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TEST RESULT CERTIFICATE

Sponsor	Boston Industrial Solutions	**Technical Initiation**	3/22/2018
Address	165 New Boston Street, M Suite # 243 Woburn, Massachusetts 01801 United States	**Technical Completion**	3/29/2018
Contact	Jayson French	**Report Date**	4/4/2018
P.O. Number	PO-0000604	**Final Non-GLP Report**	18-01055-N1

Test Article	Silicone rubber printed with NatronTM SETM Silicone Inks/ LG CT Catalyst / SE-TRM Solvent	**Ratio**	60 cm^2/20 mL
Lot/Batch #	0081518	**Vehicle**	Serum–Supplemented (complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – USP	**Extraction Conditions**	24 ± 2 hours at 37 ± 1 °C
Comments	None		

REFERENCES: The study was conducted based upon the following references: USP 40, NF 35, 2017. <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.
1	Slight	Less than or equal to 20% of the cells are round, loosely attached, and without intracytoplasmic granules; occasional lysed cells are present.
2	Mild	Greater than 20% to less than or equal to 50% of the cells are round and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells.
3	Moderate	Greater than 50% to less than 70% of the cell layers contain rounded cells or are lysed.
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	3
48 Hours	0	0	0	3

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

AUTHORIZED PERSONNEL:

4/4/2018

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