Corning Incorporated Life Sciences

Registered ISO 9001:2008

Certificate of Compliance

Catalog Number: 3786

Lot Number: 20013017

Product Description: Collagen coated - Microcarriers: 10g vial, sterile

Component Materials:

Beads - Polystyrene, meets *USP*, *Class VI* requirements for plastic containers and closures.

Surface - Collagen Type A - Porcine Gelatin, 300 Bloom

Relative Density - 1.022-1.030 vs H₂O

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization.

Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing. Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest version of EMEA 410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Surface Characterization:

The surface is coated with a proprietary concentration of Collagen Type I optimized for stem cell expansion.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:

Visual Attributes

Pass

Packaging

Cell Growth

Results:

Pass

Pass

Pass

Pass

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Judith A. Gibbs

Quality Assurance Manager

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Rev No: 3