Nelson Labs
A Sotera Health company

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MEM Elution Final Report

Test Article:	SAVEWO 3DMASK
Study Number:	1330326-S01
Study Received Date:	12 Aug 2020
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. 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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Test Article:

Dilution	Results Pass/Fail	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
		#1	#2	#3	Average		
Neat	**Pass**	2	2	2	2	3 cm^2/mL	534.1 cm^2 / 178 mL
1:2	**Pass**	1	1	1	1		
1:4	**Pass**	1	0	1	1		
1:8	**Pass**	0	0	0	0		
1:16	**Pass**	0	0	0	0		

Note: An additional 12 mL of media was added to account for absorbency.

Danielle Short electronically approved — 25 Aug 2020 20:12 (+00:00)
Study Director Danielle Short — Study Completion Date and Time

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	20 mL
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL

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 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 held at room temperature for less than four hours before testing. The extract fluids were not filtered, centrifuged or manipulated in any way following the extraction process. 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 48 ± 3 hours.

Pre and Post Extract Appearance		
Test Article	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted
Controls	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted