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REVIEW ARTICLE

Towards Standardization of Ayurvedic Formulations: Integrating Classical Pharmaceutical Principles with Modern Quality Control and Analytical Approaches

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Abstract

Ayurvedic formulations occupy a substantial share of pharmaceutical practice in India and an expanding niche internationally, yet their quality assurance remains uneven. This critical narrative review examines how classical pharmaceutical principles recorded in *Bhaishajya Kalpana* (Ayurvedic pharmaceutics) and *Rasashastra* (the Ayurvedic discipline concerned with pharmaceutical processing, including mineral and metallic substances) can be integrated with contemporary quality-control and analytical approaches. Raw-material variability, incomplete botanical authentication, adulteration, poorly documented processing, and batch-to-batch inconsistency remain persistent obstacles, and contamination surveillance repeatedly reports toxic elements and microbial hazards in herbal products. Classical frameworks, including graded extraction forms, purification, levigation, controlled thermal processing, and organoleptic completion indicators, encode process knowledge that is largely undocumented in modern pharmaceutical terms. Contemporary methods, including pharmacognostical evaluation, dosage-form-specific physicochemical testing, chromatographic fingerprinting with chemometric support, elemental and spectroscopic analysis, and contaminant screening, offer complementary tools, subject to validated, formulation-specific methods. Official infrastructure, comprising the Ayurvedic Pharmacopoeia of India, the Ayurvedic Formulary of India, statutory good manufacturing practice, and WHO guidance, provides a regulatory baseline whose coverage of compound formulations remains incomplete. The review proposes a staged integration framework, identifies research gaps, and argues that standardization should preserve the pharmaceutical identity of classical formulations while subjecting them to verifiable, reproducible quality control. No evidence was identified that classical processing alone guarantees product safety.

Keywords: Ayurvedic Formulations; *Bhaishajya Kalpana*; Pharmaceutical Standardization; Quality Control; Analytical Techniques; Good Manufacturing Practices; Quality Assurance

Introduction

Ayurvedic medicines are prepared from plant, mineral, and animal starting materials using pharmaceutical methods documented in classical compendia and, in India, codified within statutory formularies and pharmacopoeias. The Government of India has reported 645 monographs for single drugs and 203 for compound formulations in the Ayurvedic Pharmacopoeia of India, alongside 986 formulations listed in the Ayurvedic Formulary of India, a gap that signals how much of the pharmacopoeial universe still lacks finished-product standards.[1] Ensuring the identity, purity, strength, and reproducibility of these products is not a cosmetic regulatory exercise. Reviews of herbal quality control consistently show that analytical strategy must follow a clearly defined goal, and that ambiguous nomenclature, sampling, and sample preparation are themselves sources of avoidable error.[1] Comparable analyses emphasise that quality must be engineered across development, manufacture, and distribution rather than tested in at the end.[2]

The difficulty is structural. Ayurvedic formulations are frequently multi-ingredient and prepared through sequential processes whose endpoints were defined by observation rather than measurement. Botanical identity, growing conditions, harvesting, and post-harvest handling all propagate into the finished product, and standardization that relied solely on isolated chemical markers would misrepresent this complexity. The alternative developed here is to document classical process knowledge in pharmaceutical terms and to characterise products with a fit-for-purpose panel of methods. This review critically examines classical pharmaceutical principles, the principal standardization challenges, modern analytical approaches, and the regulatory framework, and proposes an integration framework. It is a narrative review based on publicly

verifiable literature and official documents; it reports no new experimental data, and it distinguishes statutory requirements from scientific recommendations throughout.

Classical Pharmaceutical Principles in *Bhaishajya Kalpana*

Graded extraction: *Panchavidha Kashaya Kalpana*. *Sharngadhara Samhita* opens its pharmaceutical section with five basic extraction forms: *Swarasa* (expressed juice), *Kalka* (paste), *Kwatha* (decoction), *Hima* (cold infusion), and *Phanta* (hot infusion), arranged in descending order of concentration (mentioned in table 1).[4] *Charaka Samhita* treats oleation and its preparations separately in *Sutra Sthana* 13, underscoring that fat-based preparations follow their own logic.[5] The pharmaceutical point is that drug-to-liquid proportion, temperature, and duration define how much, and what, dissolves. A decoction and a cold infusion of the same drug are, analytically, different extract matrices: solids content, extractive value, and chromatographic profile can be expected to differ. Published comparative analytical data across the five forms are nevertheless sparse, so treating the five forms as interchangeable in quality specifications would be an unforced error. Dosage-form-specific physicochemical parameters, as pharmacopoeial practice already recognises, follow from this heterogeneity.[14]

