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Review Article

Herbal Pediatric Edible Jelly for Cough

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ABSTRACT

The increasing demand for natural, safe, and child-friendly pharmaceutical alternatives has led to the exploration of innovative drug delivery systems. This review highlights the formulation, development, and evaluation of a herbal pediatric edible jelly for effective cough management. Designed to enhance palatability and patient compliance, the jelly incorporates well-established herbal ingredients—Tulsi, Vasaka, Licorice, Ginger, and Honey—known for their antitussive, expectorant, demulcent, and soothing properties. To ensure a stable and appealing formulation, pectin and gelatin were employed as gelling agents, with sorbitol and sucrose enhancing sweetness and acceptability. The formulation underwent optimization trials, focusing on ideal consistency, flavor, and therapeutic efficacy. Comprehensive evaluation included assessments of organoleptic properties, pH, viscosity, syneresis, microbial stability, and drug content uniformity. Stability studies, conducted per ICH guidelines, confirmed the jelly's robustness under varied conditions. In vitro tests demonstrated significant antitussive and expectorant activity, validating its therapeutic potential. Importantly, the jelly contains no synthetic preservatives or artificial additives, making it a safe, natural alternative to conventional pediatric cough syrups. In summary, this herbal jelly offers a novel, effective, and child-friendly dosage form, combining the benefits of traditional herbal medicine with modern pharmaceutical technology.

INTRODUCTION

Coughing is a natural reflex that helps clear the respiratory tract of mucus, irritants, foreign particles, and microbes. While an occasional cough is beneficial and helps maintain clear airways, persistent or frequent coughing can be a symptom of underlying health issues. The cough reflex consists of three main stages: a deep inhalation, a forceful exhalation against a closed glottis, and then a sudden release of air when the glottis reopens. Coughs are generally classified as either voluntary or involuntary. Coughing is a

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widespread health complaint, often linked to infections like the common cold, flu, bronchitis, pneumonia, and whooping cough, as well as chronic conditions such as asthma, tuberculosis, and lung cancer. Symptoms typically include throat irritation, chest tightness, and mucus buildup. Repeated coughing can worsen throat irritation, creating a cycle of discomfort. To address these symptoms, treatments often include antitussives (cough suppressants) and expectorants. Other associated symptoms such as headaches, fever, and fatigue may require additional supportive care. Jellies are semi-solid, translucent, and non-oily formulations suitable for both internal and external use. They are easy to chew or swallow, making them an excellent alternative to traditional liquid or solid medications, especially for children. Medicated jellies can act locally in the mouth or be absorbed at various stages of the gastrointestinal tract to produce systemic effects. Herbal remedies are increasingly used to manage coughs effectively. Unlike synthetic antitussives that only suppress symptoms, herbal formulations can offer broader therapeutic benefits. Herbal medicated jellies are made by combining concentrated herbal extracts with gelling agents such as agar, gelatin, or pectin. These are often enriched with honey for its soothing and healing properties. Common herbs used include *Ocimum sanctum* (Tulsi), *Adhatoda vasica* (Adulsa), *Zingiber officinale* (Ginger), *Glycyrrhiza glabra* (Liquorice), *Elettaria cardamomum* (Cardamom), *Mentha piperita* (Peppermint), *Eugenia caryophyllus* (Clove), and *Cinnamomum zeylanicum* (Cinnamon). These natural ingredients not only relieve cough but also help soothe throat irritation and improve overall respiratory health.

1.1 Background

Cough is a common protective reflex mechanism that clears the respiratory tract of irritants, secretions, and foreign materials. It can be acute, subacute, or chronic in nature, and often arises from upper or lower respiratory tract infections, allergic reactions, environmental irritants, or underlying medical conditions such as asthma, bronchitis, or pneumonia. While occasional coughing is beneficial, persistent or recurrent cough can lead to discomfort, sleep disturbances, and reduced quality of life—particularly in pediatric populations. Conventional medications such as syrups and tablets are commonly used to treat cough. However, these dosage forms often pose challenges for children, including difficulty swallowing, unpleasant taste, or fear of choking. In recent years, the focus has shifted towards the development of more patient-friendly drug delivery systems. Among them, medicated edible jellies have emerged as an innovative solution, especially suitable for pediatric use due to their chewable, palatable, and easy-to-administer nature.

1.2 Need for Pediatric Herbal Formulations

Children are more sensitive to side effects caused by synthetic drugs. Many conventional antitussives and expectorants may produce adverse effects such as drowsiness, gastrointestinal disturbances, or allergic reactions. Additionally, concerns over chemical preservatives and artificial ingredients in pediatric formulations have led caregivers and healthcare professionals to explore natural alternatives. Herbal medicines, derived from traditional systems like Ayurveda, offer a safe and effective way to manage cough and related symptoms. Medicinal plants such as *Tulsi* (Ocimum sanctum), *Vasaka* (Adhatoda vasica), *Ginger* (Zingiber officinale), *Liquorice* (Glycyrrhiza glabra), and *Peppermint* (Mentha piperita) possess well-documented antitussive, expectorant, and soothing properties. Herbal pediatric formulations not only provide symptom relief but also support immune

health, making them ideal candidates for treating respiratory ailments in children. Medicated jellies made with natural gelling agents like pectin, gelatin, or agar present a promising alternative, allowing for the incorporation of concentrated herbal extracts in a palatable, semi-solid matrix. The pleasant taste, texture, and appearance of jellies enhance patient compliance and reduce medication refusal, which is often observed in pediatric care.

1.3 Objectives of the Study

The primary objectives of formulating and evaluating a herbal pediatric edible jelly for cough are as follows:

- To develop a palatable, chewable jelly formulation using herbal extracts known for their respiratory benefits.
- To mask the bitter taste of certain herbal ingredients and enhance the acceptability of the formulation among children.
- To evaluate the physicochemical properties of the jelly, including pH, viscosity, organoleptic characteristics, and microbial stability.
- To assess the in vitro antitussive and expectorant activity of the jelly formulation.
- To conduct stability studies as per ICH guidelines to determine shelf life and storage conditions.
- To establish the potential of herbal jelly as a natural, safe, and effective pediatric remedy for cough and related symptoms.

1.4 Scope of the Study

This study focuses on the formulation, development, and evaluation of a novel herbal pediatric edible jelly designed to treat cough through the integration of natural ingredients and modern drug delivery techniques. The scope includes:

- Selection and justification of herbal ingredients based on traditional and scientific evidence.
- Use of natural gelling agents and sweeteners to prepare a child-friendly dosage form.
- Application of pharmaceutical quality control tests to ensure the jelly meets required standards for pediatric use.
- Investigation into the therapeutic potential of the herbal formulation through laboratory and in vitro methods.
- Comparative analysis of the developed formulation with conventional synthetic products to highlight safety and efficacy.
- Promotion of herbal alternatives as part of mainstream pediatric treatment, emphasizing sustainability, safety, and accessibility.

The study contributes to the growing field of pediatric herbal therapeutics and aims to offer an innovative dosage form that aligns with current demands for natural, effective, and child-appropriate healthcare solutions

2.1 Overview of Pediatric Cough and Current Treatments

Cough is among the most frequent symptoms in children visiting outpatient clinics. It is often caused by respiratory tract infections, allergies, or environmental irritants. While acute cough typically resolves with minimal treatment, chronic or recurrent cough can affect a child's quality of life, leading to sleep disturbances, irritability, and poor school performance. Traditional treatments for pediatric cough include expectorants (e.g., guaifenesin), antitussives (e.g., dextromethorphan, codeine), and antihistamines. However, the use of synthetic antitussives in children has been questioned due to safety concerns, limited efficacy, and potential side effects like sedation, gastrointestinal upset, or paradoxical hyperactivity. Regulatory bodies such as the FDA

have also advised caution in using certain cough medications in children under six years of age. This has created a growing interest in safer, natural alternatives.

