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Acute Toxicity Study of Abhraka Bhasma – “A Behavioral Observation”



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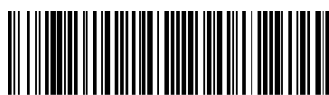
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ABSTRACT

Abhraka bhasma is mentioned in the *ayurvedic* pharmaceuticals for the treatment of various diseases. Acute toxicity of *Abhraka bhasma* was conducted on albino rats. In acute toxicity study, *Abhraka bhasma* were administered orally in albino rats of single maximum limit dose 2000 mg/kg and general behavioral observation along with any mortality was recorded. Acute toxicity study shows that there is no adverse effect of *bhasmas* on albino rats even at single dose of 2000 mg/kg body weight that reveals that *Abhraka bhasma* is safe in albino rats.



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INTRODUCTION

Normal physiological variations are known since evolution of Indian medicine. Although, metals and minerals are frequently used by *ayurvedic* physicians since 11th century A.D to cure diseases, and to maintain good health. The indications for these are totally based on the clinical observations. Thus the use of metals and minerals are empirical. The whole world has undergone through revolution therefore it is necessary to convert the empirical therapy into rational therapy hence there is a need for experimental proof using animals for toxicological studies. In order to verify the claims on scientific lines, the animal experimental study is the prime factor necessary to be supplemented with clinical research for a valid conclusion. Safety of the *ayurvedic* drugs is burning and important topic as the user of *ayurvedic* medicines are increasing globally.

Department of Ayush, Government of India and Organization for Economic Cooperation and Development (OECD) sets guidelines for toxicity study.

Abhraka bhasma is a well known *ayurvedic* drug used for the treatment purpose since long back in *ayurveda* successfully in many diseases¹.

MATERIALS AND METHODS

Materials

Pharmaceutical processing of *Abhraka* (Biotite) was done in the practical laboratory of Department of *Rasashastra*, Banaras Hindu University. 1 kg of *abhraka* (Biotite) was procured from *Ayurvedic* Pharmacy, I.M.S., B.H.U. Then this was subjected to *Shodhana* (purification) process according to traditional Ayurvedic procedures of *Nirvapa*² (Heating to red hot stage and immediately quenched in different medium) method using Decoction of *Triphala*³ {pieces of dry fruits *Haritaki* (*Emblica officinalis*), *Vibhitaki* (*Terminalia bellirica*) & *Amalaki* (*Terminalia chebula*) as media. *Dhanyabhraka*⁴ is an intermediately process in between *shodhana* (purification) and *marana* (calcinations) in case of *abhraka*. *Shodhit* (purified) *abhraka* was mixed with 1/4th of unhusked rice and tied in cotton cloth. This tied cloth was soaked in *Kanjii* (filtered product of fermented boiled rice and radish in water) for 3 days. Then this was rubbed with both palms till fine particle comes out. These fine particles were collected in vessel and evaporated. Product obtained is called *Dhanyabhraka*.

Arka Patra Swarasa (Juice of leaves of *Calotropis procera*) was selected for levigation media in *marana* (calcination)⁵.

First of all measured weight of *Dhanyabhraka* was taken and was levigated with liquid media.. After levigation pellets of uniform size & shape were made. Pellets were kept on plastic sheets for drying under sunlight. Dried pellets were kept in *sarav* (Silica casserole) and covered with another one and put in electric muffle furnace for heat treatment. Process was repeated for 24 times. Finally Brick red color powder was obtained and regarded as *Abhraka bhasma*.

Method

Acute toxicity tests are generally the first tests conducted. They provide data on the relative toxicity likely to arise from a single drug exposure. The study was conducted after obtaining Institutional Animal Ethical Committee clearance according to Rule 170, Deptt. of Ayush, Government of India and OECD guidelines 420.

Place of Experiment

Animal house, Department of Rasa Shastra, Faculty of Ayurveda, IMS, BHU.

Selection of animal species

The preferred rodent species was the Albino rat. Female sex was used in the study. Females were nulliparous and non-pregnant in between age of 8 and 12 weeks and approx 200 mg wt.

Housing and feeding conditions:

The temperature of the experimental animal room was maintained at 22°C (+ 3°C) and **Relative humidity** between 30% and 70%. Light was artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets were used with an unlimited supply of drinking water. Animals were group-caged by dose.

Preparation of animals

The animals were randomly selected, marked to permit individual identification, and kept in their cages for 7 days prior to the start of dosing to allow for acclimatization to the laboratory conditions.

Preparation of doses

The required test compound was weighed on the meter balance as per standard procedures on a butter paper. Then weighed test compound was transferred into centrifuge tube containing gum-acacia. Appropriate volume to be administered was made as per the calculated dose.

Test Compound:

Abhraka bhasma

Dose:

Animals were examined on single maximum limit dose 2000 mg/kg of each test compound.

Group

A total of ten animals of female sex were taken for the study. The each group has five animals. The two groups were made one for test group while second group as control group. The test group was treated with the test drug while control group was treated with honey.

Route of Administration:

Oral route

Duration of Drug Administration:

Single dose of each dose label was given once.

Observation:

Acute Toxicity:

Acute toxicity of *Abhraka bhasma* was evaluated in albino rats as per protocol⁶. The behavioural changes closely observed were: hyperactivity, ataxia, tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. Total observation period for eventual mortality was 14 days⁷. Animals were observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours and thereafter daily for 14 days for any mortality.

RESULTS

Body Weight Data

Body weight of animals from control and test groups exhibited comparable weight gain throughout the dosing period (Table 1).

Total water intake:

Water intake of animals from control and test groups showed increase in water intake in test group throughout the dosing period (Table 2).

Clinical signs

All the animals of control and test groups were shown no toxic clinical signs throughout the study period

Mortality

All animals from control and test groups survived throughout the study period.

CONCLUSION

In acute toxicity study albino rats did not show abnormal behavior for initial 4 hours after drug administration. No mortality was found during 14 days observation. Rat's body weights were increased along with proportionate food and water intake. The study signifies that *Abhraka bhasma* did not affect any physiological process adversely.

Acute toxicity study reveals that *Abhraka bhasma* is suitable for further clinical use.

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Table 1: Showing variation in average wt. of rats during study period due to the effect of *Abhraka Bhasma*

S.No.	Group : Dose (mg/kg)	1 st Day in gm	7 th Day in gm	14 th Day in gm
1	Control group	167.37	183.84	199.10
2	2000 mg/kg Abhraka bhasma	174.63	191.54	208.76

Table 2: Showing variation in average water intake in ml of rats during study period due to the effect of *Abhraka Bhasma*

S.No.	Group : Dose (mg/kg)	1 st Day in ml	7 th Day in ml	14 th Day in ml
1	Control group	383.8	407.6	419.5
2	2000 mg/kg Abhraka bhasma	406.4	424.8	436.2