

Large Polyethersulfone Membrane Capsule Filters

mdi AseptiCap KSO-γ are gamma sterilizable polyethersulfone membrane capsule filters offering wide pH (1-14) compatibility. These filters are specially designed for alkaline fluid streams in bio-pharma manufacturing processes, with added advantages of high throughputs and low hold up volumes.

These capsule filters offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughputs.

AseptiCap KSO-γ are validated for use in pharmaceutical and bio-pharmaceutical applications.

Application

- ◆ Bioburden removal from cell harvest supernatants
- ◆ Sterilization of bio-pharmaceuticals such as vaccines and therapeutic proteins
- ◆ Sterilization of oncology drugs
- ◆ Sterilization of buffers

Special Features

- ◆ Wide pH compatibility (1-14)
- ◆ Absolute retention
- ◆ Low protein binding
- ◆ No Elastomer seals
- ◆ Light weight and self supporting
- ◆ Minimum cleaning requirement and low installation cost
- ◆ Low hold up volume
- ◆ Very high flow rates
- ◆ 100% Integrity tested
- ◆ Total traceability



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

Specification

Maximum Differential Pressure
4 Kg/cm² @ 30 °C

Maximum Operating Temperature
80 °C @ ≤ 2 Kg/cm²

Sterilization
Gamma Irradiatable upto 50 kGy. These filters should not be autoclaved or in-line steam sterilized.

Bacterial Retention
0.2µm: LRV > 7 for *B. diminuta* ATCC 19146 per cm² of filter area
0.45µm: LRV > 7 for *S. marcescens* ATCC 14756 per cm² of filter area

Oxidizable Matter
Passes test as per USP <1231>

Fiber Release
Complies with USFDA CFR Title 21, 210.3 (b) (6)

Particle Release
The filtrate complies with USP <788> test for particulate matter in injections

Biosafety
Passes Biological Reactivity test, *In-Vivo*, as per USP <88> for Class VI plastics

TOC (Total Organic Carbon)
Meets the WFI requirements of USP <643> for Total Organic Carbon after flush with specified volume of WFI

Conductivity
Meets the WFI requirements of USP <645> for Conductivity after flush with specified volume of WFI

Material of Construction

Housing : Polypropylene
Filter Media : Polyethersulfone Membrane
Support Layer : Polypropylene

Integrity Test Data

Water Wetted Bubble Point

Pore Size	psi	Kg/cm ²
0.2 µm	≥ 50	≥ 3.52
0.45 µm	≥ 30	≥ 2.11

Air Diffusion Flow (DI Water Wetted)

Pore Size	Test Pressure	Max. Air Diffusion Flow
0.2 µm	2.60 Kg/cm ²	≤30 ml/min
0.45 µm	1.54 Kg/cm ²	≤45 ml/min

Typical Water Flow Rate (per 10" Capsule Filter)

Pore Size	Water Flow Rate @ 0.7 kg/cm ² @ 27 °C
0.2µm	40 litres per minute
0.45µm	65 litres per minute

Ordering Information

Type	Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/T-line		Sterility		Pack Size		
	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code	Code		
AseptiCap KSO-γ (0.45µm Upstream)	LK0X	5"	53	0.2µm	01	1½" Sanitary Flange	E	Yes	R	Inline	X	Non-Sterile	1	1	01
		10"	54	0.45 µm	02	¾" Sanitary Flange	S	No*	X	T-line	T	Gamma Sterile	3		
AseptiCap KSO-γ (0.8µm Upstream)	LK05	20"	55			Single Step ½" Hose Barb	Q	*Gamma Sterile Capsule Filters cannot be gamma irradiated again 0.45µm upstream layer is not available with 0.45µm pore size T-Line Capsule filters are available with 1½" Sanitary Flange only 5" Capsule Filters are not available with T-Line ¾" Sanitary Flange is available only in 5" and 10" capsule filters							
		30"	56			¾" Hose Barb	I								
						1" Hose Barb	Z								

Example:

	LK05		56		01		EE		X		X		3		01
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Example for Non Sterile: LK0X5401EERX101

Example for Gamma Sterile: LK0X5401EEX301

DST LK0XRX1501L