www.ijarp.com ISSN 2456-9992 Page: 01-13

Review Article

International Journal Advanced Research Publications

Volume: 02
Issue: 11

QUALITY CONTROL OF HERBAL DRUGS: RAW MATERIAL TO FINISHED PRODUCTS DOCUMENTATION, STANDARDIZATION, EXTRACTION AND ANALYTICAL VALIDATION

Tanishka Shivaji Pawar*[1], Prof. Akshada Patil, Dr. Tushar Shelke[3]

[1] Research Scholar, Genba Sopanrao Moze College of pharmacy, Wagholi, Pune, India.

[2] Assistant Professor, Genba Sopanrao Moze College of Pharmacy, Wagholi, Pune, India.

[3] Principal, Genba Sopanrao Moze College of Pharmacy, Wagholi, Pune, India.

Article Received: 10 October 2026, Article Revised: 30 October 2026, Published on: 18 November 2026

***Corresponding Author: Tanishka Shivaji Pawar**

Research Scholar, Genba Sopanrao Moze College of pharmacy, Wagholi, Pune, India.

Doi: https://doi-doi.org/101555/ijarp.4249

ABSTRACT

Herbal drugs are chemically complex materials whose quality is influenced by species identity, cultivation, harvesting, postharvest handling, extraction, manufacture and storage. Unlike a single chemically defined substance, botanical preparations may contain numerous constituents whose concentrations vary naturally and may change during processing. Quality control (QC) must therefore extend across the supply chain rather than depend on a single test of the finished product. This narrative review outlines a lifecycle-based approach to herbal-drug quality assurance, from botanical raw materials through extracts, formulation, packaging and post-market monitoring. It discusses good agricultural and collection practices (GACP), taxonomic authentication, macroscopic and microscopic examination, foreign matter, moisture and ash values, extractive values, chromatographic fingerprinting, marker assays, DNA-based methods and the assessment of microbial, pesticide, mycotoxin, elemental and other contaminants. It also considers solvent selection, extraction yield, in-process controls, process validation, good manufacturing practice (GMP), finished-product testing, stability, packaging compatibility, documentation and traceability. Identity, purity, strength and consistency are related but distinct attributes; no single analytical technique establishes all four. A risk-based specification should combine pharmacopoeial requirements, validated methods, representative sampling and scientifically justified acceptance criteria. Guidance from the World Health Organization (WHO), European Medicines Agency (EMA) and United States Food and Drug Administration (FDA) provides a framework, while applicable

national requirements must be confirmed for each product category. Key challenges include botanical variability, adulteration, complex mixtures, limited reference standards and the misconception that natural origin guarantees safety. Reliable herbal medicines require documented control from authenticated plant material to released batch, supported by supplier qualification, complementary analytical methods, validated processes and stability evidence.

KEYWORDS: Herbal drugs; quality control; botanical authentication; pharmacognosy; chromatographic fingerprinting; marker compounds; contaminants; good agricultural and collection practices; good manufacturing practice; stability testing.

1. INTRODUCTION

Medicinal plants and their preparations are used in traditional healthcare and in modern pharmaceutical, nutraceutical and consumer-health products. Their continued use creates a need for reliable quality systems that protect patients and support reproducible manufacturing. In this review, “herbal drug” broadly includes medicinal plant materials and preparations; the precise regulatory definition depends on jurisdiction and product category. Raw herbs, powders, extracts, tinctures and finished dosage forms present different but connected quality risks. [3,9,15]

Quality is commonly described through identity, purity, strength and consistency. Identity confirms the correct species and plant part; purity concerns foreign matter, adulterants and contaminants; strength concerns relevant constituents or a justified measure of the preparation; and consistency means that batches remain sufficiently comparable. These attributes are not interchangeable: a botanically correct sample may contain aflatoxins, while a matching chemical fingerprint may coexist with excessive pesticide residues. [1,9,10,13,14]

