Lyzme5® Pre-clinical Toxicity Study

Rat Study II
Summary Report

Study sponsor:

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Report Summary

Procedure

Eighteen Sprague-Dawley white albino rats (nine males and nine females), eight weeks of age, weighing between 201 – 291 grams each, were divided equally by gender into three groups of six animals each. Animals remained in a separate cage for the duration of the study. After a five day acclimation period, each animal was visually examined, weighed and assigned a number. Each tail was marked with a color code for easy identification. Animals received either the diluents of the Test Formulation (Lyzme5) – [orange juice], the Test Formula at 1X concentration (the amount representing a single adult human dose), or 10X concentration of the Test Formula (representing 10X the normal human dose) daily, via syringe feeding, for a total of 30 days. All animals were maintained on standard rat chow and had free access to both food and water at all times. Animals were inspected daily for skin lesions and behavioral abnormalities, and weighed at regular intervals. At the conclusion of the test, all animals were sacrificed via an overdose injection of Beuthanafia –D (I.P.). Tissue from heart, liver, kidney, and upper G.I. tract were removed from each animal, fixed according to the recommended protocol, and submitted for histopathologic examination.

Results

No definitive histopathologic substance-related tissue toxicity was confirmed in any of the samples. It was noted that all animals from both the 1X and 10X treatment groups lost interest in their food towards the end of the study indicating a loss of appetite. Product recognized as safe.