

EVALUATION OF 90-DAYS REPEATED DOSE ORAL TOXICITY STUDY OF SUVARNA BHASMA (PREMIUM) IN HOLTZMAN RATS

National Institute for Research in Reproductive Health (NIRRH), Parel East, Mumbai, Maharashtra 400012

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Raigad,
Maharashtra -410 206

ABSTRACT

Background: Suvarna Bhasma is a ayurvedic herbometalic formulation. It possesses aphrodisiac, spermatogenic, anti-aging, adaptogenic, cardiotoxic properties. Heavy metals in Ayurvedic formulations have been used for centuries with claimed efficacy and safety. However, concerns are often raised about the toxicity due to heavy metals used in Ayurvedic formulations.

Objective: To determine Sub-chronic (90 days) oral toxicity of *Suvarna Bhasma* (SB) in rats and identify target organs involved for establishing its safety in humans.

Method: Groups of ten males and ten females of Holtzman rats were administered with doses of 3 mg/kg body weight (TD), 15 mg/kg body weight (5TD) and 30 mg/kg body weight (10TD) of test substance 'Suvarna Bhasma' by oral route for consecutive 90 days and were sacrificed 24 hrs. After the administration of last dose. The rats were examined daily for clinical signs of toxicity. Body weight and food consumption were recorded during the experimental period along with the incidence of mortality and signs of ill health. Laboratory investigations like hematology & serum biochemistry were performed on blood at interim (45 day) and termination of the study. All animals, sacrificed at termination of the study were subjected to complete necropsy examination and weights of selected visceral organs were recorded.

Results: No clinical signs and symptoms of toxicity were observed in animals receiving test substance. Suvarna Bhasma did not induce any adverse effect on food intake and weekly body weight in treatment groups. The minor variations observed in few of hematology & serum biochemistry parameters were well within the normal range & were insufficient to reach any biologically significant level. Gross & histopathology evaluation showed no changes indicating non-toxicity due to Suvarna Bhasma. All the above results of the present study demonstrated that Suvarna Bhasma does not cause any observable toxicity/adverse changes at doses used (i.e. upto 30 mg/kg Body Wt.) in the Holtzman rats when administered daily over the period of 90 days.

Conclusion: Based on these outcomes of the present chronic study, the *NOEL* (*No Observed Effect Level*) for SB in Holtzman rats could be concluded at 30 mg/kg b.w.

Keywords: *Bhasma*, Chronic toxicity study, *No observed effect level* (NOEL), Suvarna Bhasma