AN ACUTE ORAL TOXICITY STUDY IN RATS WITH TAXADROL®

Guideline
FDA-CPSC

Author
Jeff Golini

Study completed on August 20th, 2009

Performing Laboratory

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

BRDL Study No.
T82009

Introduction:

The study was performed to assess the short-term toxicity of Taxadrol® 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 April 1st, 2008. The in-life phase of the study was initiated with test article stabilization on May 19th, 2008 and concluded with a veterinary examination on August 10th, 2008.

Procedure:

The single dose & 5x oral toxicity of Taxadrol® was evaluated in white male rats. A limit test was performed in which one group of 6 rats received Taxadrol® at 4 mg per kg, a second group of 6 rats received Taxadrol at 20 mg/kg and the third group of 6 rats was used as a control.

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

Each Rat was fed the same type of food and the same amount. 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 Taxadrol® was elevated to 5 x the normal dose for adults.

Conclusion:

There was not toxicity observed with Taxadrol® . In addition all animals survived, therefore the oral toxicity must be greater than the maximum administered at 5 times the recommenced dosage.

Taxadrol® is safe for human consumption at recommended dosages and 5 times recommended dosages.