Corning Incorporated
Life Sciences
Registered
ISO 9001:2008

Product Description

Catalog Number: 3786

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 H_2O

Product Dimensions:
Microcarrier Diameter   -   125-212 µm   Weight per vial   -   10 grams
Range

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: $\leq$ 0.1 EU/mL ($\leq$ 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.

Performance Testing:
Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.
Visual Attributes: Visual and microscopic examination of the product.
Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.
Cell Growth: Biocompatibility and cytotoxicity test

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.

Rev No: 3