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# A review on the formulation of herbal drugs

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**Abstract**
Herbal medicines constitute a large fraction of traditional and complementary healthcare worldwide and are increasingly being adapted into standardized dosage forms for improved safety, efficacy, and patient acceptance. This review focuses on the rationale and practical considerations for developing a polyherbal cough syrup with immunity-boosting properties using 15 medicinal herbs standardized per PCI nomenclature and common pharmaceutical excipients. Key formulation approaches include aqueous and hydroalcoholic extraction, extract standardization (phytochemical fingerprinting), selection of excipients for palatability and stability (sucrose, xanthan gum, sodium benzoate, citric acid), and appropriate suspension/viscosity control. Challenges include variability of phytoconstituents, solubility and bioavailability limitations, microbial contamination, and regulatory compliance. Recent advances such as nano-herbal carriers, phytosome technology, and green extraction methods enhance stability and bioavailability. We present a concise monograph for each herb, a stepwise syrup preparation, quality control parameters, safety notes for pediatric use, and an explanation of why the proposed formulation is non-addictive. The aim is to bridge traditional knowledge with modern pharmaceutics, enabling a safe, palatable, and standardized pediatric herb-based cough remedy and immunity booster.

**Keywords:** Herbal formulation, polyherbal, cough syrup, standardization, excipients, phytoconstituents, quality control

## Introduction
Herbal medicines are used by a large portion of populations globally due to cultural acceptance, perceived safety, and accessibility [1, 2]. Raw or crude herbal preparations, however, suffer from dose variability, stability problems, and poor patient acceptability; formulation development converts ethnobotanical knowledge into reproducible pharmaceutical products [3, 4]. The herbal drug market has shown marked growth, requiring rigorous standardization and regulatory oversight [5]. This review examines the design and formulation of a polyherbal cough syrup that also acts as an immunity booster, aligning with pharmacognostic standards and pediatric safety requirements. The aim is to present a formulation blueprint incorporating 15 herbs (PCI-standard botanical identities), appropriate excipients, process flow, quality control tests, and regulatory considerations. My contribution is the rational integration of selected herbs into a palatable, stable syrup for pediatric use and societal benefit by providing a non-addictive alternative to many synthetic cough medicines widely used in children.

## Classification of Herbal Formulations
Herbal formulations are classically categorized as:
- **Traditional formulations:** Churna, Kwatha (decoction), Asava-Arishta (fermented preparations), Taila (oils), Ghrita (medicated ghee) [6].
- **Conventional dosage forms:** Tablets, capsules, ointments, creams, powders - adapted for modern dispensing and dosing [7].
- **Novel herbal dosage forms:** Phytosomes (complexes to enhance bioavailability), nanoemulsions, liposomes, transdermal patches, herbal gels, and mouth-dissolving films for targeted delivery and improved pharmacokinetics [8, 9].

**Sources of Herbal Drugs:** Herbal materials can be derived from: whole plants, specific plant parts (leaves, roots, bark, seeds, flowers), processed extracts (aqueous, hydroalcoholic), essential oils, resins, gums and mucilage. Correct selection and authentication is critical for reproducibility [10].

**Extraction and Processing of Herbs**

Pre-processing steps include washing, drying (shade or controlled), size reduction and sieving. Extraction techniques vary by target phytochemical: maceration, percolation, Soxhlet extraction, and advanced methods like supercritical $CO_2$ and microwave-assisted extraction for higher yield and cleaner extracts [11, 12]. Extracts must be standardized for marker compounds via HPTLC/HPLC/GC-MS [13].

**Formulation Considerations**

1. **Selection of Plant Material**
   **Quality:** Good Agricultural and Collection Practices (GACP) ensure identity, absence of contaminants (heavy metals, pesticides), and correct plant part [14]. Authentication requires botanical, macroscopic and microscopic evaluation [15].
2. **Selection of Active Phytoconstituents:** Choose marker compounds for standardization (e.g., chebulinic acid for Terminalia chebula). Chemoprofiling (HPLC/HPTLC) provides batch fingerprinting [13].
3. **Choice of Dosage Form:** Liquid syrups are preferred for pediatric cough remedies because of ease of dosing, palatability, and immediate action. Viscosity, taste, and preservative efficacy are key considerations [16].
4. **Herbal Excipients:** Natural or pharmacopeial excipients such as xanthan gum (stabilizer), sucrose (sweetener), sodium benzoate (preservative), and citric acid (pH modifier, flavor) are suitable in specified amounts [17].

