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Standardization and Safety profiling of herbo-mineral drugs: A *Bhaishajya Vigyan* Approach

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Abstract
Herbo-mineral preparations, or Rasaushadhis, occupy a unique place in the therapeutic domain of Ayurveda. These formulations combine plant-derived ingredients with purified metals and minerals, providing potent remedies for chronic and otherwise intractable diseases. Despite their long-standing reputation and efficacy, concerns about their safety particularly their heavy metal content—continue to draw scrutiny in both national and international regulatory frameworks. This has brought attention to the urgent need for standardization, toxicological profiling, and quality control within the traditional framework of *Bhaishajya Vigyan*.

The present paper offers an in-depth exploration of how Ayurveda's own pharmaceutical methodology especially the principles of *Śodhana*, *Māraṇa*, and *Bhāvanā* addresses these safety concerns inherently. It further highlights how these traditional processes can be validated and supplemented with modern analytical tools like AAS, ICP-MS, and SEM to create a comprehensive standardization protocol. Drawing from classical texts, clinical practice, and laboratory research, this study presents a holistic model for ensuring the safety, efficacy, and global credibility of herbo-mineral medicines without compromising the integrity of traditional practices.

Keywords: *Bhaishajya Vigyan*, standardization, erbo-mineral drugs, erbo-mineral drugs

Introduction

Ayurveda, the science of life, is deeply rooted in the idea that the human body is an intricate interplay of biological forces, and that medicine should harmonize with these forces to restore health rather than suppress symptoms. Among its many formulations, *Rasaushadhi* or herbo-mineral drugs represent one of the most complex and refined domains. These are products of alchemical transformation, combining herbs with purified and processed metals such as mercury, gold, copper, and minerals like mica, arsenic, and sulfur. Such formulations are particularly revered in the treatment of chronic ailments like arthritis, autoimmune disorders, neurological conditions, and even certain types of cancers. The efficacy of these formulations is undisputed in traditional settings, but the inclusion of metals and minerals has sparked concern from toxicologists, modern medical practitioners, and regulatory authorities. In several cases, media reports and scientific critiques have highlighted the presence of harmful levels of lead, arsenic, or mercury in Ayurvedic formulations, sometimes due to improper processing or quality compromise. These incidents, though relatively rare, have cast a shadow over the entire domain of Rasaushadhis. Yet, such critiques often stem from a lack of understanding of the traditional pharmaceutical science known as *Bhaishajya Vigyan*. This branch of Ayurveda offers a comprehensive system for detoxifying, purifying, and transforming these substances into therapeutically safe forms. The ancient scholars did not use metals in their raw or crude form; instead, they developed meticulous procedures like *Śodhana* (purification), *Māraṇa* (incineration), and *Bhāvanā* (levigation) to ensure these substances were rendered non-toxic, bioavailable, and biocompatible. Furthermore, rigorous testing protocols like *Bhasma Parīkṣā* ensured that only properly prepared medicines were administered. This paper argues that when these classical methods are rigorously followed, the resulting herbo-mineral formulations are not only safe but therapeutically superior in many conditions. It further advocates that standardization of these formulations should not aim to replace traditional wisdom with modern parameters, but rather to harmonize classical protocols with scientific validation techniques.

The aim is not just to defend traditional medicine, but to ensure that it meets the evolving expectations of safety, transparency, and accountability in global healthcare systems.

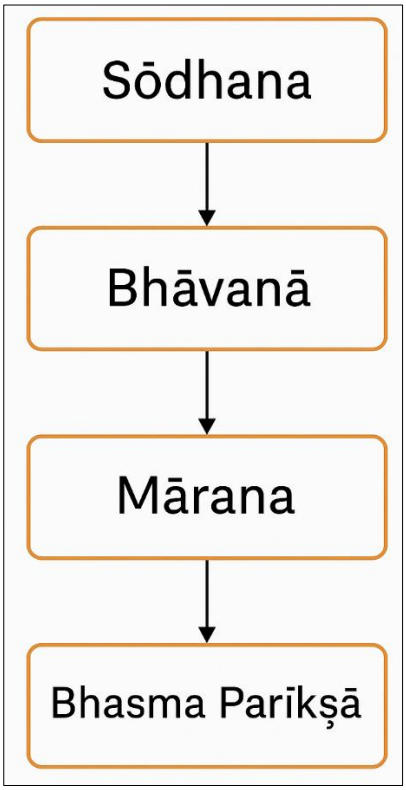

Fig 1: Traditional Flow of Herbo-Mineral Drug Preparation in Ayurveda, illustrating the sequential pharmaceutical steps of Śodhana (purification), Bhāvanā (levigation), Māraṇa (incineration), and Bhasma Parīkṣā (quality assessment)

