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Toxicological evaluation of Devathaaru Kasayam in Swiss albino mice: An acute oral toxicity study

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Abstract

Background: Peripheral neuropathy is a common neurological disorder characterized by pain, tingling, and numbness, often associated with diabetes and other systemic conditions. Conventional treatments provide limited relief and may cause adverse effects with long-term use. Devathaaru Kasayam is a traditional Siddha formulation. However, scientific data regarding its safety profile are limited. Therefore, the present study was undertaken to evaluate the acute oral toxicity of devathaaru kasayam in swiss albino mice.

Methods: An acute oral toxicity study of Devathaaru Kasayam was conducted in Swiss albino female mice following OECD Guideline 425 (limit test). A single oral dose of 2000 mg/kg body weight was administered. The animals were observed for mortality, clinical signs, body weight changes, feed consumption, and body temperature for 14 days. Gross pathological examination was performed at the end of the study.

Results: No mortality or treatment-related clinical signs of toxicity were observed in any of the animals. Normal body weight gain, feed intake, and body temperature were maintained throughout the study period. Gross pathological examination revealed no observable abnormalities in major organs. The LD_{50} of Devathaaru Kasayam was estimated to be greater than 2000 mg/kg body weight.

Conclusion: Devathaaru Kasayam appears to be safe for oral administration at a dose of 2000 mg/kg in Swiss albino mice, indicating low acute toxicity. These findings support its traditional use and suggest its potential for further pharmacological and clinical investigation in the management of peripheral neuropathy.

Keywords: Devathaaru Kasayam, Acute toxicity, OECD 425, Peripheral neuropathy, Siddha medicine, LD_{50}, Herbal safety

1. Introduction

Peripheral Neuropathy is a common neurological disorder resulting from damage to peripheral nerves, causing numbness in the soles, difficulty in flexion and extension of the lower limbs due to diffuse pain[1]. t affects approximately 1% of adults worldwide. The Overall prevalence varies from 5 to 2400 per 10,000 population in various community studies from India[2].

Peripheral neuropathy requires long-term management, and most modern treatments provide only symptomatic relief rather than a complete cure. The overall cost is high due to continuous medication and diagnostic investigations. Conventional drugs are associated with side effects such as drowsiness, dizziness, and gastric irritation. In many cases, the effectiveness is limited, with patients experiencing only partial relief and persistence of symptoms like burning and tingling. In comparison, *Devathaaru Kasayam* may serve as a safer alternative and can help in relieving symptoms.

This study aims to evaluate the acute oral toxicity of *Devathaaru Kasayam* to establish its safety for potential use in the management of peripheral neuropathy.

IEC Approval: The Institutional Ethical Committee, Government Siddha Medical College, Chennai reviewed and approved the study.

IEC No: GSMC – CH – 1243/ME – II/091/2024

CTRI No: This trial was registered in Clinical Trial Registry India

CTRI No: CTRI/2025/05/087846

"Acute Oral Toxicity"

The Organization for Economic Co-operation and Development (OECD) guidelines for testing of chemicals, No 425[3].

IAEC No. MB/IAEC/25/01/05

2. Materials and Methods

Test Substance

Details of the test substance provided by the sponsor are:

Test Substance Name	: Devathaaru kasayam
Purity	: NA
Manufacturer	: Sponsor
Batch No	: Nil
Date of Manufacture	: NA
Physical Appearance	: herbal powder
Storage Conditions	: 24±2°C

Test System

Species	: Mice (*Mus musculus*)
Strain	: Swiss Albino
Body weight Range	: 30 ±5gm
Age	: 4-8 weeks
Sex	: Female
Animal Source	: Mass Biotech.
Number of Animals	: Three nulliparous, non-pregnant female mice
Method of Identification	: Colour marking on tail and cage numbering.

2.1 Experimental Animals

Swiss albino mice were used for the study. The animals were maintained under standard laboratory conditions with controlled temperature, humidity, and a 12-hour light/dark cycle. They were provided with standard rodent diet and water ad libitum.

2.2 Study Design

The acute toxicity study was conducted using a limit test(OECD 425 guidelines). A single dose of **2000 mg/kg body weight** of *Devathaaru Kasayam* was administered orally.

Animals were fasted overnight(approximately**15–16 hours**). Observations were made at **30 minutes, 1, 2, 3, and 6 hours post-dosing**, and daily thereafter for **14 days**.

Table 1: Summary of experimental design is presented below:

No. of Mice	Dose (mg/kg)	Route	Volume (ml/kg)	Concentration (mg/ml)	Treatment Day	No. of doses	Day of Sacrifice
3	2000	Oral	10	60	1	1	14

2.3 Dose Preparation and Administration

The formulation was administered orally using a gavage technique at a dose volume of **10 ml/kg body weight**, using a stainless steel blunt-tipped cannula.

2.4 Parameters Observed

- **Mortality and Morbidity:** Observed twice daily
- **Clinical Signs:** Behavioral and physical changes
- **Body Weight:** Recorded on Day 1, Day 7, and Day 14
- **Feed Consumption:** Measured periodically
- **Body Temperature:** Recorded using an infrared thermometer
- **Gross Pathology:** Conducted on Day 14 after euthanasia

3. Results

3.1 Mortality

No mortality was observed in any of the treated animals with *Devathaaru Kasayam* at the dose level of **2000 mg/kg body weight**.

3.2 Clinical Observations

No signs of toxicity such as piloerection, tremors, lethargy, or abnormal behavior were observed. All animals remained healthy throughout the observation period.

3.3 Body Weight

All animals exhibited normal body weight gain during the study period, indicating no adverse metabolic effects.

3.4 Feed Consumption

Feed intake remained normal in all treated animals, suggesting no impact on appetite or digestion.

3.5 Body Temperature

No significant variations in body temperature were observed during the study period.

3.6 Gross Pathological Findings

Gross examination of organs revealed no abnormalities. All organs appeared normal, with no signs of toxicity or pathological changes.

Table 2: Clinical observation of individual animals

Dose (mg/kg b.wt.)	Mice No	Clinical Signs Observed after Dosing																	
		30 min.	At Hour (Day0)			On Day													
			1	2	3	*	1	2	3	4	5	6	7	8	9	10	11	12	13
	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2000	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Key: 1=Normal
*=Observation made at 6h after oral dose

Gross Pathological Findings of Individual Animals

Fig 1: Gross pathology of mice 1of 2000 mg/kg b.wt

Fig 2: Gross pathology of mice 2of 2000 mg/kg b.wt

Fig 3: Gross pathology of mice 3 of 2000 mg/kg b.wt

4. Discussion

The acute toxicity study of *Devathaaru Kasayam* suggests that the formulation is safe at a high dose of **2000 mg/kg body weight**. The absence of mortality and clinical toxicity signs indicates a wide safety margin.

The normal body weight gain, feed consumption, and physiological parameters further support the non-toxic nature of the formulation. Gross pathological findings confirmed the absence of organ damage.

These results are consistent with the traditional use of *Devathaaru Kasayam* as a safe herbal remedy. However, further studies, including sub-chronic toxicity and efficacy studies, are required to fully establish its therapeutic potential.

5. Conclusion

The present study concludes that *Devathaaru Kasayam*appears to be **safe for oral administration** at a dose of **2000 mg/kg body weight** in Swiss albino mice. The LD50 cut-off value is considered to be greater than **2000 mg/kg body weight**, indicating low toxicity.

These findings support the potential use of *Devathaaru Kasayam* in the **management of peripheral neuropathy**, warranting further pharmacological and clinical investigations.

6. References

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