0.2 µm *AseptiPrime KS* Hydrophilic PES Membrane Inline Capsule Filters

AseptiPrime KS are sterilizing grade PES membrane capsule filters specially designed for very high throughput.

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.

AseptiPrime KS filters meet key process requirements such as absolute retention, high protein recoveries and low extractables.

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

Applications

Sterile Filtration of

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

Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables
- Very low hold up volume in filters

Specifications

Construction			
Pore Size		0.2µm	
Membrane		Double layered Polyethersulfone with highly asymmetric prefilter membrane	
Plastic Components		Polypropylene	
Size			
Size		25 mm	50 mm
Effective Filtration Area (Nominal)		5 cm^2	20 cm^2
Integrity Testing/Retention			
Bubble Point (with Water)		≥ 50psi (3.52 Kg/cm^2)	
Microbial Retention		LRV>7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2	
Operational			
Max. Operating Temperature		55 °C	60 °C
Max. Differential Pressure		75 psi (5 Kg/cm^2 @25°C)	42 psi (3 Kg/cm^2) @ 30 °C
Sterilization	By Irradiation	Sterilizable by Ethylene Oxide	
	By Autoclave	Autoclavable at 125°C for 30 minutes, 25 cycles. Cannot be in-line steam sterilized	
Assurance			
Bacterial Endotoxin		Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Toxicity		Passes Biological reactivity Test, *In Vivo*, as per USP <88> for Class VI plastics	
Cytotoxicity		Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity	

DATA SHEET

Assurance	
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 flushing with a specified volume of WFI
Extractables with WFI	Passes NVR test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>
pH Compatibility	Compatible with pH range of 1-10
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1: 1995

Ordering Information

25 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiPrime KS (0.5µm optimized pre-filter)	IKX7	25mm	06	0.2 µm	01	⅛" Hose Barb	H	⅛" Hose Barb	H			Non Sterile	1	100	04
						¼" Hose Barb	B	¼" Hose Barb	B			EO Sterile	2		
						Female Luer Lock	M	Male Luer Slip	N						
								Male Luer Lock	L						

Example:

IKX7	06	01	M	N	X	X	1	04

Example for Non Sterile: IKX70601MNXX104 **Example for EO Sterile:** IKX70601MNXX204

50 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiPrime KS (0.5µm optimized pre-filter)	VKX7	50 mm	10	0.2 µm	01	¼" SHB	B	¼" SHB	B			Non Sterile	1	10	02
						¾" Sanitary Flange	S	¾" Sanitary Flange*	S			EO Sterile	2	100	04

*In vented *AseptiPrime KS* ¾" Sanitary Flange is available as outlet only

Example:

VKX7	10	01	S	S	X	X	1	04

Example for Non Sterile: VKX71001SSXX104 **Example for EO Sterile:** VKX71001SSXX204

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