

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 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- γ 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

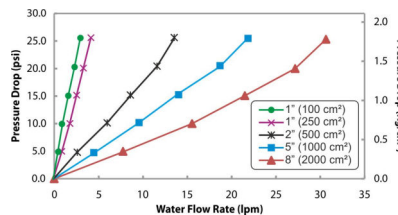
- ◆ Wide pH compatibility (1-14)
- ◆ Absolute retention
- ◆ Low protein binding
- ◆ Light weight and self supporting
- ◆ Low hold up volume
- ◆ Very high flow rates
- ◆ 100% Integrity tested
- ◆ Total traceability

Integrity Test Data

Water Wetted Bubble Point

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

Typical Water Flow Rate : 0.2 μ m 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 °C @ ≤ 2 Kg/cm²

Sterilization

By Irradiation: Gamma Irradiatable upto 50 kGy

Bacterial Retention

0.2 μ m: LRV > 7 for *B. diminuta* ATCC 19146 per cm² of filter area
0.45 μ m: 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 the Biological Reactivity tests for Class VI plastics as per USP <88>

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.

Ordering Information

Type	Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code	EFA	Code	Code	Code	Code	Code	Code		Code	Code	Code	Code
AseptiCap KSO- γ (0.45 μ m Upstream)	DKOX	1"	100 cm ²	31	0.2 μ m	01	1/4" SHB	A	Yes	R	Non-Sterile	1	01
			250 cm ²	51	0.45 μ m*	02	1/2" Hose Barb	D	No*****	X			
AseptiCap KSO- γ (0.8 μ m Upstream)	DKO5	2"	500 cm ²	52			1 1/2" Sanitary Flange	E			Gamma Sterile	3	
		5"	1000 cm ²	53			3/4" Sanitary Flange	S					
		8"	2000 cm ²	57			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							

*0.45 μ m pore size is available with 0.8 μ m upstream only
 **Single Step 1/2" Hose Barb and 3/8" Hose Barb end connections are not available 1" capsule filters
 ***Male Luer Slip end connections 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
 *****Gamma Sterile Capsule Filters cannot be gamma irradiated again

Example:

DKOX	52	01	EE	R	X	1	01
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