



PATHOLOGICAL EVALUATION OF REPEATED DOSE ORAL TOXICITY STUDY OF SUVARNA MALINI VASANT IN WISTAR RATS.

Institute for Toxicological Studies (INTOX), Shivaji Nagar Pune, Maharashtra-411 005.

Shree Dhootapapeshwar Ayurvedic Research Foundation (SDARF), Panvel, Raigad, Maharashtra-410206.

ABSTRACT

Ethnopharmacological Relevance: 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. Suvarna Malini Vasant is a Ayurvedic formulation and it is composed of heavy metal ingredients.

Objective: To determine repeated dose oral toxicity of Suvarna Malini Vasant (SMV) in rats and identify target organs involved in establishing its safety in humans.

Method: Two treatment group animals were given with Therapeutic Dose (TD) and twice of Therapeutic Dose (2TD) for repeated 90 days, which were 1 and 2 times the proposed human therapeutic dose (HTD). The 3rd group or control group, receive Carboxy Methyl Cellulose (CMC) for 90 days. The parameters measured include weekly body weight, feed intake, water intake, hematological, serum biochemical parameters, and organ weights were measured along with gross histopathological examination.

Results: Animals were evaluated using functional observation battery (FOB), and no remarkable changes were observed in gross and clinical symptoms throughout the study period. Body weights, feed, water intake in all treated animals were not significant as compare to control group animals. Values of different biochemical and hematological parameters of male and female rats from the group treated with SMV TD and 2TD were found to be comparable with those of control group animal. However, gross pathological finding showed liver slightly pale, but these changes were not significant as compare control group rats.

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

Keywords: Suvarna Malini Vasant, Heavy metals, Ayurvedic Formulation, Chronic toxicity study, *No observed effect level* (NOEL) etc