465 N. Berry St., Brea CA, 92821
Phone: (844) 641-3814
Fax: (844) 641-3813
www.mpspharma-inc.com

Certificate of Analysis

Item Number	**SYR-P-05**
Lot Number	**2022082505**
Expiration Date	**08/24/2027**

Sterilization:

Product is sterilized via an ETO cycle to a sterility assurance level (SAL) of 10^-6. All products which are labeled as "sterile" and released for sale by MPS Pharma & Medical are certified to be sterile as long as the package is unopened and undamaged.

Endotoxin (LAL) Detection:

Sampling procedure performed per internal SOP Q-028 - Product LAL Pyrogen Testing. Testing performed by outside contracting lab. Test is performed under all applicable GMP regulations and in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.

References:

- *ANSI/AAMI ST72: Bacterial Endotoxins – Test Methods, Routine Monitoring, and alternatives to batch testing*
- *USP 43, National Formulary 38 (USP), General Chapter <85>, Bacterial Endotoxins Test (2020)*
- *USP 43, National Formulary 38 (USP), General Chapter <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests (2020)*

Test Results:

Test	Method	Specifications	Results	Date Tested
Endotoxin-Article Testing	USP <161>	NMT 20 EU/ Device	0.50 EU/ Device	**09/26/2022**

USP <788> - Test Method 1:

Sampling procedure performed per internal SOP Q-056 – USP 788. Testing performed by outside contracting lab. Test is performed under all applicable GMP regulations. Outside lab follows a quality system accredited to the ISO 17025 and follows various requirements established by the FDA, ICH, and USP.

Test – Particulate Matter	Method	Specifications	Results	Date Tested
≥ 10 um	Light Obstruction	≤ 6000 / container	165 particles / container	**09/26/2022**
≥ 25 um	Light Obstruction	≤ 600 / container	2 particles / container	**09/26/2022**

Particulate Matter: Filled 10 syringes with **5** mL of particle-free water each and combined for a total volume of **50** mL.

Particulate Matter: Light Obscuration - Test Method Acceptance Criteria: Based on the methodology of USP <788>, the environment control must have no more than a total of 25 particles ≥ 10 µm when adding the counts of all five aliquots (25 mL total).

Particulate Matter: Light Obscuration – Test Method Acceptance Criteria: Based on the methodology of USP <788>, the average number of particles present in the units tested does not exceed 6000 per container equal to or greater than 10µm and does not exceed 600 per container equal to or greater than 25µm.

Biocompatibility & Materials:

Product has been evaluated with ISO 10993 "Biological Evaluation of Medical Devices", and complies with all relevant sections including cytotoxicity, irritation, sensitization, systemic toxicity, hemolysis, and pyrogenicity.

Materials of Construction	
Barrel	Polypropylene
Plunger	Polypropylene
Stopper	Polyisoprene

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Quality Control Testing & Release:

Representative batch samples are collected and inspected. Inspection records are reviewed and signed off by qualified personnel for final release. Visual inspections include AQL pulled samples inspected for debris, foreign substances, and syringe print quality. The released product meets the applicable inspection criteria.

Product Performance, Safety & Effectiveness:

Product conforms with requirements of ISO 7886 (Sterile hypodermic syringes for single use) and ISO 80369-7 (Small-bore connectors for liquids and gases in healthcare applications)

BSE/TSE Statement:

Product is certified to be produced entirely from materials of synthetic origin and therefore free from human or any other animal derived materials including bovine products. In addition, there are no animal derived components used in the manufacturing or handling processes of this product. As such, this product can be declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

Regulatory:

Manufacturing site of product is registered with FDA per 21 CFR 807 and an ISO 13485 certified facility. Products sold by MPS Pharma & Medical satisfy FDA pre-market notification requirements per 21 CFR 807. Medical devices are listed with the FDA per 21 CFR 807.

MPS Pharma & Medical is an FDA registered manufacturer. Registration number: 3018125942

MPS Pharma & Medical Inc.

Name: _____

Quality Signature: _____ **Date**: _____