



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 PTFE 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: SKLF100020H2H2H-PH-ETO & SKLF100020HLF2H-PH-ETO & SKLF100020HLFLM-PH-ETO



2H2H Fitting Configuration



LF2H Fitting Configuration



LFLM Fitting Configuration

Materials of Construction

Filter Membrane: 1.0 um PTFE Pre-filter / 0.2 um final Pharmaceutical Grade PTFE Sterilizing Grade - Hydrophobic

Supports: Polypropylene

Core: Polypropylene

Capsule Body: Polypropylene

Filter Dimensions and Specifications

Outer Diameter: 71.5 mm (2.81")

Length, Fitting to Fitting: 115 mm (4.52") (2H2H)/ 102 mm (4.01") (LF2H)

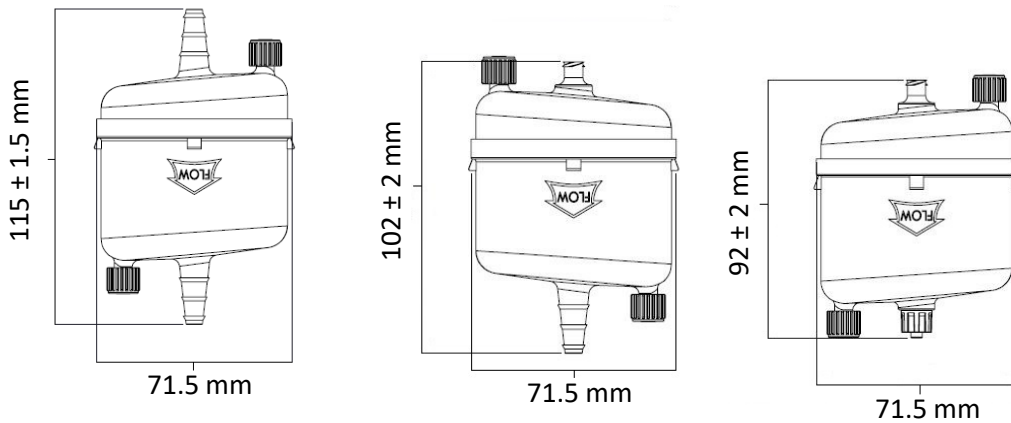
Filter Area: 680 cm² (105.4 in²)

Sterilization: The filter is factory sterilized by Ethylene Oxide Gas (ETO)

Inlet Fitting: 2H2H: ¼" - ½" Tapered Hose Barb; LF2H: - Luer Loc Female

Outlet Fitting: ¼" - ½" Tapered Hose Barb

Volume Filtered: 15 L to 33.0 L



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)	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 µm

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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