INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

IAMJ

Research Article ISSN: 2320 5091 Impact Factor: 4.018

ACUTE TOXICOLOGICAL EVALUATION OF RAJAHPRAVARTINIVATI

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Published online: September, 2018

ABSTRACT

Rajahpravartini Vati (*RPV*) has an important role in gynaecological practice in *Ayurveda*. Use of this formulation and its use for prolonged duration are seen in women. Hence, Review, Pharmaceutical Standardisation, Analytical Analysis and as well as Toxicological Evaluation are needed. Aim of the article is to evaluate acute toxicology evaluation. Here method for acute oral toxicity in dose 175mg/kg, 550mg/kg, 2000mg/kg of *RPV* was carried out in Wistar albino rats. Body weight, weekly food consumption, behavioural changes were observed in all the animals at ½, 1, 2, 3, 4, 24, 48hrs after dosing and there after daily once for mortality during the entire period of study. (i.e. 14 days) Which revealed that there was no adverse effect of RPV the classical *Ayurvedic* herbo-mineral preparation in oral consumption in wistar albino rats for 14days of study and Result was found for RPV LD_{50} was more than 2000mg/kg body weight.

Keywords: *Rajahpravartini vati*, Acute toxicity, Wistar albino rats.

INTRODUCTION

'*Ayurveda'* is now in need of factual evidence base for being accepted globally. There is a lack of information sharing, method of evaluation of safety & efficacy as common difficulties & challenges in form of traditional knowledge of medicine. In this situation, a properly planned toxicity study of classical *Ayurvedic* formulation or drug is needed.

As *RPV*[1,2] contains ingredients like *Shodhita Kasisa, Shoditha Tankana, Shodhita Hingu* and *Mosabbar* and it is indicated in *Kashtarthava and Nashtarthava* classically Review of *RPV*[4], Pharmaceutical Standardisation[5] and Analytical[6] details is cited in Priyanka et al and this article presents the results of Acute oral Toxicity[3] of 14 days to ensure that safety

of the drug, changes in body weight, in all the animals were observed at ½, 1,2, 3,4, 24,48 hrs after dosing and there after daily once for mortality during the entire period of study.

AIM:

To Evaluate the Acute Oral Toxicity of *Rajahpravartini vati* a *Ayurvedic* herbo-mineral formulation.

Materials & Methods:

Acute Oral Toxicity study

1. Animal species: Rats
2. Strain: Wistar albino
3. Source: Animal attached to SDM Research center, SDM Ayurveda College, Udupi, Karnataka.
4. Selection: A total healthy either sex of body weight 150-250gm rats were selected according to AOT software.
5. Acclimatization period: The entire selected animals were kept under acclimatization for 7 days before dosing.
6. Numbering and identification: The animals were marked with saturated picric acid solution in water for proper identification. The marking within the cage is as follows.

Table 1: Showing Marking of Rats

Animal number	Marking
1.	Head
2.	Neck
3.	Middle of the back
4.	Base of the tail
5.	No marks

The group number, animal number and sex of the animals were identified with the help of cage cards, as presented in the following table.

Table 2: Showing Rat Dosage of Acute toxicity Study

Sl no	Identification of animals	Desired dose (according to AOT)	Body weight In grams	Dose in mg/gm	Calculated dose Ml
1.	Head	175mg	198	1.7×198/100	0.33
2.	Neck	550mg	169	5.5×169/100	0.92
3.	Middle of the back	2000mg	192	2×192/200	1.92
4.	Base of the tail	2000mg	189	2×189/200	1.89
5.	No marks	2000mg	200	2×200/200	2.00

Husbandry condition:

1. Housing: Rats were housed in each cage of poly propylene with stainless steel top grill. The dry paddy husk was used as bedding material and was changed every morning.
2. Environment: The animals were exposed to 12 hours light and 12 hours dark cycles with the relative humidity 50 to 70% and ambient temperature was22±03^{0}C.
3. Diet: Sai Durga animal feed was provided throughout the study period expect on previous night of dosing i.e. (overnight) fasting before dosing. The drinking water tap water ad libitum in poly propylene bottles with stainless steel sipper tube.

Preparation of test formulation for administration:

1. Test Drug : *RPV*
2. Vehicle: Water
3. Dose preparation: The prepared test sample was made into suspension in water with suitable concentration. All the animals were dosed constant dose volume 175mg/kg, 550mg/kg, 2000mg/kg.
4. Schedule: Single dose per animal.
5. Administration: The test formulation was administered through oral route at different dose levels to respective animals through oral feeding, Needle sleeved on to disposable syringe.
6. Dose fixation: According to the AOT Software.
7. Route: Oral

8. Dose: 175mg/kg, 550mg/kg, 2000mg/kg test substance.
9. Dose volume : 1ml/100gm animal

Observation:

Examination of physical and Behavioural changes:

The animal was observed continuously for 4 hours after the dosing. The care full cage side observation was done without disturbing the animals attention and at the end of the every hour the animal was individually exposed to open area for recording the behavioural changes like increased or decreased motor activity, convulsion, straub's reaction, muscle spasm, catatonia, spasticity, opisthotonus, hyperesthesia, muscle relaxation, anaesthesia, arching and rolling, lacrimation, salivation, diarrhoea, writhing, mode of respiration, changes in skin colour, etc. exitus, CNS depression-hypo activity, passivity, relaxation, ataxia, necrosis, etc.