**Formulation Approaches for Herbal Drugs**

1. **Solid Dosage Forms:** Herbal tablets, capsules, granules and powders need binders, disintegrants, and standardized extracts to ensure dose uniformity [7].
2. **Semi-solid Dosage Forms:** Creams, ointments and gels incorporate herbal extracts in suitable bases for topical use [8].
3. **Liquid Dosage Forms:** Syrups, suspensions, decoctions and tinctures. For syrups, extract solubility, preservative system and viscosity are crucial [16].
4. **Novel Drug Delivery Systems (NDDS):** Phytosomes, nanoemulsions, liposomes, hydrogels and microencapsulation can improve solubility, protect actives, and enable sustained or targeted delivery [9, 18].

**Quality Control & Standardization**

1. **Pharmacognostic Evaluation:** Macroscopy and microscopy of raw drugs confirm identity and quality [15].
2. **Physicochemical Evaluation:** Ash values, extractive values (water/alcohol), moisture content and bulk density are standard tests [19].
3. **Phytochemical Evaluation:** TLC/HPTLC for fingerprinting, HPLC for quantification of markers, GC-MS for volatiles, and FTIR for functional group analysis [13, 20].
4. **Microbial Limit Tests:** Total aerobic count, tests for *E. coli*, *Salmonella*, *Pseudomonas* and yeast/mold are mandatory for oral syrups [21].
5. **Stability Studies:** Real-time and accelerated stability studies per ICH or local guidelines to ensure shelf life, preservative efficacy, and maintenance of phytochemical markers [22].

**Challenges in Herbal Formulation**

Key challenges include intrinsic variability of phytoconstituents, lack of universal standardization, poor solubility and bioavailability of many molecules, stability and microbial contamination, and batch-to-batch variation [23].

**Recent Advances**

Trends include nano-herbal formulations, phytosome complexes to enhance absorption, green extraction technologies (e.g., supercritical $CO_2$), marker-based standardization, and AI-enabled phytochemical profiling to optimize combinations [9, 12, 24].

**Applications of Herbal Formulations**

Herbal formulations are applied across dermatology, gastrointestinal disorders, respiratory diseases, metabolic disorders, and as immunomodulators and antioxidant therapies [2, 8].

**Regulatory Aspects**

WHO guidelines for herbal medicines, Ayurvedic Pharmacopoeia of India (API), AYUSH standards, and CDSCO notifications define quality, labeling, and safety expectations for marketed herbal products [5, 14].

**Conclusion**

Standardized herbal formulations can transform traditional knowledge into reliable, safe, and effective medicines. The proposed polyherbal cough syrup + immunity booster integrates classical herbs with modern excipients and quality controls. Clinical and stability studies are essential to confirm efficacy and safety. With appropriate regulation and standardization, such formulations can reduce reliance on sedative or habit-forming allopathic cough medicines in children.

**Monographs**

**1. Bhumi Amla (*Phyllanthus niruri* Linn.) [Herb 1]**

**Synonym(s):** Chanca piedra; Bhumi amla.
- **Family:** Phyllanthaceae.
- **Class:** Whole herb; aerial parts.
- **Biological source:** Leaves and stems of *Phyllanthus niruri*; small annual herb.
- **Therapeutic uses:** Hepatoprotective, antioxidant, antiviral, diuretic and traditionally used for throat and mild respiratory support [25, 26].

**2. Peppermint (*Mentha piperita* Linn.) [Herb 2]**
- **Synonym(s):** Garden mint.
- **Family:** Lamiaceae.
- **Class:** Aromatic leaf herb/extract.
- **Biological source:** Leaves; rich in menthol/menthone.
- **Therapeutic uses:** Antispasmodic, cooling, mild antitussive and flavoring agent; soothes throat and improves palatability [27].

**3. Lemon Balm (*Melissa officinalis* Linn.) [Herb 3]**
- **Synonym(s):** Balm, bee balm.
- **Family:** Lamiaceae.
- **Class:** Leaf herb.
- **Biological source:** Leaves with citronellal-type aroma.
- **Therapeutic uses:** Mild antiviral, anxiolytic, and demulcent properties; helpful for soothing throat and mild respiratory discomfort [28].

**4. Punarnava (*Boerhavia diffusa* Linn.) [Herb 4]**
- **Synonym(s):** Red spiderling.
- **Family:** Nyctaginaceae.
- **Class:** Aerial part herb.
- **Biological source:** Whole plant used; roots and leaves used in extracts.
- **Therapeutic uses:** Diuretic, anti-inflammatory, immunomodulatory; supportive for detoxification and inflammatory respiratory states in traditional use [29].

