Membrane Technologies

AseptiSure KS
0.1 µm polyethersulfone Membrane Mini Cartridge Filters

mdi *Aseptisure KS* 0.1µm double layer PES membrane mini 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

- Low protein binding
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Multiple autoclavable/SIP
- Heat sealed, no glues or adhesives
- Validated for retention of Acholeplasma laidlawii
- Each filter comes with an individual Certificate of quality
- Total traceability :
  Unique identification number is laser etched on each filter

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	
Microbial Retention	LRV >7 for Acholeplasma laidlawii (ATCC 23206) per cm^2	
Size		
Size	2.5″	5″
Effective Filtration Area (Nominal)	1000cm^2	2000cm^2
Operational		
Typical Water Flow Rates	2.5″	5″
	4.0 lpm @ 10 psi	8 lpm @ 10 psi
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	
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	CPKX

Size	
	Code
2.5"	50
5"	53

Pore Size	
	Code
0.1 µm	36

Adapter	
	Code
4463	E0
4463B	H0
4440	U0
Seal-K	G0*
Seal-O	F0**
Seal-M	J0

Elastomer	
	Code
Silicone	SS

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

*G0 adapter code is not available with any elastomer. Please mention XX in place of elastomer code while ordering
**Adapter code F0 is available only in 5" cartridge filters

Example

CPKX	**53**	**36**	**E0**	**SS**	**1**	**01**

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