labcorp

TEST RESULT CERTIFICATE

Sponsor	Boston Industrial Solutions, Inc.	**Technical Initiation**	3/29/2022
Address	165-C New Boston Street	**Technical Completion**	4/7/2022
	Woburn, Massachusetts 01801	**Report Date**	5/2/2022
Contact	Bonaventure Mutuku	**Amended Report Date**	5/16/2022
P.O. Number	PO-0000741	**Final Non-GLP Report**	22-00370-N1

Test Article	STC370HP + SC45X + SF / STC370HP + SC45X + SC	**Ratio**	6 cm^2/mL
Lot/Batch #	030222	**Vehicle**	Serum–Supplemented (complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – USP		
Physical State	Low viscous fluid	**Color**	Translucent
Expiration Date	Liquid Product: 2 Years [02/2025]. Coated product does not expire	**Stability**	Stable: (-67°F - 600°F)
Sterility	Not Sterile	**Extraction Conditions**	24 ± 2 hours at 37 ± 1 °C
Sterility Condition	N/S	**Storage Condition**	Room Temperature
Intended Use	Final finished device – surface contact prolonged		
Comments	None		

REFERENCES: The study was conducted based upon the following references: USP-NF 2021. <87> Biological Reactivity Tests, *In Vitro*. ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. The test article extract was prepared as stated above. A positive control (Natural Rubber) article, negative control (Negative Control Plastic) article, and untreated control (blank) were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in duplicate for 48 ± 2 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity).

EVALUATION CRITERIA:

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present, only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

The test article meets the requirements of the test if none of the cultures exposed to the test article extract show greater than a Mild Reactivity (Grade 2).

RESULTS:

Time	Test Article	Untreated Control	Negative Control	Positive Control
24 Hours	0	0	0	4
48 Hours	0	0	0	4

CONCLUSION: The test article meets the requirements of the test and is not considered to have a cytotoxic effect.

AUTHORIZED PERSONNEL:

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