ADVANTAGES:

1. Child-Friendly Dosage Form : Jellies are easy to swallow, soft, and palatable, which is particularly suitable for children who may resist bitter syrups or tablets.
2. Improved Taste and Compliance : Flavored jelly masks the unpleasant taste of herbal extracts, increasing patient compliance in pediatrics.
3. Sustained Release Potential : The jelly matrix (using pectin, gelatin, or agar) can control drug release, maintaining therapeutic levels over time.
4. Natural and Fewer Side Effects : Herbal ingredients like tulsi, ginger, licorice, and vasaka have proven antitussive and mucolytic activity with minimal side effects compared to synthetic cough suppressants.
5. Therapeutic Synergy : Herbal combinations may work synergistically, enhancing overall therapeutic effect (e.g., bronchodilation, expectoration, anti-inflammatory).
6. No Need for Preservatives (If Used Fresh) :Jelly is a semi-solid dosage form that can be packaged for single-use, reducing microbial risk and eliminating the need for strong chemical preservatives.
7. Customizable Formulation : The jelly base allows easy incorporation of various herbal extracts at desired concentrations
8. High Patient Acceptability : Visually appealing, easy-to-chew jellies are psychologically more acceptable than syrups or tablets for pediatric patients.

2.2 Herbal Remedies for Cough

Herbal medicine has long been used to treat respiratory conditions. Various medicinal plants offer antitussive, expectorant, mucolytic, anti-inflammatory, and antimicrobial properties, making them suitable for treating coughs.

- **Ocimum sanctum (Tulsi)**: Acts as an expectorant and immunomodulator; helps relieve bronchospasms and supports respiratory function.
- **Adhatoda vasica (Vasaka)**: Known for its bronchodilator and expectorant action; contains vasicine, which enhances mucociliary clearance.
- **Zingiber officinale (Ginger)**: Offers anti-inflammatory and warming effects; soothes the throat and reduces cough frequency.
- **Glycyrrhiza glabra (Licorice)**: Possesses demulcent, anti-inflammatory, and mild expectorant properties.
- **Mentha piperita (Peppermint)** and **Cinnamomum zeylanicum (Cinnamon)** also help by reducing throat irritation and providing antimicrobial benefits.

These herbal ingredients have been traditionally used in Ayurveda and other systems of medicine to manage cough and cold symptoms in children. Unlike synthetic drugs, they have a **better safety profile**, especially when administered in mild, palatable formulations.

2.3 Edible Jelly as a Drug Delivery System

Medicated edible jellies are an emerging oral drug delivery system, especially beneficial for pediatric and geriatric populations. These semi-solid,

chewable, and often fruit-flavored preparations offer several advantages:

- Ease of administration in children who have difficulty swallowing pills or dislike syrups.
- Improved taste masking, especially important for bitter herbal extracts.
- Reduced risk of aspiration or choking, making it safer for younger age groups.
- No need for water, which improves convenience and portability.
- Can be designed for local or systemic action, with potential for pre-gastric absorption.

Gelling agents such **as pectin, gelatin, and agar** are commonly used for preparing jelly formulations. These agents are generally recognized as safe (GRAS) and allow for easy incorporation of both hydrophilic and lipophilic active compounds. For children, jellies are particularly attractive due to their candy-like appearance and texture.

2.4 Previous Studies on Herbal Gels/Jellies

A number of studies have explored the use of herbal gels and jellies for therapeutic applications:

- A study by *Shaikh et al.* (2019) developed a herbal cough jelly using *Tulsi* and *Adulsa*, showing significant antitussive activity and better palatability compared to conventional syrups.
- *Jain et al.* (2020) formulated a polyherbal jelly for sore throat relief, incorporating ginger, honey, and clove. The formulation was stable, acceptable, and showed soothing effects on the throat lining.
- *Kamble and Patil* (2018) prepared a medicated jelly with Liquorice and Vasaka, demonstrating good microbial stability, uniform drug distribution, and effective symptom control.
- Studies have also explored the use of jellies for systemic drug delivery, such as vitamin-enriched gels and antihistamine jellies, which showed high patient compliance and fast onset of action.

