Lyzme5® Pre-clinical Toxicity Study

Rat Study I
Summary Report

Study sponsor:

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Report Summary

Procedure

Six Sprague-Dawley white albino rats (all male), eight weeks of age, weighing between 201 – 291 grams each, were used for the study. Animals remained in a separate cage for the duration of the study. After a seven 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 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. But, after the first week junk food was added to the diet. (candy bars, cookies, etc) 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 animal started loosing weight from week 2-4 even though they were on a high calorie junk food diet. Product recognized as safe and will move on to phase II toxicity study.