Genotype, chemotype, soil, rainfall, altitude, season, maturity, plant part and harvest time can alter composition. Drying, milling, extraction and storage can cause further changes. This narrative review synthesizes major guidance and technical principles; it is not a systematic review or meta-analysis. Its purpose is to explain practical QC decisions across the production chain. [2,16,17]

2. REVIEW APPROACH AND SCOPE

The review is structured around WHO quality-control manuals and GACP guidance, EMA guidance on herbal medicinal products, FDA botanical-drug guidance and general pharmaceutical principles for analytical validation, risk management and stability testing. It

covers dried plant materials, powders, extracts and representative finished products such as capsules, tablets, liquids and topical preparations. Universal numerical limits are not proposed: acceptance criteria must be taken from an applicable pharmacopoeial monograph, legal requirement, validated product specification or justified development data. [1–10,12,19]

3. QUALITY ATTRIBUTES AND THE LIFECYCLE MODEL

A lifecycle model links incoming-material requirements with process controls and release testing. It begins with supplier and cultivation controls, continues through harvesting, post-harvest processing, raw-material testing, extraction, intermediate control, formulation and packaging, and ends with finished-product release and stability monitoring. Complaint investigation and trend review feed information back into the system. This is more robust than final-product testing alone because some defects become difficult to detect after extraction or dilution. [11,18–21]

The control strategy should reflect the species, plant part, extraction process, route of administration, dose, patient population and known hazards. A dried root may require microscopy, moisture, ash and characteristic-constituent testing; an essential oil may require density, refractive index, optical rotation and a gas-chromatographic profile; and a water-rich syrup may need stringent microbial and preservative controls. [1,9,13,15,16]

Table 1:- Key Quality Control Focus.

Lifecycle stage	Key QC focus
Cultivation and collection	GACP records, site history, harvest records and pesticide controls
Incoming raw material	Authentication, representative sampling, microscopy, foreign matter, moisture and contaminants
Processing and extraction	Solvent, time, temperature, yield, drug-to-extract ratio and residual solvents
Manufacturing	GMP, in-process checks, hygiene, qualified equipment and validated procedures
Finished product	Identity/fingerprint, justified assay, dosage-form tests and microbial quality
Storage and distribution	Stability, packaging compatibility, transport, complaints and recall readiness

4. BOTANICAL RAW MATERIAL: SOURCING AND AUTHENTICATION

4.1 Taxonomic identity and GACP

Records should include accepted scientific name, family, plant part, source location, supplier,

lot number, harvest date and identification method. Common names alone are unreliable because one name may refer to several species. Synonyms should be checked against accepted botanical references and nomenclature should match the relevant pharmacopoeia or regulatory dossier. Authentication may involve a qualified botanist or pharmacognosist, comparison with authenticated herbarium material and retention of a voucher specimen. Cultivated material requires documentation of seed or planting-stock identity and production site; wild-collected material requires attention to permissions, sustainability, geographic origin and toxic look-alike species. [2,4,13,14,15,16]

GACP controls factors affecting identity, purity and composition before material reaches the manufacturer. These include site selection, soil and irrigation-water quality, planting-stock identity, fertilizer and pest management, harvesting conditions, worker hygiene, drying, storage and transport. Cultivation records should capture field or collection area, inputs, relevant environmental events and harvest conditions. Pesticides must comply with local requirements and documented pre-harvest intervals. Harvest timing is species- and plant-part-specific; wet material left in warm piles may undergo enzymatic change and microbial growth. [2,4,17]