Main Objective

The primary objective of this paper is to critically examine and establish how the traditional pharmaceutical processes outlined in *Bhaishajya Vigyan* specifically *Śodhana* (purification), *Māraṇa* (incineration), and *Bhāvanā* (levigation) serve as intrinsic methods of standardization and safety assurance in the preparation of herbo-mineral Ayurvedic formulations.

Literature Review

The study of herbo-mineral formulations in Ayurveda has a long-standing history that bridges classical Ayurvedic literature and emerging scientific investigations. Classical Ayurvedic treatises such as *Rasa Ratna Samuccaya*, *Rasa Tarangini*, and *Bhaishajya Ratnavali* offer detailed descriptions of the procedures and principles governing the safe use of metals and minerals in medicine. These texts outline the systematic steps of *Śodhana*, *Māraṇa*, and *Bhāvanā*, along with the importance of *Anupāna*, therapeutic indications, and post-processing qualitative tests like *Rekhāpūrnata* and *Varitaratva* to assess the quality and safety of *Bhasma*.

In *Rasa Ratna Samuccaya* (5/32), it is explicitly stated that purified and properly processed minerals, when used as per textual guidelines, do not exert toxic effects. This classical assurance forms the foundation upon which modern researchers have attempted to validate the pharmacological safety of herbo-mineral preparations. Contemporary Ayurvedic scholars such as Sharma (2011) [6] and Patgiri (2013) [5] have emphasized the need to integrate classical knowledge with scientific rigor to meet the challenges posed by regulatory bodies and public health concerns.

Scientific research over the past two decades has increasingly focused on the physicochemical characterization of *Bhasmas*. Several studies using advanced techniques like Scanning Electron Microscopy (SEM) and X-Ray Diffraction (XRD) have confirmed the nanoscale particle size and crystalline structure of *Swarna Bhasma*, *Abhraka Bhasma*, and *Tamra Bhasma*, explaining their enhanced bioavailability and clinical efficacy. Ravikumar *et al*. (2015) [7] demonstrated that Swarna Bhasma prepared via classical methods yielded particles in the range of 50-100 nm with uniform morphology, which is believed to facilitate better absorption and therapeutic response.

Toxicological assessments have also been conducted to assess the safety of these formulations. In a study published in the *Journal of Ayurveda and Integrative Medicine*, Sharma *et al*. (2011) [6] demonstrated that *Rasa Sindūra* administered under clinical supervision showed no adverse impact on hepatic or renal functions in patients with rheumatoid arthritis. Likewise, experimental studies conducted on rodents by Galib *et al*. (2012) [8] established that *Abhraka Bhasma*, when administered in therapeutic doses, did not result in any histopathological damage to vital organs.

While these findings are encouraging, researchers such as Singh (2010) [15] and Katiyar (2004) [9] have also pointed out inconsistencies in quality and safety among commercially available formulations, especially when traditional procedures are compromised. The need for batch-wise standardization, validated protocols, and harmonized guidelines with modern parameters has been strongly emphasized.

Overall, the literature supports the claim that when herbo-mineral formulations are prepared according to classical standards and validated with modern tools, they can be both safe and effective. However, the gap between traditional practice and contemporary regulatory expectations necessitates a structured and integrative approach to standardization and safety profiling a theme this paper explores further.

