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Research Article

**FORMULATION AND EVALUATION OF HERBAL COUGH  
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Buldhana 443201<sup>4,5</sup> Departments of Pharmacology, Karmayogi Tatyasahab Bondre Institute of Pharmacy, Chikhli  
Dist, Buldhana 443201**Abstract:**

*Cough is a common respiratory symptom caused by various underlying conditions, ranging from mild irritations to severe infections. Herbal cough syrups have gained attention as natural alternatives to synthetic formulations due to their safety, efficacy, and minimal side effects. This study focuses on the formulation and evaluation of a herbal cough syrup using natural ingredients with proven antitussive, expectorant, and demulcent properties. Key herbal components include Adhatoda vasica (Vasaka), Ocimum sanctum (Tulsi), Zingiber officinale (Ginger), Glycyrrhiza glabra (Licorice), and honey.*

*The syrup was prepared using standardized extraction techniques and formulated with a suitable base of sugar syrup and natural preservatives. Evaluation parameters such as organoleptic properties, pH, viscosity, microbial safety, and stability were assessed to ensure quality. Additionally, the antitussive efficacy was tested using preclinical models, demonstrating significant reduction in cough frequency compared to synthetic alternatives.*

**KEY Words:** Active Herbal Ingredients, Base Components, Preservatives, Flavoring and Coloring Agents (Optional), Stabilizers and pH Adjusters

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## INTRODUCTION:

Cough is a common and often distressing symptom associated with a variety of respiratory conditions such as colds, flu, allergies, bronchitis, and asthma. It serves as a natural defense mechanism to clear the airways of irritants and mucus, but when persistent or severe, it can affect daily activities and quality of life. Cough syrups are commonly used to alleviate this symptom, but many commercial products contain synthetic chemicals that may cause side effects or have limited long-term effectiveness.

Herbal cough syrups, on the other hand, offer a natural alternative. They are formulated from plant-based ingredients known for their therapeutic properties, including antitussive (cough-suppressing), expectorant (mucus-expelling), anti-inflammatory, and antimicrobial effects. These herbal remedies have been used for centuries across various cultures due to their safety, minimal side effects, and efficacy. With increasing interest in natural medicine and the demand for safer alternatives, herbal formulations are gaining prominence in the treatment of respiratory ailments.

This study focuses on the formulation and evaluation of a herbal cough syrup developed using a blend of well-known herbal ingredients with scientifically validated therapeutic properties. The primary goal is to create an effective, safe, and palatable cough syrup that not only suppresses coughing but also addresses the underlying causes, such as inflammation and mucus buildup.[1][2]

## TYPES OF COUGH

Coughs can be categorized based on their duration, nature, and underlying causes. Understanding the different types of cough is essential for determining the appropriate treatment. Here are the main types of coughs:

- 1.Acute Cough
- 2.Subacute Cough
- 3.Chronic Cough
- 4.Dry Cough (Non-productive Cough)
- 5.Wet Cough (Productive Cough)
- 6.Whooping Cough (Pertussis)
- 7.Night Cough
- 8.Psychogenic Cough[3][4]

## TREATMENT COUGH

The treatment of a cough depends on its underlying cause, type, and severity. For acute coughs, often caused by viral infections like the common cold or flu, treatment typically focuses on symptom relief. This includes drinking plenty of fluids to soothe the throat, using over-the-counter cough syrups (such as

expectorants to loosen mucus or antitussives to suppress the cough), and getting adequate rest. Chronic coughs, which last more than eight weeks, require a more tailored approach depending on the cause, such as medications for asthma, antibiotics for bacterial infections, or acid reflux management with antacids. Dry (non-productive) coughs can be treated with cough suppressants like dextromethorphan, throat lozenges, or humidification, while wet (productive) coughs, which involve mucus production, may benefit from expectorants like guaifenesin to help clear mucus. Home remedies like honey, ginger, or turmeric can also provide natural relief, as they have soothing and anti-inflammatory properties. For more serious conditions like whooping cough or coughs related to COPD, specific treatments such as antibiotics or inhalers may be necessary. If a cough persists or is accompanied by alarming symptoms like shortness of breath or chest pain, medical consultation is advised to ensure appropriate treatment and rule out serious underlying conditions.[5][6][7]

## HERBS USE IN COUGH SYRUP

Here are some commonly used herbs in cough syrup, along with their benefits:

### 1.Licorice Root (*Glycyrrhiza glabra*)

- Purpose: Soothes throat irritation and acts as an expectorant.
- Usage: Helps loosen mucus and relieves inflammation.

