Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number: 3505

Product Description: Corning ® 96-well, non-treated, sterile, white filter plate with 0.2µm PVDF membrane,

without lid

Component Materials:

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

closures. White concentrate

Plate bottom - Virgin Butadiene/Styrene Block Co-polymer, meets *USP, Class VI* requirements for

plastic containers and closures.

Membrane - 0.2mm Polyvinylidene Difluoride, hydrophilic

Sterilization:

The product is 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

Product Dimensions:

Length of Plate - 5.030 in. Diameter of Well @ top - .270 in. Width of Plate - 3.365 in. Diameter of Well @ - .250 in.

bottom

Depth of Well - .470 in. Height without Lid - .560 in Tolerances of - +/- .010 in. Volume per Well - .40 mL

Dimensions

Membrane Performance:

Each lot has been tested for well to well consistency using a vacuum uniformity test.

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 modified polystyrene with a PVDF membrane insert to allow filtration.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes: Visual and light box examination of the product.

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

product configuration.

Functional: Vacuum Uniformity Test

Opacity: Visual using a fluorescent compound.

Integrity: Pressure Decay 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: 4