Final Report: Test of Hygenix Mask Using MEM Elution

Dr. John Doe

2024-09-22

Table of Contents

## 1. Report Information

**Report Number:** HYX-M202309045(A)  
**Test Method:** MEM Elution  
**Standard:** 21 CFR Part 58, U.S. FDA  
**Sponsor:** Hygenix Inc.  
**Address:** 300 Main Street, Springfield, USA  
**Testing Facility:** BioTech Labs  
**Facility Address:** 123 Research Ave, BioCity, USA  
**Website:** www.biotechlabs.com  
**Contact Information:** [contact@biotechlabs.com](mailto:contact@biotechlabs.com), +1-800-555-1234

## 2. Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP (Good Laboratory Practice) regulations:

* **GLP Regulation:** 21 CFR Part 58, U.S. FDA  
  The inspections were conducted on the following dates, and the findings were reported to the Study Director and Testing Facility Management:
* **Study Protocol Inspection Date:** 2024-09-10
* **Study Procedure Inspection Date:** 2024-09-12
* **Raw Data Inspection Date:** 2024-09-20
* **Final Report Inspection Date:** 2024-09-21

The final report accurately describes the test methods, and the results are consistent with the raw data.

## 3. Test and Control Articles

### 3.1 Test Article

* **Name:** Hygenix Mask
* **Manufacturer:** Hygenix Inc.
* **Batch/Lot Number:** HYX-202305001
* **Physical State:** Solid
* **Color:** Blue
* **Size:** 180 x 95 mm
* **Storage Conditions:** Room temperature
* **Intended Use:** To provide respiratory protection in medical settings by filtering particulate matter.

### 3.2 Negative Control Article

* **Name:** Polyethylene Pellets
* **Extraction Ratio:** 3 cm²/mL
* **Physical State:** Solid
* **Color:** White
* **Storage Conditions:** Room temperature
* **Extraction Solvent:** MEM medium with 10% fetal bovine serum (FBS).

### 3.3 Positive Control Article

* **Name:** PVC Plastic
* **Extraction Ratio:** 3 cm²/mL
* **Physical State:** Solid
* **Color:** Clear
* **Extraction Solvent:** MEM medium with 10% FBS.

### 3.4 Media Control

* **Name:** MEM medium with 10% FBS

## 4. Pre and Post Extract Appearance

* **Pre-Extract Appearance:** Clear and free of particulates.
* **Post-Extract Appearance:** No significant color changes were noted for both the test article and controls.

## 5. Test System

### 5.1 Cell Line

* **Name:** HeLa Cells, obtained from ATCC (American Type Culture Collection), USA.
* **Justification:** HeLa Cells cells are widely used for cytotoxicity studies due to their sensitivity to cytotoxic extracts.

## 6. Experimental Design

### 6.1 Preparation of Extracts

* **Extraction Solvent:** MEM medium with 10% fetal bovine serum (FBS).
* **Extraction Conditions:**
  + The test article was extracted at a surface area-to-volume ratio of 3 cm²/mL at 37°C for 72 hours.

### 6.2 Procedure

* Following extraction, the cells were exposed to the test article extract, as well as the positive and negative control extracts, and the media control for 48 hours.
* The test article extract was prepared at concentrations of c(“100%”, “75%”, “50%”, “25%”).
* The cells were incubated for 24 hours, after which cytotoxicity was assessed by the percentage of cell viability using the MTT assay.
* Cell morphology was observed to evaluate any changes that could indicate cytotoxicity.

## 7. Results

### 7.1 Acceptance Criteria

| Grade | Criteria |
| --- | --- |
| 0 - None | No cell lysis observed; intracytoplasmic granules present. |
| 1 - Slight | Less than or equal to 20% rounding of cells with occasional lysed cells. |
| 2 - Mild | Greater than 20% to less than or equal to 50% rounding, with no extensive cell lysis. |
| 3 - Moderate | Greater than 50% rounding with lysed cells. |
| 4 - Severe | Nearly complete destruction of the cell layers. |

The mean reactivity score of the three replicates will be reported using Qualitative Scoring.

## 9. Record Storage

All raw data and a copy of the final report will be retained in the designated archive.

## 10. Confidentiality Agreement

All confidentiality statements were agreed upon before the initiation of the study.

## 12. Deviation Statement

No deviations from the approved study protocol were observed that would affect the validity of the data.