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STANDARDIZATION OF HERBAL CAPSULE FORMULATIONS: A REVIEW

Mohd Adil Ansari, Rohit Kumar Bijauliya *, Pushpendra Kannojia and Pankaj Kumar Shankhdhar

BIU College of Pharmacy, Bareilly International University, Bareilly - 243006, Uttar Pradesh, India.

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Correspondence to Author:
Dr. Rohit Kumar Bijauliya

Associate Professor,
BIU College of Pharmacy, Bareilly International University, Bareilly - 243006, Uttar Pradesh, India.

E-mail: rkpharma3791@gmail.com

ABSTRACT: Herbal capsule formulations have gained significant attention due to their therapeutic potential, improved patient compliance, and growing global demand. However, their quality, safety, and efficacy are challenged by variability in raw materials, lack of uniform standards, and complex multi-component nature. This review highlights the comprehensive standardization of herbal capsule formulations, including raw material evaluation, physicochemical and phytochemical analysis, chromatographic fingerprinting, and capsule quality control parameters such as weight variation, disintegration, dissolution, and content uniformity. It also discusses microbiological safety, toxicological screening, and advanced techniques like DNA fingerprinting, marker-based standardization, and chemometric analysis. Regulatory frameworks from WHO, AYUSH, US FDA, and EMA are also summarized. Despite advancements, challenges such as lack of universal markers and variability in herbal sources persist. Integration of modern analytical tools with traditional knowledge is essential to ensure consistent, safe, and effective herbal capsule products for global acceptance.

INTRODUCTION: Under AYUSH, India is a prominent center for ancient medical systems including Ayurveda, Unani, Siddha, and homoeopathy. With widespread adoption of goods including herbal medicines, nutraceuticals, cosmeceuticals, health supplements, extracts, and wellness services in both local and international markets, the AYUSH pharmaceutical sector has significant development potential. Throughout shelf life, storage, and usage, drug standardisation guarantees identification, quality, and purity. However, the lack of clear rules makes standardising Ayurvedic formulas difficult, requiring producers and regulatory organisations like PCIM&H to put in more effort [1, 2].

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The World Health Organization prioritises both qualitative and quantitative assessment, including fingerprint profiling and biomarker estimates. When known, active ingredients should be the focus of standardisation; otherwise, particular marker compounds should be used. Ensuring safety, purity, and efficacy is a crucial problem in the commercialisation of herbal medicine because of the variability in herbal raw materials caused by plant identification, seasonal, genetic, and environmental variables, as well as processing and storage conditions.

The American Herbal Products Association defines standardisation as the set of knowledge and control needed to create materials of uniform quality. It is accomplished by using stringent quality assurance procedures to cultivation, harvesting, processing, and manufacture in order to minimise inherent differences in herbal composition. These precautions guarantee safety, therapeutic dependability, and homogeneity from batch to

batch [3, 4]. Standardisation is essential to preserving the identification, potency, and purity of goods in the herbal industries. Variability in active ingredients might result in variable therapeutic results if rigorous standardisation is not implemented. Therefore, in order to guarantee the repeatability and credibility of herbal formulations in both local and foreign markets, it is imperative to employ established analytical procedures and appropriate manufacturing standards. Although the Ayurvedic system has many advantages for humanity, it currently has trouble developing strong standardisation methods to guarantee dose accuracy, consistency, and efficacy [5]. The World Health Organization claims that chromatographic techniques including GC, HPLC, and HPTLC are trustworthy instruments for standardising herbal medications by locating and measuring important biomarker chemicals [6]. These sophisticated analytical methods allow for precise evaluation of intricate polyherbal mixtures. Despite this, it is challenging to identify a single active ingredient in herbal medications due to their multi-component structure. As a result, marker-based standardisation is frequently employed. Improving the therapeutic reliability and worldwide acceptance of Ayurvedic medicines requires strengthening scientific validation and implementing contemporary analytical techniques [7, 8, 9].

