Membrane Technologies

AseptiPrime KS
Large Polyethersulfone Membrane Capsule Filters

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

These are available in a wide range of sizes and end connections to suit a multitude of sterilization applications in biopharmaceuticals for process development, pilot scale and production batch sizes.

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
- Very low hold up volume in filters

Applications

Sterile Filtration of

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

Specifications

Pore Size
0.1 µm, 0.2µm

Membrane
Hydrophilic Polyethersulfone

Microbial Retention
0.1µm: LRV >7 for *Acholeplasma laidlawii* (ATCC 23206) per cm^2
0.2µm: LRV >7 for *B. diminuta* (ATCC 19146) per cm^2

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point
0.1µm: ≥31psi (2.18 Kg/cm^2) with 50% IPA/Water Solution
0.2µm: ≥ 50psi (3.51Kg/cm^2) with Water

Sterilization
By Gas: Sterilization by Ethylene Oxide
Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle. Can not be in-line steam sterilized

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

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

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 test as per USP

Oxidizable Substances
Within limits as specified in USP

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

Ordering Information

Type		Size		Pore Size		Inlet /Outlet		X	Inline/T-Line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
AseptiPrime KS 0.3µm Upstream	LKX9	5"*	53	0.1µm	36	1½" Triclover	E		Inline	X	Non-Sterile	1	1	01
		10"	54	0.2µm	01	Single Step ½" Hose Barb	Q		T-Line**	T	EO Sterile	2		
AseptiPrime KS 0.5µm Upstream	LKX7	20"	55											
		30"	56											

***Size 5" is available in Inline Capsule filters only**
****T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections only**

Example

LKX9	56	01	EE	X	X	1	01

Note: 0.2µm capsule filters are available with 0.5µm pre-filter only

DATA SHEET