AN ACUTE ORAL TOXICITY STUDY IN RATS WITH KRE-CELAZINE

Guideline
FDA-CPSC

Author
Jeff Golini

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Performing Laboratory

BioCeutical Research & Development Laboratory
Montana Division
2376 Main Street
Room 14
Billings, MT 59105

BRDL Study No.
1250

Introduction:

The study was performed to assess the short-term toxicity of Kre-Celazine 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 1st, 2007. The in-life phase of the study was initiated with test article stabilization on July 19th, 2007 and concluded with a veterinary examination on August 20th, 2007.

Procedure:

The single dose oral toxicity of Kre-Celazine was evaluated in white male rats. A limit test was performed in which one group of four 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 5 x the recommended amount or 110.20 mg/kg body weight (equivalent to 7.5 grams for adults).

The following was the protocol:

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

Week 2-5: A). Rats were weighed each morning
B). Observation was done at 8:00 A.M., 12:00 P.M., 4:00 P.M.
*Observation included observing for sluggishness, bleeding, sores, tumors, alertness and skin temperature.

Week 6: A). Examine rats for toxicity

Dosage:

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

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

Each Rat was fed the same type of food and the same amount.

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 Kre-Celazine was elevated to 5 x the normal dose for adults.

Conclusion:

There was not toxicity observed with Kre-Celazine. In addition all animals survived, therefore the oral toxicity must be greater than the maximum administered at 7.5 grams per day for adults.