

# Polyethersulfone Membrane Cartridge Filter Type AseptiSure HS

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

AseptiSure HS cartridge filters with polyethersulfone membrane 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
- Cell culture media
- Buffers

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

CPH5

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## **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/cm²)					
Air Diffusion	≤ 30 ml/min					
Flow (10")	@37 psi(2.6kg/cm²)					

## 0.45µm Rated Cartridge

Bubble Point	$\geq$ 30 psi ( $\geq$ 2.11 Kg/cm <sup>2</sup> )					
Air Diffusion Flow (10")	$\leq$ 35 ml/min @22 psi(1.54kg/cm <sup>2</sup> )					

# Water Flow Rate (Typical) for 10" **Cartrdige Filters**

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

#### **Specification**

Pore Size Rating

0.2 μm, 0.45 μm Microbial Retention

0.2µm:LRV>7 for B.diminuta(ATCC 19146) per cm<sup>2</sup>

**0.45μm:**LRV>7 for S.marcescens (ATCC 14756) per cm<sup>2</sup>

Sterilization

25 Autoclave/In-line steam sterilization cycles at 135°C for 30 min.,  $\Delta p = 5 \text{ psi } (0.3 \text{kg/cm}^2)$ 

**Maximum Operating Pressure** 

(50 psi) 3.5Kg/cm<sup>2</sup> @ 25°C

Maximum Operating Temperature

80°C @ < 2Kg/cm<sup>2</sup> (30 psi)

**Reverse Pressure** 

< 0.7Kg/cm<sup>2</sup> @ 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 fo 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

\*\*\*FV elastomer is available with Code A0 (7P) and A1 (7P without fin) only SS

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

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#### **Ordering Information**

**EXAMPLE** 

Туре		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	'0'	D0	Viton	SV				•
AseptiSure HS	CPH3	20"	55			7P Without FIn	A1	EPDM	SE				
(0.65µm Upstream)		30"	56			28 with Fin	C0	FEP		]			
AseptiSure HS (0.45µm Upstream)	СРНХ							Encapsulated Viton	FV***				
		-								•			
*5" is available with adapter code A0 (7P) and A1 (7P without fin) only													
	**0.45µm unstream layer is not available with 0.45µm nore size												

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