WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 13, 1112-1124. Research Article ISSN 2277–7105

CHALLENGES AND FUTURE DIRECTIONS IN GLOBALIZATION OF RASASHASTRA BASED HERBO - MINERAL DRUGS

Dr. KritikaVerma[1]*, Dr. M. K. Yadav[2], Dr. Devika Balagopalan[3]

*[1]PG Scholar, PG Department of Rasa Shastra and Bhaishajya Kalpana, Patanjali Bhartiya Ayurvigyan Evum Anusandhan Sansthan Haridwar, Uttarakhand, India.

[2]Professor and HOD, PG Department of Rasa Shastra and Bhaishajya Kalpana, Patanjali Bhartiya Ayurvigyan Evum Anusandhan Sansthan Haridwar, Uttarakhand, India.

[3]Assistant Professor, Patanjali Bhartiya Ayurvigyan Evum Anusandhan Sansthan Haridwar, Uttarakhand, India.

Article Received on 04 June 2026,
Article Revised on 24 June 2026,
Article Published on 01 July 2026,

https://doi.org/10.5281/zenodo.21032782

***Corresponding Author**

Dr. Kritika Verma

PG Scholar, PG Department of Rasa Shastra and Bhaishajya Kalpana, Patanjali Bhartiya Ayurvigyan Evum Anusandhan Sansthan Haridwar, Uttarakhand, India.

How to cite this Article: Dr. KritikaVerma[1]*, Dr. M. K. Yadav[2], Dr. Devika Balagopalan[3] (2026). Challenges And Future Directions In Globalization Of Rasashastra Based Herbo - Mineral Drugs. World Journal of Pharmaceutical Research, 15(13), 1112–1124.

ABSTRACT

Background: Rasa Shastra, the specialized branch of *Ayurveda* dealing with herbo-mineral formulations, holds a rich therapeutic legacy in India. The globalization of *Rasa Shastra* medicines faces significant scrutiny due to safety, toxicity concerns, and regulatory hurdles despite their potential in chronic, metabolic, and degenerative diseases. **Objectives:** To critically evaluate the key challenges in the globalization of *Rasa Shastra* based herbo-mineral drugs and to identify potential strategies and future research directions for their safe, effective, and sustainable global acceptance. **Methods:** A narrative review was conducted by analysing classical *Ayurvedic* texts, contemporary scientific studies, regulatory frameworks of different countries, and WHO guidelines on traditional medicines. Literature was sourced from PubMed, AYUSH databases, and policy documents, focusing on safety, standardization, regulatory barriers, and translational research. **Results:** The major challenges identified include: Lack of globally acceptable standardization and quality control protocols. Heavy metal toxicity concerns due to improper preparation and lack of *Shodhana* (purification) validation. Inadequate preclinical and clinical safety studies conforming to modern biomedical standards. Stringent international regulations and limited

intellectual property protections. Poor awareness and misconceptions about *Rasa Shastra* among global medical communities. Future directions emphasize: Developing validated *Shodhana* protocols with toxicological evidence. Implementing GMP certified production and standardization techniques. Conducting multicentric clinical trials adhering to international norms. Engaging in cross-disciplinary research integrating *Ayurveda,* pharmacology, and nanotechnology. Establishing clear regulatory guidelines with the involvement of WHO and national authorities. **Conclusion:** Globalization of *Rasa Shastra* based herbo-mineral formulations is feasible with strategic interventions in safety validation, standardization, clinical evidence generation, and international collaborations. These efforts can pave the way for integrating *Rasa Shastra* therapeutics into global healthcare systems while ensuring safety, efficacy, and sustainability.

KEYWORDS: *Rasa Shastra,* Herbo-mineral Drugs, Globalization, Standardization, Safety Evaluation, Future Research Directions.

