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Formulation of Herbal Cough Syrup and Stability Testing

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Abstract: *Herbal formulations have gained considerable attention in modern pharmaceutical research due to their therapeutic efficacy, reduced side effects, and better patient compliance. Cough is one of the most common symptoms associated with respiratory tract infections and inflammatory conditions. Herbal cough syrups are widely used because of their expectorant, antitussive, demulcent, antimicrobial, and soothing activities. The present study focuses on the formulation and evaluation of herbal cough syrup using selected medicinal plant extracts with proven therapeutic activity against cough and related respiratory disorders.*

The herbal cough syrup was formulated using extracts of Tulsi (Ocimum sanctum), Vasaka (Adhatoda vasica), Ginger (Zingiber officinale), Mulethi (Glycyrrhiza glabra), and Peppermint oil. Different formulations were prepared using suitable sweetening agents, preservatives, flavoring agents, and viscosity enhancers. The prepared formulations were evaluated for various physicochemical parameters including appearance, color, odor, taste, pH, viscosity, density, specific gravity, and microbial load.

Stability studies were carried out according to ICH guidelines under accelerated and room temperature conditions. Parameters such as pH, color, odor, microbial growth, and viscosity were monitored over a specified period. The formulated herbal syrup showed satisfactory stability, acceptable physicochemical properties, and good patient acceptability.

The study concludes that herbal cough syrup can be successfully formulated using natural ingredients with good stability and therapeutic potential. The formulation may serve as a safer alternative to synthetic cough preparations.

Keywords: Herbal cough syrup, Stability testing, Tulsi, Vasaka, Ginger, Antitussive activity, Herbal formulation, ICH guidelines

I. INTRODUCTION

1.1 Introduction to Herbal Medicines

Herbal medicines are medicinal preparations derived from plants and plant extracts that are used for the prevention and treatment of diseases. Since ancient times, medicinal plants have played a significant role in healthcare systems worldwide. Traditional systems such as Ayurveda, Siddha, Unani, and Traditional Chinese Medicine rely extensively on herbal remedies for maintaining health and treating various ailments.

In recent years, there has been growing interest in herbal formulations because of their natural origin, therapeutic efficacy, lower incidence of side effects, and better patient acceptability. Herbal products are now widely used in both developed and developing countries. According to the World Health Organization (WHO), a major portion of the global population depends on herbal medicines for primary healthcare. Herbal formulations are available in various dosage forms including powders, tablets, capsules, syrups, tinctures, ointments, and extracts.

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1.2 Respiratory Disorders and Cough

Respiratory tract disorders are among the most common health problems affecting people of all age groups. These disorders include common cold, bronchitis, asthma, pharyngitis, pneumonia, tuberculosis, and allergic conditions. Cough is one of the major symptoms associated with respiratory tract diseases.

Cough is a sudden expulsive reflex mechanism that helps in clearing mucus, irritants, microorganisms, and foreign particles from the respiratory tract. It acts as a protective mechanism to maintain airway patency and prevent respiratory obstruction.

1.3 Physiology of Cough

The cough reflex is initiated by stimulation of sensory receptors present in the respiratory tract. These receptors are activated by irritants such as dust, smoke, allergens, mucus, and microbial agents.

The cough reflex pathway consists of three components:

1. Afferent pathway
2. Central cough center
3. Efferent pathway

The afferent impulses travel through the vagus nerve to the cough center located in the medulla oblongata. The efferent signals are then transmitted to respiratory muscles, resulting in forceful expulsion of air from the lungs.

The process of coughing occurs in three phases:

1. Inspiratory Phase

Deep inhalation of air occurs.

2. Compression Phase

Closure of glottis and contraction of respiratory muscles increase intrathoracic pressure.

3. Expiratory Phase

Sudden opening of glottis causes rapid expulsion of air along with mucus and irritants.

1.4 Classification of Cough

Cough may be classified based on duration and nature.

Based on Duration

1. Acute Cough

Lasts for less than three weeks and commonly caused by viral infections.

2. Subacute Cough

Persists for three to eight weeks.

3. Chronic Cough

Continues for more than eight weeks and may be associated with asthma, smoking, or chronic respiratory diseases.

1.5 Causes of Cough

Cough may occur due to several pathological and environmental factors.

Infectious Causes

- Viral infections
- Bacterial infections
- Tuberculosis
- Influenza

Non-Infectious Causes

- Allergy
- Asthma
- Smoking

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- Air pollution
- Gastroesophageal reflux disease
- Dust exposure

Drug-Induced Causes

Certain drugs such as ACE inhibitors may produce persistent cough as a side effect.

1.6 Conventional Treatment of Cough

Conventional cough therapy includes the use of:

- Antitussives
- Expectorants
- Mucolytics
- Bronchodilators
- Antihistamines
- Antibiotics

Although synthetic cough medications are effective, they may produce side effects such as:

- Drowsiness
- Constipation
- Nausea
- Dependency
- Dry mouth
- Sedation

Due to these adverse effects, there is increasing demand for safer herbal alternatives.

1.7 Herbal Cough Syrup

Herbal cough syrups are liquid oral formulations prepared using medicinal plant extracts having antitussive, expectorant, demulcent, antimicrobial, and bronchodilator properties. These formulations are widely accepted because they provide symptomatic relief while minimizing adverse effects. Herbal syrups are especially beneficial for pediatric and geriatric patients because of their pleasant taste and ease of administration.

The therapeutic activity of herbal cough syrup mainly depends upon the phytoconstituents present in medicinal plants such as alkaloids, flavonoids, glycosides, tannins, saponins, and essential oils.

1.8 Advantages of Herbal Cough Syrups

Herbal cough syrups offer several advantages over synthetic formulations.

