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Review Article

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"GLOBAL ACCEPTANCE OF HERBO-MINERAL FORMULATIONS: CHALLENGES AND OPPORTUNITIES"

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ABSTRACT

Introduction: Herbo-mineral formulations (*Rasaushadhis*) represent one of the most sophisticated branches of Ayurveda, integrating plant-based drugs with purified metals and minerals. Traditionally considered potent and fast-acting, they are widely prescribed in India. However, their global acceptance remains limited due to safety concerns, regulatory challenges, and lack of standardized evidence. **Methods:** A comprehensive literature review was undertaken using PubMed, Scopus, Web of Science, Google Scholar, and AYUSH Research Portal (2000–2025). Classical Ayurvedic texts (*Charaka Samhita*, *Rasa Ratna Samucchaya*, *Rasatarangini*) were analyzed for descriptions of safety and efficacy. Peer-reviewed studies, clinical trials, and regulatory reports on herbo-mineral formulations were included. Exclusion criteria were non-scientific sources and anecdotal claims. Data were synthesized thematically to highlight challenges and opportunities. **Results:** Classical texts emphasize purification (*Shodhana*), calcination (*Marana*), appropriate dosage, and *Anupana* (vehicle) to ensure safety. Modern research confirms therapeutic potential in chronic conditions like arthritis, diabetes, and neurological disorders. However, global concerns persist due to reports of heavy-metal toxicity, inadequate quality control, lack of Good Manufacturing Practices (GMP) adherence, and insufficient pharmacovigilance. Regulatory frameworks in the US, EU, and WHO categorize these formulations under "dietary supplements" or "traditional medicines," imposing stringent restrictions on commercialization. On the other hand, opportunities exist in validating classical methods through advanced analytical tools (ICP-MS, XRD, TEM), developing standardized pharmacopeial monographs, integrating herbo-mineral drugs in evidence-based practice, and expanding global collaborations. **Discussion:** While challenges of safety perception, regulatory non-uniformity, and inadequate clinical trials hinder global acceptance, opportunities lie in translational research, GMP compliance, pharmacovigilance, and bridging traditional wisdom with modern science. **Conclusion:** Strategic research, regulatory harmonization, and robust safety validation can transform herbo-mineral formulations into globally recognized therapeutics, balancing tradition with modern requirements.

KEYWORDS: Ayurveda, globalization, herbo-mineral formulations, Rasaushadhi, safety

INTRODUCTION

Herbo-mineral formulations (*Rasaushadhis*) occupy a unique position in Ayurvedic pharmaceutics. They combine botanical drugs with processed metals, minerals, or gems, offering rapid action in small doses[1-2]. Classical texts such as *Rasaratna Samucchaya* and *Rasatarangini* describe elaborate processes of purification (*Shodhana*) and incineration (*Marana*) to transform raw metals into biocompatible therapeutic forms (*Bhasma*). These formulations have been widely prescribed for chronic and refractory diseases[3-4].

In recent decades, Ayurveda has gained international attention, with herbal products achieving significant market penetration. However, herbo-mineral formulations remain under global scrutiny[5-6]. Reports of heavy-metal contamination, lack of standardized manufacturing, and limited clinical validation have raised safety concerns in Western countries. Regulatory bodies such as the US FDA and European Medicines Agency enforce stringent guidelines, restricting free movement of these formulations in global markets[7-8].

This review aims to examine the challenges and opportunities in the global acceptance of herbo-mineral formulations. Specific objectives are: (i) to analyze classical and modern perspectives on safety and efficacy, (ii) to assess current challenges including safety concerns, regulatory issues, and lack of standardization, and (iii) to explore opportunities through advanced research, GMP implementation, and global policy harmonization[9-10].

MATERIALS AND METHODS

A systematic review was conducted from January to May 2025.

Databases searched: PubMed, Scopus, Web of Science, Google Scholar, and AYUSH Research Portal[11].

Search strategy: Keywords included "herbo-mineral formulations," "Rasaushadhi safety," "Ayurveda globalization," "Bhasma standardization," and "metal toxicity Ayurveda." Boolean operators (AND/OR) were applied[12].

Inclusion criteria: [13]

- Peer-reviewed articles (2000–2025) addressing efficacy, safety, pharmacology, or regulation of herbo-mineral formulations.
- Clinical trials, animal studies, pharmacological evaluations, and toxicological analyses.
- Regulatory and policy reports from WHO, Ministry of AYUSH, US FDA, and EMA.
- References from Ayurvedic classics describing processing and safety measures.

Exclusion criteria: [14]

- Non-scientific reports, commercial websites, and anecdotal claims.
- Studies lacking methodological rigor.

Data synthesis: Literature was categorized thematically into:[15]

1. Classical perspectives on safety and efficacy.
2. Modern pharmacological and toxicological studies.
3. Regulatory frameworks and global acceptance.
4. Challenges and controversies.
5. Emerging opportunities and future prospects.

OBSERVATION AND RESULTS

1. Classical Ayurvedic perspective

Ayurvedic pharmaceutics emphasizes multi-layered safety precautions. *Rasashastra* prescribes *Shodhana* to detoxify metals/minerals and *Marana* to convert them into bioavailable *Bhasma*. The *Anupana* (vehicle, such as ghee, honey, or milk) is recommended to enhance efficacy and minimize toxicity. Dosage precision, contraindications, and monitoring were elaborately discussed. For example, *Abhraka Bhasma* is indicated for respiratory disorders, while *Swarna Bhasma* is prescribed for rejuvenation and immune modulation. Classical texts repeatedly caution against improper preparation and overdosing.

