International Filter Products
Revolutionary systems for your industry

STERILE CAPSULE FILTER

These filters are designed for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The product contains a pharmaceutical grade PES membrane (Sterilizing Grade) and the filters are built in a 10,000-class clean room, flushed, dried and 100% integrity tested prior to packaging. The product is factory sterilized by Ethylene Oxide gas (ETO) ensuring sterility.

Technical Data Sheet

Catalog Number: JKPDS065S020LFLM-PH-ETO

Materials of Construction

Filter Membrane: 0.65 um Pre-filter/0.2 um final Pharmaceutical Grade PES Sterilizing Grade - Hydrophilic

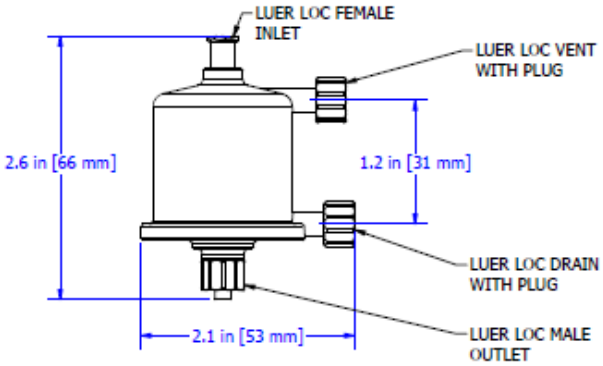
Supports: Polypropylene

Capsule Body: Polypropylene

Filter Dimensions and Specifications

- **Outer Diameter:** 41 mm (2.12”)
- **Length, Fitting to Fitting:** 65 mm (2.55”)
- **Filter Area:** 230 cm^2 (37 in^2)
- **Sterilization:** The filter is factory sterilized by Ethylene Oxide Gas (ETO)
- **Inlet Fitting:** Luer Loc Female
- **Outlet Fitting:** Luer Loc Male
- **Total Hold up Volume:** 8.6 ml
- ***Volume Filtered:** 3 L to 14.0 L

****Volume Filtered is an estimated range for Sterile Compounding, Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by the solution's viscosity, active ingredients, properties, etc... The best way to determine the exact filtration volume per filter is to try it with the solution.***



Integrity Data

Pore Size	Min, Bubble Point, 25°C	Challenge Microorganisms	CFU per cm^2
0.20 µm	≥3.5 bar (50 psi)	Brevundimonas Diminuta (ATCC 19146)	10^7

Operating Parameters

Maximum Working Pressure: 5.5 bar (80 Psi) @ 25 °C (77 °F)

Maximum differential Pressure (forward): 4.1 bar (60 Psi) @ 25 °C (77 °F)

Maximum differential Pressure (reverse): 2.1 bar (30 Psi) @ 25 °C (77 °F)

Maximum Operating Temperature: 80 °C (176 °F)

Recommended Replacement Pressure: 2.4 bar (35.3 Psi)

Safety

- UPS Bacteria Endotoxins: ≤25 EU/ml
- Factory Sterilized: Ethylene Oxide Gas (ETO)
- Product was 100% Integrity Tested and flushed with filtered water @ 0.05 um

Regulatory

- Complies with USP 797 Guidelines
- ASTM F838-05 - Bacterial Retention
- FDA 21 CFR 177.1655
- USP Class VI - Biological Reactivity
- ISO 10993-Part 1. 5 - Cytotoxicity
- ISO 14001; ISO 13485; OHSMS 18001 Certified.
- ASTM Hemolysis testing
- Human/Veterinarian Use – Applies when the requirements from CGMP CFR part 210 and 211 and additional requirement 21 CFR part 600 and 21 CFR part 680 are used in the aseptic processing.

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