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Toxicity evaluation of a standardised 50% ethanol extract of Orthosiphon stamineus.

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Abstract

AIM OF THE STUDY: The present investigation was carried out to evaluate the safety of standardised 50% ethanol extract of **Orthosiphon** stamineus plant by determining its potential toxicity after acute and subchronic administration in rats.

MATERIALS AND METHODS: For acute toxicity study, up and down method (limit dose) was adapted. A single dose of 5000 mg/kg of the standardised 50% ethanol extract of O. stamineus was given orally to 5 healthy Sprague-Dawley (SD) female adult rats. The rats were observed for mortality and clinical signs for 3 h and then periodically for 14 days. While in the subchronic toxicity study, the extract was administered orally at doses of 1250, 2500 and 5000 mg/kg per day for 28 days to female and male SD rats, respectively. The animals were sacrificed, followed by examination of their organs and blood serum.

RESULTS: In the acute toxicity study, standardised 50% ethanol extract of O. stamineus at a dose of 5000 mg/kg caused neither visible signs of toxicity nor mortality. All five rats survived until the end of observation period. While in subchronic toxicity, administration of the standardised 50% ethanol extract of O. stamineus at 1250, 2500, and 5000 mg/kg for 28 days did not produce any mortality and there were no significant differences in the general condition, growth, organ weights, hematological parameters, clinical chemistry values, or gross and microscopic appearance of the organs from the treatment groups as compared to the control group.

CONCLUSIONS: Standardised 50% ethanol extract of O. stamineus did not cause any death nor did it cause abnormalities in necropsy and histopathology findings. There were no acute or subchronic toxicity observed and this extract could be devoid of any toxic risk. The NOAEL for the standardised 50% ethanol extract of O. stamineus is 5000 mg/kg per day for 28 days.

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MeSH Terms, Substances

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