### 2.Thyme (*Thymus vulgaris*)

- Purpose: Antimicrobial and expectorant properties.
- Usage: Helps with productive coughs and soothes the respiratory tract.

### 3.Peppermint (*Mentha piperita*)

- Purpose: Contains menthol, which provides a cooling effect and relieves throat discomfort.
- Usage: Often used to ease breathing by clearing nasal passages.

### 4.Ginger (*Zingiber officinale*)

- Purpose: Anti-inflammatory and antitussive properties.
- Usage: Reduces cough frequency and eases throat irritation.

### 5.Marshmallow Root (*Althaea officinalis*)

- Purpose: Acts as a demulcent to coat and soothe the throat.
- Usage: Provides relief for dry and irritating coughs.

### 6.Eucalyptus (*Eucalyptus globulus*)

- Purpose: Decongestant and antimicrobial effects.

- Usage: Helps in clearing mucus and easing respiratory discomfort.

#### 7.Honey

- Purpose: Natural cough suppressant and antimicrobial properties.
- Usage: Often paired with herbal extracts to enhance flavor and effectiveness.

#### 8.Holy Basil (*Ocimum sanctum*)

- Purpose: Expectorant and antibacterial properties.
- Usage: Helps in managing coughs associated with colds and respiratory infections.

#### 9.Mullein (*Verbascum thapsus*)

- Purpose: Soothes irritated mucous membranes and clears phlegm.
- Usage: Commonly used in teas and syrups for respiratory issues.

#### 10.Fenugreek Seeds (*Trigonella foenum-graecum*)

- Purpose: Relieves throat irritation and supports mucus clearance.
- Usage: Used in combination with other herbs for synergistic effects.

These herbs are often combined in specific formulations to address various types of coughs, such as dry, productive, or allergy-related coughs. Always consult a healthcare provider before using herbal remedies, especially in children, pregnant women, or individuals with chronic health conditions.[8][9][10]

### TYPE OF SYRUP

There are many types of syrups, each suited for different uses. Here are some common ones

#### 1.Sweet Syrups

- Maple Syrup: Made from the sap of maple trees, commonly used on pancakes and waffles.
- Honey Syrup: A mixture of honey and water, used in cocktails and desserts.
- Corn Syrup: Derived from corn, used in candies, baked goods, and sauces.
- Simple Syrup: Made by dissolving sugar in water, a staple in cocktails and beverages.
- Golden Syrup: A thick, amber-colored syrup made from sugarcane or sugar beet juice.
- Agave Syrup: Extracted from agave plants, popular as a natural sweetener.

#### 2.Flavored Syrups

- Chocolate Syrup: Made with cocoa, sugar, and water, used in desserts and beverages.
- Caramel Syrup: A sweet, buttery syrup made by caramelizing sugar, used in coffee and desserts.

- Fruit Syrups: Includes raspberry, strawberry, or blueberry syrups made from fruit juice and sugar.

#### 3.Medicinal Syrups

- Cough Syrup: Medicated syrups to relieve cough and throat irritation.
- Herbal Syrup: Made from herbal extracts, often used as natural remedies.

#### 4.Cooking Syrups

- Molasses: A byproduct of sugar production, used in baking and savory dishes.
- Date Syrup: Made from dates, used as a natural sweetener in Middle Eastern cuisine.

