

Polyethersulfone Membrane Capsule Filters

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

Application

- ◆ Scale up of new drug delivery systems
- ◆ Bioburden removal from cell harvest supernatants
- ◆ Sterilization of bio-pharmaceuticals such as vaccines and therapeutic proteins
- ◆ Sterilization of oncology drugs
- ◆ Sterilization of buffers

Material of Construction

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

Ordering Information

Type	Code	Size	Pore Size		Inlet/Outlet			X	X	Sterility		Pack Size	
			EFA	Code	Code	Code	Code			Code	Code		
AseptiCap KSO (0.45µm Upstream)*	DKOX	1"	100 cm ²	31	0.2µm	01	1/4" SHB	A	1	1	1	01	
			250 cm ²	51	0.45 µm	02	1/2" Hose Barb	D					
AseptiCap KSO (0.8µm Upstream)	DKO5	2"	500 cm ²	52			1½ Sanitary Flange	E					
			1000 cm ²	53			3/4" Sanitary Flange	S					
			2000 cm ²	57			Quick Connector	J					
							Single Step ½" Hose Barb**	Q					
							Female Luer Lock	U					
							Male Luer Slip***	W					
							3/16" Hose Barb****	N					
							3/8" Hose Barb**	I					

Example:

DKOX	52	01	EE	X	X	1	01
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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

By Autoclave: Autoclavable at 125° C for 30 minutes, 25 cycles. Cannot be inline steam sterilized

By Gas: Sterilization by Ethylene Oxide

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 a 3 liter WFI flush

Conductivity

Meets the WFI requirements of USP <645> for Conductivity after a 3 liter WFI flush

Special Features

- ◆ Wide pH compatibility (1-14)
- ◆ Absolute retention
- ◆ Low protein binding
- ◆ Light weight and self supporting
- ◆ Low hold up volume
- ◆ Very high flow rates
- ◆ 100% Integrity tested
- ◆ Total traceability

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

Typical Water Flow Rate : 0.2 µm Capsule Filter