4.2 Post-harvest handling, drying and storage

Cleaning removes soil, stones, insects and unwanted material without unnecessary loss of characteristic constituents. Washing may introduce excess moisture or leach water-soluble constituents if poorly controlled. Cutting and particle-size reduction should be standardized because particle size affects drying, sampling and extraction. Drying reduces water activity but excessive heat, light or uncontrolled airflow can degrade thermolabile or volatile constituents. Records should capture temperature, duration, loading depth and endpoint where relevant. Dried materials should be stored in clean, dry, pest-controlled areas, protected from light and moisture, and segregated by species and lot. Packaging should prevent moisture uptake, crosscontamination and volatile loss. Periodic inspection should identify damaged packs, insects, mold, discoloration and unusual odour. [1,2,9,16,17]

5. SAMPLING AND SAMPLE PREPARATION

Laboratory results are only as representative as the sample tested. Herbal lots are heterogeneous, with variation in maturity, plant part, moisture and contamination among containers. A documented sampling plan should define the number of containers, sampling locations, sample mass, compositing, sample reduction and retention. Composite samples estimate average quality but may dilute localized contamination; targeted or separate container

testing may therefore be justified. Samples for microbiology, volatile constituents or moisture may need special containers and prompt analysis. [1,9,13,14]

Grinding can improve homogeneity but may heat the sample, accelerate oxidation or cause volatile loss. Sample preparation must preserve the attribute being measured. Reference samples should be retained under defined conditions, and chain-ofcustody records should identify sampler, date, batch, seal, storage conditions and transfers. [1,9,13]

6. PHARMACOGNOSTIC AND PHYSICOCHEMICAL TESTING

6.1 Organoleptic, macroscopic and microscopic examination

Organoleptic examination records colour, odour, texture and general appearance; taste is considered only when safe and appropriate. Macroscopy evaluates shape, size, surface, fracture, venation and diagnostic floral or fruit features. These rapid tests may reveal gross substitution, degradation or infestation, but appearance alone cannot authenticate closely related species or processed powders. Microscopy identifies tissues and structures such as stomata, trichomes, fibres, vessels, starch grains, calcium oxalate crystals, pollen and secretory structures. Powder microscopy is useful after milling, but should be compared with validated references and combined with chemical or molecular methods when necessary. [1,9,13,15,16]

6.2 Foreign matter, moisture, ash and extractive values

Foreign-matter testing estimates soil, stones, insects, unrelated plant parts and other extraneous material. Loss on drying measures mass lost under specified conditions and may include water and volatile substances; it is not automatically equivalent to water content. Karl Fischer titration provides more specific water determination when required. Water activity adds information about microbial-growth potential but does not replace microbial testing. Total ash measures inorganic residue after incineration; acid-insoluble ash helps estimate siliceous material such as sand and soil, while water-soluble ash provides additional information. Interpretation must be species-specific. [1,9,13,14]

Water- and alcohol-soluble extractive values provide broad consistency checks but do not identify individual compounds. They depend on solvent composition, particle size, extraction time and sample moisture. Other species-relevant tests may include swelling index, foaming index, bitterness value, volatile-oil content and physical constants for oils or resins. Tests should be selected because they address a defined quality attribute. [1,9,13,15]



Figure 2. Complementary tests used in herbal raw-material evaluation.

Source: Original schematic based on WHO quality-control methods and pharmacopoeial principles [1, 9, 13, 14].

7. CHEMICAL IDENTIFICATION AND STANDARDIZATION

7.1 Phytochemical screening and chromatographic fingerprints

Colour and precipitation reactions may screen broad classes such as alkaloids, tannins, flavonoids, saponins and glycosides. They are exploratory and generally lack the selectivity and quantitative reliability needed for definitive release testing. Falsepositive and false-negative reactions occur in complex extracts. TLC and HPTLC offer accessible identity and semi-quantitative comparisons; HPLC or UHPLC resolve non-volatile constituents, while GC is commonly used for volatile oils. Fingerprints can reveal substitution, degradation or compositional shifts even when a single marker remains within limits. [1,9,13,15,16]

Fingerprint methods require defined sample preparation, chromatographic conditions, reference materials, system-suitability criteria and justified similarity rules. Retention time alone is not definitive because unrelated compounds may co-elute. Peak identity should, where possible, be supported by standards, spectral data, mass spectrometry or other orthogonal evidence.