Processing methods - Beyond extraction, Ayurvedic pharmaceutics relies on *Bhavana* (levigation of powders with specified liquid media), *Shodhana* (traditional purification or processing of raw materials), *Mardana* (trituration), *Paka* (controlled heating or cooking), and *Sneha Paka* (preparation of medicated oils and ghee).[6] The evidence base for these processes is uneven. For *Shodhana* of poisonous plants, published reviews document medium-dependent transfer of toxic alkaloids: strychnine and brucine migrate into the milk medium during processing of Nux vomica, supporting a chemical rather than merely procedural reading of the step.[6,7] For *Sneha Paka*, a comparative study of the *Mridu*, *Madhyama*, and *Khara* cooking stages of Panchagavya *Ghrita* demonstrated measurable physicochemical and chromatographic differences between the classical endpoints.[8] Recent work has even instrumented classical sensory assessment, tracking perceptual changes in mercury (*Parada*) across sequential processing steps.[9] Such studies indicate that classical processes are tractable to pharmaceutical characterisation; they do not license the generalisation that processing automatically removes toxicity.

Table 1. Classical Ayurvedic pharmaceutical processes and their relevance to contemporary quality control

Classical process	Traditional purpose	Relevant pharmaceutical parameters	Potential contemporary analytical assessment
Panchavidha Kashaya Kalpana (Swarasa, Kalka, Kwatha, Hima, Phanta)	Graded extraction of therapeutic constituents from raw drugs	Drug-to-liquid proportion; heat exposure; duration; particle condition	Total solids; extractive values; density and viscosity; chromatographic profile defined per dosage form
Bhavana	Levigation of powders with specified liquid media	Number of cycles; identity of medium; grinding duration	Particle-size distribution; extractive-value change across cycles
Shodhana	Purification/processing of raw materials, classically mandatory for poisonous substances	Processing medium; temperature; duration; number of cycles	Studies of alkaloid or elemental migration into media; residual-toxicant assays
Mardana	Trituration to homogeneity	Duration; vessel material; fineness of powder	Particle-size distribution; homogeneity by stratified sampling
Paka / Sneha Paka	Controlled heating or cooking, including medicated oils and ghee	Heat intensity and duration; stage endpoints (mridu, madhyama, khara)	Physicochemical and chromatographic comparison of stage endpoints; oxidative-change markers
Siddhi Lakshana	Organoleptic indicators of process completion	Colour; lustre; texture; aroma; classical endpoint tests	Correlation studies pairing sensory endpoints with instrumental measurement

Classical quality assessment- *Siddhi Lakshana* (traditional indicators of process completion), including colour, lustre, texture, aroma, and classical endpoint tests, function as in-process checks. Their weakness is subjectivity and inter-observer variability; their strength is that they encode endpoint knowledge accumulated over long practice. Documented alongside instrumental measurements, they can be treated as process

observations to be correlated with, and eventually partly replaced by, objective parameters.[8,9]

Challenges in Standardization of Ayurvedic Formulations

The obstacles to consistent quality begin before manufacturing. Botanical raw drugs suffer substitution and adulteration, and correct identification still depends substantially on morphological expertise. Geo-climatic and seasonal variation alters phytochemical content, and harvesting and post-harvest handling are rarely controlled to a documented standard. At the manufacturing stage, formulations prepared traditionally in small batches with manual heating encounter industrial equipment whose heat-transfer characteristics differ, so the same classical recipe can yield products with different extractive profiles. Processing time and temperature, vessel material, and operator judgement introduce batch-to-batch variability that published pharmaceutico-analytical studies of individual formulations repeatedly confront. Contamination compounds the problem: a systematic review of 91 studies of herbal medicinal products in low- and middle-income countries found recurrent contamination with metals, microbial loads, mycotoxins, and pesticide residues.[10] For Ayurvedic products specifically, Saper and colleagues reported that about one fifth of seventy Ayurvedic products purchased in Boston-area stores contained potentially toxic levels of lead, mercury, or arsenic[11], and that roughly one in five internet-purchased products of both Indian and US manufacture contained detectable toxic elements.[12] In an Indian market survey of 43 preparations, metals were detected in every analysed sample, with several exceeding referenced FAO/WHO limits.[13] Whether such findings reflect deliberate herbo-mineral composition, incidental contamination, or poor practice is formulation-specific; the regulatory point is that surveillance and specifications are indispensable. Marker selection for polyherbal formulations remains genuinely difficult, because no single constituent can represent a formulation and authentic reference standards for many classical ingredients are unavailable or costly. Storage and stability complete the list, as semisolid and lipid dosage forms are particularly sensitive to oxidative and microbial change. Standardization must therefore be designed formulation by formulation rather than declared generically.

