

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
- Large 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 for (Water Wetted) 0.2µm Rated Cartridge

Bubble Point	≥ 50 psi (≥ 3.51 Kg/cm ²)
Air Diffusion Flow (10")	≤ 30 ml/min @37 psi(2.6kg/cm ²)

0.45µm Rated Cartridge

Bubble Point	≥ 30 psi (≥ 2.11 Kg/cm ²)
Air Diffusion Flow (10")	≤ 35 ml/min @22 psi(1.54kg/cm ²)

Water Flow Rate (Typical) for 10" Cartridge Filters

Pore Size	Flow Rate
0.2 µm	44 lpm @ 0.70 kg/cm ²
0.45 µm	64 lpm @ 0.70 kg/cm ²

Specification

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 14756) per cm²

Sterilization

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

Maximum Operating Pressure

(50 psi) 3.5kg/cm² @ 25°C

Maximum Operating Temperature

80°C @ < 2Kg/cm² (30 psi)

Reverse Pressure

< 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

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
AseptiSure HS (0.8µm Upstream)	CPH5	5"	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.45 µm	02	'O'	D0	Viton	SV				
AseptiSure HS (0.65µm Upstream)	CPH3	20"	55			7P Without Fln	A1	EPDM	SE				
		30"	56					FEP Encapsulated Viton	FV*				
AseptiSure HS (0.45µm Upstream)	CPHX												
5" is available with code A0 and A1 only *Available with Code A0 7(P) only 0.45µm is available with 0.8µm or 0.65µm upstream only													
EXAMPLE	CPH5		55		01				SS		1		01

DSTCPHSXXX1505E