



St. Paul
Report

**NON-GLP
FINAL STUDY REPORT**

STUDY TITLE

ISO ACUTE SYSTEMIC INJECTION TEST

TEST ARTICLE IDENTIFICATION

Silverdyne
Lot # A

STUDY COMPLETION DATE

October 18, 2007

PERFORMING LABORATORY

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

World Health Alliance
3252 Wolfe Court
Fremont, CA 94555

PROJECT NUMBER

65507



WHA01



65507



cveach@earthlink.net

ISO ACUTE SYSTEMIC INJECTION TEST RESULTS

Test Article Name: Silverdyne
Lot/Batch #: A
Stability: Not Applicable
Sterilization Method: Not Given
Storage Conditions: Room Temperature
Safety Precautions: Standard Precautions
Intended Use/Application: To eliminate bacteria

Date Sample Received: 09/28/07

Study Completion Date: 10/18/07

PURPOSE: The purpose of this test was to screen test article solution for potential toxic effects as a result of a single-dose systemic injection in mice.

TEST SAMPLE PREPARATION: The test article was prepared by adding 10 drops of the test article to 1 liter of sterile tap water. The sterile tap water with test article was allowed to sit for one hour at room temperature before dosing.

EXPERIMENTAL METHODS SUMMARY: Groups of five (5) Albino Swiss Mice (*Mus musculus*) were injected systemically with the test article solution or control at a dose rate of 50 mL extract to one kg body weight. The animals were observed for signs of toxicity immediately after injection and at 4 ± 0.75, 24 ± 2, 48 ± 2 and 72 ± 2 hours post-injection. According to ISO Guidelines, the test is considered negative if none of the animals injected with the test article solution show a significantly greater biological reaction than the animals treated with the control. A significant biological reaction is interpreted as death in two or more mice or other toxic signs such as convulsions, prostration, or body weight loss greater than 10 % in three or more mice.

RESULTS:

DATA TABLE A: MORTALITY, CLINICAL SIGNS AND WEIGHT LOSS INCIDENCE

VEHICLE	FATALITIES		TOXICITY CLINICAL SIGNS		ANIMALS WITH >10% BODY WEIGHT LOSS	
	TEST	CONTROL	TEST	CONTROL	TEST	CONTROL
Sterile Tap Water	0/5	0/5	0/5	0/5	0/5	0/5

STATISTICAL METHODS: At ten drops of test article per liter of sterile tap water, there were no signs of systemic toxicity observed.

CONCLUSION: TEST ARTICLE PASSES THE TEST.

Approval: _____

Spencer Kubo, BS – Study Director

Date: _____

10/18/07

TECHNICAL REFERENCES:

ISO 10993-11: 2006 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity

ISO 10993-12: 2002 Standard, Biological Evaluation of Medical Devices, Part 12-Sample Preparation and Reference Materials.

United States Pharmacopeia USP 30 (2007), Section 88, Biological Reactivity Test, *In Vivo*, Systemic Injection Test, page 116-117.

**DATA TABLE B: ANIMAL WEIGHTS (g) AND
STANDARD DEVIATION CALCULATIONS**

Group	Animal #	Initial	24 Hrs	48 Hrs	72 Hrs	BW Change
Test NS	1	20.3	19.3	19.0	19.3	-1.0
	2	20.3	19.3	19.2	19.4	-0.9
	3	21.5	19.6	19.4	19.8	-1.7
	4	19.7	18.4	18.5	18.4	-1.3
	5	20.2	20.0	19.5	20.0	-0.2
Average Body Weight		20.4	19.3	19.1	19.4	-1.0
Standard Deviation		0.7	0.6	0.4	0.6	0.6

Group	Animal #	Initial	24 Hrs	48 Hrs	72 Hrs	BW Change
Control NS	11	17.2	17.8	17.3	17.6	0.4
	12	21.3	21.2	21.2	21.9	0.6
	13	21.1	20.0	19.8	20.5	-0.6
	14	20.8	20.0	20.0	19.6	-1.2
	15	19.2	18.4	18.2	18.7	-0.5
Average Body Weight		19.9	19.5	19.3	19.7	-0.3
Standard Deviation		1.7	1.4	1.5	1.7	0.7