

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.



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 as per USP <85>

- 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.

Material of Construction

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

Integrity Test Data (Water Wetted) 0.2µm rated cartridge

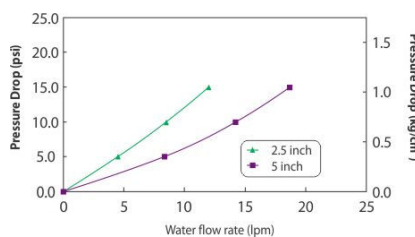
Bubble Point	≥ 50 psi (3.51 Kg/cm ²)
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0.45µm rated cartridge

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

0.2µm AseptiSure HS



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

Ordering Information

Type	Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size		
	Code	Size and EFA	Code	Code	Code	Code	Code	Code	Code	Code	Code		
AseptiSure HS (0.8µm upstream)	CPH5	2.5" 1000cm ²	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HS (0.65µm upstream)	CPH3	5" (2000cm ²)	53	*0.45 µm	02	4463B	H0	Without 'O' ring	XX				
AseptiSure HS (0.45µm upstream)	CPHX					4440	U0						
EFA: Effective Filtration Area						Seal-K	G0**	*0.45µm cartridge filter are available with 0.65µm or 0.8µm upstream layer only **Adapter code "G0" does not come with Elastomer ***Adapter code F0 is available only in 5" cartridge filters					
						Seal-O	F0***						
						Seal-M	J0						
EXAMPLE													
CPH5		50		01		E0		SS		1		01	