

Biomaterials Laboratory Test Report

TEST ARTICLE

The following information of the test article was supplied by the sponsor.

Name: Inorganic Film (Silver)

Lot No.: N/A

Model No.: N/A

Physical State: Synthetic Polymer

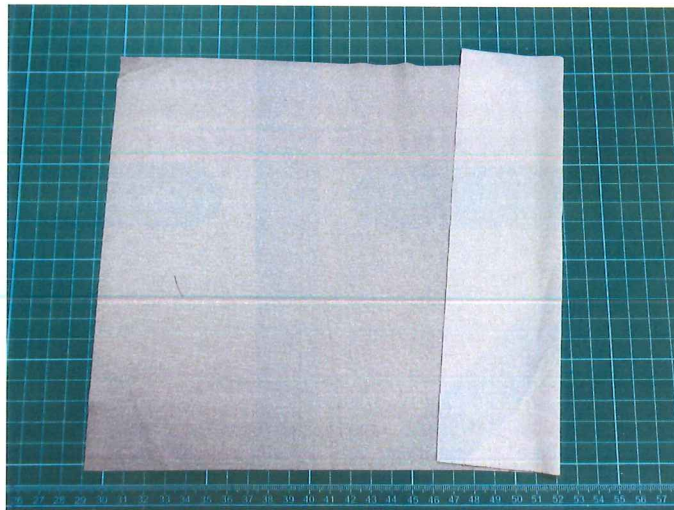
Color: Not Supplied by Sponsor

Expiration Date: Not Supplied by Sponsor

Storage Conditions: Room Temperature

Article No.: T-1080527-02

Appearance of the Test Article:



SPONSOR

Name: SowiRoc Corp.

Address: No. 8, Prosperity 1st Rd., Hsinchu Science Park, Hsinchu City 30078

Report No.: EABML(E)1080527-161

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METHODS

Extraction Method: (SOP: EA-WI-015)

The test article (120 cm²) was combined with 22.8 ml of DMEM (20 ml for extraction and 2.8 ml for preswelling) at a ratio of 6 cm² per 1 ml. The test article and control solutions were extracted at 37±1 °C for 24±2 hours.

Test Method: (SOP: EA-WI-001)

The Cells:

L-929 mouse fibroblasts were cultured in DMEM with 10 % fetal bovine serum (FBS). The cell suspension was made at density of 7.0×10⁴~1.0×10⁵ cells/ml. 1ml of this cell suspension were pipetted in each well. The 24-well cell culture plate was then incubated at 37±1 °C with 5 % CO₂.

Testing Groups:

1. Negative Control: DMEM 10 % FBS.
2. Positive Control: Dimethylsulfoxide (DMSO) final concentration 5 % in DMEM 10 % FBS.
3. Test Article: Test article extract with 10 % FBS.

Test Procedure:

A monolayer of L-929 mouse fibroblasts was grown to near confluency, in each well of a 24-well cell culture plate. The culture medium was removed from 24-well cell culture plate, and replaced with 1 ml of the test article extract or the control media. The cultures were incubated for 24 hours at 37±1 °C with 5 % CO₂. Then the monolayer was examined microscopically for cell malformation or degeneration. The cell layer was trypsinized and the cell number was counted. All the cultures were performed in triplicate.

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RESULTS

(1) Microscopic Examination

None of the cultures showed sign of cell malformation (reactivity grading = 0 or "none"), except for the positive control, where the cells became round in shape and were detached from the culture plate surface (reactivity grading = 4 or "severe").

(2) The Cell Number

The cell number within the monolayer was listed in Table 1. The cell number of the test article extract was not over 50 % less than the negative control.

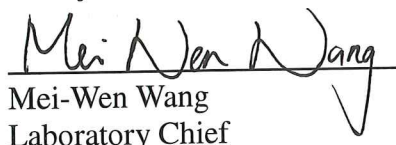
Table 1. The average cells number for each culture.

Testing Groups	Total number of cells within monolayer ($\times 10^5$)			
	#1	#2	#3	Average
Negative control	4.47	4.59	4.47	4.51 ± 0.07
Positive control	1.40	1.39	1.43	1.41 ± 0.02
Test article extract	4.47	4.43	4.47	4.46 ± 0.02

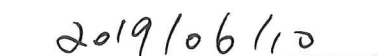
CONCLUSION

The cell number for the test article extract was not over 50 % less than the negative control and cell reactivity grading was equal to 0 (none). Therefore, the test article showed "negative" cytotoxicity.

Study Director


Mei-Wen Wang
Laboratory Chief

Completed Date


2019/06/10

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