



PATHOLOGICAL EVALUATION OF REPEATED DOSE ORAL TOXICITY STUDY OF TRIVANGA BHASMA IN WISTAR RATS.

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ABSTRACT

Ethnopharmacological Relevance: *Trivanga Bhasma*, a metallic preparation containing *Bhasmas* of *Naga* (lead), *Vanga* (tin) and *Yashada* (zinc), was studied for repeated dose toxicity in Wistar Rats to estimate No Observed Effect Level (NOEL) or No Observed Adverse Effect Level (NOAEL). There is an imminent need for assessment of a systematic study on safety profile of *Trivanga Bhasma* to generate scientific evidence of their utility and safety.

Objective: To determine pathological evaluation of *Trivanga Bhasma* in rats.

Method: Two treatment group animals were given with Therapeutic Dose (TD) 11.25 mg/kg and twice of Therapeutic Dose (2TD) 22.50 mg/kg for consecutive days, which were 1 and 2 times the proposed human therapeutic dose (HTD). The 3rd group or control group, receive Carboxy Methyl Cellulose (CMC). The rat were fasted overnight prior to the terminal necropsy and their body weights were recorded. Blood samples were obtained for laboratory investigations from all the animals before necropsy. Weights of certain organ recorded. Histopathological evaluation was performed on brain, heart, kidney, lung, spleen, liver, and adrenal in all rats.

Results: The values of biochemical and hematological of rats treated with *Trivanga Bhasma* were found to be comparable to the control group. No treatment related gross pathological changes were observed in animals from different treatment groups. The microscopic examinations of tissues revealed some incidental findings, such as acute congestion in liver and lungs, round cell infiltration in liver and acute inflammation in lungs in the treated and control group rats and was considered unrelated to exposure to the test article.

Conclusion: Based on these outcomes of the present chronic study, the NOEL (No Observed Effect Level) for *Trivanga Bhasma* in Wistar rats could be concluded at that of doubled of human dose.

Keywords: *Trivanga Bhasma*, metallic, Ayurvedic Formulation, Chronic toxicity study, No observed effect level (NOEL) etc