

## Polyethersulfone Membrane Capsule Filters

**mdi** AseptiCap KSO- $\gamma$  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- $\gamma$  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

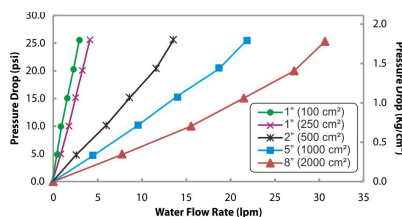
- ◆ Wide pH compatibility (1-14)
- ◆ Absolute retention
- ◆ Low protein binding
- ◆ Light weight and self supporting
- ◆ Low hold up volume
- ◆ Very high flow rates
- ◆ 100% Integrity tested
- ◆ Total traceability

### Integrity Test Data

#### Water Wetted Bubble Point

Pore Size	psi	Kg/cm <sup>2</sup>
0.2 $\mu$ m	$\geq 50$	3.52
0.45 $\mu$ m	$\geq 30$	2.11

### Typical Water Flow Rate : 0.2 $\mu$ 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/cm<sup>2</sup> @ 30 °C

**Maximum Operating Temperature**  
80 °C @  $\leq 2$  Kg/cm<sup>2</sup>

#### Sterilization

**By Irradiation:** Gamma Irradiatable upto 50 kGy

**By Autoclave:** Autoclavable at 125 °C for 30 minutes, 1 cycle after gamma irradiation. Cannot be in-line steam sterilized.

#### Bacterial Retention

**0.2 $\mu$ m:** LRV > 7 for *B. diminuta* ATCC 19146 per cm<sup>2</sup> of filter area

**0.45 $\mu$ m:** LRV > 7 for *S. marcescens* ATCC 14756 per cm<sup>2</sup> 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- $\gamma$ (0.45 $\mu$ m Upstream)	DKOX	1"	100 cm <sup>2</sup>	31	0.2 $\mu$ m	01	1/4" SHB	A	Yes	R	Non-Sterile	1	1	01
			250 cm <sup>2</sup>	51	0.45 $\mu$ m*	02	1/2" Hose Barb	D	No****	X				
AseptiCap KSO- $\gamma$ (0.8 $\mu$ m Upstream)	DKO5	2"	500 cm <sup>2</sup>	52			1 1/2" Sanitary Flange	E			Gamma Sterile	3		
		5"	1000 cm <sup>2</sup>	53			3/4" Sanitary Flange	S						
		8"	2000 cm <sup>2</sup>	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 $\mu$ m pore size is available with 0.8 $\mu$ 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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