INTRODUCTION

Rasa Shastra, a distinctive branch of *Ayurveda,* focuses on the preparation and therapeutic application of herbo-mineral formulations.[1] These formulations combine plant-based ingredients with processed metals and minerals, such as mercury (*Parada*), gold (*Svarna*), silver (*Rajata*), copper (*Tamra*), and various gemstones. The classical methods of Shodhana (purification), *Marana* (incineration), and *Bhasmikarana* (calcination) are central to detoxifying these substances, transforming them into bio-assimilable and therapeutic forms. Historically, these drugs have been reputed for their potent efficacy in managing chronic, degenerative, and metabolic disorders like diabetes, arthritis, neurological conditions, and immune disorders.[2]

Despite their ancient legacy and therapeutic potential, *Rasa Shastra* based herbo-mineral drugs face significant skepticism on the global stage. The primary concern revolves around the safety and toxicity of heavy metals present in these preparations. Modern toxicological assessments often report adverse effects linked to improperly prepared formulations or those manufactured without adhering to classical purification protocols. These findings have led to regulatory restrictions in several countries, where stringent safety standards and heavy metal limits are enforced. Consequently, the acceptance of Rasa Shastra drugs in the global pharmaceutical market remains limited.[3]

Another significant challenge in the globalization of *Rasa Shastra* medicines is the lack of standardized quality control and Good Manufacturing Practices (GMP) tailored to these unique formulations. Unlike purely herbal drugs, the herbo-mineral preparations require specialized processes to ensure consistency, safety, and efficacy. Current methodologies for standardization are inadequate in addressing the complex chemical nature of *Bhasma* and metallic preparations. This gap results in varied product quality and creates obstacles in meeting international regulatory benchmarks, further impeding their wider acceptance.[4]

Additionally, there is a notable deficit of robust scientific evidence, particularly largescale, multicentric clinical trials that meet global research standards. While traditional texts and empirical data validate the efficacy of these formulations, modern evidence-based validation through pharmacological, toxicological, and clinical research is still insufficient. This limitation not only restricts their credibility in the global medical community but also hampers integration into mainstream healthcare systems that demand stringent evidence for drug safety and efficacy.[5]

Given these challenges, the future of *Rasa Shastra* globalization necessitates a multidisciplinary approach. Collaborative research integrating *Ayurveda*, pharmacology, toxicology, and advanced technologies like nanotechnology can pave the way for safer, standardized, and scientifically validated formulations. Establishing clear regulatory frameworks with the involvement of international bodies such as the World Health Organization (WHO), promoting awareness about classical purification methods, and protecting intellectual property rights are crucial steps. These strategies can potentially bridge traditional knowledge with modern science, enabling Rasa Shastra to contribute meaningfully to global healthcare.[6]

AIM AND OBJECTIVES

Aim

To explore the challenges and propose future directions for the globalization of Rasa Shastra based herbo-mineral drugs.

Objectives

1. To identify key challenges in the international acceptance of Rasa Shastra formulations.
2. To evaluate safety, standardization, and regulatory issues related to herbo mineral drugs.
3. To assess current research gaps and scientific validation needs.

4. To suggest strategies for quality control, clinical research, and global regulatory alignment.
5. To propose integrative and multidisciplinary approaches for safe globalization.

MATERIAL AND METHODS

This study employed a narrative review methodology, sourcing information from classical *Ayurvedic* texts such as *Rasa Ratna Samucchaya*, *Rasa Tarangini*, and *Charaka Samhita* for traditional perspectives on *Rasa Shastra*. Contemporary scientific literature was reviewed through databases like PubMed, Scopus, AYUSH Research Portal, and Google Scholar to gather data on safety, standardization, pharmacology, and clinical research related to herbo-mineral formulations. Regulatory frameworks and guidelines from international agencies such as WHO, US FDA, and AYUSH were also examined to understand global regulatory challenges. The collected data were critically analysed to identify existing challenges, research gaps, and to formulate potential future directions for the safe and effective globalization of *Rasa Shastra* based medicines.

