

mdi Polyethersulfone (PES) Membrane Cartridge filters type *AseptiSure HS* are high temperature resistant filtration devices. These are designed to withstand high pressure differential at high temperature steam sterilization upto 135 °C.

AseptiSure HS cartridge filters with polyethersulfone membrane serial layers offer enhanced throughputs, thus ensuring better economics.

These are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.

Special Features

- Low protein binding
- High throughputs
- Long service life
- Non-toxic material of construction
- Heat sealed, no glues or adhesives
- Each filter comes with an individual certificate of quality
- Total traceability:
Unique Identification number is laser etched on each filter

Application

Sterile filtration of:

- Proteinaceous liquids where minimum protein loss is desired, such as sera, culture soups and recombinant proteins, antibodies etc
- Cell culture media
- Buffers
- Small volume parenterals

Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3(b)(6)
Meets and Exceeds USFDA 21 CFR 177.1520



Material of Construction

Core and Sleeve : Polypropylene
Filter Membrane : Polyethersulfone
Support Layers : Polyester

Integrity Test Data (Water Wetted) 0.2µm rated cartridge

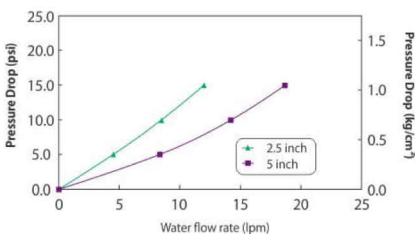
Bubble Point	≥ 50 psi (3.51 Kg/cm ²)
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0.45µm rated cartridge

Bubble Point	≥ 30 psi (2.11 Kg/cm ²)
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Water Flow rate

0.2µm AseptiSure HS



Specifications

Pore Size Rating
0.2 µm, 0.45 µm

Microbial Retention
0.2µm: LRV>7 for B.diminuta(ATCC 19146) per cm²
0.45µm: LRV>7 for S.marcescens (ATCC 19146) per cm²

Sterilization

- 25 Autoclave/In-line steam sterilization cycles at 135 °C for 30 min., Δp=5 psi (0.3kg/cm²)

Maximum Differential Pressure
50 psi (3.5Kg/cm²) @ 25 °C

Maximum Operating Temperature
80 °C @ ≤ 30psi (2Kg/cm²)

Reverse Pressure
≤ 10 psi (0.7Kg/cm²) @ 25 °C

Bacterial Endotoxin
Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test

Biosafety

- Passes the Biological Reactivity tests for Class VI plastics as per USP <88>
- Passes the Biological Reactivity Tests, In Vitro for Cytotoxicity as described in USP <87>

Oxidizable Matter
Passes test as per USP

Fiber Release
Complies with USFDA CFR Title 21, 210.3(b)(6).

Particle Release
The filtrate complies with USP <788> test for particulate matter in injections

TOC (Total Organic Carbon)
Meets the WFI requirements of USP <643> for Total Organic Carbon after a 3 liter WFI flush.

Conductivity
Meets the WFI requirements of USP <645> for Conductivity after a 3 liter WFI flush.

Ordering Information

Type	Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size		
	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code		
AseptiSure HS(with 0.8µm upstream layer)	CPH5	2.5" EFA:1000cm ²	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HS(with 0.65µm upstream layer)	CPH3	5" EFA:2000cm ²	53	*0.45 µm	02	4463B	H0						
AseptiSure HS(with 0.45µm upstream layer)	CPHX					4440	U0						
EXAMPLE	CPH5		50		01		E0				1		01

*0.45µm cartridge filter are available with 0.65µm or 0.8µm upstream layer only