AseptiCap KSO Polyethersulfone Membrane Capsule Filters

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

Special Features

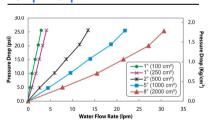
- ♦ Wide pH compatibility (1-14)
- Absolute retention
- Low protein binding
- ♦ Light weight and self supporting
- ♦ Low hold up volume
- Very high flow rates
- ♦ 100% Integrity tested
- ♦ Total traceability

Integrity Test Data

Water Wetted Bubble Point

Pore Size	psi	Kg/cm²		
0.2 µm	≥ 50	3.52		
0.45 μm	≥ 30	2.11		

Typical Water Flow Rate : 0.2 µm Capsule Filter



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 $^{\circ}$ C @ \leq 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

Х

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

Ordering Information

Туре		Size		Pore Size		Inlet/Outlet		
	Code		EFA	Code		Code		Code
AseptiCap KSO (0.45µm Upstream)*	DKOX	1"	100 cm ²	31	0.2µm	01	1/4" SHB	Α
		'	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
		5"	1000 cm ²	53			3/4" Sanitary Flange	S
	•	8"	2000 cm ²	57	1		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 Barh**	1

Χ	Sterilit	Pack Size		
		Code		Code
	Non-Sterile	1	1	01
	EO Sterile	2		

*0.45µm upstream layer is not available with 0.45µm pore size
**Single Step ½" Hose Barb and 3/8" Hose Barb connections are
not available in 1" capsule filters

Male Luer Slip is available only in 1" capsule filter as outlet *3/16" hose barb end connection is available in:

- 1" and 2" capsule filters as inlet and outlet

- 5" as outlet only

Example:							
DKOX	52	01	EE	Χ	Х	1	01

DST DKOXXXX1520C