Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number: 3904

Product Description: Costar® 96-well tissue culture treated black plate with clear flat bottom with low

evaporation lid

Component Materials:

Plate walls Medium Impact Polystyrene, meets USP, Class VI requirements for plastic containers

and closures. Black concentrate

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

closures.

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and Lid

closures.

Product Dimensions:

Length of Plate Diameter of Well @ top .270 in. 5.030 in. Width of Plate 3.365 in. Diameter of Well @ .250 in. bottom Depth of Well Height with Lid .650 in. .420 in. +/- .010 in. Tolerances of Volume per Well .36 mL

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: $\leq 0.1 \; \text{EU/mL} \; (\leq 4 \; \text{EU/device})$

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.

The product is made of opaque black 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.

Inspection for seal and barrier integrity, accurate labeling and correct Packaging:

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

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: 17