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Ayurvedic Herbo-Mineral Formulations: Safety, Toxicity and Therapeutic Potential — A Critical Review

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Abstract

Herbo-mineral medicines occupy a distinctive place in *Rasashastra*, where metals and minerals are subjected to elaborate pharmaceutical processing and combined, in many formulations, with plant materials. Classical accounts attribute small dose, rapid action, stability, and usefulness in difficult disorders to these *Rasaushadhi*. Their metallic content, however, raises legitimate questions about chemical form, batch consistency, accumulation, and organ toxicity. This narrative review examines classical processing, therapeutic claims, analytical findings, and safety concerns. The *Charaka Samhita*, *Sushruta Samhita*, *Rasa Ratna Samuccaya*, *Rasatarangini*, and *Bhava Prakasha Nighantu* were considered with literature identified through PubMed, Scopus, Web of Science, and Google Scholar. *Shodhana*, *Bhavana*, and *Marana* may alter impurities, particle size, oxidation state, crystalline phase, and association with organic material, but completion of a classical process does not by itself establish clinical safety. Reports of lead, mercury, and arsenic exposure from Ayurvedic products demonstrate the consequences of poor manufacture, inappropriate formulation, or unsupervised use. Conversely, the toxicology of a prepared *Bhasma* cannot be inferred from elemental concentration alone; speciation, solubility, dose, bioaccessibility, and tissue distribution also matter. Responsible use requires authenticated raw material, validated manufacturing, batch-specific analytical testing, qualified prescription, limited and justified exposure, adverse-event surveillance, and clinical evidence. Claims of nanomedicine or detoxification should remain provisional until supported by reproducible pharmacokinetic and toxicological data.

Keywords

Rasashastra; *Bhasma*; *Rasaushadhi*; herbo-mineral formulation; toxicity; quality control; Ayurveda

1. Introduction

Rasashastra developed specialized methods for preparing medicines from metals, minerals, gems, and plant substances. The purpose was not to administer a raw metal in ordinary form, but to transform the starting material through prescribed operations before therapeutic use [1]. Properly prepared *Rasaushadhi* are traditionally valued for potency, small *Matra*, relatively long shelf life, and disease-specific action.

Modern concern is equally well founded. Products containing lead, mercury, arsenic, or other potentially toxic elements may cause renal, hepatic, neurological, hematological, reproductive, or cardiovascular harm, particularly when manufacturing is poor or exposure is prolonged [2]. The relevant scientific question is not whether all metal-containing medicines are identical, but whether a particular authenticated formulation, produced by a controlled process, has a reproducible chemical profile, acceptable exposure, demonstrated benefit, and monitored safety.

Aim and Objectives

The review aims to critically evaluate the safety, toxicity, and therapeutic potential of Ayurvedic herbo-mineral formulations. It examines the principles of *Rasashastra*, major pharmaceutical processes, classical and modern quality tests, evidence for selected *Bhasma*, sources of toxic risk, and priorities for analytical, pharmacological, and clinical research.

2. Methodology of Literature Review

A narrative review was conducted using the *Charaka Samhita*, *Sushruta Samhita*, *Rasa Ratna Samuccaya*, *Rasatarangini*, and *Bhava Prakasha Nighantu*. PubMed, Scopus, Web of Science, and Google Scholar were searched with combinations of "herbo-mineral formulations Ayurveda," "*Bhasma* safety," "*Rasashastra* toxicity," "metal-based Ayurvedic medicine," and "pharmacological evaluation of *Bhasma*." Classical descriptions, analytical and toxicological studies, experimental research, and clinically relevant reports were considered. Unverified formulations and unauthenticated sources were excluded. Because the evidence is heterogeneous, the review does not infer class-wide safety or efficacy.

