Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number: 3886

Product Description: Corning ® 96-well half area, tissue culture treated, white plate with clear flat bottom,

without lid

Component Materials:

Plate walls - Virgin Polystyrene, meets USP. Class VI requirements for plastic containers and

closures. White concentrate

Plate bottom - Virgin Polystyrene, meets *USP*, *Class VI* requirements for plastic containers and

closures.

Product Dimensions:

Length of Plate - 5.030 in. Diameter of Well @ top - .197 in. Width of Plate - 3.365 in. Diameter of Well @ - .177 in.

bottom

Depth of Well - .452 in. Height with Lid - .650 in. Tolerances of - +/- .010 in. Volume per Well - 200 µl

Dimensions

Sterilization:

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

Sterility Assurance Level: SAL 10⁻³

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)

Surface Characterization:

Surface is characterized to be hydrophilic and negatively charged, composed of 9-17% oxygen atoms. This surface composition has been optimized for cell attachment and growth.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth utilizing an atttachment-dependent mammalian cell line in a serum supplemented media.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

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

Optical Characteristics:

The product is made of opaque white polystyrene walls to minimize well to well crosstalk and background fluorescence and /or luminescence. The bottom is made of clear polystyrene to permit direct microscopic viewing.

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.

Opacity: Visual, using a fluorescent compound.

Cell Culture Treatment: Wettability test using water to insure the presence of a hydrophilic

surface.

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: 6