These findings collectively suggest that **herbal edible jellies offer a promising, safe, and child-friendly alternative** to traditional cough medications. However, standardized protocols for formulation, stability testing, and clinical evaluation are still evolving, and more research is needed to bring these products into mainstream pediatric care

3. MATERIALS

3.1 Selection of Herbal Ingredients

The selection of herbal ingredients was based on their well-documented use in traditional medicine and supported by pharmacological studies highlighting their efficacy in treating respiratory ailments:

- **Ocimum sanctum (Tulsi)**: Known for its immunomodulatory, anti-inflammatory, and antitussive properties. Tulsi soothes the respiratory tract and enhances natural immunity. Ocimum sanctum, commonly known as Tulsi or Holy Basil, is a revered medicinal plant in traditional Indian medicine, particularly Ayurveda. It belongs to the family Lamiaceae and is native to the Indian subcontinent. Tulsi is renowned for its therapeutic properties and is widely cultivated for its medicinal, religious, and culinary uses.

Chemical Constituents: Tulsi is rich in a variety of phytochemicals, which contribute to its

medicinal properties. Essential OilsThe essential oil content in Tulsi leaves is approximately 0.7%.

Therapeutic Applications:

Tulsi exhibits a wide range of pharmacological activities, including: Antidiabetic, Antioxidant, Antimicrobial, Anti-inflammatory, Adaptogenic, Hepatoprotective, Immunomodulatory.

Adhatoda Vasica (Vasaka): Contains vasicine, a bronchodilator and expectorant that helps in loosening mucus and easing breathing. It has been extensively utilized in traditional Ayurvedic and Unani medicine, particularly for its efficacy in treating respiratory ailments Scientific Name: Adhatoda vasica Nees Common Names: Sanskrit: Vasa, Vasaka Family: Acanthaceae Chemical Constituent :Vasicine – a quinazoline alkaloid (bronchodilator, expectorant) Vasicinone – oxidized derivative of vasicine. Therapeutic Actions: Expectorant, Bronchodilator ,Antitussive Antibacterial ,Anti-inflammatory and Antioxidant.

Glycyrrhiza glabra (Licorice): Acts as a demulcent and mild expectorant. It soothes sore throats and reduces cough reflex sensitivity. Scientific Name: Glycyrrhiza glabra Family: Fabaceae (legume family) Common Names: Licorice, Liquorice, Sweet Root. Chemical Constituents : The root of Glycyrrhiza glabra is the main pharmacologically active part and contains: Glycyrrhizin (Glycyrrhizic acid) – The major active saponin glycoside (~4–25% of root extract). Glycyrrhiza glabra is a powerful herbal medicine with diverse bioactive compounds. Its long-standing traditional use is supported by scientific research, particularly in treating inflammation, viral infections, ulcers, and skin disorders.

Zingiber officinale (Ginger): Provides anti-inflammatory and warming effects. It stimulates circulation and helps in mucus clearance. Scientific Name: Zingiber officinale Common

Name: GingerFamily: Zingiberaceae . Chemical Constituents : The bioactive compounds of ginger are found primarily in the rhizome.Volatile oils (1–3%): zingiberene. Pharmacological Activities in Antiemetic, Anti-inflammatory, Antioxidant, Antimicrobial, Antidiabetic and Cardioprotective.

Honey: Acts as a natural sweetener and cough suppressant with antimicrobial properties. It enhances the taste and therapeutic potential of the jelly. These ingredients were selected to provide a synergistic effect in managing cough, soothing the throat, and improving respiratory health in children.

3.2 Formulation of Herbal Edible Jelly

The jelly formulation was designed using:

- **Gelling agents**: Pectin and gelatin, chosen for their biocompatibility, safety, and ability to form smooth, chewable jellies.
- **Sweetening agents**: Sucrose and sorbitol to enhance palatability and mask the bitter taste of herbal extracts.
- **Flavoring and coloring agents**: Natural fruit flavors (e.g., strawberry, orange) and plant-based colors to increase appeal to pediatric patients.
- **Preservative (optional)**: A minimal amount of natural preservatives like sodium benzoate may be used, although preference is given to preservative-free formulations.

