

AN ACUTE ORAL TOXICITY STUDY IN RATS WITH COR-RESTOR

Guideline
FDA-CPSC

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Performing Laboratory

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BRDL Study No.
081417

Introduction:

The study was performed to assess the short-term toxicity of Cor-Restore in white male rats when administered an oral dose as directed on the label and at 2 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, Billings, Montana. The protocol was signed by the Study Director on August 14th, 2017. The in-life phase of the study was initiated with test article stabilization on August 28th, 2017 and concluded with a veterinary examination on October 11th, 2017.

Procedure:

A single and double dose oral toxicity of Cor-Restore was evaluated in white male rats. A limit test was performed in which one group of five males received a single oral administration of the test article at a dose of 102.5 mg/lb of body weight twice daily (equivalent to 20.5 grams for adults twice daily). The second group of 5 male rats were administered a double dose at 205 mg/lb of body weight twice daily (equivalent to 41 grams for adults twice daily). The third group was used as a control group and did not receive any Cor-Restore.

All groups were fed regular rat chow keeping feeding bins full daily and they could consume what they wanted. All groups also had full access to water.

During the course of the study, the following observations were documented:

- Quality of the Coat
- Soars on body
- Activity of the animal
- Eyes
- Body Weight

The following was the protocol:

- Week 1-2: A). Weigh in of new rats and stabilization process
- Week 3-6: A). Rats were weighed each morning
B). Observation was done at 8:00 A.M.
C). Test Article administration was performed as follows:
Dose one in the A.M. and dose two mid afternoon

All animals were fed the same type of Rat Chow with unlimited access.

Summary:

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

Control rats were not very active compared to the test group and showed no signs of bleeding, sores or tumors.

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 or internal abnormalities caused by the test article. They were very consistent with the control group.

Veterinary report stated the physical exam findings were unremarkable, with all rats appearing bright, alert, and active. Auscultations of the heart and lungs indicated no signs of infection or arrhythmia and heart rates were greater than 200 beats per minute. Abdominal palpations were normal. Oral exams revealed no signs of trauma or infection. Some lower incisor teeth appeared larger than others; however, no malocclusions were observed. All rats' testicles were descended and equal in both size and shape. No abnormalities of the skin and/or coats were noted. Eyes and ears were clean with no discharge present. All blood work was in order and no indications of any internal issues with the kidney or liver. All rats were very healthy looking and in good shape.

Conclusion:

There was not toxicity observed with Cor-Retore at the recommended dose on the label and at two times the recommended dose. In addition all animals survived, therefore the oral toxicity must be greater than the maximum administered. This study shows Cor-Restore is very safe at the recommended dose and at two time that dose.


By: Dr Jeff Golini