"Sub Acute Oral Toxicity Study of Roflumilast on *Swiss Albino* Mice."

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ABSTRACT

Objective: The present study was aimed to explore the 28 days sub-acute oral toxicity study of Roflumilast in Swiss Albino mice. Information related to possible health hazards, estimate of No-Observed-Adverse-Effect-Level (NOAEL), hematology, biochemistry, organ weight & histopathological parameters were studied.

Experimental work: *Swiss albino* mice of both sexes (5-9 weeks) were divided into four groups, each consisting of six male and six female mice. Group I (Corn oil), Group II (0.25 mg/kg), III (2.5 mg/kg) and IV (25 mg/kg) were dosed at 10mL/kg body weight, daily once orally for 28 days.Clinical signs (daily); body weight & feed consumption (weekly) were taken. Blood samples were collected by retro-orbital plexus before necropsy (29^{th} day). Target organs were stored in 10% formal saline. Statistical analysis was performed using One way ANOVA followed by Duncan's New Multiple Range Test (DNMRT).

Results and Discussion: No mortality or adverse clinical signs change in body weight, feed consumption was observed as compared to control. Hematological and Biochemical variations were observed in some parameters. In target organs no significant changes were observed. Histopathological findings observed in Liver,

Lung, Uterus, Kidney, Thymus ,Intestine and Adrenal. Here all lesions founded in control and in treated group. so lesions are not related to Roflumilast toxicity.

Conclusion: Roflumilast is safer drug of class of PDE 4 inhibitors.Nephrotoxicity, hepatotoxicity and thyrotoxicity not seen from results. NOAEL of Roflumilast was at the level of 25 mg/kg for mice.

Key words: Roflumilast, NOAEL.