Nelson Labs
A Sotera Health company

Sponsor:
Bretni Kennon
Attostat, Inc.
190 N. CUTLER DR. STE D
NORTH SALT LAKE, UT 84054

MEM Elution GLP Report

Test Article:	Ag 181109-103
Purchase Order:	PO19080801
Study Number:	1216816-S01
Study Received Date:	27 Aug 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0032 Rev 10
Deviation(s):	None

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. 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:

Dilution	Results Pass/Fail	Scores			
		#1	#2	#3	Average
Neat	**Fail**	4	4	4	4
1:2	**Fail**	4	4	4	4
1:4	**Pass**	0	0	0	0
1:8	**Pass**	0	0	0	0
1:16	**Pass**	0	0	0	0

Controls:

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

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

McKenna Wild electronically approved — 05 Sep 2019 13:43 (+00:00)
Study Director McKenna Wild — Study Completion Date and Time

Test Method 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
Less than or equal to 20% rounding, occasional lysed cells.	Slight	1
Greater than 20% to less than or equal to 50% rounding, no extensive cell lysis.	Mild	2
Greater than 50% to less than 70% rounding and lysed cells.	Moderate	3
Nearly complete destruction of the cell layers.	Severe	4

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

Procedure: The liquid test article was tested by combining 16 mL of test article with a 4 mL aliquot of 5X MEM + 50% bovine calf serum. The pH was adjusted with 7.5% Sodium Bicarbonate. 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 articles and control extracts were added to the cell monolayers in triplicate. The cells were incubated at 37 ± 1°C with 5 ± 1% CO_2 for 48 ± 3 hours.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	27 Aug 2019
Phase Inspected by Quality Assurance: Cell Exposure	30 Aug 2019
Audit Results Reported to Study Director	30 Aug 2019
Audit Results Reported to Management	30 Aug 2019

Scientists	Title
Chad J. Summers	Supervisor
McKenna Wild	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Robert Montgomery electronically approved
Quality Assurance

04 Sep 2019 23:16 (+00:00)
Date and Time