

Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 8162

Product Description: Costar® Spin-X® centrifuge tube filter cellulose acetate membrane 0.45 µm pore size

Component Materials:

- | | | |
|-------------|---|--|
| Tube | - | Virgin Polypropylene, meets <i>USP, Class VI</i> requirements for plastic containers and closures. |
| Filter Unit | - | Virgin Polypropylene, meets <i>USP, Class VI</i> requirements for plastic containers and closures. |
| Membrane | - | Cellulose Acetate, 0.45 µm pore size, meets <i>USP, Class VI</i> requirements for plastic containers and closures. |

Product Dimensions:

- | | | | | | |
|-------------------------|---|----------|---------------------------|---|--------------|
| Filter Unit Length | - | .808 in. | Tube Length w/filter unit | - | 1.800 in. |
| Filter Unit ID/top | - | .380 in. | Tube OD below shoulder | - | .434 in. |
| Filter Unit OD/shoulder | - | .375 in. | Tolerances | - | +/- .050 in. |
| Working Volume | - | .5 mL | Tube Volume | - | 2 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 26 psi.

Performance Testing:

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

Integrity Testing: Forward pressurization of filter unit to 10 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