mdi
Membrane Technologies

AseptiSure KS
0.1 µm polyethersulfone Membrane Cartridge Filters

mdi *Aseptisure KS* 0.1µm double layer PES membrane cartridge filters are validated for mycoplasma removal and are used for sterile media filtration in mammalian cell culture.

The upstream PES membrane layer protects the downstream side PES membrane layer from premature clogging. The membrane pore structure is specially designed to give high throughputs, thus resulting in better economics.

Special Features

- Large filtration area
- High throughputs
- Long service life
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Multiple autoclavable/SIP
- Heat sealed, no glues or adhesives
- Low protein binding

Applications

- Sterile filtration of culture media for mammalian cell culture

Complies with USDFA 21 CFR 210.3(b)(6)
Meets and Exceeds USDFA 21 CFR 177.1520

Specifications

Construction				
Final Filter Pore Size	0.1µm			
Prefilter Pore Size	0.45 µm			
Membrane	Hydrophilic PES			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing / Retention				
Bubble Point	> 31psi (2.18Kg/cm^2) with 50% IPA/Water Solution			
Air Diffusion Flow (10")	< 29ml/min @ 50 psi (3.52 Kg/cm^2) with Water			
Microbial Retention	LRV >7 for *Acholeplasma laidlawii* (ATCC 23206) per cm^2			
Size				
Size	5″	10″	20″	30″
Effective Filtration Area (Nominal)	3000cm^2	6000cm^2	12000cm^2	18000cm^2
Operational				
Max. Operating Temperature	80 °C @ < 2 Kg/cm^2 (30 psi)			
Max. Differential Pressure	3.5 Kg/cm^2 (50 psi) @ 25 °C			
Reverse Pressure	< 0.7 Kg/cm^2 (10 psi) @ 25 °C			
Typical Water Flow Rates (10")	22 lpm @ 0.70 Kg/cm^2 @ 27 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 121 ° C for 30 minutes, 25 cycles			

Assurance	
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
pH Compatibility	Compatible with pH range of 1 - 10
Extractables with WFI	Passes NVR test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	Complies with USP <788> test for particulate matter in injections
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a specified volume of purified water flush
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices.
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Ordering Information

Type	
	Code
AseptiSure KS 0.45µm upstream	CPKX

Size	
Length and filtration Area	**Code**
5" (3000 cm^2)**	53
10" (6000 cm^2)	54
20" (12000 cm^2)	55
30" (18000 cm^2)	56

Pore Size	
	Code
0.1 µm	36

Adaptor	
	Code
7P	A0
7P without fin	A1
28 with fin	C0
'O'	D0

Elastomer	
	Code
Silicone	SS
EPDM	SE
Viton	SV
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example

CPKX	53	36	A0	SS	1	01

*** FV is available in Adapter Code A0 (7P) only**

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

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