

CERTIFICATE OF QUALITY

Autofil[®]

Catalog Number:
Membrane Type:
Pore Size:
Lot Number:
Expiration Date:

Sterilization Description:

Gamma irradiation dose is according to a quality control basis.

Sterilization:

Individually bagged and sterilized by gamma irradiation VDMax 10⁻⁶ in the US.

Membrane Bubble Point:

Each membrane pore size was certified according to an established Foxx Life Sciences' procedure to determine the bubble point.

0.2µm Pore Size	29.9 psi (2.1bar)
0.45µm Pore Size	62.4 psi (4.3 Bar)
1.0µm Pore Size	43.5 psi (3.0 Bar)

Maximum Operating Vacuum:

0.2µm Pore Size	69.6 psi (4.8 Bar)
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Microbial Retention:

0.2µm membrane samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1x 10⁻⁷ cfu per cm² using ASTM methodology.

0.45 micron membrane samples were quantitatively retentive of a minimum *S. marcescens* challenge concentration of 1x 10⁻⁷ cfu per cm² using ASTM methodology.

Good Manufacturing Practice:

This product was manufactured in a Class 100,000 clean room facility that is registered to ISO 13485 Device manufacturing.

ISO 13485 Quality Standard:

This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 13485 Quality Systems Standard.

Materials of Construction:
Filter Housing and Bottle: Polystyrene
Membrane: Polyethersulfone (PES)
Cap: Polypropylene

Component Material Toxicity:
All component materials have been tested and meet the requirements for United States Pharmacopoeia (USP) class VI Biological Test for Plastics, current edition. The plastics meet the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in 21 CFR 177.1540.

Cytotoxicity:

Plastic component materials are non-cytotoxic and meet the Elution Test 10993-5, 1999

Pyrogens:

An aqueous extraction from the component materials contains less than 20 EU/device as determined by the Limulus Amebocyte Lysate (LAL) test.

Maximum Operating Vacuum:

20in Hg (51 cm) H₂O
15in Hg (38 cm) H₂O

Temperature Range:

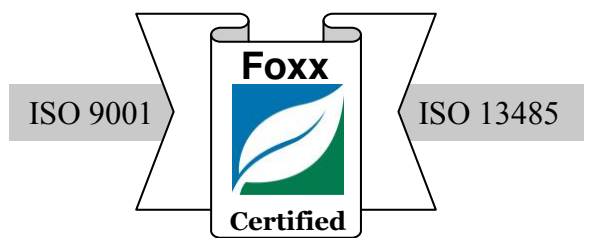
Operating Range: 39°F to 122°F (4°C to 50°C)
Unit Storage: -20° to 122°F (-30° to 50° C)

Flammability:

UL 94 V-0

Leak Test Criteria:

Leak test criteria are conducted to determine the integrity of the bioburden of the product.



Brian J. Abbott
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