#### 5.Specialty Syrups

- Grenadine: A non-alcoholic syrup made from pomegranate juice, used in cocktails.
- Barley Malt Syrup: A sweetener derived from sprouted barley grains, used in baking[11][12][13][14]

### MATERIAL AND METHODS:

The material and methods section for producing herbal cough syrup involves detailing the ingredients used, their sources, preparation processes, and formulation techniques. Here's a structured explanation[15]

#### Collection of plant material

The collection of plant material for herbal cough syrup is a critical process that involves the careful selection, harvesting, and handling of medicinal plants to ensure the efficacy and safety of the final product. Plants must be correctly identified and authenticated using botanical references or expert consultation to avoid misidentification, which could lead to ineffective or harmful products. The timing of collection is crucial, with different plant parts being harvested during their peak concentration of bioactive compounds, such as roots during dormancy, leaves before flowering, and flowers at full bloom. Harvesting is conducted in clean, pollution-free environments, away from industrial areas or contaminated sites, to prevent exposure to harmful substances like heavy metals or toxins. Sustainable and ethical practices are followed, ensuring minimal environmental impact and allowing plants to regenerate. Only mature, healthy plant parts are collected using clean tools to avoid contamination. Immediately after harvesting, plant materials are washed to remove dirt and debris, sorted to discard any damaged or spoiled parts, and dried under shaded, well-ventilated conditions to preserve volatile compounds and active ingredients. Proper storage in airtight containers protects the materials from moisture, light, and pests, maintaining their

potency until use. Quality control measures, including tests for bioactive compounds and microbial purity, are conducted to ensure that the plant material meets the required standards for therapeutic use. This process forms the foundation for preparing an effective, safe, and high-quality herbal cough syrup.[16][17]

### Preparation of extraction

Here are the steps for preparing sugar syrup by extraction

#### A) Material need preparation

- Raw materials (sugarcane, fruits, or jaggery sources)
- Crushing/extraction tools (press or grinder)
- Filtration setup (sieve or muslin cloth)
- Cooking vessel and heat source

#### B) Procedure

- Collection of Raw Materials
- Washing
- Crushing or Extraction
- Filtration
- Boiling the Extracted Juice
- Removing Impurities
- Concentration
- Cooling
- Storage[18][19][20][21]

### FORMULATION OF COUGH SYRUP

Cough syrups are liquid oral preparations formulated to relieve symptoms of cough. The formulation involves a combination of active pharmaceutical ingredients (APIs), excipients, and additives that work together to provide therapeutic benefits, ensure stability, and improve patient compliance.

The formulation of cough syrup is a delicate balance of science and art. It requires the integration of pharmaceutical knowledge to ensure the product is effective, safe, and palatable. Proper selection of ingredients and rigorous quality control are essential to create a cough syrup that meets therapeutic and patient compliance standards.[22]

### Ingredients

1.Active Ingredients (based on the type of cough being treated):

- For Dry Cough: Dextromethorphan, Diphenhydramine, or Pholcodine.
- For Productive Cough: Guaifenesin, Bromhexine, or Ambroxol.

2.Sweeteners:

- Sucrose, Sorbitol, or artificial sweeteners like aspartame (for diabetic-friendly formulations).

3.Thickening Agents:

- Xanthan gum, Carboxymethylcellulose (CMC), or other suitable viscosity agents.

4.Preservatives:

- Sodium benzoate, Methylparaben, or Propylparaben.

5.Flavors and Coloring Agents:

- Natural or artificial flavorings (e.g., menthol, cherry, or honey flavor).
- FDA-approved food coloring.

6.Solvent/Base:

- Purified water, sometimes mixed with ethanol or propylene glycol for solubility.

7.Other Additives:

- Citric acid (as a pH adjuster)
- Glycerin (for texture and moisture retention)[23][24]

### Procedure of evolution

1.Preparation of Base Solution

- Heat purified water to around 60°C to sterilize.
- Dissolve sweeteners (e.g., sucrose or sorbitol) in the water to prepare a concentrated syrup base.
- Stir continuously to ensure uniform dissolution.

2.Incorporation of Active Ingredients

- Dissolve the active pharmaceutical ingredients (APIs) in a small portion of the base or an appropriate solvent (like ethanol or propylene glycol).
- Add the dissolved active ingredients to the syrup base while stirring gently.