Mortality: All the animals were observed at ½, 1, 2, 3, 4, 24, 48hrs after dosing and there after daily once for mortality during the entire period of study. (i.e. 14 days)

Result

Experimental Evaluation of Acute Toxicity Study of RPV

1. As per the guidelines 175mg/kg of RPV was administered to rat weighing 198g i.e. 0.33ml solution. As there was no mortality and animal looked normal, for the next rat 550mg/kg of drug *RPV* was given as per the protocol and verified with AOT software. The weight of the rat was 169g i.e. 0.92ml of solution was administered. As there was no toxicity sign and no behavioral changes for next rat 2000mg/kg of drug RPV was given. The weight of the rat was 192g i.e. 1.92ml of solution was administered. As there is no mortality in previously dosed rat, once again rat dosed with 2000mg/kg of drug RPV. The weight of the rat was 189gm i.e. 1.89ml of solution was administered. As rat did not die, for next rat 2000mg/kg of drug RPV was given. The weight of the rat was 200g i.e. 2.00ml of solution was administered.

Observation:-

- Rats were observed for 0,1hr, 2hr, 3hr, 4hr, 24hr and 48hr.
- No mortality of rats was observed.
- In 2000mg dose there was Active, Rearing, Irritability, Auditory response and Tail pinch response was observed at 1hr, 2hr, 3hr and 4hr.

Physical and behavioural examination:

There are no physical and behavioural changes except Rat becoming Active, Rearing, Irritability seen in 3 rats in the group 2000mg/kg in all the treated animals on day one at 1,2,3,4 hours intervals after dosing and there after once daily for 14 consecutive days. Thus it can be inferred from the data obtained from the study on single dose administration of RPV by oral administration up to 14 days does not result in any physical and behavioural changes that may be indicative of toxic potential.

Mortality:

All the animals belonging to the treated group survived throughout the 14 days observation period after dosing.

The data was fed into AOT software to obtain LD_{50} value with confidence limit.

LD_{50} is Greater than 2000mg/ kg.

DISCUSSION

The main focus of this study was to ascertain what all are the toxic effects produced by *RPV* and evaluate toxicity of RPV. It was subjected for acute and Sub-acute toxicity study on albino rats, according to OECD guidelines 425.

Acute Toxicity Study:

Before going to acute toxicity study, sighting study was done with fixed dose levels 175mg, 550mg, 2000mg to know the probable dose which can produce toxicity according to OECD guide lines 425.

There are no physical and behavioural changes apart from increase in motor activity, seen in 3 rats in the group 2000mg/kg in all the treated animals on day one at 1,2,3,4 hours intervals after dosing and there after once daily for 14 consecutive days. Thus it can be inferred from the data obtained from the study on single dose administration of *RPV* by oral administration up to 14 days does not result any physical and behavioural changes indicative of toxic potential. The LD50 of *RPV* is more than 2000mg/kg.

CONCLUSION

Herbo-mineral formulation *Rajahpravartini vati* as it contains *Kasisa, Tankana* mineral dugs in it. Hence Acute oral toxicity study, sighting study was done with fixed dose levels 175mg, 550mg, 2000mg to know the probable dose which can produce toxicity according to OECD guide lines 425.

Behavioural changes were observed after administering the respective doses. RPV showed a LD_{50} was more than 2000mg/kg body weight. After conducting Acute Oral Toxicity [AOT] for 14days in SDM Research work in Ayurveda and Allied science Udupi, Karnataka, India.

Acknowledgement

I would like to acknowledge the Principal of TGAMC & Teaching staff of RS & BK Dept. for providing constant support & required facilities to carry out this research work in this institution.

I thank Dr. Ravishankar, Mr. Sudhakar, Mr. Ravi Mundugaru of Dept. of Pharmacology and all staff members of SDM centre in Ayurveda and Allied science Udupi for support in my research work.

I thank Principal & all Teaching staff of SASA Ayurvedic Medical College, Thimmapuram, Guntkal, Andra Pradesh for moral support.

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Photos

Figure 1: Marked rats in cage

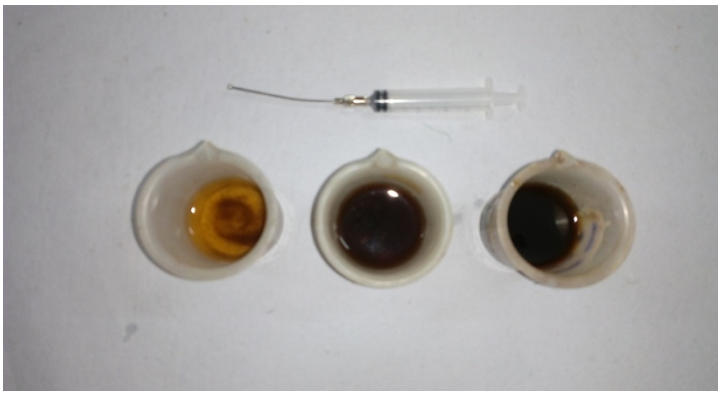

Figure 2: RPV solution and syringe

Figure 3: Oral Administration of RPV solution to rat

Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: Priyanka Gurugunti et al: Acute Toxicological Evaluation Of Rajahpravartini vati. International Ayurvedic Medical Journal {online} 2018 {cited September, 2018} Available from: http://www.iamj.in/posts/images/upload/1310_1314.pdf