**5. Revanchini (*Cressa cretica* Linn.) [Herb 5]**
- **Synonym(s):** Alkali weed.
- **Family:** Convolvulaceae.
- **Class:** Small perennial herb/shrub.
- **Biological source:** Aerial parts.
- **Therapeutic uses:** Traditionally used as an expectorant and in bronchial affections; used for cough and respiratory congestion [30].

**6. Vaividang / Vidanga (*Embelia ribes* Burm. f.) [Herb 6]**

**Synonym(s):** False black pepper.

- **Family:** Myrsinaceae / Primulaceae.
- **Class:** Dried berries (fruit).
- **Biological source:** Dried fruits/berries of *Embelia ribes*.
- **Therapeutic uses:** Anthelmintic, antimicrobial, antioxidant and immunomodulatory; used for systemic infections and digestive health [31].

**7. Haritaki (*Terminalia chebula* Retz.) [Herb 7]**

**Synonym(s):** Chebulic myrobalan.

- **Family:** Combretaceae.
- **Class:** Dried fruit (pericarp).
- **Biological source:** Dried fruit of *Terminalia chebula*.
- **Therapeutic uses:** Laxative, astringent, antioxidant, immunomodulatory and used traditionally in respiratory complaints and chronic throat irritation [1, 32].

**8. Bhringraj (*Eclipta alba* (L.) Hassk.) [Herb 8]**

**Synonym(s):** False daisy.

- **Family:** Asteraceae.
- **Class:** Aerial parts herb.
- **Biological source:** Leaves and whole aerial part used as extract.
- **Therapeutic uses:** Hepatoprotective, immunomodulatory and antioxidant; traditionally used for general tonic effects and to support systemic health [33].

**9. Rohitak Chhal (*Tecomella undulata*) [Herb 9]**

- **Synonym(s):** Rohitaka (bark).
- **Family:** Bignoniaceae.
- **Class:** Bark (cortex).
- **Biological source:** Dried bark of *Tecomella undulata*.
- **Therapeutic uses:** Traditional use in liver support, respiratory disorders and as tonic; bark extracts used in rasayana formulations [34].

**10. Kasni (*Cichorium intybus* Linn.) [Herb 10]**

**Synonym(s):** Chicory.

- **Family:** Asteraceae.
- **Class:** Roots/leaves.
- **Biological source:** Taproot and leaves of *Cichorium intybus*.
- **Therapeutic uses:** Hepatoprotective, digestive tonic, antioxidant and supportive of immunity [35].

**11. Piptapapra (*Fumaria parviflora* Lam.) [Herb 11]**

**Synonym(s):** Little fumitory.

- **Family:** Papaveraceae / Fumariaceae.
- **Class:** Aerial parts.
- **Biological source:** Entire aerial plant used for decoctions/extracts.
- **Therapeutic uses:** Traditionally used for hepatic support, cough relief and mild detoxifying action [36].

**12. Sarpunkha (*Tephrosia purpurea*) [Herb 12]**

- **Synonym(s):** Fish poison plant (common name).
- **Family:** Fabaceae.
- **Class:** Whole plant herb.
- **Biological source:** Leaves and roots of *Tephrosia purpurea*.
- **Therapeutic uses:** Anthelmintic, antipyretic, restorative and used in bronchial and cough conditions traditionally [37].

**13. Jhavuka (*Tamarix dioica*) [Herb 13]**

- **Synonym(s):** Tamarix.
- **Family:** Tamaricaceae.
- **Class:** Shrub / aerial parts.
- **Biological source:** Leaves and twigs of *Tamarix dioica*.
- **Therapeutic uses:** Traditional demulcent and used for cough and urinary complaints in folk medicine [38].

**14. Himasara (*Acacia suma*) [Herb 14]**

- **Synonym(s):** Local Acacia species.
- **Family:** Fabaceae.
- **Class:** Bark/leaves.
- **Biological source:** Bark and leaves used in decoctions.
- **Therapeutic uses:** Traditional use for cough, inflammation and as a tonic in some regional systems [39].

