Corning Incorporated Life Sciences

Product Description

Catalog Number: 3513

Product Description: Costar ® 12-Well cell culture multiple well plate, flat bottom, with lid

Component Materials:

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

closures.

Product Dimensions:

Length of Plate 5.030 in. Diameter of well @ top 0.895 in. Width of Plate 3.365 in. Diameter of well @ bottom 0.870 in. Depth of Well 0.685 in. Height with lid 0.890 in. Tolerances of Dimensions +/- 0.050 in. Working volume per well 3 mL

Regulatory Compliance - Product manufactured in a facility that is registered to the current version of ISO 9001 or ISO 13485.

Animal Content - Product does not contain materials of animal origin.

Non-Pyrogenic – Vessel tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing" and USP <85> "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

Sterilization – Product has been sterilized and dosimetrically released per the requirements ANSI/AAMI/ISO 11137 "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10⁻³.

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.

Tissue Culture – Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 95% confluency is required for acceptance.

Quality Control Testing – Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass

Packaging Inspection - Pass

Cell Attachment & Growth Treatment Verification - 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.

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