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Research Article

Toxicological Implications of Improperly Prepared Rasa Dravyas: A Comprehensive Review of Safety Concerns and Preventive Strategies

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Abstract
Rasa Dravyas, the metallic and mineral-based formulations in *Ayurveda*, have been widely used for centuries due to their potent therapeutic benefits. However, the safety of these formulations largely depends on the adherence to traditional preparation processes such as *Sodhana* (detoxification) and *Maran* (incineration). Improper preparation of *Rasa Dravyas* can lead to significant toxicological risks, including heavy metal toxicity, organ damage, and oxidative stress. This review explores the toxicological implications of improperly prepared *Rasa Dravyas*, drawing from classical *Ayurvedic* texts and modern scientific studies to mitigate risks, the review underscores the need for strict adherence to classical guidelines, quality control through Good Manufacturing Practices (GMP), and integration of *Ayurvedic* practices with modern pharmacological and toxicological frameworks.
By bridging traditional knowledge with contemporary scientific validation, the safe and effective use of *Rasa Dravyas* can be ensured, enhancing their global acceptance as a component of integrative medicine.

Key words- *Ayurveda*, *Bhasma*, GMP**,** *Rasa Dravyas*, *Rasa Shastra*, Toxicity

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Introduction

The branch of *Rasashastra* in *Ayurveda* is renowned for its use of metallic and mineral preparations (*Rasa Dravyas*), which are considered potent therapeutics for various chronic and acute disorders. These formulations, when prepared according to classical guidelines involving *Sodhana* (purification), *Maran* (incineration), and *Bhavana* (triturating with specific liquids), are deemed safe and efficacious. However, improperly prepared *Rasa Dravyas* can pose significant toxicological risks due to the presence of residual impurities or improperly transformed metals. Such risks necessitate a thorough examination of their toxicity and the establishment of stringent preparation standards. Key findings highlight that incomplete transformation of metals during preparation contributes to toxicity, with improperly processed formulations linked to clinical cases of nephrotoxicity, hepatotoxicity, and neurotoxicity. Conversely, studies validate that traditional methods like *Sodhana* significantly reduce elemental impurities, transforming metals into bioavailable and safe forms. Advanced analytical tools such as ICP-MS and XRD have been used to scientifically corroborate these claims.

This review aims to evaluate the toxicological aspects of improperly prepared *Rasa Dravyas*, their physiological impacts, and strategies for their safe utilization by integrating *Ayurvedic* principles with modern toxicological methodologies.

Aims and Objectives

Aim

To critically evaluate the toxicological implications of improperly prepared *Rasa Dravyas* (metallic and mineral-based *Ayurvedic* formulations) and propose strategies for ensuring their safety and efficacy through the integration of classical *Ayurvedic* principles with modern scientific methodologies.

Objectives

- To Analyze Classical Textual References
- To Identify Toxicological Risks
- To Assess the Role of Classical Purification Processes
- To Integrate Modern Analytical Techniques
- To Document Clinical Outcomes
- To Propose Preventive Strategies
- To Bridge Traditional and Modern Approaches

Study Design

Data Sources and Collection

1. **Classical *Ayurvedic* Texts**:
   The foundational *Ayurvedic* treatises were extensively reviewed to extract detailed descriptions of the preparation, purification, and therapeutic use of *Rasa Dravyas*.
   - *Rasaratnasamuchaya*, *Rasatarangini*, *Charaka Samhita*, *Sushruta Samhita*, and *Ashtanga Hridaya* were the primary sources.
   - Emphasis was placed on the sections detailing *Sodhana* (detoxification), *Maran* (incineration), and *Bhavana* (trituration with herbal extracts).
2. **Modern Scientific Literature**:
   A systematic search was conducted on databases like PubMed, Scopus, Google Scholar, and ResearchGate.

Study Components and Framework

The study framework was structured to address the following key components:

1. Understanding the Preparation of *Rasa Dravyas*:
2. Analysis of Toxicological Risks:
3. Validation of *Ayurvedic* Methods Using Modern Analytical Tools:
   - The role of modern analytical techniques in assessing the safety of *Rasa Dravyas* was explored.
   - ICP-MS (Inductively Coupled Plasma Mass Spectrometry) for detecting trace metal impurities.
   - XRD (X-ray Diffraction) for determining crystalline structure post-*Maran*.
   - FTIR (Fourier Transform Infrared Spectroscopy) for assessing chemical changes after *Sodhana*.
   - SEM/TEM (Scanning and Transmission Electron Microscopy) for visualizing particle size and morphology.
4. Regulatory and Quality Control Measures:
   - Existing regulations for the preparation and marketing of *Rasa Dravyas* were critically analyzed.
   - GMP standards, quality control protocols, and recommendations for ensuring product safety were reviewed.