1. **Natural Origin**

Prepared from medicinal plants and natural ingredients.

2. **Reduced Side Effects**

Generally safer with minimal adverse reactions.

3. **Better Patient Compliance**

Pleasant taste and soothing effect improve acceptability.

4. **Multifunctional Activity**

Possess antimicrobial, anti-inflammatory, antioxidant, and expectorant actions simultaneously.

5. **Economical**

Cost-effective and easily accessible.

6. **Suitable for Long-Term Use**

Can be used safely for prolonged duration under proper guidance.

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1.9 Limitations of Herbal Formulations

Despite their advantages, herbal formulations also have certain limitations.

- Lack of standardization
- Variability in phytochemical content
- Stability problems

Therefore, scientific formulation and evaluation are necessary to ensure safety, efficacy, and stability.

1.10 Medicinal Plants Used in Herbal Cough Syrup

1. Tulsi (Ocimum sanctum)

Tulsi is widely used in Ayurveda for respiratory disorders. It possesses antimicrobial, anti- inflammatory, and immunomodulatory activities.

Therapeutic Uses

- Relief from cough and cold
- Bronchitis management
- Respiratory protection

2. Vasaka (Adhatoda vasica)

Vasaka contains alkaloids such as vasicine which exhibit expectorant and bronchodilator activities.

Therapeutic Uses

- Liquefaction of mucus
- Relief from productive cough
- Bronchodilation

3. Ginger (Zingiber officinale)

Ginger possesses anti-inflammatory and antioxidant properties.

Therapeutic Uses

- Relief from throat irritation
- Reduction of inflammation
- Antimicrobial action

4. Mulethi (Glycyrrhiza glabra)

Mulethi acts as a demulcent and soothing agent.

Therapeutic Uses

- Soothing irritated throat
- Reduction of dry cough
- Expectorant activity

5. Peppermint Oil

Peppermint oil provides cooling sensation and acts as a mild decongestant.

Therapeutic Uses

- Relief from nasal congestion
- Refreshing flavor
- Soothing effect

Stability Testing of Herbal Formulations

Stability testing is an important part of pharmaceutical product development. It helps determine the shelf life, storage conditions, and packaging requirements of formulations.

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1.11 Syrup as a Pharmaceutical Dosage Form

A syrup is a concentrated aqueous preparation containing sugar or sugar substitutes with or without medicinal substances.

Advantages of Syrups

- Easy administration
- Improved palatability
- Rapid absorption
- Suitable for children and elderly patients
- Masking of unpleasant taste

Disadvantages of Syrups

- Chances of microbial growth
- Stability issues
- Need for preservatives

II. REVIEW OF LITERATURE

2.1 Herbal medicines

Herbal medicines have been extensively used for the treatment of respiratory disorders since ancient times. Several medicinal plants possess antitussive, expectorant, bronchodilator, antimicrobial, anti-inflammatory, and soothing properties that are beneficial in cough management. In recent years, scientific studies have validated the therapeutic efficacy of herbal formulations and encouraged the development of standardized herbal cough syrups.

The present chapter reviews previous research work related to herbal cough formulations, medicinal plant extracts, syrup formulations, and stability studies.

2.2 Review of Research Work on Herbal Cough Preparations

Study 1

Kokate C. K. reported that herbal medicines containing Tulsi, Vasaka, and Licorice are effective in respiratory tract disorders due to their expectorant and anti-inflammatory properties. The study emphasized the importance of phytoconstituents such as alkaloids, flavonoids, and glycosides in cough suppression.

Study 2

Mukherjee P. K. studied the role of herbal formulations in modern drug delivery systems and concluded that herbal syrups provide better patient compliance and therapeutic efficacy with reduced side effects compared to synthetic formulations.

2.3 Review of Medicinal Plants Used in Herbal Cough Syrup

2.3.1 Tulsi (Ocimum sanctum)

Tulsi is one of the most important medicinal plants used in Ayurveda. It contains several bioactive compounds including eugenol, ursolic acid, flavonoids, and essential oils.

Pharmacological Activities

- Antimicrobial activity
- Antitussive activity
- Anti-inflammatory activity
- Immunomodulatory activity
- Antioxidant activity

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Role in Cough Management

Tulsi helps relieve cough by reducing respiratory tract inflammation, enhancing immunity, and inhibiting microbial growth.

2.3.2 Vasaka (Adhatoda vasica)

Vasaka is widely used in traditional medicine for bronchial and respiratory disorders.

Active Constituents

- Vasicine
- Vasicinone
- Essential oils

Pharmacological Activities

- Expectorant
- Bronchodilator
- Mucolytic
- Antimicrobial

Role in Cough Management

Vasaka helps in removal of mucus from respiratory passages and facilitates easier breathing.

2.3.3 Ginger (Zingiber officinale)

Ginger is commonly used as a medicinal and culinary herb.

Active Constituents

- Gingerols
- Shogaols
- Zingerone

Pharmacological Activities

Anti-inflammatory

- Antioxidant
- Antimicrobial
- Analgesic

Role in Cough Management

Ginger reduces throat irritation and suppresses inflammation associated with respiratory infections.

2.3.4 Mulethi (Glycyrrhiza glabra)

Mulethi is widely used as a demulcent and soothing agent in respiratory disorders.

Active Constituents

- Glycyrrhizin
- Flavonoids
- Saponins

Pharmacological Activities

- Expectorant
- Demulcent
- Anti-inflammatory
- Antiviral

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Role in Cough Management
Mulethi forms a protective layer over irritated mucous membranes and provides relief from dry cough.