3. Addition of Preservatives and Stabilizers

- Add preservatives (e.g., sodium benzoate) and stabilizers (like citric acid) to maintain the formulation's stability and pH.

4.Incorporation of Viscosity Agents

- Slowly add thickening agents (like xanthan gum) while stirring to avoid clumping.

5.Flavoring and Coloring

- Add flavoring agents (e.g., menthol or honey flavor) and coloring agents (as needed).
- Ensure these are compatible with the other ingredients.

6.Final Adjustment and Filtration

- Check the pH of the solution (ideal pH: 4.5–6.5) and adjust with citric acid or sodium hydroxide if necessary.

- Filter the syrup through a fine mesh or muslin cloth to remove undissolved particles.

#### 7. Packaging

- Fill the prepared syrup into sterilized amber or dark-colored bottles to protect it from light.
- Seal the bottles tightly to prevent contamination.[25][26][27]

### EVALUATION OF COUGH SYRUP

The evaluation of cough syrup is a critical process to ensure its quality, safety, efficacy, and patient compliance. It involves a series of physical, chemical, microbiological, and pharmacological assessments to meet regulatory standards and consumer expectations.

#### Objectives of evaluation

1. To verify the physical, chemical, and biological stability of the product.
2. To ensure the active pharmaceutical ingredient (API) concentration meets specified limits.
3. To confirm that the formulation is free from contamination and is safe for use.
4. To assess the product's organoleptic properties (taste, color, and odor) for patient acceptability.[28]

#### Parameters for Evaluation

- A) Physical Evaluation:
  1. Appearance
  2. Viscosity
  3. pH Measurement
  4. Density and Specific Gravity
  5. Taste and Odor
  6. Color
- B) Chemical Evaluation:
  1. Assay of Active Ingredients
  2. Stability Testing
  3. Content Uniformity
  4. Preservative Content
- C) Microbiological Evaluation
  1. Sterility and Microbial Contamination Testing
  2. Preservative Efficacy Testing (PET)
- D) Pharmacological Evaluation
  1. Bioavailability Studies
  2. Efficacy Studies
  3. Safety Studies
- E) Packaging and Labeling Evolution
  1. Container Quality
  2. Volume Check
  3. Labeling Compliance[29][30]

### QUALITY CONTROL OF COUGH SYRUP

Quality control (QC) of cough syrup is a systematic process to ensure the product meets predetermined

standards for safety, efficacy, stability, and compliance with regulatory requirements. This involves evaluating various physical, chemical, microbiological, and pharmacological parameters throughout production and prior to market release. The physical assessment includes verifying the appearance, viscosity, color, and taste to ensure consistency and consumer acceptability. The syrup must be free from particulate matter, precipitation, or turbidity, with a pH maintained within the optimal range (4.5–6.5) to ensure stability and compatibility with active pharmaceutical ingredients (APIs). Chemical analysis focuses on the accurate quantification of APIs, ensuring their concentrations align with the labeled claim through techniques like high-performance liquid chromatography (HPLC) or spectrophotometry.

Preservative content, essential for microbial safety, is evaluated to confirm effectiveness without exceeding toxic levels. Microbiological testing, including sterility and total viable count (TVC) assessments, ensures the product is free from bacterial, fungal, or pathogenic contamination. Furthermore, preservative efficacy testing (PET) verifies the formulation's ability to inhibit microbial growth throughout its shelf life. Stability studies are conducted under varying environmental conditions to evaluate the product's resistance to degradation, while pharmacological studies confirm bioavailability and therapeutic efficacy. Packaging quality is also critical, as containers must be non-reactive, protect against environmental factors, and accurately label dosage, storage, and warning information.

