ISSN:3139-0935(Online)

Intemed: International Journal of Research in Integrated Medical Sciences (IJ-RIMS)

Journal homepage: www.intemed.in

Vol.: 2 | Issue: 10 | Oct 2026

Article History: Received: 02-10-2026 Accepted: 03-10-2026 Published:30-10-2026

DOI: doi.org/10.68108/intemed.v2.i10.1

Review Article

A THREE-TIER STANDARDIZATION MODEL FOR RASAOUSHADHI: INTEGRATING CLASSICAL *SIDDHI LAKSHANA*, PHARMACEUTICAL QUALITY ATTRIBUTES AND ADVANCED ANALYTICAL CHARACTERIZATION

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ABSTRACT

Rasaushadhi are pharmaceutical preparations in which metals, minerals and/or other substances undergo defined classical processing before use. Although classical *Siddhi Lakshana* provide formulation-specific evidence of completion, contemporary quality assessment increasingly requires objective information on identity, composition, physical attributes, process consistency and safety. This review aimed to develop a practical standardization framework that preserves classical pharmaceutical logic while incorporating modern quality-control and analytical approaches. Published literature on *Rasaushadhi* standardization, Bhasma characterization, pharmaceutical quality assurance and analytical validation was examined together with the supplied classical-quality-control literature. The synthesis supports a three-tier model: Tier I, classical process and end-point verification comprising *Shodhana*, *Bhavana*, *Marana*, *Bhasma Pariksha* and *Siddhi Lakshana*; Tier II, pharmaceutical quality attributes covering identity, purity, moisture, particle characteristics, elemental profile, process consistency, microbial quality where applicable and stability; and Tier III, advanced characterization using appropriately selected techniques such as powder X-ray diffraction, Fourier-transform infrared spectroscopy, electron microscopy with energy-dispersive analysis, elemental spectroscopy and particle-size analysis. A key principle is that classical tests and instrumental measurements should be treated as complementary rather than automatically equivalent. The proposed *Rasaushadhi* Quality Matrix links critical process variables with critical material attributes and a minimum analytical reporting dataset, providing a product-specific pathway for batch-to-batch comparability and risk-based safety assessment. The framework is intended as a research and quality-assurance model and requires formulation-specific validation before regulatory adoption.

Keywords: *Rasaushadhi; Bhasma; standardization; Siddhi Lakshana; quality control; pharmaceutical characterization; analytical characterization; batch consistency*

INTRODUCTION

Rasaushadhi represent a distinctive pharmaceutical class within Ayurveda in which metals, minerals and other materials are transformed through sequential operations such as *Shodhana*, *Bhavana* and *Marana*. Classical literature describes

defined process steps and end-point observations intended to establish suitability of the finished material. The supplied literature specifically documents classical Bhasma quality-control parameters including *Varna*, *Gata Rasatva*, *Nishchandratva*, *Apunarbhava*ta, *Niruttha*, *Varitara*, *Unnama*, *Rekhapurnatva*, *Slakshnatva* and *Susukshma*. These parameters reflect the traditional emphasis on process completion and finished-product characteristics. [1]

Modern standardization, however, requires more than a single end-point observation. Published characterization studies demonstrate that processing can be associated with changes in crystalline phase, morphology, particle characteristics and elemental composition. Studies of *Swarna Makshika* Bhasma, *Muktā* Bhasma, *Praval Bhasma* and *Suvarna Bhasma* have used combinations of powder X-ray diffraction, microscopy, energy-dispersive analysis, infrared spectroscopy, particle-size analysis and elemental assays to establish product fingerprints. [2-5] More recent work on Hridayarnava Rasa further illustrates the value of combining classical observations with powder X-ray diffraction, electron microscopy with energy-dispersive spectroscopy, elemental analysis, infrared spectroscopy, thermal analysis and particle-size distribution. [6]

At the same time, safety cannot be inferred from the presence of a classical label alone. Experimental evidence is formulation- and dose-specific, while reports of variable marketed products and clinical toxicity demonstrate the importance of manufacturing consistency, chemical form, exposure and pharmacovigilance. [7-10] The supplied safety literature similarly shows that a study-specific absence of selected toxicological changes does not establish universal safety for all *Rasaushadhi*. [7]

Accordingly, the central requirement is not replacement of classical standardization by modern analytical testing, but integration of the two within a traceable quality system. The purpose of this review is to propose a three-tier standardization model for *Rasaushadhi* that connects classical pharmaceutical operations and *Siddhi Lakshana* with pharmaceutical quality attributes and formulation-appropriate advanced analytical characterization.

