

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 431220

Product Description: Corning® syringe filter, surfactant free cellulose acetate (SFCA) membrane, 0.45 µm pore size, 28 mm diameter, individually packaged

Component Materials:

- | | | |
|----------|---|--|
| Housing | - | Acrylic Copolymer meets <i>USP, Class VI</i> requirements for plastic containers and closures. Heavy metal free (meets <i>CONEG</i> req.) color concentrate. |
| Membrane | - | Surfactant Free Cellulose Acetate (SFCA), 0.45 µm pore size, meets <i>USP, Class VI</i> requirements for plastic containers and closures. |

Product Dimensions:

- | | | | | | |
|---------------------------|---|----------------------|--------------------------|---|-----------------------|
| Diameter of unit | - | 1.30 in. (33 mm) | Length of syringe filter | - | 1.02 in. (26 mm) |
| Diameter of membrane | - | 1.10 in. (28 mm) | Tolerances | - | +/- 0.05 in. (1.3 mm) |
| Effective filtration area | - | 6.20 cm ² | | | |

Sterilization:

This product has been irradiated and dosimetrically released based on the *Sterilization of healthcare products- Requirements for validation and routine control-Radiation sterilization*.

Sterility Assurance Level: SAL 10⁻⁵

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: less than 0.1 EU/mL

Membrane Bubble Point:

The product has been tested according to an established procedure to determine the water bubble point of the product. The product meets the established criteria.

Housing Burst Pressure Test:

This product has been tested according to an established procedure to determine the housing burst pressure. The product meets the established criteria.

Flow Rate Test:

The product has been tested according to an established procedure to determine the flow rate. The product meets the established criteria.

Bacterial Challenge:

This product has been tested and determined to be quantitatively retentive when challenged with a concentration of 10⁷ organisms per cm² using *Brevundimonas diminuta*.

Performance Testing:

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

Pressure Hold Test:

Forward pressurization of the unit to 1.0 bar.

Visual Attributes:

Visual examination of the product.

Packaging:

Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Rev No: 4