Mechanisms of Toxicity

Improperly prepared *Rasa Dravyas* may result in the retention of toxic metal impurities, which, when consumed, can lead to a variety of toxicological effects. The primary mechanisms of toxicity include:

1. Heavy Metal Bioaccumulation

Many *Rasa Dravyas* contain metals such as Mercury (known as *Parad*), Lead (as *Vanga*), Arsenic (as *Sankhiya*), and Copper (as *Tamra*). If these metals are not adequately purified or incinerated during the preparation process, they may retain their original toxic properties.

- Bioaccumulation occurs when heavy metals accumulate in the body over time, primarily in organs like the liver, kidneys, and brain, due to the inability of the body to efficiently excrete them.
- These metals can disrupt cellular processes by interacting with proteins, enzymes, and DNA, leading to long-term damage to organs and tissues. For example, mercury and lead are known to accumulate in the brain and kidneys, leading to neurotoxicity and nephrotoxicity.
- Mercury (*Parad*), if improperly purified, can cause a range of toxic effects, including neurological damage, memory loss, tremors, and in severe cases, organ failure. Similarly, lead toxicity can lead to anemia, kidney dysfunction, and developmental issues in children.

2. Oxidative Stress and Cellular Damage

Oxidative stress is a critical mechanism through which improperly prepared *Rasa Dravyas* cause cellular damage.

- Oxidative stress arises when the body's antioxidant defense mechanisms are overwhelmed by free radicals and reactive oxygen species (ROS) generated by the presence of residual toxic metals.
- Heavy metals like mercury, lead, and arsenic can catalyze the formation of ROS, which can damage cellular components such as lipids, proteins, and DNA.
- This leads to cellular apoptosis (programmed cell death), DNA mutations, and mitochondrial dysfunction, which are associated with diseases like cancer, neurodegenerative disorders (e.g., Alzheimer's, Parkinson's), and cardiovascular diseases.
- Arsenic, for example, is known to induce oxidative damage by increasing ROS production and inhibiting the activity of antioxidant enzymes like glutathione peroxidase. This oxidative damage can lead to severe organ damage, including liver and lung toxicity.

3. Disruption of Enzyme Activity

Heavy metals in *Rasa Dravyas* can interfere with the normal functioning of enzymes that are critical for metabolic processes.

- These metals can bind to enzyme active sites or displace essential metal cofactors (such as zinc, iron, or magnesium) needed for enzyme function.
- Lead and Mercury, for instance, are known to inhibit enzymes involved in neurotransmission, causing neurotoxic effects. Lead interferes with enzymes involved in heme biosynthesis, leading to anemia, while mercury can inhibit enzymes that are vital for cellular respiration and detoxification.
- Enzyme inhibition can lead to an accumulation of waste products, cellular dysfunction, and damage to vital organs.

4. Immune System Dysregulation

Improperly prepared *Rasa Dravyas* may also induce immune system dysregulation, making the body more susceptible to infections, inflammation, and autoimmune diseases.

- Toxic metals can alter immune cell function by interacting with immune cell receptors or altering the function of lymphocytes, macrophages, and neutrophils.
- Heavy metals like mercury and lead have been shown to suppress the function of immune cells, impairing the body's ability to fight infections and increasing the risk of autoimmune diseases.
- Additionally, mercury is a potent immunotoxin that can alter the balance between Th1 and Th2 immune responses, contributing to inflammation, autoimmune disorders, and allergic reactions.

5. Endocrine Disruption

Heavy metals from improperly prepared *Rasa Dravyas* may also lead to endocrine disruption, interfering with the body's hormone-regulating systems.

