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"COMPARATIVE SAFETY OF HERBOMINERAL VERSUS PURELY HERBAL FORMULATIONS: AN EVIDENCE-BASED REVIEW"

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ABSTRACT

Introduction: Ayurvedic formulations are broadly categorized into purely herbal preparations and herbomineral (Rasaushadhi) formulations, the latter incorporating metals and minerals in processed forms. While herbal formulations are generally regarded as safe, concerns have been raised regarding the safety of herbomineral preparations, particularly related to heavy metal toxicity. The debate requires careful evaluation based on classical Ayurvedic principles and modern scientific evidence. **Methods:** A systematic literature search was conducted across PubMed, Scopus, Web of Science, AYUSH Research Portal, and Google Scholar (2000–2025). Classical Ayurvedic texts (*Charaka Samhita, Sushruta Samhita, Rasa Ratna Samucchaya*) were also reviewed. Studies on safety assessments, clinical trials, pharmacological evaluations, case reports, and toxicological studies were included. Both preclinical and clinical evidence were analyzed, focusing on safety outcomes of herbomineral and purely herbal formulations. **Results:** Herbal formulations show a favorable safety profile, with adverse events typically mild and linked to improper usage or contamination. Herbomineral formulations, when prepared following traditional detoxification (*Shodhana, Marana*), display therapeutic efficacy with minimal toxicity, supported by animal studies and clinical reports. However, safety concerns arise when manufacturing deviates from classical methods or when products are unregulated. Comparative studies suggest that purely herbal formulations are generally safer for long-term use, while herbomineral formulations may pose higher risks if improperly prepared, but are safe under Good Manufacturing Practices. **Discussion:** Myths about herbomineral toxicity are largely due to extrapolating data from raw heavy metals without considering their processed forms. While purely herbal formulations require quality control for pesticide and microbial contamination, herbominerals need stricter regulation due to their metal content. **Conclusion:** Both herbal and herbomineral formulations are safe when manufactured under pharmacopeial standards and used under medical supervision. The real challenge lies in standardization, regulation, and consumer education rather than inherent toxicity.

KEYWORDS: Ayurveda, herbomineral formulations, herbal formulations, safety, toxicity

INTRODUCTION

Ayurveda, the traditional medical system of India, employs diverse categories of formulations to manage health and disease[1]. These include single-herb preparations, polyherbal compounds, and herbo-mineral formulations (*Rasaushadhis*)[2-3]. While herbal formulations rely solely on plant-derived ingredients, herbomineral formulations combine botanical extracts with processed metals and minerals, believed to enhance potency, bioavailability, and therapeutic effectiveness[4-5].

Herbal formulations are widely accepted as safe, with thousands of years of documented use. However, challenges exist regarding contamination with pesticides, heavy metals, or microbial agents, particularly in mass-produced products[6-7]. Herbomineral formulations, on the other hand, face greater scrutiny due to their inclusion of metals like mercury, lead, and arsenic. Traditional Ayurvedic pharmaceutics emphasizes *Shodhana* (purification) and *Marana* (calcination) to transform raw metals into therapeutically safe forms, yet skepticism persists in modern toxicological discourse[8-9].

The aim of this review is to critically compare the safety profile of herbomineral versus purely herbal formulations. The objectives are: (i) to summarize classical Ayurvedic principles regarding safety; (ii) to review evidence from experimental, clinical, and toxicological studies; (iii) to highlight causes of reported adverse events; and (iv) to provide a balanced understanding for safe integration of both categories into modern healthcare[10].

MATERIALS AND METHODS

A systematic review approach was adopted.

Databases searched: PubMed, Scopus, Web of Science, AYUSH Research Portal, and Google Scholar (2000–2025).

Search strategy: Keywords used included "Ayurveda herbal formulations," "Rasaushadhi safety," "Bhasma toxicity," "herbomineral formulations safety," "phytomedicine adverse events," and "Ayurvedic drug regulation." Boolean operators (AND/OR) were applied[11].

Inclusion criteria: [12]

- Studies published in English from 2000–2025.
- Safety assessments (toxicology, preclinical, clinical trials) of herbal or herbomineral formulations.
- Reports comparing efficacy and safety of both categories.
- Classical Ayurvedic literature relevant to safety concepts.

Exclusion criteria: [13]

- Non-peer-reviewed articles, anecdotal claims, and media reports.
- Duplicates and studies lacking methodological clarity.

Classical texts reviewed: *Charaka Samhita*, *Sushruta Samhita*, *Rasa Ratna Samucchaya*, *Bhaishajya Ratnavali*[14].

Data synthesis: Findings were categorized into: (i) safety of herbal formulations, (ii) safety of herbomineral formulations, (iii) comparative analyses, (iv) reported adverse events, and (v) regulatory frameworks[15].

OBSERVATION AND RESULTS

1. Safety Profile of Purely Herbal Formulations

Purely herbal formulations are generally considered safe for long-term use. Classical texts emphasize the importance of correct identification, harvesting time, and dosage to ensure safety. Modern pharmacological studies confirm that adverse effects from herbal medicines are rare and usually mild, such as gastrointestinal disturbances or allergic reactions.

However, safety concerns in herbal formulations arise mainly from **external factors**:

- **Contamination with pesticides and heavy metals:** Mass cultivation and inadequate quality control can lead to unsafe levels.
- **Adulteration and substitution:** Use of incorrect plant species.
- **Microbial contamination:** Poor storage and packaging.