2. The Classical Philosophy of Rasaushadhi and *Bhaishajya Vigyan*

In Ayurveda, the approach to medicine is deeply philosophical, as well as empirical. Every material is seen not only in terms of its physical properties but also in terms of its guna (qualities), rasa (taste), virya (potency), vipāka (post-digestive effect), and prabhāva (unique effect). Metals and minerals were not used arbitrarily; their inclusion was based on these subtle but scientifically observed properties. The science of *Rasa Shastra* sometimes translated as Ayurvedic alchemy emerged from the need to enhance the potency and shelf life of medicines. These herbo-mineral combinations were observed to act faster, require smaller doses, and often had a curative impact on diseases considered incurable by herbal formulations alone. A central tenet of this practice is the idea that a substance is not inherently toxic or non-toxic; its toxicity depends on its state, dose, and method of preparation. For instance, raw mercury is undoubtedly poisonous. However, the same mercury, when subjected to systematic *Śodhana* and *Māraṇa*, transforms into a bioavailable compound such as

Rasa Sindūra, which is therapeutically used for rejuvenation and immune enhancement. Ayurvedic texts like *Rasa Ratna Samuccaya*, *Rasa Tarangini*, and *Bhaishajya Ratnavali* offer detailed instructions on how to detoxify these metals, indicating the required heating cycles, number of *Bhāvanās*, appropriate media, and necessary herbal additives. The Śodhana process, which may involve repeated heating, quenching, soaking, or triturating in specific herbal juices or decoctions, is aimed at removing both physical impurities and inherent toxicity. The *Māraṇa* process transforms these purified substances into fine ash or *Bhasma* through controlled incineration. This ash, when subjected to traditional quality tests, demonstrates remarkable properties such as being able to float on water (*Varitara*), penetrate minute lines on the finger (*Rekhāpūrṇata*), and not react with acidic substances (*Niruttha*), indicating its fineness, assimilation capacity, and stability. These classical tests, although qualitative, show surprising correlation with modern physicochemical attributes such as particle size, porosity, and solubility.

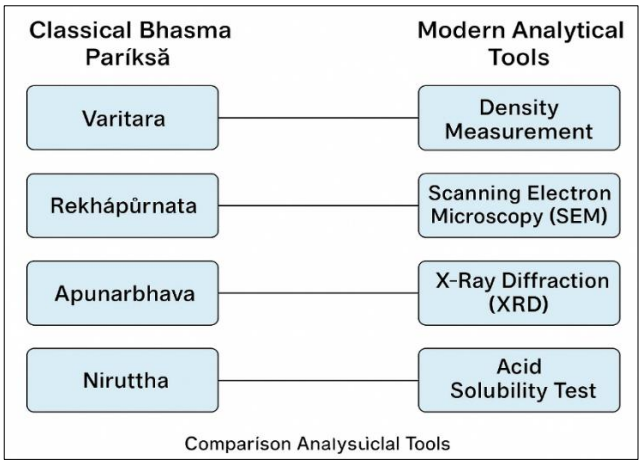

Fig 2: Comparative flowchart illustrating traditional Bhasma Parīkṣā methods in Ayurveda alongside their modern analytical equivalents, showing alignment between classical quality assessment and contemporary scientific validation

3. Modern validation techniques and the integration imperative

While the traditional systems provided reliable methods within the Ayurvedic paradigm, modern scientific tools allow us to peer deeper into the physicochemical structure and biological behavior of these formulations. The need to integrate these tools has become pressing, not only to comply with regulatory expectations but also to dispel misinformation and mistrust. Techniques such as X-Ray Diffraction (XRD) and Scanning Electron Microscopy (SEM) allow us to observe the crystal structure and particle size of *Bhasmas*, often revealing that they fall within the nanometric range. This size reduction, achieved through traditional incineration cycles, likely explains the rapid absorption and cellular penetration of these medicines. Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Atomic Absorption Spectroscopy (AAS) help quantify the presence of heavy metals and determine whether they are in safe forms and acceptable limits. Interestingly, in properly processed *Bhasmas*, these metals are often present in bound forms (like sulfides or oxides) that are poorly soluble and hence minimally toxic. Clinical pharmacokinetic studies also support the claim that Ayurvedic *Bhasmas*, when administered with proper Anupāna (vehicle like ghee, honey, or milk), demonstrate high bioavailability without causing systemic toxicity. For example, *Abhraka Bhasma* prepared with multiple *Putas* and administered with *Madhu-Ghṛta* shows improved hemoglobin levels and tissue rejuvenation in patients with anemia, without signs of liver or kidney burden. Despite such promising evidence, standardization challenges persist. Variations in raw material source, deviation from classical procedures, and lack of batch-specific quality checks can compromise safety. Therefore, a hybrid standardization protocol is necessary one that respects and retains classical principles but supplements them with modern quality assurance tools.

