465 N. Berry St., Brea CA, 92821
Phone: (844) 641-3814
Fax: (844) 641-3813
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Certificate of Analysis

Item Number	**LEI-002**
Lot Number	**M64838**
Expiration Date	**05/31/2027**
Sterile Load Number	**X088-22**

Sterilization:

Product is sterilized with a validated Gamma cycle to a sterility assurance level (SAL) of 10^-6. Gamma sterilization performed by outside contracting facility. Operating facilities of contractor are in compliance with applicable state and federal regulations (FDA, NCR, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2016, and in alignment with EN ANSI/AAMI/ISO 11137:2017. Product is certified by contractor to have been processed under doses within the precision and accuracy of the dosimetry system used.

Test Results:

Dosage Specification	Result
Minimum Specified Dosage (kGy): 25.0	**27.1**
Maximum Specified Dosage (kGy): 40.0	**35.4**

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	**104%** (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).

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**: September 06, 2022