In places like Africa, China, Egypt, India, and South America, medicinal plants have been utilised for ages as one of the first healthcare systems. Nearly 80% of the world's population is said to rely on herbal treatments for primary healthcare, especially when it comes to treating serious and chronic illnesses like malaria, cancer, and AIDS. Approximately 800 medicinal plants are used in many ancient systems, including as Ayurveda, Siddha, and Unani. With increasing global demand, herbal products are now formulated into modern dosage forms such as capsules, improving patient compliance, dosage accuracy, and stability while preserving their therapeutic potential [10, 11, 12].

Capsules offer advantages such as:

- Accurate dosing
- Improved patient compliance
- Masking unpleasant taste and odor
- Enhanced stability

However, unlike synthetic drugs, herbal products contain complex mixtures of bioactive compounds, making standardization a challenging but critical process [13].

Need for Standardization: The increasing complexity and interconnection of contemporary systems, industries, and international markets necessitate standardisation since efficiency, safety, and quality control depend on uniformity and consistency. By establishing uniform rules, requirements, and processes, standardisation makes it possible for various businesses, goods, and services to collaborate easily, minimising misunderstandings and mistakes while enhancing communication and interoperability. Additionally, it makes mass manufacturing easier, reduces expenses, and guarantees that customers obtain dependable and secure goods [14]. Standardisation fosters innovation in industries including technology, healthcare, manufacturing, and education by offering a solid foundation for the development and comparison of novel concepts. In the end, it promotes international commerce, strengthens stakeholder trust, and advances general economic and social progress.

TABLE 1: FACTORS AFFECTING STANDARDIZATION AND ITS SIGNIFICANCE IN HERBAL FORMULATIONS [15, 16]

Category	Factor / Aspect	Explanation
Challenges in Standardization	Variability in plant materials	Medicinal plants show variation due to geographical location, climatic conditions, soil type, and harvesting time, which affects the concentration of active constituents.
	Adulteration and substitution	Intentional or unintentional replacement with inferior or incorrect plant species leads to reduced efficacy and potential safety risks.
	Differences in extraction and processing	Variations in extraction methods, solvents, temperature, and processing techniques can alter the chemical profile and therapeutic activity of herbal products.
	Safety concerns (heavy	Contamination with toxic metals, pesticide residues, and microbial load

	metals, pesticides, microbes)	can compromise safety and lead to harmful effects in consumers.
Importance of Standardization	Quality assurance	Ensures that the herbal product meets defined quality parameters for identity, purity, and strength.
	Batch-to-batch consistency	Maintains uniformity in composition and therapeutic effect across different production batches.
	Regulatory compliance	Helps manufacturers meet national and international regulatory guidelines and quality standards.
	Global acceptance	Enhances credibility and facilitates acceptance of herbal products in international markets.

Components of Standardization:

- Material Standardization Parameters
- Physicochemical Parameters

TABLE 2: RAW MATERIAL STANDARDIZATION PARAMETERS IN HERBAL FORMULATIONS [17]

Parameter	Description	Significance
Botanical identification (macroscopic and microscopic)	Involves visual examination (color, size, shape, odor, texture) and microscopic evaluation (cell structure, tissues, fibers, trichomes) of plant materials.	Ensures correct identification of the plant species and prevents use of wrong or inferior materials.
Authentication using taxonomical methods	Scientific classification and verification of plant species based on morphological and taxonomical characteristics, often supported by herbarium records.	Confirms the genuine source of the plant and avoids misidentification.
Detection of adulterants	Identification of unwanted, inferior, or substituted plant materials using physical, chemical, or analytical techniques.	Prevents adulteration, ensuring safety, efficacy, and product integrity.
Evaluation of foreign matter	Determination of extraneous materials such as soil, stones, dust, insects, or other plant parts not intended for use.	Maintains purity and quality of raw material by eliminating contaminants.