Modern Quality Control and Analytical Approaches

Pharmacognostical evaluation- Authentication begins with macroscopic and microscopic examination, including organoleptic characters and powder microscopy of diagnostic structures, methods consolidated in the WHO quality-control manual for herbal materials.[14] Molecular identification adds resolving power where morphology fails, and DNA barcoding now forms part of the herbal quality-control repertoire.[1] Its applicability to extensively heated, calcined, or fermented formulations is methodologically constrained, so genetic authentication is best applied at the raw-material stage.

Physicochemical standardization - Loss on drying, total and acid-insoluble ash, water- and alcohol-soluble extractives, pH, viscosity, specific gravity, and particle-size distribution constitute the standard panel; which parameters apply is a function of dosage form and pharmacopoeial monograph rather than a universal checklist.[3,14] Their value lies less in any single value than in defining a product's own acceptance ranges from development batches, an approach that respects formulation specificity and avoids importing specifications from unrelated products.

Chromatographic technique- TLC and HPTLC provide accessible fingerprinting, and a standardised HPTLC approach with defined validation parameters supports quality control and stability testing of herbals.[15] HPLC quantifies selected markers, while GC-MS and LC-MS extend coverage to volatile and to thermolabile or polar constituents. Chromatographic fingerprinting, developed originally for traditional Chinese medicines, addresses identity, stability, and batch-to-batch consistency of complex extracts,[16] and fingerprints are defended as representing the chemical integrity of an herbal medicine better than single markers can.[17] Recent reviews consolidate fingerprint techniques and their coupling with chemometrics, including similarity analysis, classification, and regression, as the current state of the art.[18,19] Two cautions follow. A fingerprint documents consistency; it does not by itself demonstrate therapeutic equivalence. And a single marker compound,

even rigorously quantified, cannot establish the overall quality of a multi-ingredient formulation.

Spectroscopic and elemental analysis- FTIR and UV-Visible spectroscopy offer rapid, low-cost orthogonal confirmation, and X-ray diffraction characterises crystalline phases in herbo-mineral preparations where classical tests cannot specify chemistry. Atomic absorption spectroscopy and ICP-MS quantify elemental content and are indispensable for toxic-element screening.[11,12,13] For mineral-containing formulations, however, total elemental content is not synonymous with toxicity: chemical speciation, matrix binding, and bioavailability determine biological behaviour, and few published studies bridge that gap for classical preparations. Method choice should follow the quality attribute of interest rather than instrumental availability.

Microbial quality and contaminant assessment- Microbial limits, pesticide residues, aflatoxins, and toxic elements form the contaminant panel. WHO's 2007 guidelines frame the assessment of contaminants and residues in herbal medicines,[26] and its 2011 manual specify test methods.[14] Applicable acceptance limits are set by national pharmacopoeial and legal provisions and differ between raw materials and dosage forms; identical specifications should not be assumed across formulations, and numerical limits are deliberately not restated here because they must be applied from the operative legal text rather than reproduced from memory. Method validation underpins all of these approaches. ICH Q2(R1) defines the validation characteristics of accuracy, precision, specificity, detection and quantitation limits, linearity, and range,[20] and has recently been revised as Q2(R2).[21] ICH texts are not binding for Ayurvedic drugs in India, but they remain the most developed available framework for demonstrating that an analytical method is fit for purpose, and adapting them to complex matrices is itself a research task.