2.3.5 Peppermint Oil
Peppermint oil is obtained from Mentha piperita.
Active Constituents
- Menthol
- Menthone

Pharmacological Activities
- Cooling effect
- Mild decongestant action
- Antimicrobial activity

Role in Cough Management
Peppermint oil relieves nasal congestion and provides soothing sensation.

2.4 Research Gap
Although many herbal cough formulations are available in the market, several limitations still exist:
- Lack of standardization
- Limited scientific validation
- Inadequate stability data
- Variation in herbal constituents
- Limited quality control studies

Therefore, the present study focuses on the formulation and scientific evaluation of herbal cough syrup with stability testing according to ICH guidelines.

III. AIM AND OBJECTIVES

3.1 Aim of the Study
To formulate and evaluate a stable herbal cough syrup using selected medicinal plant extracts possessing antitussive, expectorant, antimicrobial, and soothing activities, and to perform stability studies according to ICH guidelines.

3.3 Objectives of the Study
The major objectives of the present research work are as follows:
Primary Objectives
- To Select Suitable Medicinal Plants
- To prepare suitable herbal extracts from selected medicinal plants using appropriate extraction methods such as Soxhlet extraction or maceration.
- To formulate herbal cough syrup using herbal extracts along with suitable pharmaceutical excipients.
- To Optimize the Formulation
- To Evaluate Organoleptic Properties of the prepared herbal syrup formulations.
- To Determine Physicochemical Parameters
- To determine microbial load and ensure microbial safety of the prepared herbal syrup.
- To Study Compatibility of Ingredients
- To ensure compatibility between herbal extracts and excipients used in the formulation.

To carry out stability studies according to ICH guidelines.

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3.3 Expected Outcome of the Study

The expected outcomes of the present research work include:

- Successful formulation of herbal cough syrup
- Acceptable organoleptic properties
- Good physicochemical stability
- Effective microbial safety
- Improved patient compliance
- Stable formulation under accelerated conditions
- Potential use as an alternative to synthetic cough preparations

3.4 Plan of Work

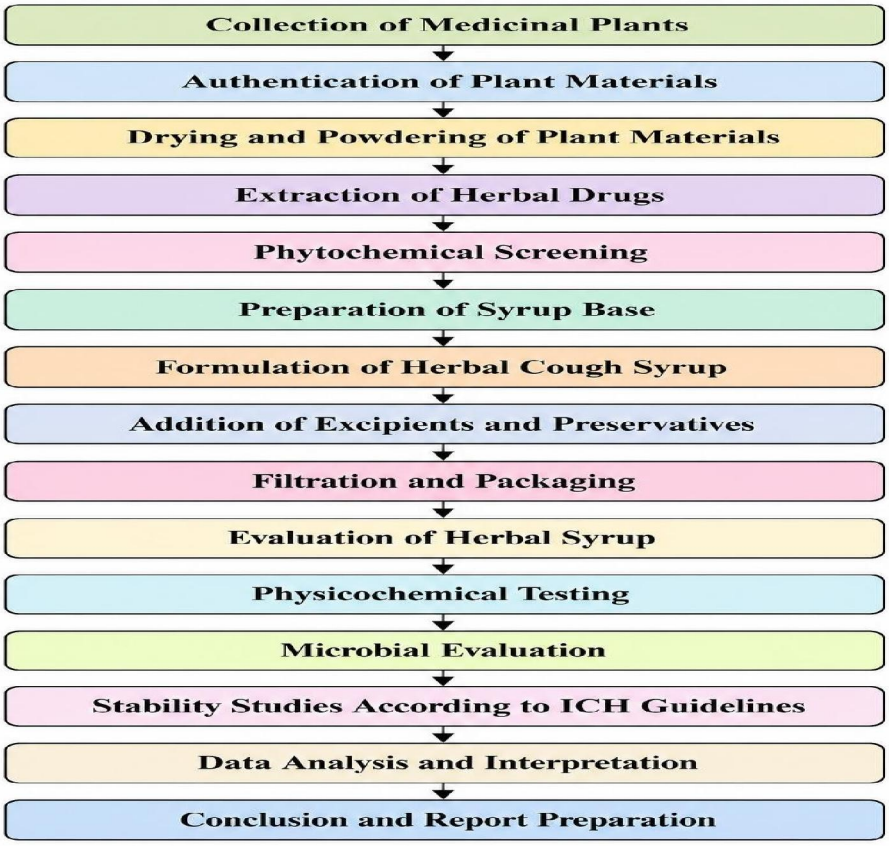

Fig. 1: Plan of Work

IV. DRUG AND EXCIPIENT PROFILE

The selection of suitable herbal drugs and pharmaceutical excipients is an important step in the formulation of herbal cough syrup. Herbal ingredients provide therapeutic activity, while excipients improve stability, palatability, viscosity, preservation, and overall quality of the formulation. The present formulation contains medicinal plant extracts such as Tulsi, Vasaka, Ginger, Mulethi, and Peppermint oil due to their proven effectiveness in respiratory disorders. Various pharmaceutical excipients including sucrose, sodium benzoate, glycerin, and citric acid were also used to prepare a stable and acceptable syrup formulation.

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4.1 Profile of Herbal Drugs

4.1.1Tulsi

Biological Source: Tulsi consists of dried leaves of Ocimum sanctum Linn.

Family: Lamiaceae

Common Names: Holy Basil, Tulasi

Chemical Constituents:

- Eugenol
- Ursolic acid
- Rosmarinic acid
- Flavonoids
- Essential oils

Fig. 2: Tulsi (Ocimum sanctum)

Pharmacological Activities

- Antimicrobial
- Anti-inflammatory
- Antioxidant
- Immunomodulatory
- Antitussive

Therapeutic Uses

- Cough
- Cold
- Bronchitis
- Asthma
- Fever

Mechanism of Action

Tulsi helps reduce respiratory tract inflammation and inhibits microbial growth responsible for respiratory infections.

