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

Certificate of Analysis

Item Number	**AC211635-1**
Lot Number	**M63596**
Expiration Date	**04/28/2027**
Sterile Load Number	**MPS-EO-011-22**

Sterilization:

Product is sterilized with a validated ETO cycle to a sterility assurance level (SAL) of 10^-6. ETO Sterilization performed by outside contracting facility in compliance with applicable state & federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI ISO 11135

Product released via Sterility-Direct Transfer Method Embedded Spore Strip accredited to the ISO 17025. Test performed under all applicable GMP regulations and in compliance with ISO 13485 standard:

Sterility Test Results:

Article Tested	Result
Embedded Spore Strip	Pass
Positive Control	Pass

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 Article Extract Dilution	**1**
Positive Product Control Percent Recovery	**78%** (between 50% and 200% is acceptable)
Test Article Extract	**<0.00500** EU/mL (Total Concentration) **<0.200** EU/Device

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).

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

USP <788> - Test Method 1:

Sampling procedure performed per internal SOP Q-056 – USP 788 Testing for Bottles. 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	6 particles / container	**05/27/2022**
≥ 25 um	Light Obstruction	≤ 600 / container	0 particles / container	**05/27/2022**

Particulate Matter: Filled 10 containers with **10** mL of particle-free water each and combined for a total volume of **100** 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.

Regulatory:

MPS Pharma & Medical products are manufactured in accordance FDA Good Manufacturing Practice guidelines.

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

MPS Pharma & Medical Inc.

Name: __*Patricia Cortes*__

Quality Signature: _____ **Date**: _____