TABLE 3: PHYSICOCHEMICAL PARAMETERS IN HERBAL DRUG STANDARDIZATION [18, 19, 20]

Parameter	Description	Significance
Loss on drying (moisture content)	Measures the amount of water and volatile matter present in the sample by drying it at a specified temperature.	Indicates moisture content, which is critical for preventing microbial growth, degradation, and ensuring stability of the formulation.
Ash values (total ash, acid-insoluble ash)	Total ash represents the total inorganic residue remaining after incineration, while acid-insoluble ash indicates the presence of siliceous matter such as sand and soil.	Helps determine the purity and quality of the drug and detects contamination or adulteration with inorganic materials.
Extractive values (water/alcohol soluble)	Determines the amount of active constituents extracted using specific solvents like water or alcohol.	Provides an estimate of the chemical constituents present and helps evaluate the quality and consistency of the herbal material.
pH determination	Measures the acidity or alkalinity of the herbal formulation using a pH meter.	Important for stability, solubility, and compatibility of the formulation, and can influence therapeutic activity and shelf life.

Phytochemical Standardization:

a) Qualitative Analysis

b) Spectrophotometry

c) Chromatographic Techniques

TABLE 4: PRELIMINARY PHYTOCHEMICAL SCREENING PARAMETERS [21, 22, 23]

Phytoconstituent	Description	Common Tests	Significance
Alkaloids	Nitrogen-containing organic compounds commonly found in	Dragendorff's test, Mayer's test, Wagner's	Possess pharmacological activities such as analgesic, antimicrobial, and

	many medicinal plants.	test	antihypertensive effects.
Flavonoids	Polyphenolic compounds widely distributed in plants, responsible for pigmentation.	Shinoda test, Alkaline reagent test	Known for antioxidant, anti-inflammatory, and cardioprotective properties.
Tannins	Polyphenolic compounds capable of precipitating proteins.	Ferric chloride test, Gelatin test	Exhibit astringent, antimicrobial, and wound-healing properties.
Saponins	Glycosides with soap-like foaming characteristics.	Froth test, Foam test	Show expectorant, anti-inflammatory, and immune-boosting activities.
Glycosides	Compounds consisting of a sugar moiety linked to a non-sugar component (aglycone).	Keller-Killiani test, Borntrager's test	Important for therapeutic effects such as cardiac activity, laxative, and anti-inflammatory actions.

TABLE 5: QUANTITATIVE ANALYSIS BY SPECTROPHOTOMETRY IN HERBAL STANDARDIZATION [24, 25]

S. no.	Phytoconstituent / Parameter	Method / Reagent Used	Wavelength (nm)	Principle of Estimation	Application in Herbal Standardization
1	Total Phenolics	Folin–Ciocalteu reagent	650–765 nm	Reduction of phosphomolybdic–phosphotungstic acid complexes to blue-colored complex	Estimation of total phenolic content for antioxidant potential
2	Flavonoids	Aluminum chloride colorimetric method	415–430 nm	Formation of yellow complex with $AlCl_3$	Quantification of flavonoid content in plant extracts
3	Alkaloids	Bromocresol green / UV methods	420–470 nm (varies)	Complex formation between alkaloids and reagents	Estimation of total alkaloid content for bioactivity assessment
4	Tannins	Ferric chloride / Folin–Denis method	725–760 nm	Formation of colored complex with phenolic groups	Measurement of tannin content for astringent properties
5	Saponins	Vanillin–sulfuric acid method	544–560 nm	Formation of red–purple chromogen	Estimation of saponin content for surfactant and therapeutic activity
6	Glycosides	UV spectrophotometric or colorimetric assays	400–500 nm (varies)	Hydrolysis and color complex formation	Quantification of glycosidic compounds for pharmacological evaluation

TABLE 6: CHROMATOGRAPHIC TECHNIQUES IN HERBAL FORMULATION STANDARDIZATION [25, 26]

