

mdi Polyethersulfone (PES) membrane cartridge filters type *AseptiSure HSR* are high temperature resistant filtration devices. These are designed to withstand high pressure differential at high steam sterilization temperature upto 135 °C. These filters exhibit high mechanical stability, and wide chemical compatibility even with alkaline process fluids.

These filters come with Polyethersulfone membrane serial layers and Polypropylene support layers to offer 1-14 pH compatibility.

mdi *AseptiSure HSR* cartridge filters 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

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 : Hydrophilic PES

Support Layers : Polypropylene

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	Code	Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
<i>AseptiSure HSR</i> (0.45µm Upstream)	CHRX	5**	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1		01
		10*	54		0.45 µm**	02	'O'		D0				
<i>AseptiSure HSR</i> (0.65µm Upstream)	CHR3	20*	55			7P Without Fin	A1	EPDM	SE				
		30*	56			28 with Fin	C0		FEP Encapsulated Viton				
<i>AseptiSure HSR</i> (0.8µm Upstream)	CHR5												
EXAMPLE	CHRX		55		01		A0		SS		1		01

*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

**0.45µm cartridge filters are available with 0.8µm and 0.65µm upstream only

***FV is available in Adapter Code A0 7(P) and A1 (7P without fin) only