Adherence to Good Manufacturing Practices (GMP) and compliance with pharmacopeial standards (e.g., USP, BP, IP) are fundamental in ensuring the reliability of the quality control process. By implementing these rigorous checks, the manufacturer guarantees a cough syrup that is safe, effective, and meets consumer expectations while aligning with regulatory standards.[31]

### QUALITY ASSURANCE OF COUGH SYRUP

Quality assurance of cough syrup involves a comprehensive set of practices to ensure the safety, efficacy, and quality of the product throughout its development, manufacturing, and distribution. The process begins with sourcing high-quality raw materials, including active pharmaceutical ingredients (APIs) and excipients, which must meet predefined standards and regulatory requirements. During formulation development, rigorous testing is conducted to optimize the syrup's stability, flavor, and therapeutic effectiveness.

Good Manufacturing Practices (GMP) are followed during production, ensuring proper equipment calibration, contamination prevention, and adherence to standardized operating procedures. Analytical testing, such as High-Performance Liquid Chromatography (HPLC), is performed to confirm the active ingredient's concentration and identify any impurities. Microbial testing ensures the syrup is free from harmful bacteria, molds, or other pathogens. Batch-to-batch consistency is verified through uniformity and stability tests, ensuring the product remains effective over its shelf life under varying storage conditions. Packaging is also scrutinized to ensure it protects the syrup from contamination, degradation, and leakage, while providing clear labeling with dosage instructions and safety warnings.

Additionally, post-marketing surveillance is carried out to monitor adverse reactions and ensure continued compliance with regulatory standards. By maintaining a robust quality assurance system, manufacturers can deliver cough syrups that meet stringent safety and therapeutic standards, thereby safeguarding consumer health and trust.[32]

## ADVANCEMENTS OF HERBAL COUGH SYRUP

Advancements in herbal cough syrup production have significantly enhanced their safety, efficacy, and acceptance in both traditional and modern medicine. Improved extraction techniques, such as supercritical fluid extraction and ultrasonic-assisted extraction, now allow for the isolation of highly concentrated and pure bioactive compounds from medicinal plants, ensuring greater therapeutic potency.

The incorporation of nanotechnology has further enabled the development of nano-formulations, enhancing the bioavailability and absorption of herbal constituents. Standardization processes have also evolved, ensuring uniformity in the active ingredients across batches, which was historically a challenge in herbal medicine.

Here's an overview of the advancements in herbal cough syrups, focusing on their formulation, efficacy, and market trends:

### 1.Enhanced Formulations

- **Standardization of Active Ingredients:** Modern herbal cough syrups are standardized to ensure consistent levels of active compounds like alkaloids, flavonoids, and saponins, improving efficacy and safety.

- **Combination with Modern Science:** Integration of traditional herbs with modern pharmaceutical techniques has led to optimized formulations for better absorption and action.
- **Multi-Herb Synergy:** Combining herbs with complementary effects (e.g., licorice for soothing, tulsi for immunity, and ginger for expectoration) enhances the overall effectiveness.

### 2.Improved Delivery Systems

- **Liquid Extracts and Syrups:** Advanced extraction techniques (like supercritical CO<sub>2</sub> extraction) retain more potent bioactive compounds.
- **Nano-Formulations:** Nano-encapsulation improves the bioavailability of herbal components, ensuring better relief with smaller doses.
- **Sugar-Free and Alcohol-Free Options:** Catering to specific consumer needs like diabetics and children.

### 3.Evidence-Based Efficacy

- **Clinical Trials:** Many herbal syrups are now backed by scientific studies, showing their effectiveness in reducing symptoms like coughing, throat irritation, and congestion.
- **Pharmacological Insights:** Better understanding of the mechanisms of action of herbal ingredients, such as mucolytic and anti-inflammatory properties.

### 4.Customization for Target Groups

- **Pediatric Formulations:** Gentle, child-friendly syrups with reduced bitterness and safe dosages.
- **Allergy-Friendly Options:** Products tailored for individuals with allergies to synthetic compounds.

### 5.Focus on Sustainability

- **Organic Sourcing:** Many brands now emphasize using organically grown herbs to ensure purity and eco-friendliness.
- **Eco-Friendly Packaging:** Advances in biodegradable and recyclable packaging align with sustainability goals.

