0.2 µm *AseptiPrime KS* Polyethersulfone Membrane Cartridge Filters

Membrane Technologies

DATA SHEET

AseptiPrime KS are sterilizing grade PES membrane cartridge filters specially designed for very high throughputs. The special optimized pre-filter membrane layer offers high loading and volume handling capacities to provide enhanced protection to the final membrane layer.

These filters meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility etc.

Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables

Applications

Sterile Filtration of

- Cell culture media
- Cell culture media containing serum
- Media additives
- Buffers
- pH adjusters
- Final product concentrates

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

Specifications

Membrane
Hydrophilic Polyethersulfone

Microbial Retention
LRV >7 for *B.diminuta* (ATCC 19146) per cm^2

Maximum Operating Temperature
80°C @ ≤ 30 psi (2 Kg/cm^2)

Maximum Differential Pressure
50 psi (3.5 Kg/cm^2) @ 25°C

Bubble Point
≥ 50psi (3.52 Kg/cm^2) with Water

Sterilization
In-line steam sterilizable at 135°C for 30 minutes at a maximum differential pressure of 3 psi (0.21 kg/cm^2), 25 cycles

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

Bacterial Endotoxin
Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Fiber Release
Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release

Particle Release:
The filtrate complies with USP <788> test for particulate matter in injections

TOC and Conductivity
Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a specified minimal flush

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>

Bioburden
Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 117371: 1995

Ordering Information

Type		Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiPrime KS 0.5µm Upstream	CKH7	5"*	53	0.2µm	01	7P	A0	Silicone	SS	Non-Sterile	1	1	01
		10"	54			7P without Fin	A1	Viton	SV				
		20"	55			28 with Fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV**				

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

**** FV is available in Adapter Code A0 (7P) and A1 (7P without fin) only**

Example

CKH7	56	01	A0	SS	1	01

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