

Catalog Number: 431221

Product Description: Corning® syringe filter, surfactant free cellulose acetate (SFCA) membrane, 0.80 µm pore size, 28 mm diameter, individually packaged

Component Materials:

- Housing - Acrylic Copolymer, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Membrane - Surfactant Free Cellulose Acetate (SFCA), 0.80 µm pore size, meets *USP, Class VI* 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 0.1EU/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 0.5 bar.

Visual Attributes:

Visual examination of the product.

Packaging:

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

Revision Date:

01-24-19

Rev No: 5