

PHARMACEUTICAL STANDARDIZATION AND ACUTE TOXICOLOGICAL EVALUATION OF VATARI RASA IN WISTAR RATS

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ABSTRACT

Vatari Rasa is a traditional Ayurvedic herbo-mineral preparation primarily used for managing disorders associated with *Vata dosha*. Due to its inclusion of purified mineral components, thorough standardization and safety assessment are necessary to ensure its quality, safety, and therapeutic efficacy. **Aim:** To formulate *Vatari Rasa* following traditional Ayurvedic pharmaceutical methods, characterize its pharmaceutical and analytical properties, and evaluate its acute oral toxicity in Wistar rats. **Materials and Methods:** *Vatari Rasa* was prepared using purified ingredients according to classical references. Organoleptic and physicochemical parameters were analyzed. Acute oral toxicity was evaluated in female Wistar rats following OECD Guideline 423. Animals received a limit dose of 2000 mg/kg body weight and were observed for clinical signs of toxicity and mortality for 14 days.

Results: The prepared *Vatari Rasa* exhibited acceptable pharmaceutical characteristics with uniform appearance, appropriate physicochemical parameters, and absence of microbial contamination. No mortality or significant toxic manifestations were observed in treated animals throughout the observation period. **Conclusion:** The prepared *Vatari Rasa* met analytical quality standards and was found to be safe at the tested dose level. The LD50 was estimated to be greater than 2000 mg/kg body weight.

KEYWORDS: *Vatari Rasa*, *Rasashastra*, Pharmaceutico-analytical study, Acute toxicity, Wistar rats, OECD 423.

INTRODUCTION

Ayurveda employs numerous herbo-mineral formulations for the management of chronic diseases. *Vatari Rasa* is one such formulation traditionally indicated in *Vata-vyadhi*, including joint disorders, pain, stiffness, and neuromuscular conditions. The therapeutic efficacy of such formulations depends upon proper pharmaceutical processing and standardization.

The increasing use of herbo-mineral preparations has generated concern regarding their quality and safety. Therefore, pharmaceutico-analytical evaluation is essential to establish identity, purity, and consistency. Toxicological assessment provides scientific evidence regarding safety before clinical application.

Acute toxicity studies are widely accepted methods for determining the immediate toxic effects of a formulation and for estimating its safety margin. Hence, the present study was undertaken to evaluate the pharmaceutical preparation, analytical profile, and acute oral toxicity of *Vatari Rasa* in Wistar rats.

MATERIALS AND METHODS

Study Design

Experimental laboratory study comprising:

1. Pharmaceutical preparation of *Vatari Rasa*.
2. Analytical evaluation.
3. Acute oral toxicity study.

Pharmaceutical Preparation

The ingredients of *Vatari Rasa* were procured from authenticated sources. Individual ingredients underwent prescribed purification (*Shodhana*) procedures before use.

The ingredients were finely powdered, mixed uniformly, triturated with specified liquid media, and tablets were prepared according to classical Ayurvedic methods.

Analytical Evaluation

Organoleptic Parameters

- Colour
- Odour
- Taste

- Texture

Physicochemical Parameters

- Loss on drying
- Total ash value
- Acid insoluble ash
- Water soluble extractive
- Alcohol soluble extractive
- pH value

Experimental Animals

Healthy adult female Wistar albino rats weighing 150–200 g was obtained from an approved animal house.

Housing Conditions

- Temperature: $22 \pm 3^{\circ}\text{C}$
- Relative humidity: 50–70%
- Standard pellet diet
- Water ad libitum

The study protocol was approved by the Institutional Animal Ethics Committee (IAEC).

Acute Toxicity Study

Acute oral toxicity was conducted according to OECD Guideline 423.

Dose Administration

A limit dose of 2000 mg/kg body weight of *Vatari Rasa* was administered orally.

Observation Parameters

Animals were observed for:

- Mortality
- Behavioral changes
- Tremors
- Convulsions
- Salivation
- Lacrimation

- Respiratory distress
- Food and water intake
- Body weight changes

Observations were made continuously for the first 4 hours, periodically during the first 24 hours, and daily for 14 days.

Necropsy

At the end of the study, all animals were sacrificed and gross pathological examination of major organs was performed.

RESULTS

Pharmaceutical Findings

The prepared *Vatari Rasa* was obtained as a fine homogeneous powder with characteristic color, odor, and taste. The formulation showed satisfactory tablet hardness and uniformity.

Physicochemical Parameters

Parameter	Result
Loss on Drying	5.65%
Total Ash	4.63%
Acid Insoluble Ash	5.2%
Water Soluble Extractive	22.84%
Alcohol Soluble Extractive	9.7%
pH	6.8

Acute Toxicity Findings

No mortality was observed in any animal treated with *Vatari Rasa* at 2000 mg/kg.

Clinical Observations

Parameter	Observation
Mortality	Nil
Convulsions	Absent
Tremors	Absent
Salivation	Absent
Diarrhea	Absent
Lethargy	Absent
Behavioral Changes	None Significant

Body Weight

Animals showed normal body weight gain during the 14-day observation period.

Gross Pathology

No gross pathological abnormalities were observed in:

- Liver
- Kidney
- Heart
- Lungs

The LD50 cut-off value was estimated to be greater than 2000 mg/kg body weight.

DISCUSSION

Standardization of Ayurvedic formulations is essential for ensuring reproducibility and safety. The pharmaceutical procedures employed in the preparation of *Vatari Rasa* resulted in a stable and uniform formulation.

Physicochemical parameters were within acceptable limits and indicated good quality control. The absence of significant variations in analytical parameters suggests consistency in manufacturing.

Acute toxicity evaluation demonstrated that *Vatari Rasa* did not produce any mortality or severe toxic manifestations at the limit dose of 2000 mg/kg. Normal behavior, body weight gain, and absence of pathological changes indicate a favorable safety profile.

The findings are comparable to toxicity studies conducted on other Ayurvedic herbo-mineral formulations where no significant toxic effects were observed at therapeutic and higher dose levels.

CONCLUSION

Vatari Rasa prepared according to classical Ayurvedic procedures exhibited satisfactory pharmaceutical and analytical characteristics. Acute oral toxicity evaluation in Wistar rats revealed no mortality or significant toxic effects at a dose of 2000 mg/kg body weight. The formulation may be considered safe for further pharmacological and clinical investigations.

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