AseptiSure HS
0.1µm Polyethersulfone Membrane Mini Cartridge Filters

Membrane Technologies

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.

Complies with
USFDA 21 CFR 210.3(b)6)

Meets and Exceeds
USFDA 21 CFR 177.1520

Special Features

- Low protein binding
- Non-toxic material of construction
- Multiple Autoclave
- 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

Material of Construction

Core and Sleeve : Polypropylene

Filter Membrane : Polyethersulfone

Support Layers : Polyester

Integrity Test Data for 0.1µm Rated Cartridge

Bubble Point (50% IPA)	≥ 31 psi (2.18 Kg/cm²)
Air Diffusion Flow (Water wetted)	≤ 15ml/min @50psi (3.51 kg/cm²)

Water Flow Rate (Typical) for Cartrdige Filters

Size	Flow Rate
2.5”	4.5 lpm @ 10 psi
5”	8 lpm @ 10 psi

Specifications

Pore Size Rating

0.1 µm

Microbial Retention:

LRV>7 for Acholeplasma laidawii (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

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.

Ordering Information

Data Sheet

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure HS (0.45µm upstream)	CPHX	2.5" EFA:1000 cm²	50	0.1 µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HS (0.2µm upstream)	CPH1	5" EFA:2000 cm²	53			4463B	H0						
						4440	U0						
						Seal-K	G0						
						Seal-O	F0*						
						Seal-M	J0						

*Adapter Code F0 is available only in 5” cartridge filters

EXAMPLE	CPHX	50	36	E0	SS	1	01

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