MATERIALS AND METHODS

This was a structured narrative review and conceptual framework-development study. The supplied source material on *Rasaushadhi* pharmaceutics and safety was examined first, with particular attention to *Shodhana*, *Bhavana*, *Marana*, classical *Bhasma Pariksha* and *Siddhi Lakshana*. [1,7] External literature was then verified through PubMed-indexed publications and authoritative quality-guidance sources.

The evidence set was selected to represent four domains: (i) classical *Rasaushadhi* pharmaceutical processing and quality parameters; (ii) formulation-specific physicochemical characterization; (iii) safety and toxicity considerations; and (iv) general pharmaceutical quality-assurance and analytical-validation principles. Relevant reports were identified using combinations of the terms *Rasaushadhi*, Bhasma, *Shodhana*, *Marana*, *Siddhi Lakshana*, standardization, quality control, X-ray diffraction, infrared spectroscopy, electron microscopy, elemental analysis and particle-size analysis. The final framework was derived by mapping classical process controls and finished-product observations against modern critical quality attributes and analytical measurements.

No new human or animal experiment was performed for this review; therefore, institutional ethical approval was not applicable. Analytical techniques are presented as potential tools for characterization rather than as mandatory tests for every *Rasaushadhi*. Selection should depend on the material, intended claim, known risks, classical method of preparation and the analytical question being addressed. Where an analytical procedure is used for a defined quality decision, its suitability for the intended purpose should be established using appropriate validation principles. [11]

RESULTS

Evidence Synthesis

The reviewed evidence supports three complementary standardization domains. Classical procedures define the pharmaceutical identity of the preparation; pharmaceutical quality attributes define measurable release and consistency characteristics; and advanced analytical characterization explains material attributes that cannot be established reliably by visual or simple classical tests alone. The domains should be connected through documented process parameters and batch records rather than treated as independent checklists.

Tier I: Classical Pharmaceutical Standardization

Tier I begins with authenticated raw materials and controlled execution of the formulation-specific *Shodhana*, *Bhavana* and *Marana* sequence. Classical *Bhasma Pariksha* and *Siddhi Lakshana* are retained as essential formulation-specific end-point observations. Their value lies in confirming whether the material conforms to the expected classical state. However, a classical observation should not be assigned a modern analytical identity without direct validation.

Tier II: Pharmaceutical Quality Attributes

Tier II converts the manufacturing process into measurable quality attributes. The minimum set should include identity of starting materials; documentation of critical process variables; appearance and organoleptic characteristics where relevant; moisture or loss on drying where justified; particle characteristics; elemental composition and specified impurities; process yield and mass balance; microbial quality where applicable; packaging and storage conditions; and stability-related observations. For formulations containing intentionally added metals or minerals, total elemental content should be distinguished from chemical form/speciation and from contaminant assessment.

Tier III: Advanced Analytical Characterization

Tier III is question-driven rather than technology-driven. Powder X-ray diffraction is appropriate when phase or crystallinity information is required. Fourier-transform infrared spectroscopy can provide molecular or functional-group information, particularly where organic processing media may contribute to the final matrix. Scanning or transmission electron microscopy can document morphology and microstructural features; energy-dispersive spectroscopy can provide localized elemental information but should not be treated as a substitute for quantitative bulk elemental analysis. Inductively coupled plasma optical emission or mass spectrometry, or another validated elemental method, may be selected for quantitative elemental profiling. Particle-size analysis can complement microscopy, while thermal analysis may be useful when thermal transitions, decomposition or residual volatile components are relevant. Published *Rasaushadhi* studies demonstrate that combinations of these methods can produce formulation-specific analytical fingerprints. [2-6]

Integrated *Rasaushadhi* Quality Matrix

The proposed *Rasaushadhi* Quality Matrix links each critical process step to an expected material attribute, a classical verification point, a modern quality attribute and, where justified, an instrumental method. This prevents the common error of using an analytical instrument simply because it is available. For example, *Rekhapurnatva* may be considered a classical indication of fineness, but it should be described as a potential correlate of particle characteristics rather than as a validated equivalent of a numerical particle-size distribution. Likewise, *Nishchandratva* should not automatically be reported as proof of a particular crystalline phase, and *Apunarbhava* or *Niruttha* should not be declared equivalent to a specific X-ray diffraction or chemical result without formulation-specific evidence.

