mdi
Membrane Technologies

AseptiSure KR Polyethersulfone Membrane Cartridge *Filters*

mdi *AseptiSure KR* Cartridge filters incorporate a low protein binding PES membrane with polypropylene drainage layers to ensure pH compatibility from 1-14 making these ideal for alkaline fluid streams.

Special Features

- Low protein binding
- Very wide chemical compatibility, even with very high alkaline solutions.
- Large filtration area
- High throughputs
- pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Multiple steam sterilizable
- Heat sealed, no glues or adhesives

Applications

- Sterile filtration of alkaline solutions for pH control

Microbially Validated as per ASTM F 838-05
Complies with USDFA 21 CFR 210.3(b)(6)
Meets and Exceeds USDFA 21 CFR 177.1520

Specifications

Construction				
Final Filter Pore Size	0.2µm		0.45µm	
Membrane	Hydrophilic PES			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing / Retention				
Bubble Point	> 50psi (3.51Kg/cm^2) with Water		> 30psi (2.11Kg/cm^2) with Water	
Air Diffusion Flow (10")	< 40ml/min @ 37 psi (2.6Kg/cm^2) with Water		< 35ml/min @ 22 psi (1.54Kg/cm^2) with Water	
Microbial Retention	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2		LRV >7 for Serratia marcescens (ATCC 14756) 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")	40 lpm @ 0.70 Kg/cm^2 @ 27 °C		55 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 Bioreactivity 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
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 - 14
Extractables with WFI	Passes test as per USP
Oxidizable Substances	Within limits as specified in USP
Particle Shedding	Passes USP test for particulates in injectables
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water
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-9001:2008 Certified
USFDA	DMF No. 015554

Ordering Information

Type	
	Code
AseptiSure KR	CPKR

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
0.2 µm	01
0.45 µm	02

Adaptor	
	Code
7P	A0
7P without fin	A1
'0'	D0

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

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example

CPKR	55	01	A0	SS	1	01

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

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

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