[6,7,9,13]

7.2 Marker assays and DNA-based methods

A marker is selected to support identity, consistency or quantification. It may be an active constituent, a constituent associated with activity or a characteristic analytical marker. It should not be called the active ingredient unless evidence supports that designation. Assays may use HPLC-UV/DAD, GC-FID, LC–MS/MS, GC–MS or UV-visible spectrophotometry. Referencestandard identity, purity, storage and traceability should be documented. Extract specifications may also state native extract ratio, drug-to-extract ratio, solvent and marker range. [6,7,9,13,15]

DNA barcoding and species-specific PCR can support botanical identity when morphology is unavailable or substitution involves related species. However, DNA may be degraded by extraction or heating, may not distinguish chemically different chemotypes and does not establish contaminant absence or marker content. Highly processed extracts may contain

insufficient recoverable DNA. Molecular testing should complement, not replace, pharmacognostic and chemical analysis. [9,15,16]

8. CONTAMINANTS, ADULTERATION AND SAFETY

Potential hazards include bacteria, yeasts and molds, mycotoxins, pesticide residues, toxic elements, residual solvents, foreign botanical material, undeclared pharmaceuticals and process-related contaminants. Risk depends on species, plant part, geography, agricultural practices, processing, storage and intended use. Testing should follow a documented risk assessment and applicable limits, with stronger controls for high-risk materials and suppliers. [10,13,14,16,19]

8.1 Microbial quality and mycotoxins

Microbial tests may include total aerobic microbial count, total yeast and mold count and specified objectionable organisms according to route and pharmacopoeia. The aim is compliance with justified limits, not necessarily sterility. Plant constituents may inhibit microbial recovery, so methods must be suitable for the matrix. Drying and low water activity reduce growth potential but do not necessarily eliminate viable organisms or preformed toxins. Aflatoxins may remain after visible mold disappears. Risk-based monitoring may use immunoassays for screening and HPLC or LC–MS/MS for confirmation; sampling is critical because contamination may be localized. [1,9,10,13]

8.2 Pesticides, toxic elements and adulteration

Pesticide residues may arise from crop protection, drift, contaminated soil or post-harvest treatment. Multi-residue GC–MS/MS and LC–MS/MS methods cover many compounds, but the panel should reflect likely inputs, geography and applicable maximum residue limits. Lead, cadmium, mercury and arsenic may enter through soil, water, pollution or equipment; testing commonly uses atomic absorption or ICP techniques. Arsenic speciation may be necessary where toxicity differs by chemical form. Limits should reflect daily exposure and relevant standards. [10,13,14]

Adulteration may involve cheaper species, exhausted material, incorrect plant parts, synthetic compounds, undeclared pharmaceuticals or dilution. Visual inspection and a single marker assay may miss sophisticated substitution. A layered approach combines supplier qualification, identity testing, fingerprints, targeted adulterant tests and investigation of unexpected peaks. Suspect lots should be quarantined and related lots assessed. Herbal origin does not guarantee safety; contamination, toxic constituents, interactions and poor preservation remain possible. [3,5,9,10,12,19]

9. EXTRACTION AND HERBAL PREPARATIONS

Extraction transfers selected constituents into a solvent or other medium. Methods include maceration, percolation, infusion, decoction, reflux, Soxhlet, ultrasound-assisted, pressurized and supercritical-fluid extraction. Selection depends on target constituents, solvent compatibility, thermal sensitivity, scale, safety, cost and intended product. Higher yield does not necessarily mean higher quality because inactive or undesirable substances may also be extracted. [9,15,16]

