Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

Catalog Number: 8160

Product Description: Costar® Spin-X® centrifuge tube filter cellulose acetate membrane 0.22 μm pore size

Component Materials:

Tube - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and

closures.

Filter Unit - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and

closures.

Membrane - Cellulose Acetate, 0.22 um pore size, meets USP, Class VI requirements for plastic

containers and closures.

Product Dimensions:

Tube Length w/filter unit -Filter Unit Length .808 in. 1.800 in. Filter Unit ID/top .380 in. Tube OD below shoulder -.434 in. Filter Unit OD/shoulder +/- .050 in. .375 in. Tolerances Working Volume Tube Volume 2 mL .5 mL

Maximum RCF:

16,000

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 10⁻³

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing.

Results: < 0.1 EU/mL (< 4EU/device)

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

Membrane Bubble Point Integrity:

The membrane has been tested according to an established procedure to determine the water bubble point. The membrane meets the established criteria of minimum 37 psi.

Membrane Bacterial Retention:

The membrane has been tested according to the HIMA document No. 3, Vol. 4 "Microbiological Evaluation of Filters for Sterilizing Liquids."

Performance Testing:

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

Integrity Testing: Forward pressurization of filter unit to 12 psi.

Visual Attributes: Visual examination of the product.

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

product configuration.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product is manufactured and packaged with animal free materials.

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: 10