Advantages in Cough Syrup

- Soothing effect on throat
- Enhances immunity
- Reduces cough frequency

4.2.2 Vasaka

Biological Source: Vasaka consists of dried leaves of Adhatoda vasica Nees. Family: Acanthaceae

Common Names: Malabar Nut, Adulsa Pharmacological Activities

- Expectorant
- Bronchodilator
- Mucolytic
- Antimicrobial

Fig. 2: Vasaka (Adhatoda vasic

Therapeutic Uses

- Productive cough
- Bronchitis
- Asthma
- Respiratory congestion

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Mechanism of Action
Vasicine present in Vasaka helps liquefy mucus and facilitates easy expulsion from respiratory passages.

4.2.3 Ginger

Biological Source: Ginger consists of dried rhizomes of Zingiber officinale Roscoe.
Family: Zingiberaceae
Common Names: Ginger, Adrak Pharmacological Activities

- Anti-inflammatory
- Antioxidant
- Antimicrobial
- Analgesic

Fig. 4: Ginger (Zingiber officinale)

Therapeutic Uses

- Sore throat
- Cough
- Cold
- Nausea

Mechanism of Action
Ginger reduces inflammation in respiratory tissues and provides soothing effect to irritated throat.

4.2.4 Mulethi

Biological Source: Mulethi consists of dried roots of Glycyrrhiza glabra Linn.
Family: Fabaceae
Common Names: Licorice, Yashtimadhu
Pharmacological Activities

- Demulcent
- Expectorant
- Anti-inflammatory
- Antiviral

Fig. 5: Mulethi (Glycyrrhiza glabra)

Therapeutic Uses

- Dry cough
- Throat irritation
- Bronchitis
- Gastric irritation

Mechanism of Action
Mulethi forms a protective layer over mucous membranes and reduces irritation.

4.2.5 Peppermint Oil

Biological Source: Peppermint oil is obtained from the leaves of Mentha piperita.
Family: Lamiaceae
Pharmacological Activities

- Cooling effect
- Mild decongestant
- Antimicrobial activity

Fig. 6: Peppermint

Therapeutic Uses

- Nasal congestion
- Cold
- Cough

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Headache Mechanism of Action
Menthol produces cooling sensation and relieves respiratory congestion. Storage
Store in tightly closed container away from light.

4.3 Role of Combined Herbal Ingredients in Cough Management

The combination of selected medicinal plants provides synergistic therapeutic action.

Herbal Ingredient	Therapeutic Role
Tulsi	Antimicrobial and immunomodulatory
Vasaka	Expectorant and bronchodilator
Ginger	Anti-inflammatory
Mulethi	Demulcent and soothing
Peppermint oil	Cooling and decongestant

The polyherbal combination helps provide:

- Relief from cough
- Reduction in throat irritation
- Improved mucus clearance
- Better respiratory comfort

V. MATERIALS AND METHODS

Materials and methods play a crucial role in the successful development of pharmaceutical formulations. Proper selection of raw materials, extraction procedures, formulation techniques, and evaluation methods ensures the quality, safety, efficacy, and stability of the final product.

The present study involved the preparation of herbal cough syrup using selected medicinal plant extracts possessing antitussive, expectorant, anti-inflammatory, antimicrobial, and soothing activities. The prepared formulations were evaluated for various physicochemical and microbiological parameters followed by stability studies according to ICH guidelines.

5.1 Materials Required

5.2.1 Herbal Ingredients

Sr. No.	Herbal Drug	Biological Name	Part Used
1	Tulsi	Ocimum sanctum	Leaves
2	Vasaka	Adhatoda vasica	Leaves
3	Ginger	Zingiber officinale	Rhizome
4	Mulethi	Glycyrrhiza glabra	Root
5	Peppermint oil	Mentha piperita	Oil

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5.2.2 Pharmaceutical Excipients

Sr. No.	Excipient	Category
1	Sucrose	Sweetening agent
2	Sodium benzoate	Preservative
3	Glycerin	Humectant and viscosity enhancer
4	Citric acid	pH adjusting agent
5	Purified water	Vehicle

5.3 Equipment Required

Sr. No.	Equipment
1	Soxhlet apparatus
2	Analytical balance
3	Mechanical grinder
4	Hot air oven
5	Water bath
6	Brookfield viscometer
7	Digital pH meter
8	Magnetic stirrer
9	Stability chamber
10	Measuring cylinders
11	Beakers and glassware
12	Filtration apparatus

5.4 Collection and Authentication of Plant Materials

The medicinal plants used in the study were collected from local herbal suppliers and authenticated by a qualified botanist/pharmacognosist.

Importance of Authentication

- Ensures purity of crude drugs
- Prevents adulteration
- Maintains reproducibility of results
- Confirms identity of medicinal plants

The authenticated plant materials were stored in clean and dry conditions before further processing.

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5.5 Preparation of Plant Materials

5.5.1 Cleaning

The collected plant materials were washed thoroughly with water to remove:

- Dirt
- Dust
- Foreign particles

5.5.2 Drying

The cleaned plant materials were shade dried at room temperature for several days.

Advantages of Shade Drying

- Prevents decomposition of phytoconstituents
- Preserves volatile oils
- Reduces microbial contamination

5.5.3 Powdering

The dried plant materials were powdered using mechanical grinder and passed through suitable sieve to obtain uniform particle size.

Advantages of Powdering

- Increases surface area
- Improves extraction efficiency
- Enhances solvent penetration

The powdered materials were stored in airtight containers until use.