Minimum Analytical Reporting Dataset

For a publishable characterization study, the minimum reporting dataset should include: authenticated raw-material identity; complete classical processing sequence; critical process parameters; batch size and yield; classical *Siddhi Lakshana*; physicochemical quality attributes; quantitative elemental profile with specified impurities; structural or phase characterization when relevant; morphology and particle characteristics where relevant; analytical method details and suitability/validation information; storage and stability information where available; and batch-to-batch comparison. Reporting raw and processed material together is strongly encouraged because it allows the direction and magnitude of process-related changes to be demonstrated rather than inferred. [2-6,11]

Table 1. Proposed Classical–Modern Quality Correlation Matrix

Classical parameter	Primary classical meaning	Potential modern investigation	Interpretation
Rekhapurnatva	Fineness/ability to enter finger furrows	Particle-size distribution; microscopy	Potential correlate; not an automatic analytical equivalent
Varitara / Unnama	Floating behaviour of the powder	Bulk density, wettability and particle/morphology studies	Classical functional test requiring product-specific correlation
Nishchandratva	Absence of metallic lustre	Microscopy/optical assessment with phase characterization	Supportive evidence; not equivalent to X-ray diffraction
Apunarbhava	Non-reversion to metallic state	Formulation-specific chemical/metallurgical assessment	Requires direct validation for the material studied
Niruttha	Resistance to restoration of metallic form	Phase/chemical characterization where scientifically relevant	Complementary classical end-point
Varna	Characteristic colour/appearance	Standardized colour/appearance assessment plus phase/composition data	Supportive identity/consistency attribute

Table 2. Minimum Analytical Reporting Dataset for *Rasaushadhi* Standardization

Domain	Minimum information	Examples of appropriate evidence
Raw materials	Identity, source, authentication, specifications	Classical identity criteria; pharmacopoeial/validated identity testing
Process	*Shodhana*, *Bhavana*, *Marana* and critical parameters	SOP, batch record, time, temperature, media, number of cycles, yield
Classical end point	*Siddhi Lakshana* and *Bhasma Pariksha*	Formulation-specific classical tests
Physicochemical quality	Moisture, ash/other relevant attributes, particle characteristics	Validated routine QC methods
Elemental profile	Major elements and specified impurities	ICP-OES/ICP-MS/AAS or validated alternative
Structure and morphology	Phase, crystallinity, morphology	XRD, SEM/TEM, EDAX/EDS where justified
Chemical fingerprint	Relevant molecular/functional information	FTIR/Raman or formulation-appropriate method
Safety and stability	Risk-based safety, storage and stability observations	Validated limits, stability study, pharmacovigilance
Reproducibility	Batch-to-batch comparability	Multiple independent batches and predefined acceptance criteria

DISCUSSION

The proposed three-tier model addresses a central limitation in current *Rasaushadhi* standardization: classical tests, routine pharmaceutical quality tests and advanced instrumental characterization are often reported as parallel lists rather than as a connected quality system. Earlier scientific reviews highlighted the need for standards covering both methods of preparation and finished products. [12] Formulation-specific studies subsequently demonstrated that processing can alter mineral phase, morphology and particle characteristics, supporting the use of complementary analytical fingerprints. [2-6]

A major advantage of the model is that it preserves the classical process as a source of pharmaceutical identity rather than treating it as historical background. *Shodhana* and *Marana* are not simply preliminary steps; they are potential critical process stages whose variation can influence the finished material. Experimental work on *Lauha Bhasma*, for example, demonstrated measurable effects associated with purification steps and treating media. [13] Therefore, process documentation should record parameters that can be reproduced and compared across batches.

The model also prevents overinterpretation of classical-modern correlations. A classical test may capture a functional or perceptual attribute that is influenced by several material properties. A single instrumental result may likewise describe only one dimension of a complex material. Consequently, one-to-one equivalence should be claimed only when correlation has been experimentally established. This is particularly important for statements about particle size, phase transformation and chemical speciation.

