ALL AMERICAN
PHARMACEUTICAL

An Acute Oral Toxicity Study in Rats with GlutaZorb®

Guidelines

U.S. Food and Drug Administration (FDA)
Consumer Product Safety Commission (CPSC)

Author

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Study Completed

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August 20, 2008

Performing Laboratory

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BRDL Study Number

1151

Introduction

The study was performed to assess the short-term toxicity of GlutaZorb® in white male rats when administered an oral dose at prescribe amounts and 5 times the recommended dose. The study was intended to provide information on the potential health hazards of the test article with respect to oral exposure. Data from this study may serve as a basis for classification and/or labeling of the test article.

The study was performed by BioCeutical Research & Development Laboratory at 2376 Main Street, Room 14, Billings, Montana. The protocol was signed by the Study Director on July 1 , 2008. The in-life phase of the study was initiated with test article stabilization on July 15, 2008 and concluded with a veterinary examination on August 19, 2008.

Procedure

The single dose oral toxicity of GlutaZorb® was evaluated in white male rats. A limit test was performed in which one group of twelve males received a single oral administration of the test article at a dose of 22.04 mg/kg of body weight (equivalent to 1.5 grams for adults) for the first two weeks than a elevated dose of 5X the recommended amount or 110.20 mg/kg body weight (equivalent to 7.5 grams for adults).

The following protocol was used for the study:

Week 1: A). Weigh in of new rats and stabilization

Weeks 2-5: A). Rats were weighed each morning

B). Observations were done at 8:00 A.M., 12:00 P.M., 4:00 P.M. Observations included observing for sluggishness, bleeding, sores, tumors, alertness and skin temperature.

Week 6: A). Examined rats for toxicity

Dosage

Weeks 2 & 3: 22.04 mg per day (equivalent to 1.5 grams in adult humans)

Weeks 4 & 5: 110.20 mg per day (equivalent to 7.5 grams in humans or 5X the recommended amount)

Each animal was fed normal rat chow with no restriction to amount and free access to water.

Summary

All test rats remained very active and showed no signs of sluggishness, bleeding, sores, or tumors. All rats remained very alert and attentive during the study.

No mortality occurred during the study. No clinical abnormalities were observed during the study. Body weight gain was noted for all animals during the test period. No significant gross internal or external findings were observed during the examination of the animals. The final examination also concluded that there were no microscopic lesions caused by the test article.

Under the conditions of this test, the acute oral dose of GlutaZorb® was elevated to 5X the normal dose for adults.

Conclusion

There was no toxicity or side effects observed with GlutaZorb®. In addition all animals survived; therefore, the oral toxicity must be greater than the maximum administered at 7.5 grams per day for adults.