

**Pharmacovigilance: A Key to Safe Use of Rasaushadhis in Ayurveda**Dr Suraj Sharad Kundle<sup>1</sup>, Dr Shraddha Sandip Shelke<sup>2</sup>

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**Abstract**

Rasaushadhis, the potent herbo-mineral preparations of Ayurveda, have been a cornerstone in treating chronic and complex diseases. However, concerns regarding their safety and potential toxicity necessitate robust pharmacovigilance measures. This research article reviews the significance of pharmacovigilance in Rasashastra, discusses classical references emphasizing drug safety, identifies potential adverse effects, and highlights the role of modern pharmacovigilance programs. The article also underscores the essential role of BAMS students in ensuring the safe practice of Rasashastra, thereby bridging the wisdom of ancient science with modern healthcare needs.

**Keywords:** Pharmacovigilance, Rasaushadhi, Rasashastra, Ayurveda, Adverse Drug Reaction, AYUSH

**Introduction**

Ayurveda, India's ancient science of life, emphasizes not only the cure of diseases but also the safety of therapeutic interventions. Rasashastra, a specialized branch studied during the 2nd year of BAMS, deals with the preparation and therapeutic use of Rasaushadhis—medicines formulated using metals, minerals, and herbs. These drugs are known for their **quick action, low dosage, and effectiveness in stubborn diseases**.

However, the use of metals like mercury (Parada), gold (Swarna), arsenic (Haritala), and lead (Naga) in medicine raises safety concerns, especially when not processed properly. Thus, **Pharmacovigilance**—defined by WHO as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem”—is essential for the safe use of Rasaushadhis.

The concept of ensuring drug safety is not new to Ayurveda. It is deeply embedded in classical texts, which meticulously describe drug purification, proper usage, dosage, and contraindications.

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## Ayurvedic Perspective on Drug Safety

### Classical Shlokas Emphasizing Safety

Several shlokas in Ayurvedic texts highlight the significance of safety in drug preparation and administration:

#### Charaka Samhita states:

“न हि सर्वाणि भेषजानि सर्वेषु सर्वदा हितानि भवन्ति □”

“*Na hi sarvāṇi bheṣajāni sarveṣu sarvadā hitāni bhavanti.*”

(*Cha. Su. 26/84*)

*Translation: All drugs are not suitable for everyone at all times.*

This emphasizes individualization in drug administration—a key preventive measure against adverse drug reactions (ADRs).

Another crucial reference comes from Rasa Ratna Samuccaya:

“यथार्हं शोधनं कृत्वा ततः सिद्धिर्न संशयः □”

“*Yathārhaṃ śodhanaṃ kṛtvā tataḥ siddhirna saṁśayaḥ.*”

(*Rasa Ratna Samuccaya, 3/13*)

*Translation: Proper purification (Shodhana) ensures the success of medicine without any doubt.*

These shlokas underscore the ancient wisdom that improper processing can lead to drug toxicity—a principle that perfectly aligns with modern pharmacovigilance.

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## Potential Toxicities of Rasaushadhis

Despite their benefits, improperly prepared or misused Rasaushadhis can cause significant harm:

- **Hepatotoxicity:** Damage to liver due to residual metals
- **Nephrotoxicity:** Kidney dysfunction from heavy metals
- **Neurological Toxicity:** Symptoms like tremors, confusion, or neuropathy
- **Gastrointestinal Issues:** Nausea, vomiting, abdominal pain
- **Heavy Metal Accumulation:** Chronic exposure leading to systemic toxicity

For instance, mercury-based drugs like Rasasindura are effective in conditions like syphilis or skin disorders but require meticulous preparation to remove toxicity.

## Factors Leading to ADRs in Rasashastra

Several factors increase the risk of ADRs with Rasaushadhis:

- Use of **adulterated or low-quality raw materials**
- Improper **Shodhana** or **Marana** processes
- Incorrect **dosage** or **Anupana** (vehicle)
- Administration in **incompatible conditions (Viruddha Aahara/Vihara)**
- Lack of proper patient assessment (Prakriti, Avastha, Dosha)

Classical texts like Rasa Ratna Samuccaya emphasize strict adherence to pharmaceutical procedures to avoid toxicity:

“कुर्वीत भैषज्यं युक्त्या”

(Cha. Su. 1/120)

*Translation: Medicines should be prepared and administered with proper rationale.*

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## Modern Pharmacovigilance and AYUSH Systems

Recognizing safety concerns, the Ministry of AYUSH launched the **Ayush Pharmacovigilance Programme** in 2017. Objectives include:

- Monitoring ADRs from Ayurveda, Siddha, Unani, and Homoeopathy drugs
- Training healthcare professionals
- Developing reporting systems for adverse events
- Establishing regional and peripheral pharmacovigilance centers

The Pharmacovigilance Programme of India (PvPI) under the Indian Pharmacopoeia Commission (IPC) collaborates with AYUSH sectors to improve patient safety.

Tools used include:

- **ADR Reporting Forms**
- Mobile apps for real-time reporting
- Training sessions for students and practitioners

Despite these advancements, underreporting remains a challenge due to lack of awareness or fear of professional consequences.

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## BAMS Students' Role in Pharmacovigilance

As future Ayurvedic physicians, 2nd year BAMS students have a crucial role in ensuring drug safety:

- **Mastering pharmaceutical techniques:** Correct Shodhana, Marana, and Bhavana to ensure safety.

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- **Observation skills:** Identifying signs of ADRs such as digestive disturbances, skin reactions, or neurological symptoms.
  - **Patient Counseling:** Explaining drug dosages, Anupana, and necessary dietary precautions.
  - **Documentation:** Learning to fill ADR reporting forms accurately and confidently.
  - **Research Participation:** Involving in safety studies to generate evidence for Rasaushadhi efficacy and safety.
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## Discussion

Pharmacovigilance bridges traditional knowledge and modern scientific practice. The meticulous procedures described in classical texts reflect an early form of pharmacovigilance. Rasaushadhis, when prepared and administered correctly, can provide life-saving benefits, but improper use can lead to severe toxicity. Modern pharmacovigilance efforts seek to systematically document and analyze such adverse reactions.

Interestingly, Ayurveda's individualized approach aligns with modern personalized medicine. Factors like Doshha, Prakriti, and Rogavastha significantly influence drug response. Thus, Ayurveda inherently supports pharmacovigilance through personalized therapeutic planning.

Moreover, Ayurveda's concepts of Anupana and Viruddha Aahara demonstrate an ancient awareness of drug-food interactions, a critical component of pharmacovigilance today.

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## Challenges in Pharmacovigilance for Rasaushadhis

Despite progress, challenges persist:

- Underreporting due to lack of training
- Variability in pharmaceutical practices
- Fear of blame among practitioners
- Limited scientific validation of ancient processes
- Difficulty in standardizing multi-component formulations

Overcoming these challenges requires:

- Improved pharmacovigilance training in BAMS curricula
  - Collaborative research between modern scientists and Ayurvedic scholars
  - Stronger regulatory oversight of pharmaceutical manufacturing
  - Increased public and professional awareness
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## Conclusion

Pharmacovigilance is indeed **a key to the safe use of Rasaushadhis in Ayurveda**. Ancient wisdom clearly emphasizes drug safety through rigorous pharmaceutical processes and individualized therapy. Integrating this wisdom with modern pharmacovigilance systems ensures patient safety and builds public confidence in Ayurvedic medicine. As future practitioners, BAMS students must embrace pharmacovigilance not

merely as a regulatory obligation but as a professional responsibility. It is only through vigilant practice that Ayurveda can continue to offer safe and effective healing to humanity.

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