- Lead and Mercury have been shown to interfere with thyroid, adrenal, and gonadal hormone synthesis.
- Lead can disrupt the synthesis of thyroid hormones by affecting iodine uptake, leading to hypothyroidism.
- Mercury exposure has been linked to alterations in reproductive hormones, such as estrogen and testosterone, which can affect fertility and development.
- This disruption of endocrine functions can result in developmental delays, hormonal imbalances, and reproductive issues.

6. Neurotoxicity

One of the most significant risks associated with improperly prepared *Rasa Dravyas* is neurotoxicity.

- Metals such as mercury, lead, and arsenic are known neurotoxicants that can affect the central nervous system.
- Mercury, when not properly processed, can lead to cerebellar ataxia, tremors, mood swings, and cognitive impairments.
- Lead exposure can cause irreversible damage to the brain, particularly in children, leading to developmental delays, lower IQ, and attention disorders.
- Arsenic has neurotoxic effects that contribute to peripheral neuropathy, where patients experience numbness and tingling sensations in the limbs. It also affects cognitive function and has been linked to neurodegenerative diseases like Alzheimer's.

7. Organ-Specific Toxicity

The major target organs for toxicity resulting from improperly prepared *Rasa Dravyas* are the liver, kidneys, brain, and heart.

- Hepatotoxicity: Lead, mercury, and arsenic can accumulate in the liver, leading to hepatocellular damage, fibrosis, and cirrhosis.
- Nephrotoxicity: Metals like cadmium, mercury, and lead are particularly nephrotoxic, causing tubular damage, renal failure, and electrolyte imbalances.
- Cardiotoxicity: Arsenic and cadmium have been associated with cardiovascular diseases, including hypertension, atherosclerosis, and myocardial infarction.
- The ability of these metals to accumulate in these organs and disrupt cellular function can result in chronic diseases, leading to organ failure if exposure continues over time.

8. Alteration of Gut Microbiota

Emerging research has indicated that heavy metals from *Rasa Dravyas* may also affect the gut

microbiota, which plays a crucial role in metabolism, immune function, and overall health.
- Lead and mercury have been shown to disrupt the balance of gut microbes, leading to dysbiosis (imbalanced gut flora).
- Dysbiosis can result in gastrointestinal issues, impaired digestion, increased intestinal permeability, and even systemic inflammation.
- The gut microbiota also plays a role in metabolizing and detoxifying certain substances, so disruption of the microbiome can lead to reduced detoxification capacity, further exacerbating toxicity.

Role of *Sodhana* and *Maran* in Mitigating Toxicity

In *Ayurveda*, the preparation of therapeutic substances from metals, minerals, and herbs plays a crucial role in ensuring their effectiveness and safety for human use. Among the most significant processes are *Sodhana* (purification) and *Maran* (calcination), both of which are central to the preparation of *Rasa Dravyas* (medicinal metals and minerals). The purpose of these procedures is to reduce or eliminate inherent toxicity, transforming raw materials into substances that are not only safe for consumption but also potent in their therapeutic actions.

1. *Sodhana* (Purification) - The First Step in Ensuring Safety

The primary aim of *Sodhana* is to purify raw materials, especially metals and minerals, by eliminating toxins, impurities, and contaminants that may cause harm to the human body. Raw metals, such as mercury, lead, and arsenic, are inherently toxic in their natural state. However, when subjected to proper purification, these metals are made suitable for medicinal use. *Sodhana* can be considered as a detoxification process, which ensures the safety and therapeutic value of the substance.

- **Types of *Sodhana*:**

  - **Physical *Sodhana***:

Physical purification techniques include washing, grinding, and rubbing of metals with specific substances such as herbal decoctions, oils, or water. These methods are intended to remove mechanical impurities and surface-level toxins. For example, mercury (*Parad*) is purified through grinding with herbal powders like *Triphala* or *Haritaki*, which help cleanse the surface of harmful elements.

  - **Chemical *Sodhana***:

Involves the use of herbal juices, sour liquids, and acidic or alkaline substances that chemically react with metal or mineral, dissolving harmful compounds. This method works by breaking down toxic impurities and transforming them into less harmful forms. An example is the use of Sour buttermilk or lime juice for purifying metals like mercury, which reacts with these substances to form safer compounds.

  - **Thermal *Sodhana***:

Thermal purification involves heating the metal or mineral to high temperatures in the presence of specific substances or under controlled conditions. Metals like lead and mercury undergo structural changes during this process, which helps in removing toxic residues.

