NELSON LABORATORIES

Sponsor:
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MEM Elution GLP Report

Test Article: 1) LOT#1 TiN SAMPLE COLOR (Gold)
2) LOT#2 TiAlN SAMPLE COLOR (Black)
3) LOT#3 Alpha SAMPLE COLOR (Yellow)
4) LOT#4 CrN SAMPLE COLOR (Silver)
Purchase Order: 20080597
Laboratory Number: 629095
Study Received Date: 09 Apr 2012
Test Procedure(s): Standard Test Protocol (STP) Number: STP0032 Rev 07
Protocol Detail Sheet (PDS) Number: 201201431 Rev 01

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Results:
Test Article:

Identification	Results Pass/Fail	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount	Post Extraction Appearance
		#1	#2	#3	Average			
1	**Pass**	0	0	0	0	3 cm^2/mL	117.8 cm^2 / 39.3 mL	Clear; Particulate Free
2	**Pass**	0	0	0	0	3 cm^2/mL	117.8 cm^2 / 39.3 mL	Clear; Particulate Free
3	**Pass**	0	0	0	0	3 cm^2/mL	117.8 cm^2 / 39.3 mL	Clear; Particulate Free
4	**Pass**	0	0	0	0	3 cm^2/mL	117.8 cm^2 / 39.3 mL	Clear; Particulate Free

ACLASS ACCREDITED TESTING

Christine Walton
Study Director

18 Apr 2012
Study Completion Date

Controls:

Identification	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount	Post Extraction Appearance
	#1	#2	#3	Average			
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL	Clear; Particulate Free
Media Control	0	0	0	0	N/A	20 mL	Clear; Particulate Free
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL	Clear; Particulate Free

Acceptance Criteria: The United States Pharmacopeia & National Formulary (USP 87) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

Conditions of All Cultures	Reactivity	Grade
No cell lysis, intracytoplasmic granules.	None	0
Not more than 20% rounding, occasional lysed cells.	Slight	1
Not more than 50% rounding, no extensive cell lysis.	Mild	2
Not more than 70% rounding and lysed cells.	Moderate	3
Nearly complete cell destruction.	Severe	4

The results from the three wells were averaged to give a final cytotoxicity score.

Procedure: The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at 37 ± 1°C with agitation. Multiple well cell culture plates were seeded with a verified quantity of industry standard L-929 cells (ATCC CCL-1) and incubated until approximately 80% confluent. The test extracts were added to the cell monolayers in triplicate. The cells were incubated at 37 ± 1°C with 5 ± 1% CO_2 for 72 ± 3 hours.