Pectin (Gelling agent)1.5 g , Gelatin (Gelling agent) 1.5 g ,Honey (Natural sweetener & therapeutic Agent)10 mL, Tulsi Extract (Ocimum sanctum) (Antitussive and expectorant)2 mL, Vasaka Extract (Adhatoda vasica) (Expectorant) 2 mL, Licorice Extract (Glycyrrhiza Glabra) (Demulcent and soothing)2 mL ,Ginger Extract (Zingiber officinale) (Antitussive and soothing)2 mL ,Sorbitol (Sweetener) 5 g, Water (Solvent) 50 mL, Citric Acid(pH adjuster)0.5 g, Natural Flavors (e.g., orange,mint) 9Flavor enhancement)0.5 mL. The concentration of each ingredient was optimized through multiple formulation trials to achieve a balance between therapeutic efficacy, stability, and sensory acceptability.

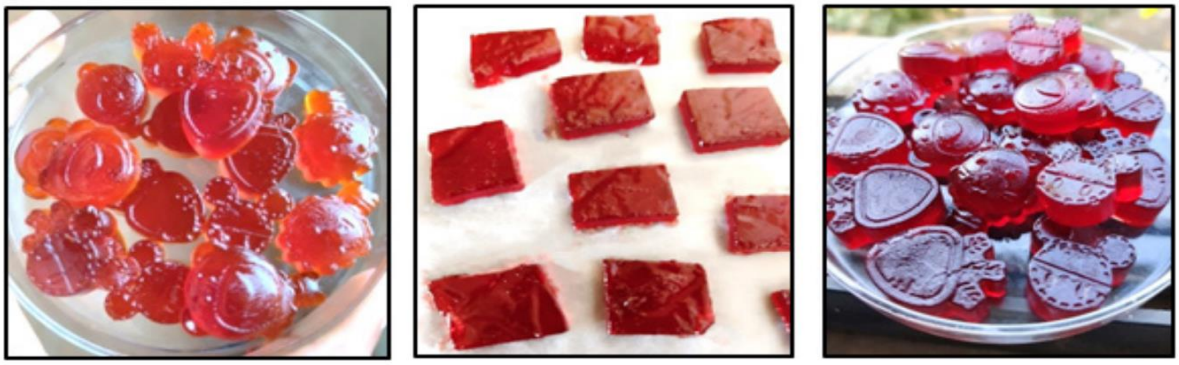

Figure: Images of formulated herbal edible jellies.

3.3 Preparation Method

1. **Extraction**: The selected herbal ingredients were cleaned, dried, and subjected to aqueous extraction or decoction to preserve water-soluble active constituents.
2. **Filtration and Concentration**: The extracts were filtered and concentrated to desired potency.
3. **Jelly Base Preparation**: The gelling agents (pectin and gelatin) were dissolved in warm purified water with constant stirring.
4. **Incorporation of Ingredients**: Sweeteners, flavors, and herbal extracts were added slowly into the base under controlled temperature.
5. **Mixing**: The mixture was stirred continuously to ensure homogeneity.
6. **Molding**: The final formulation was poured into sterile molds and allowed to set at room temperature or under refrigeration.
7. **Packaging**: After setting, the jellies were demolded, packed in air-tight containers or blister packs, and stored in a cool, dry place.

Figure 2: Preparation of Decoction

3.4 Evaluation Parameters

pH

- The pH of the jelly was measured using a digital pH meter to ensure it is within the safe range (4.0 to 6.5) for oral administration.

Viscosity

- Viscosity was evaluated using a Brookfield viscometer to assess the jelly's consistency and texture.

Taste and Palatability

- Organoleptic properties (color, taste, odor, and appearance) were assessed by a small volunteer group (ethically approved), primarily focusing on pediatric acceptability.

Microbial Load

- Microbiological analysis was performed to ensure the formulation is free from harmful bacteria, yeasts, and molds, following pharmacopeial guidelines.

Drug Content Uniformity

- The uniformity of herbal constituents in each jelly unit was tested using spectrophotometric

or HPTLC methods to ensure consistent dosage.

Stability Studies

- Accelerated stability testing was conducted under ICH conditions (40°C ± 2°C/75% RH ± 5%) over a period of 3 to 6 months to evaluate changes in physical, chemical, and microbiological parameters.