5.6 Extraction of Herbal Drugs

5.6.1 Method of Extraction

Soxhlet extraction method was used for extraction of active phytoconstituents from herbal drugs.

5.6.2 Principle of Soxhlet Extraction

Soxhlet extraction works on the principle of continuous extraction using repeated cycles of solvent evaporation and condensation.

The solvent repeatedly passes through crude drug powder and extracts active constituents efficiently.

5.6.3 Procedure for Soxhlet Extraction

Step 1: Weighing of Powder

Accurately weighed powdered plant materials were taken.

Step 2: Loading into Thimble

The powdered material was placed into Soxhlet thimble.

Step 3: Addition of Solvent

Ethanol or hydroalcoholic solvent was added into round bottom flask.

Step 4: Heating

The apparatus was heated using heating mantle.

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Step 5: Continuous Extraction
Continuous extraction was carried out for 6–8 hours.

Step 6: Filtration
The extract was filtered to remove insoluble matter.

Step 7: Concentration
The filtrate was concentrated using water bath.

Step 8: Storage
The concentrated extract was stored in airtight container.

5.6.4 Advantages of Soxhlet Extraction

- Efficient extraction process
- Better yield of active constituents
- Continuous solvent circulation
- Suitable for herbal materials

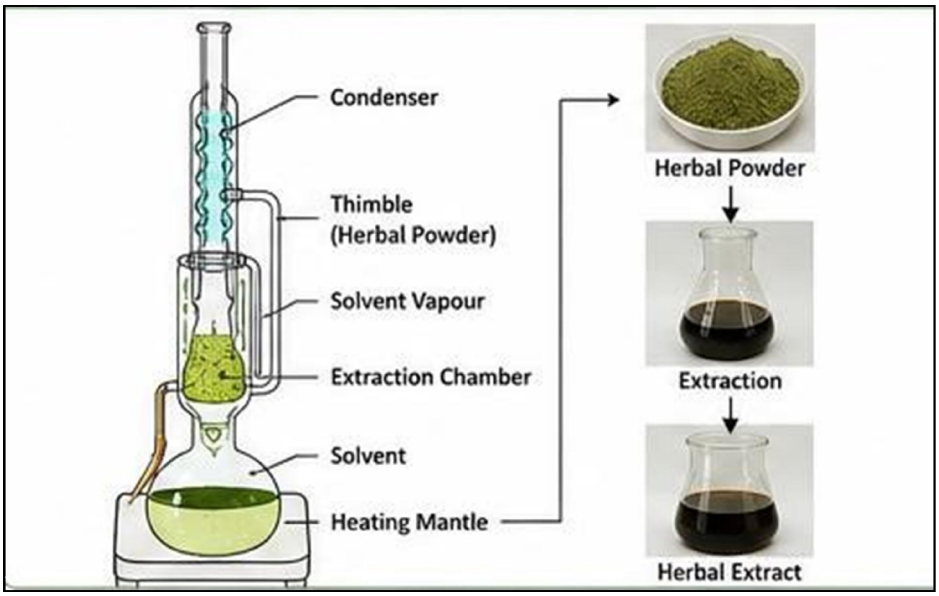

Fig. 7: Extraction Process (Soxhlet Extraction)

5.7 Preliminary Phytochemical Screening

The herbal extracts were subjected to phytochemical screening to identify active constituents.

5.7.1 Tests Performed

Phytoconstituent	Test
Alkaloids	Dragendorff's test
Flavonoids	Shinoda test

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Tannins	Ferric chloride test
Glycosides	Keller-Killiani test
Saponins	Foam test
Phenolic compounds	Ferric chloride test

5.7.2 Importance of Phytochemical Screening

- Confirms presence of active constituents
- Helps in standardization
- Predicts therapeutic activity
- Supports formulation development

5.8 Formulation of Herbal Cough Syrup

5.8.1 Formula for Herbal Cough Syrup

Ingredients	F1	F2	F3
Tulsi extract	2%	3%	4%
Vasaka extract	2%	3%	4%
Ginger extract	1%	2%	3%
Mulethi extract	1%	1.5%	2%
Sucrose	60%	60%	60%
Sodium benzoate	0.2%	0.2%	0.2%
Glycerin	10%	10%	10%
Citric acid	q.s.	q.s.	q.s.
Purified water	q.s.	q.s.	q.s.

5.8.2 Method of Preparation of Herbal Cough Syrup

Step 1: Preparation of Syrup Base

Sucrose was dissolved in purified water with gentle heating to prepare syrup base.

Step 2: Preparation of Preservative Solution

Sodium benzoate was dissolved separately in small quantity of purified water.

Step 3: Addition of Herbal Extracts

Measured quantities of herbal extracts were added slowly into syrup base with continuous stirring.

Precautions

- Uniform mixing maintained
- Avoided overheating
- Prevented lump formation

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Step 4: Addition of Glycerin and Citric Acid
Glycerin and citric acid were added to improve viscosity and adjust pH.

Step 5: Addition of Flavoring Agent
Peppermint oil was added to improve flavor and provide cooling effect.

Step 6: Volume Adjustment
Final volume was adjusted using purified water.

Step 7: Filtration
The prepared syrup was filtered using muslin cloth/filter paper to remove suspended particles.

Step 8: Packaging
The filtered syrup was filled into amber-colored bottles and properly labeled.