Development records should define botanical input, particle size, solvent identity and grade, plant-to-solvent ratio, temperature, duration, mixing, extraction cycles, filtration, concentration and drying. Yield must be calculated on a clear and consistent basis. Solvent quality affects chemical profile and safety; residual-solvent testing and limits should reflect toxicological class, process and applicable standards. Extract specifications may include appearance, identity, fingerprint, marker content, moisture, ash where relevant, residual solvents, microbial quality, contaminants and native extract ratio. Native extract should be distinguished from preparations containing carriers or excipients. [3,5,7,9,12,13]

10. GMP AND IN-PROCESS CONTROL

GMP translates quality requirements into controlled operations. Core elements include trained personnel, qualified premises and equipment, sanitation, maintenance, pest control, validated or verified procedures, controlled documents, supplier management, deviation handling, change control and batch traceability. Herbal manufacturing requires attention to airborne dust, carryover between botanicals, shared equipment, variable bulk density and contamination by potent or toxic constituents. [11,18,20,21]

In-process controls should detect variation early. Examples include blend uniformity, granule moisture, particle-size distribution, extraction pH, temperature and time, filtration clarity, concentrate solids, tablet weight, capsule fill mass, liquid fill volume, pH, viscosity and packaging-seal integrity. Process validation documents that the process can consistently meet predetermined requirements and should address critical parameters, quality attributes and scale-up. Supplier and seasonal variation make continued verification and trend review important. [6,7,11,18,20,21]

11. FINISHED-PRODUCT QUALITY CONTROL

Finished-product testing confirms compliance with approved specifications but cannot compensate for an uncontrolled process. Specifications should reflect composition, dosage

form, route, intended population and risk. Methods, acceptance criteria, sampling and handling of out-of-specification (OOS) results must be defined. An OOS result requires a documented scientific investigation; repeated testing until a passing result appears is unacceptable. [3,5,11,12,18,20]

Tablets and capsules may require appearance, identity, assay or marker content, dosage-unit uniformity, disintegration, dissolution where appropriate, moisture, microbial quality and packaging-integrity tests. Oral liquids may require appearance, pH, viscosity, fill volume, assay, microbial limits and preservative effectiveness. Topical creams and gels may require pH, viscosity, homogeneity, spreadability, phase-separation and container-compatibility tests. Essential oils may require physical constants, chromatographic profile and oxidation-related measures. Each test should be linked to a defined risk or quality attribute. [1,5,9,12,13,14]

Where marker content is used for release, the assay must address matrix interference and extraction recovery. For multiingredient products, fingerprints, selected markers and manufacturing controls may be more realistic than measuring every constituent. Packaging should protect against moisture, oxygen, light, contamination and physical damage. Labels should accurately state botanical names, plant parts, preparation, strength where required, batch number, expiry or retest date, storage instructions and warnings. Requirements vary by jurisdiction and product classification. [3,5,12,13,14]



Figure 3. Simplified finished-product batch review and release pathway.

Source: Original schematic based on herbal-product quality, GMP and analytical validation guidance [5, 6, 18, 21, 22].

12. ANALYTICAL VALIDATION, DATA INTEGRITY AND STABILITY

A method used for a quality decision must be fit for purpose. Depending on application, validation may address specificity, accuracy, precision, linearity, range, detection and quantitation limits and robustness. Chromatographic methods require system-suitability criteria. Method transfer requires evidence that the receiving laboratory performs reliably; established pharmacopoeial methods may need verification in the actual matrix and laboratory conditions. Herbal matrices can cause coelution, variable recovery, pigment interference and seasonal compositional changes. Complementary methods may be needed when one technique lacks adequate resolution. [6,7,13]

Data integrity requires attributable, legible, contemporaneous, original and accurate records. Chromatograms, spectra, calculations, audit trails, instrument maintenance and reference-standard records should be retained. Undocumented integration changes, manual transcription errors and selective reporting undermine QC reliability. [6,11,20]