2. *Maran* (Calcination) - Enhancing Potency and Safety

Once the raw materials have undergone *Sodhana* to remove surface-level toxins and impurities, the next critical step is *Maran*, a calcination process that further refines the metal or mineral. The purpose of *Maran* is to heat the purified substance to a high temperature, thereby changing its chemical composition and making it therapeutically potent. Calcination also enhances the metal's bioavailability and ensures its compatibility with the human body.

- **Purpose of *Maran***:

The primary goal of *Maran* is to render metals and minerals in a form that is not only safe for consumption but also therapeutically effective. This process is essential in making the metal suitable for internal administration, as it alters the structure of the material, enabling better absorption by the body and enhancing its therapeutic properties.

- **Process of *Maran***:

Maran involves heating the purified metal or mineral at high temperatures, often with the addition of specific herbal materials that help in the transformation. The procedure typically takes place in a crucible, where controlled heating ensures that the metal undergoes a complete transformation.

- **Effects of *Maran* on Toxicity**:

During *Maran*, the metal undergoes oxidation, sublimation, or reduction, depending on the substance and the method used. These changes alter the toxicological profile of the substance, reducing its toxicity and making it suitable for medicinal use. The process also enhances the therapeutic efficacy of the metal by making it more compatible with the body's biochemistry.

Modern Validation of *Ayurvedic* Processes

1. Analytical Techniques in Modern Toxicology

Modern toxicology provides advanced tools for detecting and quantifying toxic substances, enabling a more rigorous evaluation of the safety of *Ayurvedic* formulations. Among the most widely used techniques are Inductively Coupled Plasma Mass Spectrometry (ICP-MS), X-ray Diffraction (XRD), Scanning Electron Microscopy (SEM), and Fourier Transform Infrared Spectroscopy (FTIR). These analytical methods allow researchers to track changes in the chemical composition, crystalline structure, and toxicity levels of metals and minerals throughout the processes of *Sodhana* and *Maran*.

- **Inductively Coupled Plasma Mass Spectrometry (ICP-MS):**

ICP-MS is a powerful technique used to measure trace elements in a sample with high precision. It is particularly useful in detecting and quantifying metals such as lead, mercury, arsenic, and other heavy metals, which are commonly found in raw materials before they undergo purification processes.

- **X-ray Diffraction (XRD):**

XRD is used to identify the crystallographic structure of materials. In the case of *Rasa Dravyas*, XRD helps to monitor changes in the molecular and crystalline structure during *Sodhana* and *Maran*.

- **Scanning Electron Microscopy (SEM):**

SEM provides high-resolution images of the surface structure of materials, enabling the study of their micro and nanoscopic features. When applied to the evaluation of *Ayurvedic* metals like *Swarna bhasma* (gold ash) or *Parada Bhasma*, SEM can reveal how the *Sodhana* and *Maran* processes affect the particle size and surface morphology.

- **Fourier Transform Infrared Spectroscopy (FTIR):**

FTIR is an analytical technique that measures the absorption of infrared light by a sample, revealing information about its molecular composition and functional groups. This method can be used to study the chemical bonds present in *Ayurvedic* metals before and after *Sodhana* and *Maran*.

2. **Validation of Toxicological Safety**

Modern toxicological studies, such as acute toxicity studies and sub-chronic toxicity studies, are essential for determining the safety of *Ayurvedic* formulations containing *Rasa Dravyas*. These studies help to identify any potential harmful effects that may arise from the consumption of improperly prepared or unprocessed metals. Through the use of animal models, these studies evaluate the effects of *Ayurvedic* formulations on organ systems and overall health.

- **Acute Toxicity Studies:**

Acute toxicity studies aim to determine the immediate toxic effects of a substance following a single dose administration. These studies help assess the potential risks associated with the consumption of raw or improperly processed *Rasa Dravyas*.

- **Sub-Chronic and Chronic Toxicity Studies:**

These studies assess the potential long-term toxic effects of *Ayurvedic* medicines containing *Rasa Dravyas*. By administering *Ayurvedic* preparations over a longer period, researchers can observe any cumulative or delayed toxic effects on organ systems such as the liver, kidneys, and nervous system.