4. Safety Considerations: Classical Assumptions and Modern Realities

One of the most enduring criticisms of herbo-mineral drugs arises from concerns about toxicity, particularly due to the involvement of metals like mercury, lead, and arsenic. However, this concern is valid primarily in cases of improper manufacturing, non-adherence to classical processing methods, or spurious and adulterated products. It must be emphasized that toxicity arises not from the material alone but from its unrefined, impure, or unstandardized state. In classical Ayurveda, the idea that a purified substance, when correctly prepared and administered, can act as both a curative and rejuvenator is foundational. The preparation process transforms potentially toxic materials into therapeutic agents. Take, for instance, mercury an element widely criticized in modern toxicology. Ayurveda does not use elemental mercury directly but combines it with sulfur, repeatedly purifies and incinerates it, and binds it with herbs to create *Rasa Sindūra*. Modern studies have revealed that such formulations contain mercury in the form of cinnabar (HgS), which is relatively stable and poorly absorbed in the gastrointestinal tract, thus possessing limited systemic toxicity. There are also indications that *Māraṇa* reduces particle size to the nanoscale, which enhances biological compatibility. Scanning Electron Microscopy (SEM) studies on *Swarna Bhasma* and *Tamra Bhasma* have revealed uniform, non-aggregated, spherical particles in the range of 50 to 100 nanometers. These findings explain the rapid action and better tissue targeting seen in clinical use. Additionally, clinical safety has been observed when herbo-mineral formulations are administered with appropriate *Anupānas* or carriers. For example, *Guduchi Svarasa* is used as an Anupāna with *Tamra Bhasma* to improve hepatoprotection and minimize any residual toxicity. These traditional carriers may play a pharmacological role by modifying the absorption rate, reducing irritation to the gastrointestinal lining, or binding to any unprocessed metal residue. Despite this, toxicity remains a genuine concern when traditional methods are not followed properly, when industrial shortcuts replace multi-stage *Śodhana* or *Māraṇa*, or when inferior raw materials are used. In many commercial formulations, a lack of traceability, insufficient purification, and absence of batch-wise quality control have been identified. These lapses justify skepticism among scientists and regulators and make a strong case for implementing structured safety protocols alongside traditional methods. There is a growing body of modern research that supports the safety of properly prepared formulations. Acute and

chronic toxicity studies conducted in rats for various *Bhasmas* (e.g., *Abhraka*, *Mandura*, *Swarna*) have consistently shown safe dosage ranges and no signs of organ damage at therapeutic levels. Clinical studies, including randomized controlled trials on *Rasa Sindūra* in rheumatoid arthritis, *Yogendra Rasa* in neurological conditions, and *Swarna Bhasma* in immune-compromised patients, have shown not only safety but also enhanced efficacy when compared to herb-only controls. Still, much of this data remains unpublished or scattered in postgraduate Ayurvedic theses, regional journals, or institutional reports. The lack of centralized toxicity data hampers confidence and makes it difficult for these formulations to pass international scrutiny. A national or international pharmacovigilance initiative focused specifically on herbo-mineral formulations could bridge this critical gap.

5. The regulatory landscape and the case for standardization

The global Ayurvedic market is expanding, but so are the challenges. International regulatory bodies such as the US FDA, UK MHRA, and Health Canada have raised red flags about the presence of heavy metals in Ayurvedic products. While some of these warnings are due to improperly prepared or exported formulations, the overall credibility of Ayurveda suffers from the actions of a few irresponsible manufacturers.

In India, the Ministry of AYUSH has issued several guidelines and Good Manufacturing Practices (GMP) for Ayurvedic drug manufacturers. The Ayurvedic Pharmacopoeia of India (API) now includes monographs on various *Bhasmas* and *Rasaushadhis*, specifying physicochemical parameters, qualitative identification tests, and permissible limits for heavy metals. However, compliance remains uneven.

Regulators, both domestic and foreign, require consistent answers to the following:

- What are the upper permissible limits of metals in formulations?
- Are these metals bioavailable in toxic forms or in safely bound, poorly absorbed forms?
- Are toxicity studies and safety profiles publicly accessible and validated?
- Is there batch-to-batch consistency and traceability in manufacturing?