Rasashastra based herbo-mineral drugs

Rasa Shastra is a specialized and intricate branch of *Ayurveda* that primarily deals with the use of metals, minerals, and gems combined with herbal components to prepare potent therapeutic formulations. This discipline is deeply rooted in *Ayurvedic* philosophy, aiming not just to treat diseases but to promote *Rasayana* (rejuvenation), longevity, and immunity enhancement. The term *Rasa* signifies mercury, which is considered the prime element in *Rasa Shastra,* while *Shastra* refers to the scientific method of processing and formulating medicines. The distinctiveness of *Rasa Shastra* lies in its ability to transform otherwise toxic metals and minerals into safe, bioavailable, and therapeutically effective agents through meticulous procedures.[7]

Principles and Processing Techniques

The core principle of *Rasa Shastra* is based on *Shodhana* (purification), *Marana* (incineration), *Jarana* (digestive processing), *Satvapatana* (extraction of metallic essence), and *Bhasmikarana* (calcination). These stages are designed to detoxify metals such as *Parada* (mercury), *Svarna* (gold), Rajata (silver), *Tamra* (copper), *Vanga* (tin), *Naga* (lead), and minerals like *Abhraka* (mica), *Makshika* (pyrite), and *Shilajatu*. Purification processes involve specific herbal juices, decoctions, and mechanical methods that eliminate physical and chemical impurities and reduce toxicity. *Marana* involves subjecting metals to controlled

heating with herbal agents, transforming them into *Bhasma*, which is an ash-like substance claimed to be safe, stable, and biologically assimilable.[8]

Texts like *Rasa Ratna Samucchaya*, *Rasa Tarangini*, and *Bhaishajya Ratnavali* systematically describe these processes, emphasizing the need for precision, specific conditions of heat, duration, and the use of organic binders for ensuring the desired therapeutic properties. These classical methods not only detoxify but also enhance the efficacy and shelf-life of the preparations. The unique concept of *Yogavahi* in *Rasa Shastra* refers to certain substances (like mercury) that have the ability to synergistically enhance the therapeutic potential of other ingredients by facilitating their deeper tissue penetration and targeted action.[9]

Types of Herbo-Mineral Preparations

Rasa Shastra includes various types of formulations such as:

1. *Bhasma:* Calcinated metallic and mineral preparations processed to fine ash for safe internal use.

2. *Parpati Kalpana:* Thin, brittle flakes prepared using purified mercury, sulfur, and other metals, useful in gastrointestinal and metabolic disorders.

3. *Kupipakwa Rasayana:* Medicines prepared by sublimation in sealed glass apparatus, primarily used for chronic and complex disorders like tuberculosis.

4. *Kharaliya Rasayana:* Triturated preparations made using minerals and herbs, providing quicker bioavailability.

5. *Sindura:* Bright red-coloured preparations derived from sublimation processes, especially beneficial in neurological and degenerative diseases.

Therapeutic Applications

These formulations have been traditionally used to manage a wide array of diseases including but not limited to:

- *Prameha* (Diabetes Mellitus)
- *Amavata* (Rheumatoid Arthritis)
- *Kustha* (Skin Disorders)
- *Unmada* (Psychiatric disorders)
- *Rajayakshma* (Tuberculosis)
- Neurological conditions like *Pakshaghata* (Paralysis) and *Apasmara* (Epilepsy).

The efficacy of these formulations is attributed to their nano-sized particles, biocompatibility, and their capability to restore doshic balance (*Vata*, *Pitta*, *Kapha*). Some recent studies suggest that the particle size of Bhasma lies within the nanometer range, which aligns with modern nanomedicine principles of drug delivery, enhancing absorption and targeted action.[10]

CHALLENGES IN GLOBALIZATION

Safety and Toxicity Concerns

The foremost challenge in the globalization of *Rasa Shastra* based drugs is the safety concern due to the presence of heavy metals like *Parada* (mercury), *Naga* (lead), and *Vanga* (tin). Western regulatory bodies and healthcare systems perceive these metals as toxic, which raises apprehension about their safety, especially when classical *Shodhana* and *Marana* procedures are not standardized or scientifically validated. Sporadic reports of lead and mercury poisoning from improperly prepared or adulterated formulations have further intensified global mistrust.[11]

