

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



Specifications

Membrane

Hydrophilic Polyethersulfone

Microbial Retention

LRV >7 for *Acholeplasma laidlawii* (ATCC 23206) per cm²

Maximum Operating Temperature

80°C @ ≤30 psi (2 Kg/cm²)

Maximum Differential Pressure

50 psi (3.5 Kg/cm²) @ 25°C

Bubble Point

≥ 31psi (2.18 Kg/cm²) with 50% IPA/Water Solution

Sterilization

In-line steam sterilizable at 135°C for 30 minutes at a maximum differential pressure of 3 psi (0.21 kg/cm²), 25 cycles

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Complies with USFDA 21 CFR 210.3(b)(6)

Meets and Exceeds USFDA 21 CFR 177.1520

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	Code	Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size		
			Code		Code		Code		Code		Code		Code	
AseptiPrime KS 0.3μm Upstream	CKH9	2.5"	50	0.1μm	36	4463	E0	Silicone	SS	Non-Sterile	1	1	01	
		5"	53			4463B	H0							
AseptiPrime KS 0.5μm Upstream	CKH7					4440	U0							
						Seal-K	G0*							
						Seal-O	F0*							
						Seal-M	J0							

*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

CKH7	53	36	E0	SS	1	01
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