

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

AseptiSure HS is a serial layered membrane filter with a larger pore size upstream layer to protect the final layer for enhanced throughputs.

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

Special Features

- Low protein binding
- Non-toxic material of construction
- Multiple Autoclave
- Long service life
- 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 culture media for mammalian cell culture

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

Bubble Point (50% IPA/Water Wetted)	≥ 31 psi (2.18 Kg/cm ²)
Air Diffusion Flow 5" Cartridge (Water Wetted)	≤ 15 ml/min @ 50 psi (3.52 kg/cm ²)
Air Diffusion Flow 10" Cartridge (Water Wetted)	≤ 29 ml/min @ 50 psi (3.52 kg/cm ²)

Water Flow Rate (Typical) for 10" Cartridge Filters

Pore Size	Flow Rate
0.1µm	20 lpm @ 0.70 kg/cm ² @ 27°C

Specification

Pore Size Rating

0.1 µm

Microbial Retention

LRV>7 for *Acholeplasma laidlawii* (ATCC 23206) 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

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 <1231>

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 (0.45µm Upstream)	CPHX	5"	53	0.1 µm	36	7P	A0	Silicone	SS	Non Sterile	1	1 01
		10"	54			'O'	D0	Viton	SV			
AseptiSure HS (0.2µm Upstream)	CPH1	20"	55			7P without Fin	A1	EPDM	SE			
		30"	56			28 with Fin	C0	FEP Encapsulated Viton	FV**			
<p>*5" is available with adapter code A0 (7P) and A1 (7P without fin) only **FV elastomer is available with Code A0 (7P) and A1 (7P without fin) only</p>												
EXAMPLE	CPHX	55		36		A0		SS		1		01