### 6.Global Acceptance and Expansion

- **Regulatory Approvals:** Herbal cough syrups increasingly meet international regulatory standards (e.g., FDA, EMA), enhancing trust and marketability.
- **Ayurvedic and Traditional Medicine Integration:** Growing global interest in Ayurveda and traditional Chinese medicine boosts herbal syrup development.

### 7.Technology Integration

- AI and Machine Learning: Used in R&D to analyze historical data on herbal efficacy and optimize formulations.
- Blockchain for Authenticity: Ensures the traceability of raw materials, promoting transparency.

### 8.Holistic Benefits

- Beyond treating coughs, herbal syrups often offer additional benefits like boosting immunity, reducing inflammation, and promoting respiratory health.[33]

### USES OF COUGH SYRUP

Cough syrups are medicinal formulations designed to alleviate symptoms associated with coughing and other respiratory issues. They are widely used for various purposes based on the type and composition. Here's an overview of the primary uses:

#### 1.Soothing Throat Irritation

- Many syrups contain demulcents (e.g., glycerin, honey, or marshmallow root) that coat the throat lining, reducing irritation and discomfort.

#### 2.Reducing Inflammation

- Anti-inflammatory ingredients, often derived from herbs like turmeric, ginger, or tulsi, help reduce swelling in the respiratory tract.

#### 3.Combating Respiratory Infections

- Herbal cough syrups with ingredients like thyme, tulsi, and licorice may possess antimicrobial properties, helping to fight bacterial or viral infections causing the cough.

#### 4.Relieving Congestion

- Decongestant syrups often include ingredients like pseudoephedrine or menthol, which help reduce nasal and chest congestion.

#### 5.Allergy Management

- Some cough syrups contain antihistamines like diphenhydramine or promethazine, which help manage coughs caused by allergic reactions.

#### 6.Enhancing Sleep

- Night-time formulations often include sedative ingredients like diphenhydramine or valerian root to help the patient sleep despite coughing.

#### 7.Supporting Overall Respiratory Health

- Herbal syrups often provide additional benefits, such as strengthening the immune system or improving lung function, especially in chronic conditions.[34]

### PRECAUTIONS AND CONSIDERATION OF COUGH SYRUP

- Always choose the correct type of cough syrup (antitussive, expectorant, or combination) based on the nature of the cough.
- Avoid overuse or misuse, as some syrups may cause drowsiness or other side effects.
- Not all syrups are suitable for children, pregnant women, or individuals with certain medical conditions.[35]

### CONCLUSION:

The formulation and evaluation of herbal cough syrup have demonstrated its potential as an effective, natural remedy for managing cough and related respiratory symptoms. By incorporating well-researched medicinal herbs with known pharmacological properties, these syrups offer multiple therapeutic benefits such as cough suppression, expectoration, soothing throat irritation, and boosting overall respiratory health.

The following conclusions can be drawn:

- 1.Safety and Efficacy: Herbal cough syrups, when formulated with standardized extracts, provide a safe and effective alternative to synthetic syrups, with fewer side effects.
- 2.Natural Ingredients: Active compounds from herbs like licorice, ginger, tulsi, and honey offer synergistic effects, enhancing the syrup's ability to alleviate various types of coughs.
- 3.Sustainability: Using naturally sourced ingredients makes herbal syrups eco-friendly, catering to the growing demand for sustainable and organic healthcare solutions.
- 4.Patient Compliance: Pleasant flavors, reduced bitterness, and the availability of sugar-free formulations improve patient acceptability, especially among children and those with dietary restrictions.
- 5.Pharmaceutical Advancements: Modern extraction techniques and improved delivery systems have optimized the bioavailability and potency of herbal ingredients, ensuring better therapeutic outcomes.
- 6.Market Potential: The global trend towards natural and holistic remedies indicates a promising future for herbal cough syrups, with opportunities for further innovation in formulation and clinical validation.

In conclusion, herbal cough syrups represent a significant advancement in respiratory care, combining traditional knowledge with modern pharmaceutical techniques. Continuous research and rigorous clinical evaluations will further validate their efficacy and expand their acceptance in mainstream medicine.

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