

5. Method

Prior to dosing, the mice were individually identified, weighed and arbitrarily assigned to a treatment group as shown below:

Extract	Treatment Group	Number of Animals	Sex	Dose	Route of Administration
SC	Test	5	Male	50 mL/kg	Intravenous
	Control	5	Male	50 mL/kg	Intravenous
SO	Test	5	Male	50 mL/kg	Intraperitoneal
	Control	5	Male	50 mL/kg	Intraperitoneal

A single dose of each test article extract was injected into the designated group of mice. Each control blank was similarly injected into the separate group of designated control mice. Dosing occurred on Day 0. Mice were observed for any adverse clinical reactions immediately after injection. The animals were then returned to their cages. The animals were observed for signs of systemic reactions at 4, 24, 48 and 72 hours after injection. The animals were weighed daily for three days after dosing. After the test was completed, all animals were euthanized according to IACUC approved NAMSA procedure.

6. Evaluation

If during the observation period, none of the mice treated with the individual test extract exhibited a significantly greater reaction than the control mice, the test article met the requirements. If two or more mice died, or if abnormal behavior such as convulsions or prostration occurred in two or more mice, or if body weight loss greater than 2 grams occurred in three or more mice, the test article did not meet the test requirements.

7. Results

Clinical Observations

All animals appeared clinically normal throughout the study. The clinical observations are presented in Table 1 in the appendices.

Mortality Rate Data

There was no mortality during the study. The mortality rate data are presented in Table 2 in the appendices.

Body Weight

Body weight data were acceptable. Body weight data are presented in Table 3 in the appendices.

8. Conclusion

Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts. The test article extracts met the requirements of the study.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

10. References

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 1996.

International Organization for Standardization (ISO) 10993-2, *Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements* (2006).

International Organization for Standardization (ISO) 10993-11, *Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity* (2006).

Office of Laboratory Animal Welfare (OLAW), *Public Health Service Policy on Humane Care and Use of Laboratory Animals*.