Technique	Description	Principle	Significance
Thin Layer Chromatography (TLC)	A simple and rapid technique where components are separated on a thin layer of adsorbent (silica gel/alumina) coated on a plate.	Separation occurs based on differential adsorption and migration of compounds under the influence of a solvent system.	Useful for preliminary identification, detection of adulterants, and development of fingerprint profiles.
High Performance Thin Layer Chromatography (HPTLC)	An advanced form of TLC with improved resolution, automation, and densitometric scanning.	Similar to TLC but uses finer particle size and controlled conditions for better separation and quantification.	Provides accurate and reproducible fingerprinting, suitable for quality control and quantification of marker compounds.
High Performance Liquid Chromatography (HPLC)	A highly sensitive and precise technique used to separate, identify, and quantify components in a liquid sample.	Compounds are separated based on their interaction with stationary and mobile phases under high pressure.	Widely used for quantitative estimation of active constituents and marker-based standardization of herbal drugs.
Gas Chromatography (GC)	A technique used for separation and analysis of volatile compounds present in herbal formulations.	Separation occurs based on volatility and interaction with the stationary phase in a gaseous mobile phase.	Ideal for analysis of essential oils, volatile constituents, and detection of contaminants like pesticide residues.

These techniques help generate fingerprint profiles for consistency.

Standardization of Capsule Dosage Form:

a) Pre-formulation Studies

b) Capsule Evaluation Parameters

c) Stability Studies

TABLE 7: FLOW PROPERTIES OF POWDER [27, 28, 29]

Property	Definition	Formula / Method	Interpretation / Significance
Angle of Repose	The maximum angle formed between the surface of a pile of powder and the horizontal plane	$\theta = \tan^{-1}$ (h / r), where *h* = height of pile, *r* = radius of base	Indicates flowability of powder; smaller angle (<30°) = good flow, larger angle (>40°) = poor flow
Bulk Density	Mass of powder divided by its bulk volume (includes void spaces between particles)	Bulk Density = Mass / Bulk Volume	Reflects packing ability of powder; important for storage, transport, and dosage form design
Tapped Density	Density of powder after mechanically tapping the container to reduce void spaces	Tapped Density = Mass / Tapped Volume	Indicates how powder settles under vibration; used to assess compressibility
Carr's Index (Compressibility Index)	Measure of compressibility of powder based on bulk and tapped density	Carr's Index = [(Tapped Density − Bulk Density) / Tapped Density] × 100	<15% = good flow, 15–25% = fair, >25% = poor flow
Hausner Ratio	Ratio of tapped density to bulk density	Hausner Ratio = Tapped Density / Bulk Density	≤1.25 = good flow, >1.25 = poor flow

TABLE 8: COMPATIBILITY STUDIES [30, 31]

Study Method	Purpose	Procedure	Observations / Indicators	Significance
Physical Observation	To detect visible incompatibility between drug and excipients	Mix drug with excipients and store under specified conditions	Color change, odor development, liquefaction, caking	Simple and quick method to identify obvious incompatibilities
Thermal Analysis (DSC)	To study thermal behavior and interactions	Differential Scanning Calorimetry is performed on drug–excipient mixture	Shift, disappearance, or appearance of peaks	Indicates possible chemical or physical interaction
Infrared Spectroscopy (FTIR)	To identify chemical interactions	FTIR spectra of drug and mixture are compared	Changes in characteristic peaks or new peaks	Detects functional group interactions
X-ray Diffraction (XRD)	To study crystallinity changes	Analyze diffraction pattern of mixture	Change in crystalline peaks or amorphous nature	Shows polymorphic or structural changes

TABLE 9: CAPSULE EVALUATION PARAMETERS [32, 33, 34, 35]