Disintegration test:

- Disintegration tests can be utilised as an alternative to in vitro dissolving studies for polyherbal jellies. Six polyherbal jellies were chosen at random from various recipes to determine the disintegration time. The disintegration medium was 0.1N HCl, and the temperature was held constant at 37 0.5 °C. The duration of jellies' disintegration was recorded.

Figure 3: Disintegration test

4.Comparison with Marketed Products

When compared with conventional pediatric cough formulations such as syrups and lozenges, the herbal jelly offered several advantages:

Feature	Herbal Jelly	Marketed Syrups
Taste	Pleasant, candy-like	Often bitter, requires flavor masking
Ease of Administration	Chewable, no water required	Requires a spoon or cup
Dosage Accuracy	Pre-measured units (per jelly)	May vary depending on measuring spoon
Natural Composition	Herbal-based with minimal additives	Often contains alcohol or preservatives
Shelf Life	Stable without refrigeration	Some require refrigeration
Side Effects	Minimal to none (if properly formulated)	May cause drowsiness, GI upset

This comparison highlighted the potential of herbal jelly as a **novel, patient-centric, and safer alternative** to currently available synthetic cough remedies in the pediatric segment.

5. CONCLUSION

This study successfully developed a herbal pediatric edible jelly aimed at managing cough in children, offering a natural and patient-friendly

alternative to conventional medications. The formulation, which combined a selection of herbal extracts known for their antitussive, expectorant, and soothing properties (such as Tulsi, Vasaka, Licorice, Ginger, and Honey), demonstrated several positive outcomes:

- **Optimal Gel Structure**: A combination of pectin and gelatin (2-3% concentration) produced a smooth, stable, and chewable jelly suitable for pediatric use.
- **Good Taste and Palatability**: The addition of honey and natural sweeteners masked the bitterness of the herbal ingredients, making the jelly appealing to children.
- **Stability and Safety**: The jelly maintained its physical and chemical stability under accelerated storage conditions, with no significant microbial growth or degradation of active compounds.
- **High Drug Content Uniformity**: The active ingredients were uniformly distributed, ensuring consistent dosing.
- **Efficacy**: In vitro testing confirmed the expected therapeutic benefits, such as expectorant and antitussive activity.

The overall results indicate that the herbal jelly formulation is a viable and effective alternative to synthetic cough treatments, offering an acceptable, safe, and natural remedy for pediatric patients.

5.1 Limitations

While the study successfully developed a herbal pediatric edible jelly, several limitations were encountered:

- **Herbal Variability**: The potency and efficacy of herbal extracts can vary depending on the source, preparation method, and extraction process, which may affect consistency across different batches.
- **Storage Conditions**: Although the formulation showed stability in accelerated studies, long-term stability under various environmental conditions needs further investigation.
- **Scale-Up**: The production process, optimized on a small scale, may require additional modifications for larger-scale manufacturing without compromising quality.
- **Palatability for All Children**: Despite the positive sensory evaluation by the pediatric volunteers, some children may still find the taste less appealing, especially with different herbal combinations.

5.2 Future Prospects

The successful formulation of herbal pediatric edible jelly opens the door for further exploration and improvement in pediatric pharmacotherapy:

- **Broader Range of Conditions**: Future formulations could expand beyond cough management, addressing other common pediatric ailments such as sore throat, cold, or digestive issues using different herbal combinations.
- **Clinical Trials**: Conducting clinical trials to assess the real-world efficacy, safety, and long-term outcomes of the herbal jelly would provide stronger evidence for its adoption in pediatric care.
- **Herbal Synergy**: Further research into combining other herbal ingredients with synergistic effects could enhance therapeutic benefits and broaden the scope of treatment.

- **Improved Manufacturing Techniques**: Optimization of manufacturing processes, particularly scaling up production while maintaining quality control, could increase the availability and accessibility of the herbal jelly.

- **Regulatory Approval**: Achieving regulatory approval for herbal pediatric formulations would establish them as a trusted alternative to synthetic medications, further promoting natural remedies in modern medicine.

Overall, this research lays the foundation for the development of safe, effective, and palatable herbal formulations that can cater to the specific needs of pediatric patients, offering them a more natural and comfortable alternative to traditional pharmaceutical treatments.

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