Lack of Standardization and Quality Control

Unlike synthetic pharmaceuticals, herbo-mineral formulations of *Rasa Shastra* lack universally accepted parameters for standardization, dose precision, and shelf-life assessment. Techniques like *Shodhana*, *Marana*, and *Bhasmikarana* vary among traditional practitioners and manufacturers, leading to inconsistency in product quality. The absence of defined chemical markers, particle size consistency, and validated manufacturing protocols hinders the acceptance of these formulations in the global market.[12]

Regulatory Restrictions and Compliance Barriers

Many countries have strict regulatory frameworks for the import, sale, and use of medicines containing metals and minerals. For instance, the US FDA and European Medicines Agency (EMA) impose heavy restrictions on products with even trace amounts of mercury, lead, and arsenic, irrespective of their processed or detoxified status. The lack of harmonized regulations and absence of globally recognized pharmacopoeial standards for *Rasa Shastra* drugs create significant barriers to international commercialization.[13]

Inadequate Scientific Evidence and Clinical Trials

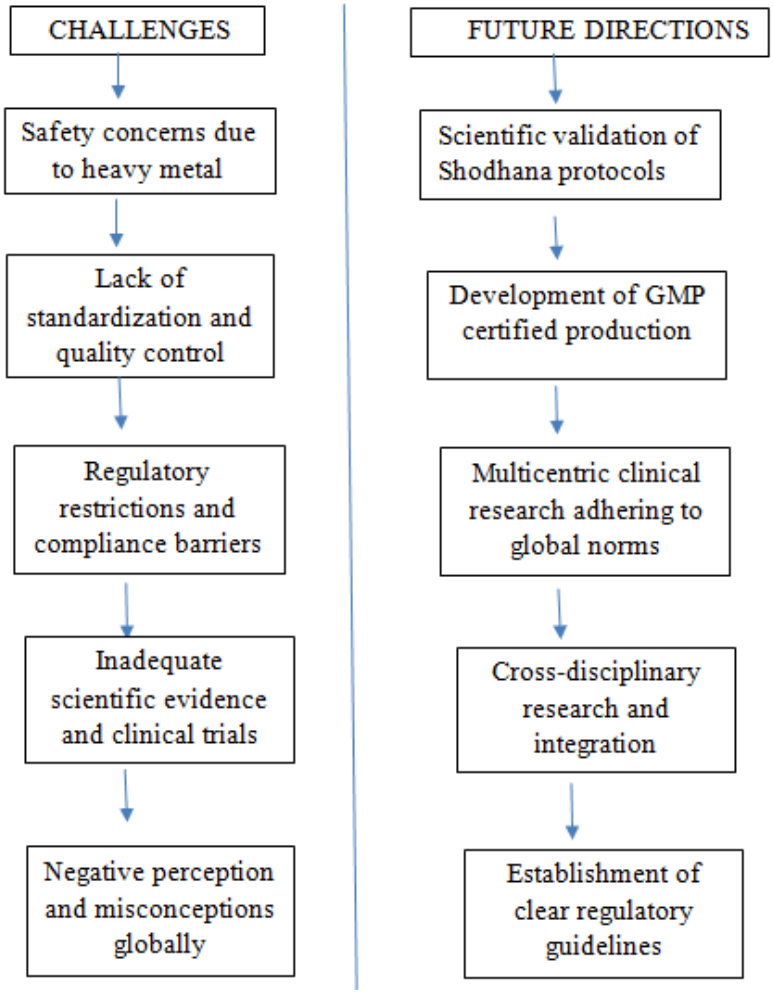
There is a significant dearth of comprehensive preclinical, clinical, and toxicological studies on *Rasa Shastra* formulations that meet the stringent criteria of modern evidence-based

medicine. Most of the existing data are anecdotal or derived from classical texts, which are insufficient for global regulatory approvals. The absence of large-scale, randomized controlled trials (RCTs) further limits their credibility and integration into mainstream healthcare systems.[14]