5.9 Flowchart of Formulation Process

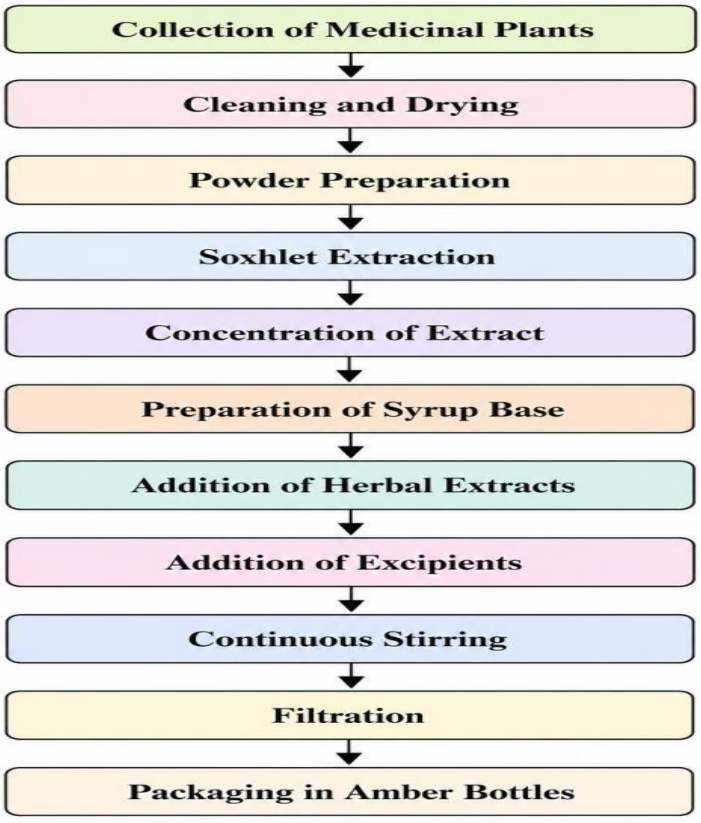

Fig. 8: Flowchart of Formulation Process

5.10 Evaluation of Herbal Cough Syrup
The prepared formulations were evaluated for various parameters.

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5.10.1 Organoleptic Evaluation

The formulations were evaluated for:

- Color
- Odor
- Taste
- Appearance

5.10. 2 Determination of pH

Procedure

The pH of formulation was measured using calibrated digital pH meter.

Importance

- Ensures stability
- Prevents irritation
- Maintains preservative efficacy

5.10.3 Determination of Viscosity

Instrument Used

Brookfield viscometer

Importance

- Determines pourability
- Influences patient acceptability
- Indicates formulation consistency

5.10.4 Determination of Specific Gravity

Specific gravity was determined using pycnometer method.

5.10.5 Determination of Density

Density of syrup was measured using standard procedure.

VI. EVALUATION PARAMETERS

6.1 Evaluation of pharmaceutical formulations

Evaluation of pharmaceutical formulations is an essential step in formulation development to ensure quality, safety, efficacy, stability, and patient acceptability. Herbal formulations require detailed evaluation because herbal ingredients may vary in composition, stability, and physicochemical characteristics.

The prepared herbal cough syrup formulations were evaluated for organoleptic, physicochemical, microbiological, and stability parameters according to standard pharmaceutical procedures. Evaluation studies help in determining the suitability of the formulation for therapeutic use and commercial development.

6.2 Objectives of Evaluation

The main objectives of evaluation were:

- To assess physicochemical quality of formulation
- To determine stability of herbal syrup
- To evaluate microbial safety
- To ensure patient acceptability
- To compare different formulations
- To select optimized formulation

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6.3 Organoleptic Evaluation

Organoleptic evaluation refers to examination of formulation using sensory organs.

Parameters Evaluated

- Color
- Odor
- Taste
- Appearance
- Clarity

6.3.1 Color

Procedure

The color of syrup formulations was observed visually against white background.

Importance

- Indicates formulation uniformity
- Detects degradation during storage
- Influences patient acceptability

Expected Observation

Brownish or dark brown color due to herbal extracts.

6.3.2 Odor Procedure

The odor of syrup was examined by smelling carefully.

Importance

- Indicates freshness of formulation
- Detects spoilage or degradation
- Improves patient compliance

Expected Observation

Pleasant aromatic odor due to peppermint oil and herbal extracts.

6.3.3 Taste

Procedure

A small quantity of syrup was tasted carefully.

Importance

- Determines palatability
- Influences patient acceptability
- Important for pediatric formulations

Expected Observation

Sweet and pleasant taste with mild herbal flavor.

6.3.4 Appearance and Clarity

Procedure

The formulation was visually examined for:

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- Uniformity
- Presence of suspended particles
- Clarity
- Sedimentation

Importance

- Indicates physical stability
- Ensures formulation elegance
- Detects incompatibility

6.4 Physicochemical Evaluation

Physicochemical parameters are important for determining formulation quality and stability.

6.4.1 Determination of pH

Principle

pH measurement determines acidity or alkalinity of formulation.

Instrument Used

Digital pH meter Procedure

1. pH meter was calibrated using standard buffer solutions.
2. Syrup sample was taken in clean beaker.
3. Electrode was immersed into syrup.
4. pH reading was recorded.

7.4.2 Determination of Viscosity

Principle

Viscosity indicates resistance of liquid to flow.

Instrument Used

Brookfield viscometer

Procedure

1. Syrup sample was placed in viscometer container.
2. Appropriate spindle was selected.
3. Rotation speed was adjusted.
4. Viscosity reading was recorded.

6.4.3 Determination of Specific Gravity

Principle

Specific gravity is the ratio of density of syrup to density of water.

Specific Gravity = Density of Syrup / Density of Water

Procedure

1. Empty pycnometer was weighed.
2. Pycnometer filled with syrup.
3. Final weight recorded.
4. Specific gravity calculated.