3. **Clinical Trials and Evidence of Efficacy**

Clinical trials serve as the final validation of the therapeutic efficacy of *Ayurvedic* formulations containing *Rasa Dravyas*. These trials are critical in establishing the practical benefits of *Sodhana* and *Maran* in treating various diseases and conditions. Clinical trials provide robust evidence of how these purified and calcined substances can be used safely and effectively in modern medical practice.

- **Efficacy in Rheumatic Diseases:**

Clinical trials have demonstrated that purified and processed *Rasa Dravyas*, such as *Swarna bhasma*, are effective in treating conditions like rheumatoid arthritis and osteoarthritis. These conditions are marked by inflammation, joint pain, and stiffness. In clinical trials, patients receiving *Swarna bhasma* reported significant reductions in pain and inflammation, with improvements in joint function.

  - The successful clinical use of *Swarna bhasma* confirms the therapeutic efficacy of *Ayurvedic* preparations containing *Rasa Dravyas* and reinforces the importance of proper purification and calcination to ensure both safety and potency.

- **Efficacy in Neurological Conditions:**

Tamraa Bhasma has been studied in the context of neurological disorders, including Parkinson's disease and Alzheimer's disease. Clinical research has shown that this formulation helps improve cognitive function, reduce tremors, and enhance overall quality of life in patients with these conditions.

  - The clinical evidence supports the use of purified and calcined copper as a therapeutic agent, further demonstrating that the *Sodhana* and *Maran* processes play a vital role in ensuring the safety and efficacy of *Ayurvedic* medicines.

4. Integration of Traditional and Modern Practices

The integration of traditional *Ayurvedic* practices with modern scientific validation enhances the credibility of *Ayurveda* as a medical system. As modern research continues to validate *Ayurvedic* processes such as *Sodhana* and *Maran*, there is increasing recognition of the effectiveness and safety of *Ayurvedic* formulations in contemporary medical practice.

- By combining ancient wisdom with modern toxicological methods, *Ayurvedic* medicine can evolve to meet the standards of evidence-based medicine. This integration allows for the formulation of medicines that are both scientifically validated and rooted in traditional healing practices, offering a holistic approach to health and well-being.

Preventive Strategies for Safe Use of *Rasa Dravyas*

1. Ensuring Proper Standardization of *Rasa Dravya* Preparations

The first step toward the safe use of *Rasa Dravyas* is ensuring that the raw materials are sourced, processed, and standardized according to well-established protocols. Standardization is vital in reducing

variations in the composition, potency, and toxicity of the final product. *Ayurveda* emphasizes specific methodologies for preparing and purifying metals, including the use of herbal decoctions, mineral solvents, and calcination procedures, but modern validation methods are required to verify the consistency and safety of these formulations.

- **Raw Material Sourcing:**

The quality of raw materials directly impacts the final product's safety and effectiveness. It is essential to source metals and minerals from reliable and standardized suppliers who adhere to quality control practices. Materials that are contaminated with environmental toxins or other harmful impurities can result in unsafe formulations. Ensuring that *Rasa Dravyas* are sourced from certified and authenticated suppliers can help mitigate risks associated with contaminated raw materials.

- **Standard Operating Procedures (SOPs):**

In clinical and manufacturing settings, implementing Standard Operating Procedures for the preparation of *Rasa Dravyas* can reduce errors and ensure consistency. SOPs should outline the specific *Sodhana* and *Maran* techniques, including the precise types of herbal decoctions, time intervals, temperatures, and methods used during calcination. These protocols should be rigorously followed to guarantee that the purification and transformation processes are properly carried out, minimizing any potential risks of improper preparation.

- **Integration of Modern Scientific Analysis:**

Regular use of modern scientific techniques such as High-Performance Liquid Chromatography (HPLC), Inductively Coupled Plasma Mass Spectrometry (ICP-MS), and Atomic Absorption Spectroscopy (AAS) is essential for ensuring the standardization of the metal content, purity, and absence of contaminants like heavy metals. These tests help verify the exact concentration of active ingredients in the final formulation and ensure that toxic substances are below acceptable levels.

2. Training and Education for *Ayurvedic* Practitioners and Manufacturers

The success of preventive strategies depends heavily on the training and education of *Ayurvedic* practitioners and manufacturers who prepare *Rasa Dravyas*. A comprehensive understanding of both the traditional knowledge of *Ayurveda* and modern toxicological principles is essential for ensuring the safe and effective use of medicinal metals and minerals.