Negative Perception and Cultural Bias

Globally, there exists a cultural and scientific bias against traditional medicines containing heavy metals. The western medical community often views *Rasa Shastra* with skepticism, partly due to unfamiliarity with Ayurvedic pharmacology and partly due to historical reports of toxicity from contaminated or improperly prepared products. This perception barrier affects research funding, policy support, and consumer confidence internationally.[15]

***Rasa Shastra* Based Herbo-Mineral Drugs**



FUTURE DIRECTIONS

Scientific Validation

There is an urgent need to scientifically validate the *Shodhana, Marana*, and *Bhasmikarana* processes using advanced analytical techniques such as X-ray diffraction (XRD), Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), and Inductively Coupled Plasma Mass Spectrometry (ICP-MS). These techniques can establish the particle size, chemical composition, and crystalline structure of *Bhasma,* ensuring reproducibility and safety.[16]

Global Standardization Protocols

Establishing standardized protocols for the production, quality control, and shelf-life of herbo-mineral drugs is imperative. This includes defining specifications for raw materials, intermediates, and finished products. Developing monographs for *Rasa Shastra* formulations in international pharmacopoeias would facilitate regulatory approvals and global trust.[17]

Integration of Modern Technologies

Modern pharmaceutical technologies like nanotechnology can be integrated with *Rasa Shastra* principles to enhance bioavailability, reduce dosage, and improve therapeutic targeting. Nano formulations of *Bhasma* can potentially overcome concerns related to particle size and toxicity, aligning traditional practices with contemporary drug delivery systems.[18]

Clinical Research and Evidence Generation

Well-designed, multicentric clinical trials adhering to international research standards are essential to substantiate the safety and efficacy claims of Rasa Shastra drugs. Establishing pharmacokinetic, pharmacodynamic, and toxicological profiles will provide the scientific evidence required for global acceptance. Collaboration between *Ayurvedic* institutions, medical universities, and international research bodies can expedite this process.[19]

Policy Advocacy and Regulatory Harmonization

There is a need for policy advocacy to sensitize global regulatory bodies about the traditional methods of detoxification and preparation in *Rasa Shastra*. India's Ministry of AYUSH and WHO's Traditional Medicine Strategy can play pivotal roles in creating globally accepted guidelines and regulatory frameworks specific to herbo-mineral drugs.[20]

Capacity Building and Education

Training programs for *Ayurvedic* practitioners, researchers, and manufacturers on standardized production techniques and modern quality control methods can ensure consistency in product quality. Similarly, educating the global medical community about the principles and safety of *Rasa Shastra* through scientific publications, conferences, and workshops is essential to overcome biases.[21]

Intellectual Property Rights (IPR) and Traditional Knowledge Protection

Documenting traditional knowledge in digital libraries and securing IPR for *Rasa Shastra* formulations can protect India's heritage while encouraging innovation and global collaborations. This will also prevent biopiracy and unauthorized commercialization of indigenous knowledge.[22]

RESULTS AND FINDINGS

- Safety concerns due to heavy metal toxicity in *Rasa Shastra* drugs.
- Lack of standardization and uniform quality control protocols.
- Strict international regulatory restrictions on metal-based formulations.
- Insufficient clinical trials and scientific validation.
- Negative perception and cultural bias in global markets.
- Advanced analytical tools show potential for validating safety and efficacy.
- Need for interdisciplinary and translational research.
- Absence of specific global regulatory frameworks for herbo-mineral drugs.
- Opportunities to integrate nanotechnology for safer formulations.
- Future scope includes standardization, clinical research, policy advocacy, and education.