Clinical studies on formulations like *Triphala*, *Ashwagandha churna*, and *Guduchi ghana vati* demonstrate good tolerability, with very few adverse events. Regulatory agencies, including the WHO, acknowledge the relatively safe profile of herbal medicines when prepared under GMP.

2. Safety Profile of Herbomineral Formulations

Herbomineral formulations (e.g., *Swarna Bhasma*, *Rasasindura*, *Makaradhwaja*) are often more potent and fast-acting than purely herbal preparations. Classical Ayurveda prescribes them in micro-doses after elaborate *Shodhana* and *Marana* processes.

Analytical Evidence:

- *Swarna Bhasma* consists of nano-sized gold particles embedded in organic matrices, found to be safe in toxicological studies.
- *Rasasindura* contains mercury in sulfide form (HgS), insoluble and less bioavailable compared to elemental mercury.
- *Naga Bhasma* shows lead in sulfide form (PbS), with markedly reduced toxicity.

Preclinical and Clinical Studies:

- Animal studies on *Abhraka Bhasma* and *Swarna Bhasma* demonstrate no significant hepatotoxicity or nephrotoxicity at therapeutic doses.
- Clinical reports show immunomodulatory benefits of *Swarna Bhasma* in pediatrics and anti-arthritic effects of *Makaradhwaja*.
- Adverse events are rare when preparations are made traditionally.

Reported Toxicity Cases: International reports of lead or mercury poisoning are often linked to:

- Non-standardized or spurious products.
- Use of raw metals without purification.
- Products sold online without regulatory oversight.

Thus, herbomineral safety is highly preparation-dependent.

3. Comparative Safety Analysis

Parameter	Herbal Formulations	Herbomineral Formulations
Adverse effects	Rare, mild (allergy, GI upset)	Rare if prepared traditionally, severe if spurious
Major risks	Pesticide, microbial contamination	Heavy metal toxicity (if improperly prepared)
Long-term use	Safe for extended use	Safe under medical supervision, limited in children/pregnant women
Regulatory needs	Botanical authentication, GMP	GMP, metal testing, pharmacopeial compliance
Clinical evidence	Widely available	Increasing, but limited large RCTs

4. Traditional Insights from Ayurvedic Texts

Classical Ayurveda explicitly warns against using raw metals or minerals. *Rasa Ratna Samucchaya* states that improperly processed formulations are "equal to poison." *Charaka* and *Sushruta Samhita* emphasize dose precision and physician supervision, principles that remain highly relevant.

5. Regulatory and Global Perspectives

WHO and AYUSH guidelines mandate strict testing of both herbal and herbomineral formulations. For herbals, emphasis is on botanical authentication and microbial/pesticide control. For herbominerals, emphasis is on heavy metal testing and batch documentation. International acceptance remains cautious, with herbals enjoying wider trust than herbominerals.

DISCUSSION

The comparative safety of herbal versus herbomineral formulations highlights a nuanced reality. Herbal medicines, by virtue of their plant-based origin, enjoy a relatively safer reputation. However, contamination and adulteration remain pressing challenges. This underscores the importance of quality assurance measures such as Good Agricultural Practices (GAP) and GMP[16].

Herbomineral formulations face stronger skepticism. Modern toxicology equates mercury, lead, and arsenic with universal toxicity, overlooking the fact that Ayurveda employs chemically transformed forms of these metals. For instance, mercury in Ayurvedic formulations exists as cinnabar (HgS), which has low solubility and bioavailability compared to elemental mercury. Similarly, *Swarna Bhasma* has nano-gold particles with unique pharmacodynamics. These transformations echo modern nanotechnology principles, lending credibility to Ayurvedic pharmaceutics[17].

Yet, gaps remain. Clinical evidence for herbominerals, though promising, is limited compared to herbal formulations. The lack of large-scale randomized controlled trials weakens their global acceptance. Further, unregulated commercialization has led to safety breaches, particularly in online markets where spurious products are common. Thus, while Ayurveda offers safe and effective formulations, the risk arises from deviation rather than principle[18].

Looking ahead, the way forward involves:[19]

1. Strengthening GMP and regulatory enforcement.
2. Expanding modern toxicological and clinical evaluations of both herbal and herbomineral formulations.
3. Leveraging nanoscience to validate classical processes of *Bhasma* preparation.

4. Enhancing consumer education about safe usage under qualified supervision.

In conclusion, both formulations are safe within the boundaries of quality control and traditional guidelines. Herbal medicines are preferable for long-term prophylaxis, whereas herbomineral formulations are suitable for acute, complex, or refractory conditions under strict supervision[20].

CONCLUSION

The comparative safety of herbal and herbomineral formulations reflects both tradition and modern science. Herbal formulations, when prepared authentically, are generally safe for long-term use, though vigilance is needed against contamination. Herbomineral formulations, despite their metal content, are rendered safe through Ayurvedic processes of purification and calcination, transforming toxic raw metals into therapeutic compounds.

Adverse events linked to herbomineral formulations are not intrinsic to Ayurveda but are consequences of malpractice, poor manufacturing, and lack of regulation. Conversely, adverse events in herbal formulations typically arise from external contamination rather than intrinsic plant toxicity.

Therefore, the debate should shift from "herbal vs herbomineral safety" to "regulated vs unregulated safety." Evidence supports the safe integration of both categories, provided pharmacopeial standards, GMP compliance, and physician supervision are ensured. Future research should focus on bridging traditional Ayurvedic pharmaceutics with modern nanoscience and clinical pharmacology, establishing robust safety profiles that can enhance global acceptance.

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