Importance

- Indicates concentration of syrup
- Determines uniformity
- Ensures batch consistency

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6.4.4 Determination of Density

Principle

Density is mass per unit volume of formulation.

Importance

- Indicates formulation consistency
- Useful for packaging calculations
- Helps maintain uniformity

6.5 Stability Evaluation

Stability evaluation was carried out according to ICH guidelines.

6.5.1 Objectives of Stability Studies

- Determine shelf life
- Study effect of storage conditions
- Assess physical and chemical stability
- Monitor microbial safety

6.5.2 Storage Conditions

Study Condition	Temperature	Humidity
Long-term study	25°C ± 2°C	60% RH
Accelerated study	40°C ± 2°C	75% RH

6.5.3 Parameters Evaluated During Stability Study

- Color
- Odor
- Taste
- pH
- Viscosity
- Sedimentation
- Microbial growth

6.6 Evaluation Table

Parameter	Observation
Color	Brown
Odor	Pleasant
Taste	Sweet and aromatic
Appearance	Clear
pH	5.7–5.9
Viscosity	Acceptable
Sedimentation	Absent
Microbial growth	Absent

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6.7 Significance of Evaluation Parameters

Evaluation parameters help in:

- Maintaining product quality
- Ensuring therapeutic efficacy
- Improving patient acceptability
- Confirming stability
- Standardizing formulation

6.8 Interpretation of Evaluation Results

The prepared herbal cough syrup formulations exhibited:

- Acceptable organoleptic properties
- Suitable viscosity
- Stable pH
- Good physical appearance
- No microbial contamination
- Good stability during storage

These findings indicated that the formulations were suitable for oral administration.

VII. STABILITY STUDIES

7.1 Stability studies

Stability studies are an important part of pharmaceutical product development. Stability testing helps determine the shelf life, storage conditions, packaging requirements, and quality maintenance of pharmaceutical formulations during storage. Herbal formulations are more susceptible to instability because plant constituents may undergo degradation due to environmental factors such as temperature, humidity, light, oxidation, and microbial contamination. Therefore, stability evaluation is essential to ensure that the herbal cough syrup maintains its safety, efficacy, appearance, and therapeutic activity throughout its shelf life.

7.2 Definition of Stability

Stability of a pharmaceutical product may be defined as the ability of a formulation to retain its:

- Physical properties
- Chemical properties
- Microbiological properties
- Therapeutic properties
- Toxicological properties

within specified limits during storage and use.

7.3 Objectives of Stability Studies

The main objectives of stability studies are:

- To determine shelf life of formulation
- To establish storage conditions
- To monitor physical changes
- To evaluate chemical stability
- To assess microbiological safety
- To ensure therapeutic efficacy
- To evaluate packaging suitability

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7.4 Importance of Stability Studies

Stability studies are essential because they:

- Ensure product safety
- Maintain therapeutic efficacy
- Prevent degradation of active constituents
- Detect formulation incompatibilities
- Help in quality assurance
- Support regulatory approval

7.5 Types of Stability Studies

According to ICH guidelines, stability studies are classified into:

7.5.1 Long-Term Stability Studies

These studies are performed under recommended storage conditions for longer duration.

Storage Condition

- Temperature: 25°C ± 2°C
- Relative Humidity: 60% RH ± 5%

Purpose

- Determine actual shelf life
- Evaluate long-term stability

7.5.2 Intermediate Stability Studies

These studies are conducted under moderate stress conditions.

Storage Condition

- Temperature: 30°C ± 2°C
- Relative Humidity: 65% RH ± 5%

Purpose

- Evaluate effect of moderate environmental stress

7.5.3 Accelerated Stability Studies

Accelerated stability studies are conducted under elevated temperature and humidity conditions.

Storage Condition

- Temperature: 40°C ± 2°C
- Relative Humidity: 75% RH ± 5%

Purpose

- Predict long-term stability
- Detect degradation rapidly
- Estimate shelf life

7.6 Factors Affecting Stability of Herbal Syrup

Several factors influence stability of herbal formulations.

7.6.1 Temperature

High temperature may:

- Degrade phytoconstituents
- Cause discoloration
- Reduce viscosity

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- Accelerate oxidation

7.6.2 Humidity

Excess humidity may:

- Promote microbial growth
- Cause hydrolysis
- Affect preservative efficacy

7.6.3 Light

Exposure to light may:

- Cause oxidation
- Lead to discoloration
- Degrade essential oils

7.6.4 Oxygen

Oxygen may react with phytoconstituents causing:

- Oxidation
- Loss of therapeutic activity

7.7 Stability Study Protocol

The formulated herbal cough syrup samples were packed in amber-colored bottles and subjected to stability testing under specified storage conditions.

7.7.1 Storage Conditions Used

Study Type	Temperature	Humidity
Long-term study	25°C ± 2°C	60% RH
Accelerated study	40°C ± 2°C	75% RH

7.7.2 Duration of Study

The formulations were evaluated over a period of three months.

Observation Intervals

- Initial
- 1 month
- 2 months
- 3 months

VIII. RESULTS AND DISCUSSION

8.1 Introduction

Results and discussion are important components of pharmaceutical research because they provide interpretation and scientific analysis of experimental findings. The present study involved formulation and evaluation of herbal cough syrup using medicinal plant extracts such as Tulsi, Vasaka, Ginger, Mulethi, and Peppermint oil.

The prepared formulations were evaluated for organoleptic properties, physicochemical characteristics, microbial safety, and stability according to standard pharmaceutical procedures and ICH guidelines.

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The obtained results indicated that the prepared herbal cough syrup possessed satisfactory quality, stability, and patient acceptability.

