



35 Industrial Parkway  
Branchburg, New Jersey 08876  
USA Tel. (908) 526-2828

SOP #: SOP-1081

Report Number:

2265-52-5.doc

**CYTOTOXICITY REPORT - FOR INTERNAL USE ONLY** **FOR PUBLIC RELEASE**

**MEM ELUTION TEST**

**SAMPLE DESCRIPTION:**

Sample ID: \_\_\_\_\_ Polypropylene Tube \_\_\_\_\_ Person: Tom

Sample Description: \_\_\_\_\_ Lot book #: \_\_\_\_\_

Hydromer coating used: \_\_\_\_\_ 5-TS-72P / 6-TS-51 \_\_\_\_\_

**PURPOSE:**

To determine the in vitro cytotoxicity of an extract of the test materials on L929 mouse fibroblast cells in an elution test.

**METHOD:**

An in vitro biocompatibility study, based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity, is conducted on the test materials. Solid materials, 6cm<sup>2</sup>/ml (thickness ≤ 0.5mm), 3cm<sup>2</sup>/ml (thickness > 0.5mm), or 0.1-0.2g/ml of cell culture, are extracted 24 hours in cell culture medium with 5% FBS (MEM) and the extracts are then placed in duplicate 35mm containers of L-929 cells monolayers. All monolayers are incubated at 37°C in the presence of 5% CO<sub>2</sub>. Cells are examined by optical microscope at 24, 48 and 72 hours for signs of toxicity.

Cell exposure time: ( ) 24 hours Screening; ( ) 48 hours USP (X) 72 hours ISO 10993

**OTHER METHOD DETAILS:**

**RESULTS ARE BASED AT REACTIVITY GRADES FOR ELUTION TEST:**

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmic granules; no cell lysis
1	Slight	Not more than 20% of the cells are round, loosely attached, and without intracytoplasmic granules; occasional lysed cells
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules; extensive cell lysis and empty areas
3	Moderate	Not more than 70% of the cell layers contain rounded cells and/or are lysed
4	Severe	Nearly complete destruction of the cell layers

**RESULTS:** 0

**CONCLUSION:**

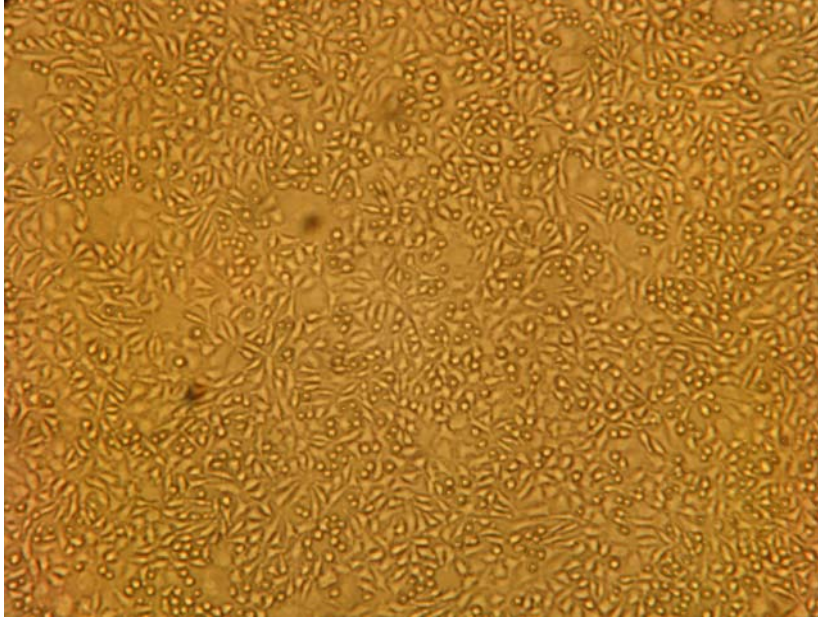
( ) fulfills screening requirements ( ) fulfills USP requirements

(X) fulfills ISO 10993 requirements ( ) does not fulfill requirements

Date: January 16, 2006

Chemist: Xin Qu Ph.D.

\* This report provides preliminary results and is for internal use only. For final independent results, the tests have to be conducted at authorized labs such as NAMSA.

**CYTOTOXICITY REPORT - FOR INTERNAL USE ONLY****FOR PUBLIC RELEASE****CYTOTOXICITY TEST PHOTOS:****Negative Control Sample:****Tested Sample:**