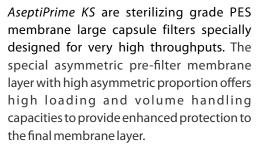


AseptiPrime KS Large Polyethersulfone Membrane Capsule Filters



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

 $0.1 \, \mu m, 0.2 \mu m$

Membrane

Hydrophilic Polyethersulfone

Microbial Retention

0.1μm: LRV >7 for Acholeplasma Particle Release:

laidlawii (ATCC 23206) per cm²

19146) per cm²

Maximum Operating Temperature

 $80 \,^{\circ}\text{C} \,@ < 30 \,\text{psi} \,(2 \,\text{Kg/cm}^2)$

Maximum Differential Pressure

60 psi (4 Kg/cm²) @ 30 °C

Bubble Point

0.1µm: \geq 31psi (2.18 Kg/cm²) with 50%

IPA/Water Solution

0.2μm: ≥ 50psi (3.51Kg/cm²) 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

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

The filtrate complies with USP <788> **0.2μm:** LRV >7 for *B. diminuta* (ATCC 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

**T-Line is not available in 5" capsule filters

***1" hose barb connection is not available in 5" capsule filter

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

Ordering Information

Туре		Size		Pore Size		Inlet /Outlet		Х	Inline/T-Line		Sterility		Pack :	
	Code		Code		Code		Code			Code		Code		
AseptiPrime KS 0.3µm Upstream	LKX9	5″*	53	0.1µm	36	1½" Sanitary Flange	Е		Inline	Х	Non-Sterile	1	1	ſ
		10"	54	0.2µm	01	Single Step ½" Hose Barb	Q		T-Line**	Т	EO Sterile	2		
AseptiPrime KS 0.5µm Upstream	LKX7	20"	55			3/4" Sanitary Flange****	S	*Size 5" is available in Inline Capsule filters only **T-line Capsule Filter are available with 11/2"Sanitary Flange I/O only					•	
		30"	56]		1" Hose Barb***	Z						only	

3/8" Hose Barb

****3/4" Sanitary Flange is available only in 5" and 10" capsule filters Example LKX9 56 01 Χ 01

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

Size Code 01