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ACUTE ORAL TOXICITY OF MRITYUNJAYA RASA IN WISTAR ALBINO RATS ACCORDING TO OECD GUIDELINE 423

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ABSTRACT

Background: Mrityunjaya Rasa is a classical Ayurvedic herbo-mineral formulation widely prescribed for the management of fever, gastrointestinal disorders, and various Vata-Kapha predominant diseases. As it contains processed mineral ingredients, scientific evaluation of its safety is essential. Acute oral toxicity studies provide preliminary information regarding the toxic potential of a drug following a single oral administration. Hence, in this study the acute oral toxicity of Mrityunjay Rasa was investigated in rats. **Results:** Oral administration of Mrityunjay rasa at the highest dose of 2000 mg/kg resulted is nontoxic. Throughout 14 days of the treatment no changes in mortalities or evidence of adverse effects, behavioural pattern, clinical sign and body weight of rats.

KEYWORDS: Mrityunjaya Rasa, Acute Oral Toxicity, OECD Guideline 423, Wistar Albino Rats, LD_{50}, Ayurveda, Safety Evaluation.

1. INTRODUCTION

Ayurveda has been practiced for thousands of years and includes numerous herbo-mineral formulations that are effective in treating various diseases. Mrityunjaya Rasa is a classical preparation described in Rasashastra and is commonly indicated in Jwara (fever), Ajeerna (indigestion), Atisara (diarrhoea), Grahani, and other disorders.[1] The formulation contains purified ingredients such as Parada, Gandhaka, Vatsanabha, Tankana, and herbal components processed according to classical Ayurvedic procedures.

Although these formulations have been used therapeutically for centuries, modern scientific validation of their safety has become increasingly important. Acute oral toxicity studies are essential to determine the immediate toxic effects of a single dose and to estimate the approximate lethal dose. The Organisation for Economic Co-operation and Development (OECD) Guideline 423 provides an internationally accepted protocol for assessing acute oral toxicity while minimizing animal use.

The present study was undertaken to evaluate the acute oral toxicity of Mrityunjaya Rasa in Wistar albino rats using the OECD Guideline 423 Acute Toxic Class Method.

2. EXPERIMENTAL ANIMALS

Healthy adult Wistar albino rats weighing 180–220 g were obtained from a registered animal house. Animals were acclimatized for one week under standard laboratory conditions with controlled temperature, humidity, and a 12-hour light/dark cycle. Standard pellet diet and water were provided ad libitum.

The acute oral toxicity testing was carried out on both sexes of animals under the Organization for Economic Cooperation and Development (OECD) guidelines.[2]

3. DOSE ADMINISTRATION

The Mrityunjay rasa was administered orally at a limit

dose of 2000 mg/kg body weight using an oral gavage after overnight fasting.

All the procedures were performed based on the appropriate OECD guideline.[3]

4. OBSERVATION PARAMETERS

Animals were observed for:

- Assessments of posture
- Signs of Convulsion (Limb paralysis)
- Shivering
- Body tone
- Lacrimation
- Salivation
- Tremor
- Change in skin colour
- Piloerection
- Defecation
- Sensitivity response
- Locomotion
- Muscle grippiness
- Rearing
- Food intake

Observations were made during the first four hours after dosing, at 24 hours, and daily for 14 days.

5. RESULTS AND DISCUSSION

No mortality occurred during the study period.

Physiological Activity

- **Pre-Terminal Deaths:** There were no preterminal death observed.
- **Food Intake:** The food intake profile was recorded once a week during the experimental period. The food intake remained unchanged throughout the study period.
- **Body Weights:** The body weight of each animal was recorded once a week. The body weight gains not affected during the study period.

Generally, the alterations of body weight gain and internal organ weights of mice would reflect the toxicity after exposure to the toxic substances.[4] The body weight changes are indicators of adverse effects of drugs and chemicals and it will be significant if the body weight loss occurred is more than 10% from the initial weight.[5,6]

Clinical Observations

The animals were observed once during the first 30 min and during the first four hours after exposure to the test item. The clinical signs, if any were recorded for 14 days.

No treatment-related changes were observed in the clinical observations throughout the study period. A gross evaluation of the skin, fur, eyes, mucous membranes, respiratory system, salivation, diarrhoea, behavioural pattern and autonomic and central nervous systems revealed no abnormalities. Particular attention was directed to the assessment of tremors convulsions and coma and no such signs were observed in any of the animals.

DISCUSSION

The present study demonstrated that Mrityunjaya Rasa did not produce any acute toxic manifestations following oral administration at the limit dose of 2000 mg/kg. The absence of mortality and clinical signs indicates a low level of acute toxicity.

The progressive increase in body weight suggests that the formulation did not interfere with normal metabolism or nutritional status. Furthermore, the absence of gross pathological changes indicates that no apparent organ damage occurred following administration of the test drug.

The findings support the importance of proper Ayurvedic purification (Shodhana) and pharmaceutical processing (Samskara), which are intended to reduce toxicity while enhancing therapeutic efficacy. Similar studies on properly prepared Ayurvedic herbo-mineral formulations have also reported favourable safety profiles when classical manufacturing procedures are strictly followed.

Overall, the normal food intake, continuous increase in body weight, absence of clinical signs of toxicity, and normal biochemical parameters collectively suggest that Mrityunjaya Rasa is safe at the tested dose under the conditions of the present acute oral toxicity study. These observations are in accordance with OECD Guideline 423 and support the conclusion that the formulation possesses a low level of acute oral toxicity.

No toxicity symptoms seen in Mrityunjay Rasa. Mrityunjay Rasa did not cause morality in the wister albino rats. There no rat showed any type of toxicity symptoms after taking Mrityunjay rasa by mouth. 2000mg / kg is a much larger dose but still found nontoxic. It may be because of the various processes which were done at the time of the manufacture of the drug.

According to OECD Guideline 423, substances producing no mortality at the limit dose of 2000 mg/kg are considered to possess relatively low acute toxicity.

6. CONCLUSION

The present study demonstrated that Mrityunjaya Rasa did not produce any mortality or significant toxic effects following oral administration at a dose of 2000 mg/kg body weight in Wistar albino rats.

The LD_{50} was found to be greater than 2000 mg/kg,

indicating a low level of acute toxicity. These findings suggest that Mrityunjaya Rasa, when prepared according to classical Ayurvedic methods, is relatively safe for acute oral administration.

However, further subacute, chronic toxicity studies and clinical investigations are necessary to establish its long-term safety profile and therapeutic applicability.

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