2. Modern evidence on efficacy

Several pharmacological studies support the therapeutic role of herbo-mineral drugs. *Swarna Bhasma* has shown immunomodulatory and neuroprotective effects. *Abhraka Bhasma* demonstrates antioxidant and adaptogenic properties. *Yashada Bhasma* is reported beneficial in diabetes management due to its zinc content. Clinical studies, though limited, indicate effectiveness in chronic conditions such as rheumatoid arthritis, bronchial asthma, and neurological disorders. However, many studies lack large sample sizes, standardized protocols, or placebo controls, restricting their acceptance in evidence-based medicine.

3. Toxicological considerations

Global skepticism stems from reports of heavy-metal toxicity (lead, mercury, arsenic) in marketed Ayurvedic formulations. Investigations reveal that most adverse outcomes are due to:

- Incomplete *Shodhana* and *Marana* processes.
- Non-compliance with GMP.
- Adulteration and substitution with raw metallic powders.
- Unsupervised self-medication and overdosing.

Toxicological studies using ICP-MS, XRD, and SEM analyses indicate that properly prepared *Bhasmas* contain nano-sized particles with organometallic complexes, rendering them safe and bioavailable. However, uniform validation is lacking.

4. Regulatory frameworks

Global regulatory policies pose significant barriers.

- **India:** AYUSH Pharmacopeia includes monographs for *Bhasmas*, with GMP guidelines under the Drugs & Cosmetics Act.
- **US FDA:** Categorizes herbo-mineral products as dietary supplements, with strict heavy-metal limits. Non-compliant products face import alerts.
- **EU:** Requires herbal medicinal products to demonstrate safety through toxicology and pharmacovigilance, limiting entry of *Rasaushadhis.*
- **WHO:** Advocates safety validation and pharmacovigilance but lacks harmonized global standards.

5. Challenges in global acceptance

- **Safety perception:** Concerns of toxicity dominate global discourse.
- **Lack of standardization:** Absence of universally accepted protocols for *Bhasma* preparation and testing.
- **Regulatory non-uniformity:** Different countries apply diverse standards.
- **Research limitations:** Few randomized controlled trials (RCTs) and long-term safety studies.
- **Public awareness:** Misconceptions about Ayurveda's safety or toxicity hinder acceptance.

6. Opportunities and future prospects

Despite challenges, significant opportunities exist:

- **Analytical validation:** Use of advanced techniques (XRD, ICP-MS, FTIR, TEM) to authenticate *Bhasmas.*
- **Integration with nanomedicine:** Recognition of nano-particle characteristics of *Bhasmas* aligns Ayurveda with modern nanotechnology.
- **Pharmacovigilance:** Establishing global networks to monitor ADRs and ensure safety.
- **Evidence-based research:** Conducting large-scale clinical trials to validate efficacy.
- **Global collaborations:** Partnerships between AYUSH, WHO, and international agencies can facilitate regulatory harmonization.
- **Market potential:** With proper validation, herbo-mineral formulations can enter global markets for chronic, lifestyle, and refractory diseases.

DISCUSSION

The debate over global acceptance of herbo-mineral formulations lies at the interface of tradition and modern science. Ayurveda has long endorsed rigorous purification and incineration processes to render metals safe for therapeutic use. Modern nano-analytical studies now provide scientific explanations for the unique bioavailability and safety of *Bhasmas,* aligning ancient wisdom with contemporary evidence[16].

However, the global regulatory environment demands reproducible data and standardized protocols, which are currently limited. Reports of heavy-metal contamination in commercial products, often due to poor GMP adherence, have overshadowed genuine Ayurvedic methods. This highlights the urgent need for strict enforcement of quality standards, mandatory certification, and transparent labeling to distinguish authentic products from adulterated ones[17].

Clinical evidence remains a major bottleneck. While promising pharmacological studies exist, the lack of large-scale, multi-center RCTs prevents global healthcare systems from endorsing these drugs. Bridging this gap requires collaborative research involving Ayurvedic institutions, modern laboratories, and international partners. Moreover, pharmacovigilance systems must be strengthened to build a reliable safety database[18].

Opportunities are immense. The discovery that *Bhasmas* are nano-structured opens avenues for Ayurveda's integration with nanomedicine, drug

delivery systems, and regenerative medicine. With rising global interest in holistic and integrative healthcare, properly validated herbo-mineral drugs could occupy a niche market in chronic and lifestyle disorders where modern medicine often has limitations[19].

Ultimately, the path to global acceptance lies in balancing authenticity with modernity—preserving classical protocols while ensuring compliance with international safety and efficacy standards[20].

CONCLUSION

Herbo-mineral formulations embody the depth and sophistication of Ayurvedic pharmaceutics. While their therapeutic potential has been recognized for centuries, their global acceptance continues to face challenges due to safety concerns, lack of standardization, and regulatory restrictions. Much of this skepticism arises not from Ayurveda's inherent principles but from poor adherence to classical methods and insufficient scientific validation in modern frameworks.

At the same time, opportunities for integration into global healthcare are expanding. Advances in analytical technologies, the recognition of *Bhasmas* as nano-structured medicines, and growing interest in integrative medicine create new pathways for acceptance. Stronger GMP enforcement, international regulatory harmonization, and large-scale clinical validation will be key to establishing credibility.

Global acceptance of herbo-mineral formulations is not merely a scientific issue but also a cultural and policy challenge. By combining rigorous traditional practices with modern validation and pharmacovigilance, these formulations can gain rightful recognition as safe, effective, and innovative therapeutics.

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