caregiver counseling text (how to administer, what to do if swallowed whole, storage).

Clinical evaluation, acceptability and pharmacovigilance

Pediatric formulations require pediatric-appropriate clinical evidence for safety and efficacy. Design clinical/acceptability studies stratified by age, with endpoints that include palatability, tolerability (gastrointestinal effects from sweeteners), local symptom relief, and adverse events. Post-marketing pharmacovigilance must capture pediatric-specific events (accidental ingestion, choking, allergic reactions). Consider dose-ranging and PK/PD bridging studies where systemic exposure is relevant.[17]

Regulatory and ethical considerations

Comply with pediatric labeling and pediatric investigation plan requirements of relevant regulatory agencies. Ethical considerations for pediatric trials include minimal risk design, parental consent and child assent where appropriate. Keep claims conservative and evidence-based; avoid implying systemic benefits in children unless supported by pediatric data.

Alternative pediatric-friendly designs and mitigation strategies

If lozenges are unsuitable for certain ages, consider**:** mucosal sprays, dissolvable thin films, chewable lozenges/tablets with size and hardness appropriate for older children, or liquid syrups with taste-masked extracts. For herbs with poor taste or narrow therapeutic windows, microdosing via liquid formulations may be preferable. For lozenges, consider producing a pediatric-specific formulation (reduced active per unit, modified excipients) and clear caregiver dosing charts.[18]

Recommended Ingredients and Safety

- Natural sweeteners (jaggery, honey, sugar) for improved taste and energy.
- Safe herbal extracts appropriate for pediatric use (e.g., basil, betel, myrobalan, mint, clove).
- Excipients like corn flour, gelatin, acacia, or PEG to aid texture and stability.
- Keep batch sizes and mold shapes child-friendly, and avoid allergens or strong spices.

5. Methods of Preparation

Melting and Molding Technique

- Prepare herbal extracts by grinding or soaking leaves, roots, or powders, and filtering out the pulp or water content.
- Dissolve a natural sweetener such as jaggery, sugar, or honey in a small amount of water and heat until it forms a viscous syrup (typically heated to 90–150°C depending on formulation type).
- Add herbal extracts or powdered herbs to the molten syrup base, stir thoroughly to achieve homogenous mixing, and continue heating as required for consistency.
- Pour the hot mixture into pre-sized molds and allow it to cool and solidify naturally at room temperature. [21]

Heating and Congealing Technique

- Dissolve sucrose or other sugars in water and heat, maintaining temperatures around 105–110°C until a thick syrup forms.
- After partial thickening, add active herbal ingredients and any flavoring or plasticizer ingredients, continue stirring and heating for another 30–45 minutes.
- Once the mass is adequately thick and plastic, lower the temperature (to around 40°C), and pour into lubricated molds.
- Allow the molded mixture to cool and set, then air-dry or store as required.

Hand Roll/Non-Heat Methods (Soft Lozenges)

- Triturate powdered herbal constituents with oils and binders such as mannitol, honey, or gelatin until a soft dough-like mass forms.
- Roll the mass on a lozenge board, cut to desired size and shape, and allow to air-dry or store in moisture-proof containers.
- Suitable for thermolabile herbal ingredients or where heat is undesirable.

6. Evaluation

Herbal pediatric lozenges are evaluated on parameters including their safety, effectiveness, physical properties, and patient acceptability, especially for use in children above 6 years of age. Studies have shown that herbal lozenges often containing medicinal extracts like Justicia adhatoda, Aegle marmelos, betel leaves, and others can help relieve symptoms related to cough, sore throat, and mild respiratory conditions. They deliver active ingredients locally in the mouth and throat, offering soothing, anti-inflammatory, and demulcent effects[21]

Conclusion

Herbal lozenges offer a scientifically grounded and child-friendly alternative for managing throat discomfort, cough, and mild respiratory or oral mucosal irritation in pediatric populations. Their slow-dissolving design ensures prolonged mucosal contact and controlled release of phytoconstituents, enabling targeted demulcent, antimicrobial, anti-inflammatory, and antioxidant effects without systemic exposure or first-pass metabolism. Careful selection of botanicals, optimization of dosage strength, and incorporation of safe, palatable excipients are essential to address pediatric-specific needs such as taste sensitivity, choking risk, and excipient tolerability. Manufacturing approaches including melting–molding, heating–congealing, and non-heat soft lozenge techniques support the stable integration of herbal actives while preserving their functional integrity. Evaluation of physical, chemical, microbial, and sensory attributes further ensures product quality and acceptability for children. Although current literature supports the symptomatic benefits of herbal lozenges, broader pediatric clinical studies are needed to strengthen evidence on efficacy and safety. With appropriate standardization and adherence to age-specific guidelines, herbal pediatric lozenges hold strong potential as a safe, effective, and natural therapeutic option for pediatric throat and respiratory care.

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