



## 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: SKLS080020L2H2H-PH-ETO**



### **Materials of Construction**

**Filter Membrane:** 0.80 um PES Pre-filter / 0.2 um final Pharmaceutical Grade PES Sterilizing Grade - Hydrophilic

**Supports:** Polypropylene

**Core:** Polypropylene

**Capsule Body:** Polypropylene

### **Filter Dimensions and Specifications**

**Outer Diameter:** 71.5 mm (2.81")

**Length, Fitting to Fitting:** 209 mm (8.2")

**Filter Area:** 2600 cm<sup>2</sup> (403 in<sup>2</sup>)

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

**Inlet Fitting:** 2H2H: ¼" - ½" Tapered Hose Barb

**Outlet Fitting:** ¼" - ½" Tapered Hose Barb

**Volume Filtered:** 50 L to 100 L



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## **Integrity Data**

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

## **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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