Integration of Classical Principles with Modern Quality Assurance

The classical record can be read as a proto-quality system: named processes, proportions, sequences, and endpoints. Integration therefore means translation rather than replacement. Raw-material qualification combines pharmacognostical authentication with contaminant screening before processing. Classical procedures should be transcribed into standard operating procedures that fix drug-to-liquid proportions, media, vessel, heat intensity, and duration, the parameters classical texts indicate but rarely quantify. Critical process parameters can then be identified and their influence on finished-product characteristics studied in the spirit of quality by design; quality by design is proposed here as a scientific framework, not claimed as an implemented or mandatory standard for Ayurvedic manufacture. In-process checks pair Siddhi Lakshana with measurable surrogates, and the Sneha Paka stages provide the model, since classical endpoints there correspond to demonstrable physicochemical differences.[8] Finished-product specifications combine the physicochemical, chromatographic, and contaminant panels discussed above; analytical methods require documented validation in the ICH sense;[20] and batch manufacturing records with site GMP compliance are statutory obligations under Schedule T.[22] Stability assessment, packaging, and storage conditions complete the system, and periodic review of specifications closes the loop. Throughout, the classical identity of the formulation, meaning its ingredients, proportions, and process sequence, is the object being protected: documentation and instrumentation serve the reproducibility of the traditional product, not its redesign.

Regulatory Framework and Pharmacopoeial Standards

In India, statutory quality obligations are specific. Licensing to manufacture Ayurvedic drugs is governed by Rule 158-B of the Drugs and Cosmetics Rules, 1945, and compliance with the good manufacturing practices of Schedule T is mandatory for licensed manufacturers, together with adherence to pharmacopoeial quality standards.[22,24] The Pharmacopoeia Commission for Indian Medicine and Homoeopathy publishes and revises the Ayurvedic Pharmacopoeia of India, whose standards become part of the Drugs and Cosmetics regulatory framework once notified.[3] The Ayurvedic Formulary of India, maintained through periodic amendments, compiles classical and patent-proprietary formulae,[25] and 2014 GMP guidelines elaborated the Schedule T requirements for larger manufacturing

units.[23] WHO guidance provides an international reference for contaminants and residues[26] and for test methods.[14] The distinction between law and best practice matters here. Compliance with Schedule T and applicable pharmacopoeial monographs is obligatory; chromatographic fingerprinting, chemometrics, validated species authentication, and quality-by-design process characterisation are, by contrast, scientific recommendations that current Indian regulations do not generally mandate for Ayurvedic products. Monograph coverage is also incomplete: as officially reported, published API monographs cover a minority of the formulations listed in the AFI, so many marketed compound formulations lack finished-product monographs and manufacturers must develop in-house specifications. Stating this plainly is more useful than implying that pharmacopoeial coverage is comprehensive.

Proposed Framework for Standardization of Ayurvedic Formulations

A practical framework follows from the preceding analysis and is summarised in Table 2.

Table 2. Proposed integrated framework for standardization of Ayurvedic formulations

Standardization stage	Classical pharmaceutical consideration	Contemporary quality-control approach	Expected quality objective	Validation requirements
Raw-material authentication and qualification	Classical identity of the dravya; seasonal collection guidance	Pharmacognosy; DNA barcoding; contaminant screening	Authenticated, uncontaminated starting material	Method suitability for matrix; documented reference specimens
Verification of classical formulation reference	Formulae and process sequence in classical texts	Verified edition; cross-check with AFI entries	Traceable formula provenance	Edition and chapter documented
Documentation of traditional process	Kalpana procedure; proportions; media; sequence	Transcription into standard operating procedures	Reproducible batch protocol	SOP review against the classical source
Identification of critical manufacturing parameters	Heat, duration, and ratios implied classically	Critical process parameter mapping (quality-by-design style)	Defined and justified parameter ranges	Formulation-specific experimental study
Physicochemical testing	Dosage-form character recognised classically	Loss on drying, ash, extractives, pH, viscosity, particle size	In-house acceptance ranges	Pharmacopoeial methods where available
Chromatographic fingerprinting	Process defines the product's chemical profile	TLC/HPTLC/HPLC fingerprinting with chemometrics	Batch-to-batch chemical consistency	Validated method with ICH-style parameters
Contaminant and microbial assessment	Not addressed classically as such	Microbial limits; pesticide, aflatoxin, elemental testing	Safety conformance	Accredited laboratory testing
Analytical method validation	Not addressed classically	ICH Q2(R1)/Q2(R2)-style validation	Fit-for-purpose analytical methods	Documented validation report
Batch reproducibility evaluation	Consistency of craft outcomes	Fingerprint similarity analysis; specification conformity	Acceptable, defined variability	Statistical evaluation across batches
Stability and packaging assessment	Limited classical storage guidance	Stability studies; container-closure evaluation	Justified shelf-life and storage conditions	Stability-indicating methods
Documentation and regulatory compliance	Provenance of the formulation	Batch records; Schedule T GMP; labelling	Regulatory conformance	GMP audit readiness
Periodic review of specifications	Critical textual transmission	Specification review; complaint and recall data	Continuous improvement	Scheduled management review