Stability testing evaluates whether the product remains within specification during storage. Relevant changes include marker degradation, volatile loss, colour or odour change, moisture uptake, precipitation, phase separation, altered viscosity, dosageform changes and microbial growth. Protocols should define batches, packaging, storage conditions, intervals, methods and acceptance criteria. Long-term studies support shelf life; accelerated studies help identify degradation pathways but should not alone justify an extended shelf life. Fingerprints, multiple markers and physical tests may better describe complex botanical changes. Retest periods for raw materials and extracts should be data-based. [8,12,13]

13. DOCUMENTATION, TRACEABILITY AND REGULATORY FRAMEWORK

Traceability links a finished batch to species, plant part, supplier, field or collection source, incoming lot, processing records, extract batch, excipients, packaging components and release results. Batch records should permit reconstruction of quantities, equipment, process parameters, deviations, yields and reconciliations. Risk management prioritizes controls according to probability, consequence and detectability. High-risk attributes include species substitution, toxic look-alike plants, mycotoxins, pesticides, toxic elements, potent adulterants and inadequate microbial control. Risk assessments should be updated when suppliers, regions, processes, solvents, equipment or packaging change. [11,18,19,20,21]

Supplier qualification should consider technical capability, quality history, authenticity controls, traceability, audits and response to deviations. Certificates of analysis are useful but should not be accepted uncritically, particularly for high-risk materials or new suppliers; independent verification helps confirm reliability. WHO guidance addresses medicinal-plant quality control and GACP; EMA guidance addresses herbal-product specifications and manufacturing; FDA botanical-drug guidance emphasizes consistent raw materials, chemistry and manufacturing controls. Pharmacopoeial monographs provide recognized tests and limits for specified materials. Where no monograph applies, specifications must be justified using botanical references, analytical characterization, safety information, process knowledge and batch data. National requirements should be checked for the relevant product category. [1–5,12–14,18,21,22]

14. COMMON QC FAILURES AND EMERGING TOOLS

Wrong species or plant part requires quarantine, confirmation by complementary methods and supplier investigation. High moisture or mold requires assessment of microbial and mycotoxin risk and review of drying and storage. Unexpected fingerprints call for review of sample preparation, reference materials, source, process and stability. Low marker content requires investigation of raw-material quality, extraction, degradation and dilution. Excess pesticide or toxic elements require confirmation, exposure assessment and supplier qualification. Microbial or stability failures require root-cause investigation, evaluation of related batches and corrective and preventive action (CAPA). CAPA should address root causes rather than only the immediate batch; distributed-batch defects may require notification or recall. [3,5,9,10,11,19,21]

LC–MS, GC–MS and nuclear magnetic resonance can provide detailed chemical information. Near-infrared and Raman spectroscopy, digital imaging and chemometric models may support rapid screening and process monitoring when trained on representative authenticated samples. Their performance can be affected by moisture, particle size, lighting, instrument differences and model drift. Machine-learning systems require independent validation across suppliers, seasons, geographic sources and adulteration scenarios. DNA metabarcoding and untargeted metabolomics may broaden characterization but have interpretation and reference-library limitations. Orthogonal methods that measure different properties are more defensible than reliance on one advanced platform. [6,7,9,15,16]

15. DISCUSSION AND FUTURE PERSPECTIVES

Herbal-drug quality is determined by the whole chain of custody. Quality cannot be tested into a product at the end if the wrong species was collected, material was contaminated before drying or extraction was uncontrolled. Supplier qualification and cultivation records are preventive controls; laboratory tests verify their effectiveness. Analytical identity and biological efficacy are different questions: a fingerprint supports chemical consistency but does not prove therapeutic benefit, and marker content may not represent the activity of a complex mixture. Claims should reflect the available evidence. [2,3,9,15,16,17]