DISCUSSION

Rasa Shastra, an ancient *Ayurvedic* discipline, offers a distinctive therapeutic approach by integrating metals, minerals, and herbs into potent formulations. While these preparations have been traditionally validated for efficacy in chronic, degenerative, and metabolic disorders, their acceptance on the global stage faces significant hurdles. The primary concern remains the potential toxicity of heavy metals such as mercury, lead, and arsenic, especially in the absence of adherence to classical purification (*Shodhana*) and incineration (*Marana*) methods. Modern toxicology highlights these metals as hazardous, thus creating skepticism and regulatory barriers in international healthcare systems.[23]

Standardization is another critical challenge that hampers the globalization of *Rasa Shastra* medicines. Unlike allopathic drugs that have precise compositions and reproducible manufacturing protocols, herbo-mineral formulations often lack consistent preparation methods, leading to variability in safety and efficacy. There is currently no universally accepted protocol for the quality assessment of *Bhasma* and other *Rasa Shastra* products. This inconsistency fuels regulatory concerns and prevents these formulations from meeting Good Manufacturing Practice (GMP) standards required globally.[24]

Scientific evidence supporting the safety, pharmacodynamics, and clinical efficacy of *Rasa Shastra* formulations remains inadequate by modern research standards. While classical *Ayurvedic* texts and clinical practice demonstrate therapeutic success, there is a paucity of well-structured preclinical studies, toxicological evaluations, and large-scale clinical trials conforming to international norms. This gap in empirical data limits the credibility of these formulations among the global scientific community and healthcare practitioners.[25]

However, recent advancements in analytical techniques and nanotechnology offer promising avenues to bridge this gap. Studies using tools like XRD, SEM, TEM, and ICP-MS have demonstrated that Bhasma often exists in nanoparticle form, which may explain its high bioavailability and reduced toxicity when properly prepared. Integrating such technologies with classical methods can modernize the preparation of *Rasa Shastra* drugs, ensuring safety and enhancing therapeutic outcomes. Interdisciplinary research combining *Ayurveda*, pharmacology, toxicology, and material science is essential for developing standardized, scientifically validated formulations.[26]

For successful globalization, there is also a need for policy-level interventions and international regulatory harmonization. Collaborative efforts between governments, the Ministry of AYUSH, WHO, and scientific bodies can aid in establishing regulatory frameworks tailored to traditional herbo-mineral medicines. Additionally, educating global medical communities, promoting awareness about traditional detoxification techniques, and protecting intellectual property through proper documentation will be key strategies in promoting *Rasa Shastra* on a global platform.[27]

CONCLUSION

The globalization of *Rasa Shastra* based herbo-mineral drugs presents both significant opportunities and critical challenges. While these formulations possess immense therapeutic

potential rooted in centuries of traditional use, concerns related to heavy metal toxicity, lack of standardization, inadequate scientific validation, and stringent global regulatory norms impede their international acceptance. Addressing these challenges requires an integrated approach involving scientific validation of classical processes, advanced analytical research, robust clinical trials, and the development of global standardization protocols. With interdisciplinary collaboration, policy support, and regulatory harmonization, Rasa Shastra can be positioned as a credible and safe component of integrative global healthcare systems.

CONFLICT OF INTEREST- Nil.

SOURCE OF SUPPORT- NONE.

REFERENCES

1. Sharma S. Rasa Shastra: The Mercurial System of Ayurvedic Medicine. Varanasi: Chaukhambha Orientalia; 2012.
2. Mishra LC, Singh BB, Dagenais S. Scientific basis for the therapeutic use of Withania somnifera (Ashwagandha): a review. Altern Med Rev., 2000; 5(4): 334-346.
3. Saper RB, Phillips RS, Sehgal A, Khouri N, Davis RB, Paquin J, et al. Lead, mercury, and arsenic in US- and Indian-manufactured Ayurvedic medicines sold via the Internet. JAMA, 2008; 300(8): 915-923.
4. Patgiri BJ, Prajapati PK. Standard manufacturing procedure for Abhraka Bhasma. Indian J Nat Prod Resoure, 2011; 2(4): 403-408.
5. Gogte VM. Ayurvedic Pharmacology and Therapeutic Uses of Medicinal Plants. Mumbai: Bharatiya Vidya Bhavan; 2000.
6. Patwardhan B, Warude D, Pushpangadan P, Bhatt N. Ayurveda and traditional Chinese medicine: a comparative overview. Evid Based Complement Alternat Med., 2005; 2(4): 465-473.
7. Shastri K. Rasa Tarangini. 11th ed. Varanasi: Motilal Banarsidass, 2004.
8. Singh RH. The Ayurvedic system of medicine: introduction and overview. Afr J Tradit Complement Altern Med., 2007; 4(3): 319-337.
9. Thatte U, Chiplunkar S, Bhalerao S. Immunological basis of Ashwagandha pharmacology. Indian J Med Res., 2022; 156(Suppl 1): 74-S81.
10. Jagtap CY, Jagtap PR, Pande PR. Nano Ayurvedic medicine: the need of hour. Int J Pharm Sci Rev Res., 2016; 38(1): 114-117.