It sequences twelve stages: authentication and qualification of raw materials; verification of the classical formulation reference; documentation of the traditional process; identification of critical manufacturing parameters; dosage-form-specific physicochemical testing; development of chromatographic fingerprints; contaminant and microbial assessment; analytical method validation; evaluation of batch-to-batch reproducibility; stability and packaging assessment; documentation and regulatory compliance; and periodic

review of specifications. Each stage carries an explicit classical counterpart where one exists, because in Ayurvedic pharmaceutics the process is the product, and each requires formulation-specific validation. The framework is offered as an author-proposed synthesis of published guidance; it is not an officially approved standard, and its stages will require adaptation to dosage form, manufacturing scale, and regulatory context.

Research Gaps and Future Directions

Several gaps are evident from the reviewed literature. Method development is rarely formulation-specific, and validated, stability-indicating methods are scarce for classical preparations. Multi-marker quantification and fingerprint-chemometric combinations are established conceptually[18,19] but applied unevenly to Ayurvedic dosage forms. Process analytical technologies, including in-line temperature, viscosity, or near-infrared monitoring, could convert *Siddhi Lakshana* into continuous measurements but await systematic study. Raw-material traceability from cultivation site to factory is poorly documented in published form. Comparative studies of traditional and industrial processing of the same formulation are rare, as are multicentre analytical validation exercises. Complex polyherbal and herbo-mineral formulations remain the hardest cases, and authentic reference materials are a limiting resource. Reproducible methods, transparent reporting of process parameters, and shared data would raise the evidentiary ceiling faster than isolated single-laboratory studies.

Discussion

Three conclusions emerge from this synthesis. First, classical pharmaceutical principles and modern quality control are complementary rather than competing: classical texts define what the process is, and analytical science defines what was made. The distinction between traditional completion criteria and measurable quality attributes is therefore not a dismissal of the former but a translation of it, since *Siddhi Lakshana* encode endpoints that can, in favourable cases such as graded *Sneha Paka*,[8] be shown to correspond to physicochemical differences.

Second, chemical standardization establishes identity and consistency, not efficacy or clinical safety. A rigorously fingerprinted formulation may still lack evidence of therapeutic benefit, and contaminant surveillance[10,13] shows that quality failures are frequent and consequential. Neither clinical claim follows from analytical conformity, and neither should be made.

Third, implementation is stratified by resources. Advanced instrumentation, validated methods, and chemometric infrastructure are realistically available to larger manufacturers and academic centres, whereas much of the sector operates at a smaller scale where Schedule T compliance itself remains an achievement. Standardization strategies that ignore this gradient risk becoming formal compliance exercises, documentation without scientific substance. What existing evidence supports is clear: authenticated raw materials, defined processes, dosage-form-appropriate physicochemical testing, fingerprint-based consistency, and contaminant screening. What remains investigational is the correlation of classical process variables with finished-product attributes across formulations, and the clinical meaning of analytical consistency. Acknowledging that boundary is a condition of credible integration, not a concession.

Conclusion

Standardization of Ayurvedic formulations is best understood as a translation project: classical pharmaceutical knowledge provides the process definition, and modern quality systems provide the measurement, documentation, and regulatory interface. Raw-material authenticity, manufacturing consistency, analytical characterisation, contamination control, and pharmacopoeial compliance are the load-bearing elements, and none is optional. Current approaches remain limited by incomplete monograph coverage, the scarcity of formulation-specific methods, and uneven implementation capacity, and every quality specification ultimately requires validation in the context of the individual formulation. The responsible position is neither nostalgia nor dismissal: preserve the pharmaceutical identity of classical formulations, subject them to verifiable quality control, and let the resulting products be judged on evidence.

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