

Catalog Number: 431225

Product Description: Corning® syringe filter, nylon (NY) membrane, 0.45 µM pore size, 25 mm diameter, individually packaged

Component Materials:

- Housing - Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Membrane - Nylon (NY), 0.45 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 unit | - | 0.92 in. (23.3 mm) |
| Diameter of membrane | - | 0.98 in. (25 mm) | Tolerances | - | +/- 0.05 in. (1.3 mm) |
| Effective filtration area | - | 4.80 cm ² | | | |

Sterilization:

This lot has been sterilized according to *Medical Devices - Validation and routine control of ethylene oxide sterilization* and released after successful sterility testing of Biological Indicators.

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

HPLC Certified:

The product has been tested to ensure there are no extraneous peaks in the UV range.

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 of >2.2 bar.

Housing Burst Pressure Test:

The product has been tested according to an established procedure to determine the housing burst pressure. The product meets the established criteria of >6 bar (approx. 87 psi).

Flow Rate Test:

The product has been tested according to an established procedure to determine the flow rate. The product meets the established criteria of >130 mL/min/bar.

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.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year.

Revision Date:

01-24-19

Rev No: 3