11. Saper RB, Kales SN, Paquin J, Burns MJ, Eisenberg DM, Davis RB, et al. Heavy metal content of Ayurvedic herbal medicine products. JAMA., 2004; 292(23): 28682873.
12. Chhajed M, Prakash P. Quality Control and Standardization of Ayurvedic Bhasma: Need of the Day. J Ayurveda Integr Med Sci., 2020; 5(5): 233-238.
13. US Food and Drug Administration. Guidance for Industry: Botanical Drug Development. US Department of Health and Human Services, 2016.
14. Choudhary N, Sekhon BS. An overview of advances in the standardization of herbal drugs. J Pharm Educ Res., 2011; 2(2): 55-70.
15. Patwardhan B, Mashelkar RA. Traditional medicine-inspired approaches to drug discovery: can Ayurveda show the way forward? Drug Discov Today, 2009; 14(1516): 804-811.
16. Singh N, Chaudhary A. Role of ICP-MS, XRD and TEM in standardization of Ayurvedic Bhasma: A Review. J Pharmacogn Phytochem., 2018; 7(2): 137-143.
17. Bhalerao S, Mehendale N. Standardization and quality assurance of Bhasma: traditional approach and modern tools. Int J Res Ayurveda Pharm., 2010; 1(1): 3036.
18. Sharma M, Devi S, Sharma PK. Nanotechnology: An emerging dimension of Ayurveda. Ayu., 2020; 41(3): 131-137.
19. Patgiri BJ, Prajapati PK. Clinical trials in Ayurveda: Issues, challenges, and way forward. J Ayurveda Integr Med., 2019; 10(3): 216-220.
20. WHO. WHO Global Report on Traditional and Complementary Medicine 2019. Geneva: World Health Organization, 2019.
21. Ministry of AYUSH, Government of India. AYUSH Research Portal. Available from: https: //www.ayushportal.nic.in
22. Gupta RC, Kumar S, Srivastava A, Sharma R, Agarwal M. Ayurveda and Intellectual Property Rights: The Need for Awareness. J Intellect Prop Rights, 2015; 20(34): 147-154.
23. Dahanukar SA, Kulkarni RA, Rege NN. Pharmacology of medicinal plants and natural products. Indian J Pharmacol., 2000; 32(4): 81-118.
24. Prajapati PK, Jani HP, Vyas SN. Standardization and quality control of herbomineral preparations: challenges and solutions. Indian J Tradit Knowl., 2010; 9(3): 498-504.
25. Kumar A, Nair AGC, Reddy AVR, Garg AN. Characterization of Ayurvedic Bhasmas using modern techniques. Indian J Tradit Knowl., 2006; 5(3): 331-335.
26. Jagtap CY, Jagtap PR. A scientific insight of Bhasma with special reference to nanoparticle characterization. J Ayurveda Integr Med Sci., 2017; 2(4): 200-205.

27. Sharma R, Galib, Prajapati PK. Globalization of Ayurveda: The Need for Policy Support and Regulatory Harmonization. Ayu., 2011; 32(1): 3-8.