

Facility Registration Number 16-R-0029

REV 1.0 2018

10 Dogs assigned to column E of this report were used in non-clinical laboratory studies to evaluate the safety of test compounds in accordance to Food and Drug Administration requirements under Good Laboratory regulations 21 CFR 58. The animals were used on studies to determine the potential target organs of toxicity and no effect levels of test articles that were administered. These animal exhibited one or more clinical signs on one or more days that included decreased activity, emesis, blepharospasm, hypothermia, hyperthermia, anaphylaxis, facial erythema, diarrhea, altered gait, tremors, decreased appetite, and dehydration. The dogs were not given other drugs such as analgesics or sedatives that might confound interpretation of toxic effects of test article or induce their own inherent toxicities or drug-drug interactions. Animals were, however, provided fluids, nutritional supplements and other palliative care that mitigated these signs.

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NOV 26 2018

26 NHPs assigned to column E of this report were used in non-clinical laboratory studies to evaluate the safety of test compounds in accordance to Food and Drug Administration requirements under Good Laboratory regulations 21 CFR 58. The animals were used on studies to determine the potential target organs of toxicity and no effect levels of test articles that were administered. These animal exhibited one or more clinical signs on one or more days that included hunched posture, decreased activity, emesis, diarrhea, hypothermia, dehydration, slow movement, tremors, anemia, irregular respiration, rapid breathing, and tachycardia. The NHPs were not given other drugs such as analgesics or sedatives that confound interpretation of toxic effects of test article or induce their own inherent toxicities or drug-drug interactions. Animals were, however, provided fluids, nutritional supplements and other palliative care that mitigated these signs.