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ACUTE ORAL TOXICITY STUDY OF *KARMARANGADI LEHA* IN WISTAR ALBINO RATS

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ABSTRACT

Karmarangadi leha is herbal compound formulation used by folklore practitioners for treatment of respiratory disorders, especially *Kaphaja kasa*. However, till date, no safety profile of this formulation has been reported. Hence in present study freshly prepared sample of *Karmarangadi leha* was evaluated for acute toxicity. Acute oral toxicity test was evaluated as per OECD 425 guidelines with 2000 mg/kg as limit test in wistar albino rats. Test formulation was administered to overnight fasted animals and parameters like body weight, behavioural changes, mortality were assessed for 14 days. Results showed no significant changes in terms of behavioural changes, morbidity and body weight. Hence this study shows that sample of *Karmarangadi leha* is relatively safe up to the dose of 2000 mg/kg.

KEYWORDS: Acute toxicity, *Karmarangadi leha*, respiratory disorder, *kaphaja kasa*, OECD 425.

INTRODUCTION

Acute respiratory infections are a major cause of morbidity and mortality in children and is more significant in developing country like India. Since the immune system is immature or is

still developing in children they are more prone to infectious disorder among which respiratory illness is predominantly seen and cases of URTI is more than LRTI. *Karmarangadi leha* is herbal compound formulation used by folklore practioners in treatment of *Kasa* especially effective in productive cough the symptoms of which can be correlated with *Kaphaja kasa*. Till date no safety profile of this formulation has been reported .Hence this study has been carried out.

MATERIALS AND METHODS

The plant materials (table 1) of the test formulation was collected after careful botanical identification and leha was prepared in GMP certified Anchan pharmacy. These samples were converted into fine powder and fruit pulp has been extracted and *leha* has been prepared as per classical method of *avaleha* preparation just prior to administration to the animals.

Table 1: Formulation composition of *Karmarangadi leha.*

INGREDIENTS	BOTANICAL NAME	PART USED	Part
Karmaranga[1]	*Averrhoa carambola* Linn	Fruit	1 Part
Lavanga[2]	*Syzigium aromaticum* M.P	Flower bud	1/8th P
Shunti[3]	*Zingiber officinale* Roscoe	Rhizome	
Jatiphala[4]	*Myristica fragrens* Houtt	Seed	
Twak[5]	*Cinnamomum zeylenica*	Bark	
Patra[6]	*Cinnamomum tamala* Nees and Ebera	Leaf	
Nimbu swarasa[7]	*Citrus limon* Linn	Fruit	
Sita[8]	Sugar candy	-	½ part
Kshoudra[9]	Honey	-	½ part

Animal source

Wistar albino rats of either sex weighing 150-200 grams were procured from animal house attached to Pharmacology and Toxicological laboratory of SDM Centre for Research in Ayurveda and allied Sciences, Udupi. Five animals in each group were housed in separate cage made up of poly propylene with stainless steel top grill. The dry wheat waste was used as bedding material and was changed every morning. The animals were maintained at a temperature in range of 25-27 degree Celsius, humidity of 53 % and natural light and dark cycles. Animals were fed with rat pellet feed supplied by Sai Durga feeds Bengaluru and water ad libitum. Protocol used in this study for use of animals was approved by institutional animals ethics committe. (IAEC)

Acute oral toxicity study

Acute toxicity is usually defined as the unfavourable changes occurring immediately or within a short period of time after being exposed to a substance or substances once or for a short period of time or as unfavourable changes occurring after the administration of a single dose of a substance or multiple doses given within 24 hours.[10]

Acute oral toxicity study for *Karmarangadi leha* was carried out as per OECD guideline 425 with 2000 mg/kg as limit test. Five animals were selected for study. Single animal dose in sequence usually at 48 h intervals. Using the default progression factor, doses were selected from the sequence 175, 550 and 2000 mg/kg (because no estimate of the substance's lethality was available, dosing was initiated at 175 mg/kg) as recommended in OECD Guidelines 425(Ref. 22). Food, but not water was withheld for overnight before the experiment and further 2 hours after administration of test drug. As there was no mortality was observed even at 2000 mg/kg, additional 4 more animals were dosed with 2000 mg/kg and observed for 14 days with different parameters.

Mortality

All the animals were observed at ½, 1, 2, 3, 4, 5, 6 and 24 h after dosing and there after daily once for mortality during the entire period of the study (14 days).

DISCUSSION

Drugs intended for therapeutic use should always undergo toxicity evaluation before being considered safe for human administration. This is critical, as incomplete knowledge about a drug's toxicity profile can pose potential risks to recipients. *Karmarangadi Leha*, as described in the introduction, has been traditionally used by folklore practitioners for treating various types of respiratory illnesses, particularly *Kaphaja Kasa*. In the present study, acute oral toxicity was assessed in Wistar albino rats according to OECD 425 guidelines. Observations revealed no mortality, behavioural changes, or significant variations in body weight at doses up to 2000 mg/kg. These findings indicate that the formulation does not produce observable acute toxicity in this animal model. Wistar albino rats are widely accepted as a standard preclinical model because their physiology, metabolism, and organ systems share many similarities with humans, including children. Data from such animal studies are routinely used to predict pediatric safety, especially when combined with historical human use. Given the long-standing traditional use of *Karmarangadi Leha* in

children without reported adverse effects, these results strongly suggest a favorable safety profile and low risk of acute toxicity in pediatric populations.

CONCLUSION

The present study demonstrates that *Karmarangadi Leha* is relatively safe when administered orally at acute doses up to 2000 mg/kg in Wistar albino rats, with no observed mortality, behavioral abnormalities, or significant changes in body weight. Wistar rats, widely used in preclinical studies, provide a reliable model to predict human, including paediatric, safety. Considering the traditional use of *Karmarangadi Leha* in children for respiratory ailments without reported adverse effects, these findings suggest a favourable safety profile and indicate that the formulation can be used safely at therapeutic doses in pediatric populations.

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