Comprehensive testing must be balanced with practical feasibility. A tiered system can combine supplier and botanical controls, basic pharmacognostic and physicochemical tests, chromatographic fingerprints and targeted assays, with specialized contaminant testing outsourced to competent laboratories where necessary. Outsourcing does not transfer the manufacturer’s responsibility. Product-specific acceptance criteria are essential because

universal limits may be misleading. Future priorities include authenticated reference collections, validated methods for complex mixtures, harmonized criteria, adulterant libraries, improved surveillance and long-term stability data. Digital traceability and shared reference datasets may improve trend analysis if data governance is strong. New technologies should be judged by demonstrated gains in detection, reliability, cost or decision quality. [1,6,7,9,10,19,20]

16. CONCLUSION

Quality control of herbal drugs requires an integrated, risk-based system extending from raw-material sourcing to finishedproduct release and stability monitoring. Botanical authentication, GACP, representative sampling, pharmacognostic examination, physicochemical tests and contaminant assessment establish incoming-material quality. Extraction controls, marker assays and chromatographic fingerprints characterize preparations and support batch consistency. GMP, in-process controls, validated methods, suitable finished-product testing, packaging controls and stability studies preserve quality through manufacture and shelf life. No single test is sufficient: microscopy, DNA methods, fingerprints and marker assays answer different questions and should be combined according to risk. Reliable herbal medicines require documented identity, purity, strength, consistency and traceability, with clear separation between analytical quality, safety and clinical efficacy. [1–22]

17. REFERENCES

1. World Health Organization. Quality control methods for medicinal plant materials. Geneva: WHO; 1998.
2. World Health Organization. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Geneva: WHO; 2003.
3. U.S. Food and Drug Administration. Botanical Drug Development: Guidance for Industry. Silver Spring, MD: FDA; 2016.
4. European Medicines Agency. Guideline on good agricultural and collection practice (GACP) for starting materials of herbal origin. Revision 1. Amsterdam: EMA; 2025.
5. European Medicines Agency. Questions and answers on quality of herbal medicinal products/traditional herbal medicinal products. Revision 7. EMA/HMPC/41500/2010; 2024.
6. International Council for Harmonisation. ICH Q2(R2): Validation of Analytical Procedures. Geneva: ICH; 2023.
7. International Council for Harmonisation. ICH Q14: Analytical Procedure Development.

Geneva: ICH; 2023.

8. International Council for Harmonisation. ICH Q1A(R2): Stability Testing of New Drug Substances and Products. Geneva: ICH; 2003.
9. World Health Organization. Quality control methods for herbal materials. Geneva: WHO; 2011.
10. World Health Organization. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues. Geneva: WHO; 2007.
11. World Health Organization. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. 2nd updated ed. Geneva: WHO; 2007.
12. European Medicines Agency. Guideline on quality of herbal medicinal products/traditional herbal medicinal products. EMA/HMPC/201116/2005; current revision.
13. European Directorate for the Quality of Medicines & HealthCare. European Pharmacopoeia. Strasbourg: Council of Europe; current edition.
14. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Ghaziabad: IPC; current edition.
15. Evans WC. Trease and Evans Pharmacognosy. 16th ed. Edinburgh: Saunders Elsevier; 2009.
16. World Health Organization. WHO monographs on selected medicinal plants. Geneva: WHO; various volumes.
17. Basak BB, Thondaiman V, Saha A, Manivel P. Good agricultural and collection practices of medicinal plants for supply of quality raw herbal drug. Indian Farming. 2018.
18. U.S. Food and Drug Administration. Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR Parts 210 and 211. Washington, DC: U.S. Government Publishing Office; current edition.
19. International Council for Harmonisation. ICH Q9(R1): Quality Risk Management. Geneva: ICH; 2023.
20. International Council for Harmonisation. ICH Q10: Pharmaceutical Quality System. Geneva: ICH; 2008.
21. World Health Organization. WHO good manufacturing practices for herbal medicines. Geneva: WHO; 2007.
22. European Medicines Agency. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products. EMA/HMPC/162241/2005; current revision.