Parameter	Definition	Procedure	Acceptance Criteria / Limits	Significance
Weight Variation	Test to check uniformity of weight among capsules	Weigh individual capsules, remove contents, weigh empty shells, calculate net fill weight	As per pharmacopeial limits (e.g., ±10% for most capsules depending on fill weight)	Ensures uniform dose and proper filling during manufacturing
Disintegration Time	Time required for capsule to break down into smaller particles	Place capsules in disintegration apparatus with suitable medium at 37°C	Usually ≤15–30 minutes for hard gelatin capsules (as per standards)	Ensures capsule releases contents for dissolution and absorption
Dissolution Profile	Rate and extent of drug release from capsule into dissolution medium	Use dissolution apparatus (USP type I or II), measure drug release over time	Specific % drug release within a set time (e.g., 80% in 30–45 min, depending on drug)	Predicts bioavailability and therapeutic effectiveness
Content Uniformity	Ensures each capsule contains the intended amount of drug	Assay individual capsules using suitable analytical method	Typically 85–115% of label claim with acceptable variability	Critical for potent drugs to ensure accurate dosing and safety

TABLE 10: STABILITY STUDIES OF FORMULATION [36, 37, 38]

Parameter	Definition	Details / Conditions	Observations / Examples	Significance
Storage	Environmental factors	Store in a cool, dry place	Exposure may cause moisture	Ensures stability,

Conditions	required to maintain stability of capsule powders	(usually below 25°C), protect from light, moisture, and air; use airtight containers	absorption, softening of capsules, or drug degradation	potency, and shelf life of the formulation
Temperature Sensitivity	Effect of heat on drug and capsule shell	Avoid high temperatures; gelatin capsules may soften or deform	Melting, brittleness, or leakage	Maintains physical integrity of capsules
Humidity Control	Effect of moisture on powder and capsule shell	Store at controlled humidity (typically 30–50% RH)	Hygroscopic powders may clump; capsules may become soft or hard	Prevents physical instability and microbial growth
Light Protection	Protection from photodegradation	Use amber containers or blister packs	Color change or loss of potency in light-sensitive drugs	Preserves drug stability
Degradation Patterns	Chemical or physical breakdown of drug over time	Includes hydrolysis, oxidation, photolysis, and thermal degradation	Change in color, odor, potency, or formation of impurities	Helps in predicting shelf life and proper formulation
Hydrolysis	Degradation due to reaction with water	Occurs in presence of moisture	Breakdown of ester or amide drugs	Common in hygroscopic formulations
Oxidation	Reaction with oxygen leading to degradation	Accelerated by light, heat, and metal ions	Discoloration, rancid odor	Requires antioxidants or protective packaging
Photolysis	Degradation caused by light exposure	UV or visible light sensitive drugs affected	Fading, color change, reduced potency	Requires light-resistant packaging
Thermal Degradation	Breakdown due to high temperature	Occurs during improper storage or processing	Loss of activity or change in physical form	Emphasizes need for controlled temperature storage

Microbiological and Safety Evaluation [39, 40, 41]:

Microbial Load Testing:

Total Bacterial Count: Total bacterial count measures the number of viable bacteria present in a sample, usually expressed as colony-forming units (CFU) per gram or milliliter.

It is determined by plating diluted samples on nutrient agar and incubating them. This test ensures that microbial levels remain within acceptable pharmacopeial limits for safety.

Total Fungal Count: Total fungal count estimates the number of yeasts and molds in a sample, expressed as CFU per gram or milliliter. It is performed using suitable media like Sabouraud dextrose agar under controlled incubation. This test helps detect fungal contamination that may affect product stability, quality, and patient safety.

Detection of Pathogens (*E. coli, Salmonella*): This test identifies the presence of specific harmful microorganisms such as Escherichia coli and Salmonella species. Selective culture media and biochemical tests are used for detection. The absence of these pathogens is mandatory, as their presence can cause serious infections and indicates poor hygiene or contamination.

Toxicological Evaluation:

Heavy Metals (Lead, Arsenic, Mercury, Cadmium): Heavy metal testing determines the presence of toxic elements such as lead, arsenic, mercury, and cadmium in pharmaceutical products. These metals are detected using techniques like atomic absorption spectroscopy or ICP-MS. Their levels must remain within prescribed limits, as excessive exposure can cause serious health hazards and toxicity.