**15. Kasmarda (*Cassia occidentalis*) [Herb 15]**

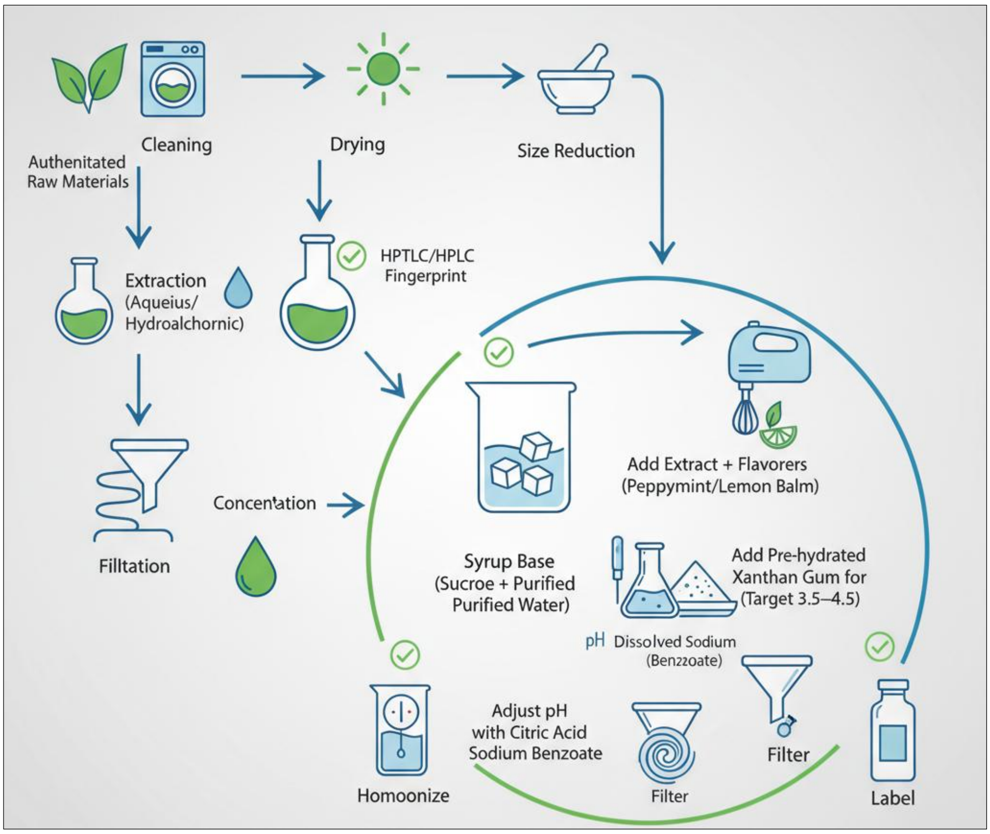
- **Synonym(s):** Coffee senna (common name).
- **Family:** Fabaceae.
- **Class:** Whole plant / seeds.
- **Biological source:** Leaves and seeds used as extracts.
- **Therapeutic uses:** Anti-inflammatory, antimicrobial, hepatoprotective and used traditionally for infections and supportive therapy [40].

**16. Sucrose (Excipient) [Ingredient]**

- **Synonym(s):** Table sugar; saccharose.
- **Class:** Sweetening agent.
- **Biological source:** Extracted from sugarcane/sugar beet.
- **Functional use:** Masks bitter taste of extracts, improves palatability for pediatric dosing; use limited due to dental considerations [17].

**Excipients, Solvent & Formulation Diagram Prompts**
**Excipient list**

- **Excipient (functional):** Xanthan gum - stabilizer/viscosity modifier [17].
- **Solvent:** Purified water - extraction solvent or syrup vehicle [11].
- **Sweetener:** Sucrose - palatability agent [17].
- **Preservative:** Sodium benzoate - antimicrobial preservative (within limits) [21].
- **pH modifier:** Citric acid - taste and preservative enhancement [17].




**Detailed Cough Syrup + Immunity Booster (Sample Formula & Process)**
**Target product:** 1000 mL oral syrup (concentrated polyherbal syrup)

**Ingredients**

- Combined standardized polyherbal extract (equivalent to 50 g crude herbs) - 60 mL (as 6% w/v concentrate, adjust based on marker assay). [use extract standardized to key markers].
- Purified water - q.s. to 1000 mL (solvent and vehicle).
- Sucrose - 500 g (50% w/v syrup base) [adjust if diabetic considerations apply].
- Xanthan gum - 2.0 g (0.2% w/v) - viscosity/stabilizer.
- Sodium benzoate - 1.0 g (0.1% w/v) - preservative (within accepted limits).
- Citric acid (anhydrous) - 3.0 g (q.s. to pH 3.8-4.2).
- Flavors (peppermint & lemon balm extracts) - 2-4 mL (flavoring).
- Color (optional, pharmacopeial edible color) - q.s.