3. Historical and Pharmaceutical Background

Rasashastra evolved from the use and processing of mineral substances for therapeutic and *Rasayana* purposes. Over time, detailed procedures were developed to change their physical and chemical behavior [3]. Herbo-mineral formulations may combine materials such as iron, copper, gold, mica, or mercury-derived compounds with plant drugs including *Guduchi*, *Triphala*, or *Ashwagandha*. The exact formula, sequence of operations, heating conditions, and endpoint tests are integral to product identity.

4. Principal Pharmaceutical Processes

Shodhana encompasses material-specific operations often translated as purification or detoxification. Heating, quenching in selected liquids, washing, grinding, or other procedures may remove contaminants, reduce brittle material, or change surface chemistry [4]. The word "detoxification" should not be taken as proof that every toxic risk has been eliminated; the effect must

be demonstrated for the specified process and element.

During *Bhavana*, a powdered material is triturated with a prescribed plant juice or decoction. This can improve mixing, reduce particle size, and introduce organic constituents that affect agglomeration and surface characteristics. *Marana* uses controlled cycles of processing and heating to produce *Bhasma*. Analytical studies of some preparations report oxides, sulfides, or other mineral phases rather than unreacted free metal [5]. The result depends heavily on temperature, atmosphere, fuel, number of cycles, and starting material.

5. Classical and Modern Quality Assessment

Classical tests include *Varitaratva*, or floating on water; *Rekhapurnatva*, the capacity of fine material to enter the lines of the fingers; and *Nischandratva*, absence of metallic luster. These practical tests reflect fineness and loss of gross metallic character but cannot identify elemental composition, contamination, oxidation state, or bioavailability. Modern evaluation should add particle-size distribution, microscopy, X-ray diffraction, elemental analysis, chemical speciation, leachability, microbial quality, and stability. Neither classical nor instrumental testing should be used alone.

6. Therapeutic Potential of Selected *Bhasma*

Lauha Bhasma is used traditionally in Pandu and weakness and may provide iron in a chemically distinct matrix. Its hematinic value and tolerability should be compared with established iron preparations using hemoglobin, ferritin, gastrointestinal adverse effects, and markers of excess exposure. *Abhraka Bhasma* is prescribed in respiratory and chronic debilitating disorders; preliminary reports describe antioxidant or adaptogenic activity [6], but clinical confirmation remains limited.

Suvarna Bhasma is traditionally used in selected *Rasayana* and immune-related contexts, while *Tamra Bhasma* is used in specific digestive and metabolic disorders. The high value and toxicological importance of these substances make identity, dose, and contamination control essential. Traditional indication cannot substitute for randomized evidence, and one *Bhasma* cannot be generalized to all products containing the same element.

7. Safety and Toxicological Considerations

Safety depends on raw-material identity, pharmaceutical process, batch consistency, chemical form, *Matra*, duration, Anupana, indication, patient factors, and co-medication [7]. Improperly manufactured or mislabeled products may expose patients to toxic quantities. Children, pregnant women, and people with renal, hepatic, neurological, or hematological disease require particular caution.

Surveys and case reports have identified lead, mercury, and arsenic in some Ayurvedic products [8]. Such findings must not be dismissed as merely a misunderstanding of *Bhasma*, because documented poisoning is clinically real. At the same time, total elemental concentration alone does not fully predict toxicity. Solubility, speciation, particle behavior, gastrointestinal bioaccessibility, and cumulative dose influence risk. A credible safety claim must integrate all these variables and include human monitoring.

8. Mercury-Containing Preparations

Parada has a central role in several *Rasashastra* traditions. Classical procedures such as *Svedana*, *Mardana*, *Murcchana*, and *Jarana* are intended to purify and transform it before incorporation into stable compounds. Some analytical studies report

mercury predominantly in sulfide or complex mineral forms rather than as elemental mercury [9]. Chemical

transformation may change absorption, but it does not establish absence of toxicity. Vapor exposure during manufacture, batch variability, interaction with other ingredients, and long-term tissue burden must be evaluated.