To address these questions, a two-level standardization framework should be proposed. First, Ayurvedic manufacturers must strictly follow classical processing guidelines, including *Śodhana*, *Bhāvanā*, and the minimum number of *Putas*. Second, they must be required to verify the final product using modern laboratory methods particle size analysis, ICP-MS testing for heavy metals, microbial load testing, and even clinical trials where possible.

Rather than rejecting traditional systems outright, modern regulation should recognize the safety embedded in these systems while demanding demonstrable accountability through documentation and analysis. This integrative approach respects Ayurveda's epistemology while satisfying modern standards of reproducibility and safety.

6. A Unified Approach for Future Integration

To ensure that the therapeutic potential of herbo-mineral drugs is preserved and protected, a unified approach must be adopted one that combines traditional methods with contemporary scientific protocols. This approach requires not only infrastructural investment but also educational reform, research collaboration, and clinical transparency.

Firstly, Ayurvedic educational institutions must upgrade their practical training facilities. Rasa Shala (traditional pharmacies) should be integrated with analytical laboratories. Every batch of Bhasma prepared by postgraduate students should be subjected to modern testing to inculcate a habit of dual validation from the training phase itself.

Secondly, research institutions should prioritize long-term toxicological studies using modern markers, including genetic, histological, and metabolic parameters. Collaborative research with universities, CSIR labs, and pharmacology departments should be encouraged under-funded consortia.

Thirdly, clinical case repositories should be established where Ayurvedic physicians can log patient recovery patterns, side effects, drug interactions, and long-term outcomes using standardized digital platforms. These observations would help build a post-marketing surveillance framework that can guide future prescribing norms.

Lastly, government bodies like the Ministry of AYUSH, along with international health regulators and WHO Traditional Medicine Program, should work together to develop globally acceptable monographs and Good Processing Practice (GPP) models for herbo-mineral formulations. Such frameworks could guide international trade, improve consumer confidence, and prevent the misuse or misbranding of Rasaushadhis.

7. Conclusion

The science of herbo-mineral formulations in Ayurveda, built upon the principles of *Bhaishajya Vigyan*, represents a remarkable synthesis of empirical wisdom, alchemical transformation, and clinical intuition. Through millennia of practice, these preparations have demonstrated efficacy in managing complex and chronic diseases, delivering therapeutic benefits that are often unmatched in conventional herbal-only remedies. However, the growing scrutiny of these formulations in the context of heavy metal toxicity, regulatory compliance, and international acceptability necessitates a robust and transparent approach to standardization and safety profiling.

This paper has highlighted that Ayurveda is not devoid of scientific logic in this regard it contains within its classical framework a highly evolved system of purification, processing, and quality control. Techniques such as *Śodhana*, *Māraṇa*, and *Bhāvanā* are not mere rituals but structured pharmaceutical procedures that effectively transform toxic metals into therapeutically potent and biologically compatible agents. Traditional tests like *Bhasma Parīkṣā* offer a qualitative understanding of product safety, while the use of *Anupāna* ensures proper pharmacokinetic behavior in the host body.

Modern science, rather than dismissing these formulations, must engage constructively by applying its powerful analytical tools SEM, ICP-MS, XRD, AAS, and long-term clinical toxicology to validate what has been known through generations of Ayurvedic practice. The convergence of traditional knowledge with contemporary pharma-covigilance models offers an exciting pathway for the global resurgence of Ayurvedic pharmaceutics.

However, the future of herbo-mineral drugs does not lie in simply defending them against criticism. It lies in advancing them through rigorous dual-standardization honoring the classical processes while applying transparent, quantifiable modern validation. It involves education reform, institutional infrastructure, collaborative research, and global regulatory engagement. Only then can Ayurveda's deep pharmaceutic knowledge gain its deserved place in the evidence-based global health discourse.

The goal is not to modernize Ayurveda by stripping away its traditional core, but to illuminate its precision, safety, and therapeutic integrity in the language the world understands today. With this approach, Rasaushadhis will not merely survive contemporary scrutiny they will thrive as a testament to timeless medical science, ethically practiced, meticulously standardized, and globally respected.

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