Safety should be incorporated into the quality model but not reduced to total metal concentration alone. Reviews emphasize that the chemical form of an element, bioaccessibility, exposure and product composition influence risk assessment. [8] Comparative evaluation of marketed *Naga Bhasma* products has also demonstrated variability in particle size, metal form and lead content, illustrating why product identity and manufacturing consistency matter. [9] Conversely, a controlled animal study of selected Ayurvedic formulations found no significant changes in several neurobehavioral and oxidative-stress measures at tested doses, while brain heavy-metal levels were nevertheless increased; this illustrates the importance of interpreting toxicological evidence within its formulation, dose and endpoint boundaries. [7]

Clinical safety signals cannot be dismissed solely because a product is described as properly processed. A published case report has documented severe liver injury associated with consumption of an Ayurveda Bhasma product. [10] Such reports do not establish that all Bhasma are unsafe; rather, they reinforce the need for product-specific quality assurance, appropriate clinical evaluation and pharmacovigilance. The proposed framework therefore treats safety as a separate evidence stream that interacts with, but is not replaced by, pharmaceutical characterization.

From a contemporary pharmaceutical-quality perspective, the model is compatible with the principle that analytical procedures should be fit for their intended purpose. [11] It also aligns with the broader quality-assurance approach in which identity, purity, manufacturing controls, testing, stability and post-marketing surveillance are considered across the product life cycle. [14] For *Rasaushadhi*, however, these concepts must be adapted to the distinctive material complexity and classical manufacturing logic of each formulation.

The proposed framework is therefore best regarded as a research and quality-assurance model rather than a universal monograph. Different

formulations will require different analytical packages. A calcium-based shell Bhasma may require phase and elemental characterization, whereas a mercury- or arsenic-containing formulation may require much more stringent speciation and impurity assessment. The appropriate analytical panel should be determined by composition, processing pathway, intended use, known hazards and the quality decision that the test is expected to support.

Proposed Workflow

RAW MATERIAL AUTHENTICATION → CLASSICAL PROCESS CONTROL → TIER I: *SIDDHI LAKSHANA* AND *BHASMA PARIKSHA* → TIER II: PHARMACEUTICAL QUALITY ATTRIBUTES → TIER III: ADVANCED ANALYTICAL CHARACTERIZATION → INTEGRATED *RASAUSHADHI* QUALITY PROFILE → BATCH-TO-BATCH COMPARABILITY → RISK-BASED SAFETY AND STABILITY EVALUATION.

This workflow is intentionally sequential: an advanced instrument should not compensate for an uncontrolled classical process, and a satisfactory classical end point should not be used as a substitute for quantitative characterization when a measurable safety or quality attribute requires it.

Strengths and Limitations

The strength of this model is its integration of classical pharmaceutical identity with contemporary quality science and its emphasis on formulation-specific validation. Its principal limitation is that the model itself is conceptual and has not yet been prospectively validated across multiple *Rasaushadhi* formulations and manufacturing sites. Future work should test the framework using multiple independent batches, predefined acceptance criteria, inter-laboratory comparisons and, where relevant, stability and biological studies.

CONCLUSION

Rasaushadhi standardization should evolve from a checklist of isolated tests to a traceable, product-specific quality system. A three-tier structure integrating classical *Siddhi Lakshana*, pharmaceutical quality attributes and advanced analytical characterization provides a practical pathway for doing so. The proposed *Rasaushadhi* Quality Matrix and Minimum Analytical Reporting Dataset preserve the classical pharmaceutical foundation while making critical material attributes measurable, comparable and scientifically communicable. The framework does not assume that any single classical test or analytical technique proves safety; instead, it supports convergence of process control, finished-product characterization, batch consistency, stability and formulation-specific safety evidence. Its next step is prospective validation across representative *Rasaushadhi* classes before use as a formal standardization or regulatory framework.

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ACKNOWLEDGEMENTS

None.

FIGURE

Figure 1. Proposed three-tier *Rasaushadhi* standardization framework.

Legend: Classical pharmaceutical processing is linked to measurable quality attributes and formulation-appropriate advanced characterization. The framework is proposed for validation and should not be interpreted as a universal regulatory monograph.

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