9. *Bhasma* and the Nanoparticle Perspective

Microscopy has identified nanoscale or submicron particles in some *Bhasma*, often within larger aggregates and mixed mineral-organic matrices [10]. This observation is scientifically interesting but should not be treated automatically as an advantage. Particle size can change surface area, dissolution, cellular uptake, distribution, and inflammatory potential. "Nano" is a descriptive feature, not evidence of improved efficacy or safety. Complete characterization must include composition, shape, aggregation, surface chemistry, dose, and biological fate.

10. Quality Control and Standardization

A reproducible product requires controlled sourcing, documented *Shodhana* and *Marana*, calibrated heating, in-process endpoints, and release specifications. Routine physicochemical tests may include moisture, ash, pH where relevant, and particle size. X-ray diffraction, scanning and transmission electron microscopy, atomic absorption spectroscopy, and ICP-MS can define mineral phase, morphology, and elemental content [11]. Speciation and dissolution testing are especially important for toxic elements. Reference materials and inter-laboratory methods are needed so that results can be compared across manufacturers.

Classical element	Contemporary quality or safety question
Shodhana	What impurities or chemical characteristics changed?
Bhavana	How did trituration and plant media alter size and surface chemistry?
Marana	Which mineral phases formed, and is unreacted metal present?
Bhasma Pariksha	Do classical endpoints agree with instrumental results?
Matra and Anupana	What exposure, absorption, and interaction profile results?
Pathya and clinical selection	Which patient factors modify benefit or risk?

11. Clinical Applications and Evidence

Herbo-mineral medicines are used in practice for selected anemia, respiratory, neurological, metabolic, and chronic disorders. The evidence base is uneven: many studies are small, single-center, open-label, or inadequately characterized chemically. A clinical trial should name the complete formulation and manufacturer, provide batch data, justify *Matra* and duration, report concurrent therapy, and monitor organ-specific safety. Benefit should be assessed against an appropriate comparator, not inferred from preclinical antioxidant or immune findings [12].

12. Ayurveda and Modern Toxicology

Both classical pharmacy and modern toxicology recognize that identity, preparation, dose, route, and host susceptibility determine outcome. Their methods differ. Classical assessment uses process fidelity, *Bhasma* tests, *Matra*, Anupana, and clinical

suitability; modern evaluation quantifies exposure, chemical form, absorption, distribution, metabolism, excretion, target-organ injury, and dose-response. A robust safety framework should combine them. Invoking *Shodhana* without analytical data is insufficient, just as interpreting a complex prepared material only as its raw element may be incomplete.

13. Research Gaps and Limitations

Major gaps include manufacturer variability, limited batch-level characterization, inadequate pharmacokinetic data, few multicenter trials, and insufficient long-term surveillance. Experimental studies often use products whose preparation cannot be reproduced. Future work should compare classical and modified processes, quantify bioaccessible and absorbed fractions, evaluate genotoxicity and reproductive toxicity where relevant, and follow cumulative exposure. Standard case definitions for suspected adverse reactions would strengthen pharmacovigilance.

14. Future Perspectives

Analytical science can help identify which processing steps produce desirable and reproducible chemical changes. Metal-herb interactions, dissolution behavior, targeted delivery, and personalized prescribing are legitimate research areas, but nanomedicine language should not outrun evidence. The most useful path is formulation-specific: authenticate the product, define the chemistry, demonstrate a plausible exposure range, establish toxicological margins, and then test clinical effectiveness under monitored conditions.

15. Conclusion

Ayurvedic herbo-mineral formulations are a specialized pharmaceutical tradition, not a uniform group of raw-metal remedies. *Shodhana*, *Bhavana*, and *Marana* can substantially alter a material, yet correct processing must be demonstrated rather than presumed. Reports of toxic metal exposure require serious attention, while the safety of a particular *Bhasma* must be evaluated through chemical form, dose, bioaccessibility, cumulative exposure, and clinical monitoring. Therapeutic potential may exist for selected standardized formulations, but responsible use depends on qualified prescription, rigorous manufacturing, batch-specific testing, pharmacovigilance, and well-designed clinical trials.

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