8.2 Results of Phytochemical Screening

Preliminary phytochemical screening confirmed the presence of various bioactive constituents responsible for therapeutic activity.

8.2.1 Phytochemical Screening Results

Phytoconstituent	Observation
Alkaloids	Present
Flavonoids	Present
Tannins	Present
Glycosides	Present
Saponins	Present
Phenolic compounds	Present

8.2.2 Discussion of Phytochemical Screening

The presence of alkaloids, flavonoids, tannins, glycosides, and phenolic compounds indicated significant therapeutic potential of the herbal extracts.

- Alkaloids contributed to expectorant and bronchodilator activity.
- Flavonoids exhibited antioxidant and anti-inflammatory properties.
- Tannins provided antimicrobial activity.
- Saponins helped in mucus clearance.

These phytoconstituents collectively contributed to the effectiveness of herbal cough syrup.

8.3 Organoleptic Evaluation Results

The prepared formulations were evaluated for color, odor, taste, and appearance.

8.3.1 Organoleptic Evaluation Table

Parameter	**Observation**
Color	Brown
Odor	Pleasant aromatic
Taste	Sweet and slightly herbal
Appearance	Clear and uniform
Sedimentation	Absent

8.3.2 Discussion of Organoleptic Evaluation

The formulations showed acceptable organoleptic characteristics.

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- Brown color was due to herbal extracts.
- Pleasant odor resulted from peppermint oil and herbal constituents.
- Sweet taste improved patient compliance.
- No sedimentation indicated physical stability.

The overall appearance was satisfactory for oral administration.

8.4 Physicochemical Evaluation Results

Physicochemical parameters such as pH, viscosity, density, and specific gravity were evaluated.

pH Evaluation

Result Table

Formulation	pH
F1	5.8
F2	5.7
F3	5.9

8.4.2 Discussion of pH Results

The pH of all formulations remained within acceptable range for oral syrup preparations.

Acceptable pH range:

4.5 ≤pH ≤6.5

The acidic pH helped:

- Improve preservative efficacy
- Prevent microbial growth
- Maintain formulation stability

No significant pH variation was observed during study.

8.4.3 Viscosity Evaluation

Result Table

Formulation	Viscosity (cps)
F1	118
F2	120
F3	123

8.4.1 Discussion of Viscosity Results

The formulations exhibited suitable viscosity for oral administration.

- Glycerin contributed to appropriate consistency.
- Syrups showed good pourability.
- Moderate viscosity improved mouth feel and patient acceptability.

The formulations remained physically stable without phase separation.

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8.4.5 Specific Gravity Results

Result Table

Formulation	Specific Gravity
F1	1.21
F2	1.23
F3	1.25

8.4.6 Discussion of Specific Gravity

The obtained specific gravity values indicated:

- Proper concentration of syrup
- Uniform formulation consistency
- Adequate sugar content

No abnormal variation was observed among formulations.

Density Results

Result Table

Formulation	Density (g/ml)
F1	1.18
F2	1.20
F3	1.22

8.4.8 Discussion of Density Results

The density values confirmed:

- Uniformity of formulation
- Proper incorporation of ingredients
- Suitable consistency

8.5 Microbial Evaluation Results

Microbial load testing was performed to evaluate microbiological safety.

8.5.1 Microbial Evaluation Table

Test	Observation
Total bacterial count	Within acceptable limits
Total fungal count	Within acceptable limits
Pathogenic microorganisms	Absent

8.5.2 Discussion of Microbial Evaluation

The microbial load was found within acceptable limits indicating good microbiological quality.

- Sodium benzoate effectively prevented microbial contamination.

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- Proper handling and packaging reduced contamination risk.
- No pathogenic microorganisms were detected.

The formulations were considered microbiologically safe.

- Acceptable organoleptic characteristics
- Stability under accelerated conditions

The herbal ingredients provided synergistic therapeutic action due to presence of bioactive phytoconstituents such as alkaloids, flavonoids, glycosides, and phenolic compounds.

The study confirmed that herbal cough syrup can be developed as a stable and effective alternative to synthetic cough preparations.

XI. CONCLUSION

Conclusion

The present research work entitled "Formulation of Herbal Cough Syrup and Stability Testing" was successfully carried out with the objective of developing a stable, effective, and patient- friendly herbal cough syrup using selected medicinal plant extracts.

The medicinal plants selected for the study, namely:

- Tulsi (Ocimum sanctum)
- Vasaka (Adhatoda vasica)
- Ginger (Zingiber officinale)
- Mulethi (Glycyrrhiza glabra)
- Peppermint oil

possess significant therapeutic activities such as antitussive, expectorant, anti-inflammatory, antimicrobial, bronchodilator, antioxidant, and soothing properties which are beneficial in the management of cough and respiratory disorders.

The herbal extracts were successfully prepared using Soxhlet extraction method and incorporated into syrup formulations using suitable pharmaceutical excipients such as sucrose, glycerin, sodium benzoate, citric acid, and purified water.

9.2 Findings of the Study

The prepared herbal cough syrup formulations were evaluated for various organoleptic, physicochemical, microbiological, and stability parameters.

The study revealed the following important findings:

9.3 Advantages of Developed Herbal Cough Syrup

The developed formulation offers several advantages:

- Natural and safe formulation
- Reduced side effects compared to synthetic drugs
- Better patient compliance
- Pleasant taste and aroma
- Easy administration
- Suitable for pediatric and geriatric patients
- Economical and easily accessible

9.4 Limitations of the Study

Although the study showed satisfactory results, certain limitations were observed:

- Clinical evaluation was not performed

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- Long-term stability studies were limited
- Advanced analytical standardization was not conducted
- Large-scale manufacturing studies were not performed

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