3. Monitoring and Quality Control of *Ayurvedic* Medicines

Regular monitoring and quality control processes are critical to identifying potential risks associated with *Rasa Dravya* preparations and their usage. A proactive approach to monitoring can help detect any adverse effects that may arise from improperly prepared formulations and allow for timely corrective actions.

4. Regulatory Oversight and Compliance with Safety Standards

For *Rasa Dravyas* to be used safely and effectively, regulatory oversight is essential to enforce safety standards in their production, formulation, and administration. *Ayurvedic* medicines, especially those containing metals and minerals, must comply with stringent safety protocols and guidelines established by health authorities.

- **Regulatory Bodies and Guidelines:**

Regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO) in India and the Food and Drug Administration (FDA) in other countries are crucial in setting standards for *Ayurvedic* products. These organizations ensure that *Ayurvedic* medicines meet safety, quality, and efficacy standards before they are released to the public.

- **Good Manufacturing Practices (GMP):**

Adhering to Good Manufacturing Practices (GMP) ensures that *Ayurvedic* medicines are consistently produced and controlled according to established quality standards. GMP guidelines include specifications for the quality, safety, and efficacy of drugs, which are crucial for ensuring that *Rasa Dravyas* are manufactured in a safe environment, free from contamination, and under controlled conditions.

Discussion

The study of improperly prepared *Rasa Dravyas* from a toxicological perspective sheds light on a critical area where traditional *Ayurvedic* practices intersect with modern safety standards. *Ayurveda's* centuries-old methods of *Sodhana* (purification) and *Maran* (calcination) are designed to transform naturally toxic metals and minerals into therapeutically beneficial substances. However, improper preparation or deviations from classical methods can lead to residual toxicity, posing risks to patient's health. This highlights the need for rigorous evaluation and standardization to ensure the safety and efficacy of *Rasa Dravyas*. Improper preparation of *Rasa Dravyas* often results in the presence of toxic heavy metals, such as mercury, arsenic, and lead, which can cause severe physiological harm if consumed in excess. The ancient purification methods, as described in classical *Ayurvedic* texts, are intended to detoxify these substances. For example, immersing metals in herbal decoctions during *Sodhana* not only reduces their toxicity but also enhances their bioavailability. However, modern toxicological studies indicate that the effectiveness of these processes can vary depending on the quality of the materials used, adherence to preparation protocols, and the skill of the practitioner. Thus, the traditional processes require validation using contemporary scientific tools. Another important consideration is the synergistic role of herbal additives in mitigating toxicity. Herbs used during

purification and preparation not only detoxify metals but may also provide antioxidant and anti-inflammatory properties, enhancing the therapeutic profile of *Rasa Dravyas*. Future research should explore these interactions at the molecular level to better understand the mechanisms underlying their protective effects. Regulatory frameworks are essential to standardize the preparation and usage of *Rasa Dravyas*. *Ayurvedic* pharmacopoeias must incorporate clear guidelines for the purification processes, permissible metal limits, and mandatory safety testing of finished products. Collaborative efforts between *Ayurvedic* practitioners, toxicologists, and regulatory authorities can help establish global standards, ensuring the safe integration of *Rasa Dravyas* into modern healthcare systems.

Conclusion

The toxicological evaluation of improperly prepared *Rasa Dravyas* underscores the critical need to balance traditional *Ayurvedic* wisdom with modern scientific rigor. *Rasa Dravyas*, when prepared following classical methods of *Sodhana* (purification) and *Maran* (calcination), hold immense therapeutic potential. However, deviations from these methods can result in toxic metal residues, posing significant health risks. By embracing advancements in modern toxicology, such as analytical techniques and toxicokinetic studies, we can validate the safety and efficacy of these formulations, ensuring their proper use in contemporary medicine. Standardization of preparation processes and adherence to regulatory frameworks are vital for ensuring safety and quality. Collaborative efforts between *Ayurvedic* practitioners, scientists, and regulatory authorities can bridge gaps in knowledge, establish global safety standards, and bolster confidence in the therapeutic use of *Rasa Dravyas*. Additionally, research on the detoxifying role of herbal additives used in preparation methods highlights the synergistic potential of *Ayurveda's* holistic approach.

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