Pesticide Residues: Pesticide residue analysis detects traces of chemicals used during cultivation or storage of raw materials. Methods such as gas chromatography or liquid chromatography are employed for identification and quantification. Ensuring pesticide levels are within permissible limits is essential to avoid toxic effects and to maintain product safety and regulatory compliance.

Aflatoxins: Aflatoxins are toxic metabolites produced by fungi, especially Aspergillus species, contaminating raw materials. Their detection is carried out using methods like HPLC or ELISA. Even at low concentrations, aflatoxins can be carcinogenic, making it crucial to ensure their absence or presence within strict regulatory limits.

Advanced Standardization Techniques [42, 43]:

DNA Fingerprinting: DNA fingerprinting is a molecular technique used to confirm the identity of plant materials by analyzing their genetic profile. It helps distinguish authentic species from closely related or substituted ones. This method is highly reliable and is also used to detect adulteration, ensuring purity and authenticity of herbal raw materials.

Marker-Based Standardization: Marker-based standardization involves identifying and quantifying specific bioactive compounds (markers) present in herbal formulations. These markers may be responsible for therapeutic activity or serve as quality indicators. This approach ensures batch-to-batch consistency, maintains efficacy, and supports quality control of herbal medicines.

Chemometric Analysis: Chemometric analysis uses statistical and mathematical tools to interpret complex data obtained from herbal formulations. It helps analyze multiple chemical components simultaneously, identify patterns, and ensure quality consistency. This method is especially useful for standardizing complex herbal mixtures and detecting variations or adulteration.

Regulatory Guidelines: Various international bodies provide guidelines for herbal standardization [44, 45, 46, 47]:

WHO Guidelines for Herbal Medicines: The World Health Organization provides global guidelines for the quality, safety, and efficacy of herbal medicines. These include standards for raw material identification, good agricultural and collection practices (GACP), quality control, and stability testing to ensure safe and effective use worldwide.

AYUSH Guidelines (India): The Ministry of AYUSH regulates traditional medicine systems like Ayurveda, Yoga, Unani, Siddha, and Homeopathy. It sets standards for herbal drug manufacturing, quality control, labeling, and licensing under GMP guidelines to ensure safety, authenticity, and therapeutic effectiveness in India.

US FDA Botanical Drug Guidelines: The U.S. Food and Drug Administration provides specific guidance for botanical drug development, covering requirements for safety, efficacy, and quality. It includes recommendations on clinical trials, chemistry, manufacturing, and controls (CMC), ensuring botanical products meet the same standards as conventional drugs.

European Medicines Agency (EMA): The European Medicines Agency regulates herbal medicinal products in Europe through the Committee on Herbal Medicinal Products (HMPC). It provides monographs, guidelines for quality, safety, and efficacy, and supports traditional herbal medicine registration across European Union member states.

Challenges in Standardization:

- Complexity of multi-component systems
- Lack of universal markers
- Seasonal and geographical variation
- Limited scientific validation
- Inadequate regulatory harmonization [48]

Future Perspectives:

- Integration of modern analytical techniques
- Development of global standards
- Use of artificial intelligence in phytochemical profiling
- Increased clinical validation
- Stronger regulatory frameworks

CONCLUSIONS: Standardization of herbal capsule formulations is essential to ensure their safety, efficacy, and quality in both domestic and global markets. The complex nature of herbal drugs demands a multidisciplinary approach involving pharmacognostic, physicochemical, phytochemical, microbiological, and advanced analytical techniques. Quality control parameters and regulatory guidelines play a crucial role in achieving batch-to-batch consistency and therapeutic reliability. Although significant progress has been made, challenges such as variability in raw materials and lack of standardized markers still exist. The integration of

modern technologies like DNA fingerprinting, chemometrics, and chromatographic fingerprinting with traditional knowledge systems can strengthen herbal drug development. A robust standardization framework will enhance global acceptance and clinical credibility of herbal capsule formulations.

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