**Process**

1. Prepare herbal extracts by aqueous extraction (or hydroalcoholic if needed) of authenticated herbs; concentrate to obtain viscous extract and standardize marker content [11, 13].
2. Make a simple syrup: dissolve sucrose in ~600 mL purified water by heating to 60-70 °C; cool to <40 °C.
3. Dissolve sodium benzoate in small portion of purified water and add to syrup.
4. Prehydrate xanthan gum in 50 mL water (to avoid lumps); add under high shear to the syrup to achieve desired viscosity.
5. Add standardized herbal extract slowly with stirring.
6. Add flavors and citric acid to adjust pH to ~3.8-4.2.
7. Make up volume to 1000 mL with purified water; filter if needed; fill into sterile amber bottles.
8. Perform microbial and organoleptic checks; label batch.

**Rationale for amounts:** Sucrose at ~50% w/v provides adequate sweetness and syrup body common in pediatric syrups; sodium benzoate at 0.1% is commonly used as preservative in acidic syrups; xanthan at 0.1-0.3% gives a palatable viscosity.

**Why this formulation is non-addictive for children**
**Best place to include:** In the *Formulation Considerations* or *Safety* subsection and repeated in *Conclusion*.

**Explanation:** The proposed syrup contains no opioid, sedative or centrally acting antitussive agents (such as codeine, morphine derivatives, or potent dextromethorphan doses). Instead, it relies on herbs with anti-inflammatory, expectorant, demulcent, immunomodulatory and antimicrobial actions that do not engage reward/addiction neurocircuits. The excipients (sucrose, xanthan gum, sodium benzoate, citric acid) are non-psychoactive and are used at pharmacopeial levels; hence the formulation does not present physiological pathways associated with chemical dependence or addiction in children [16, 21, 23].

**Safety, Pediatric Considerations & Warnings**

- **Sugar content:** Advise parents on dental hygiene due to sucrose; consider sorbitol or sucralose alternatives in diabetic or long-term use cases.
- **Preservative limits:** Sodium benzoate should be within regulatory pediatric limits; avoid benzoate in neonates or very young infants without clinical supervision [21].
- **Allergy / botanical cross-reactivity:** Screen for known plant allergies (Asteraceae family - Bhringraj, Kasni; Fabaceae family - Sarpunkha, Kasmarda).
- **Drug interactions:** Monitor possible herb-drug interactions (e.g., hepatoprotective herbs altering drug metabolism) and advise healthcare professionals to check concomitant therapy.
- **Clinical testing:** Dose optimization and clinical trials in pediatric populations are necessary before wide recommendation.

**Quality Control Tests to be Performed**

- Organoleptic evaluation (appearance, taste, odor)
- pH measurement (target 3.8-4.2)
- Viscosity/rheology (Brookfield)
- Assay of marker phytoconstituents (HPLC)
- Microbial limit tests (Total viable count, pathogens absent)
- Preservative efficacy test (challenge test)
- Accelerated stability (40 °C/75% RH) and real-time stability (25 °C) studies [22].

**Advantages & Societal Impact**

- Non-addictive alternative for pediatric cough management.
- Integrates evidence-based herbs with quality controls.
- Readily acceptable taste for children.
- Potential to reduce inappropriate use of opioid or sedating cough medicines.

**Limitations & Future Research**

- Need for rigorous clinical trials in pediatric populations.
- Evaluation of pharmacokinetics and bioavailability of key actives from syrup matrix.
- Long-term safety monitoring for sugar load and herb-drug interactions.
- Exploration of sugar-free versions and advanced delivery systems (phytosomes/nanoparticles) to increase bioavailability.

**Recent advances relevant to this work**

- Phytosome and nano-carrier systems improving oral absorption of polyphenols [9].
- Green extraction methods (supercritical $CO_2$) yielding solvent-free extracts [12].
- HPTLC/HPLC fingerprinting for batch standardization widely applied in herbal industries [13, 24].

**Regulatory Aspects**

Follow WHO monographs, Ayurvedic Pharmacopoeia of India (API) for identity and quality, and CDSCO/AYUSH labeling rules for marketed products. Ensure compliance with local pediatric excipient guidance [5, 14, 21].

**Conclusion**

A standardized polyherbal cough syrup + immunity booster can be formulated using the 15 PCI-standard herbs and pharmacopeial excipients (sucrose, xanthan gum, sodium benzoate, citric acid, purified water). With proper standardization, quality control, and clinical validation, such a formulation offers a culturally aligned, palatable, and non-addictive alternative for pediatric cough management. Future work should focus on clinical efficacy, safety trials, and advanced delivery systems to enhance bioavailability.

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