

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

It incorporates a highly asymmetric PES membrane prefilter to provide enhanced protection to the well proven and widely accepted sterilization grade final mdi PES membrane.

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.

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

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

Pore Size

0.2µm

Membrane

Double layered Polyethersulfone with highly asymmetric prefilter membrane

Microbial Retention

LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm²

Maximum Operating Temperature

80°C @ ≤30 psi (2 Kg/cm²)

Maximum Differential Pressure

60 psi (4 Kg/cm²) @ 30°C

Bubble Point

≥ 50psi (3.51 Kg/cm²) with Water

Sterilization

Autoclave: Autoclavable at 125°C for 30 minutes, 3 cycles. Can not be in-line steam sterilized

Gas: Sterilization by Ethylene Oxide

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

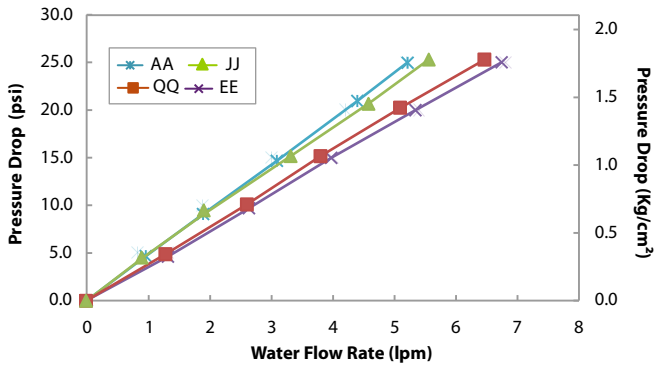
Passes test as per USP <1231>

Bioburden

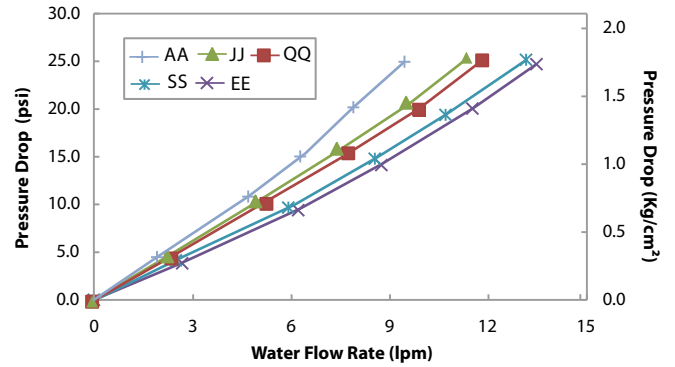
Bioburden level is <1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1:1995

Typical Water Flow Rates

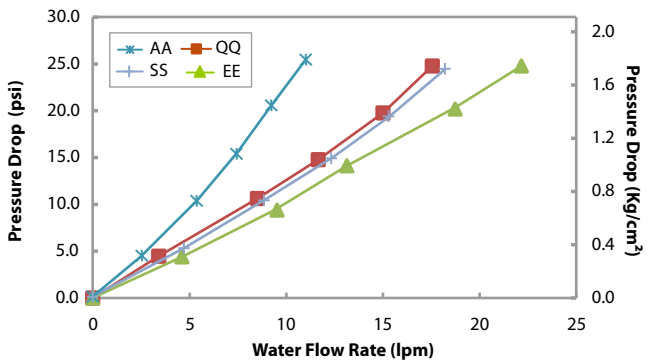
0.2 μm AseptiPrime KS, 1" Capsule Filters



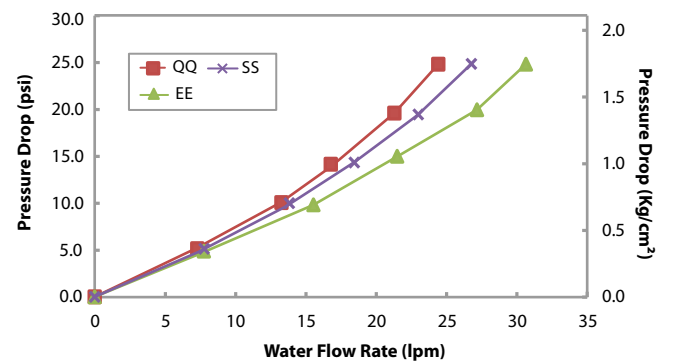
0.2 μm AseptiPrime KS, 2" Capsule Filters



0.2 μm AseptiPrime KS, 5" Capsule Filters



0.2 μm AseptiPrime KS, 8" Capsule Filters



End Connection Type:

A: 1/4" Stepped Hose Barb **Q:** Single Step 1/2" Hose Barb **E:** 1 1/2" Sanitary Flange **J:** Quick Connector **S:** 3/4" Sanitary Flange

Ordering Information

Type	Size		Pore Size		Inlet /Outlet		X	Bell		Sterility		Pack Size	
	Code	Code	Code	Code	Code	Code		Code	Code	Code	Code	Code	
AseptiPrime KS 0.5μm Asymmetric Upstream	DKX7	1"	51	0.2μm	01	1/4" SHB	A	Yes****	B	Non-Sterile	1	1	01
		2"	52			1/2" Hose Barb	D				EO Sterile		
		5"	53			1.5" Triclover	E			No		X	
		8"	57			3/4" Sanitary Flange	S						
						Quick Connector	J						
						Single Step 1/2" Hose Barb*	Q						
						Female Luer Lock	U						
						Male Luer Slip**	W						
						3/16" Hose Barb***	N						
						3/8" Hose Barb*	I						

*1" capsule filter is not available with Single Step 1/2" Hose Barb and 3/8" hose barb connection
 **Male luer slip end connection is available as outlet only in 1" capsule filters
 ***3/16" hose barb end connection is available in:
 - 1" and 2" capsule filters as inlet and outlet
 - 5" as outlet only
 ****Bell or Bell with Cover is available with
 - 1/4" outlet in 1" capsule filters only.
 - 1/2" Hose Barb outlet connections in 1", 2", 5" and 8" capsule filters

Example

DKX7	53	01	DD	X	X	1	01
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