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

Certificate of Analysis

Item Number	**G82721-M**
Lot Number	**M59930**
Expiration Date	**2026/10/04**
Sterile Load Number	**MPS-EO-026-21**

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	**119%** (between 50% and 200% is acceptable)
Test Article Extract	**<0.00500** EU/mL (Total Concentration) **<0.400** EU/Device

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Functional Verification:

The manufacturing lot was sampled, tested, and released via internal procedure QC-001 per the following functional testing:

Testing Performed	Result
Air Leakage test under water. (15 PSI air pressure for at least 10 seconds). Test per SOP-Q-008.	Pass
Bond strength test (pull test) per SOP Q-010 Pull Force Test. Test all tubing to connector joints.	Pass
Luer Leak Test (equal to or less than 0.35 with lead tester set at 15 PSI) Test per SOP Q-009.	Pass
Flow Check Occluded (ensure that fluid flows through the set using gravity, syringe, etc.) Test per SOP Q-015.	Pass

Product Conformances:

All fluid pathway materials used in the manufacturing of these products have been reviewed againstmaterial biocompatibility requirements as defined in ISO 10993.

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:

Device Listing Number: D442496 // Product Code: JTB

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**: _May 10, 2022_____