Polyethersulfone Membrane

Bioburden Reduction Small Capsule Filters

The *BioPro KSO-γ* is designed for protecting your critical and high value downstream systems.

It helps in significant reduction of bioburden and complete removal of particulate contamination. It is ideal for applications which do not require sterilization but where reduction in bio load in the process fluid is the objective.

It improves the process efficiency by reducing filter sizing and prolonging life of expensive sterilizing filters.

These filters provide easy scalability from process development labs to actual manufacturing processes.

Special Features

- Validated for high bio-burden reduction
- High flow rates
- · High throughput
- Low protein binding
- No media migration
- · Biologically inert
- Easy installation

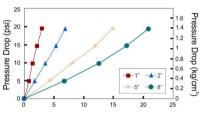
Applications

- Clarification of cell harvest
- Buffer filtration
- In process protein filtration
- Prefiltration to sterile filtration
- Prefiltration to virus filtration

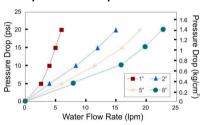
mdi manaman

Typical Water Flow Rates

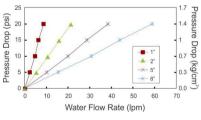
0.1μm BioPro KSO-γ



0.2μm BioPro KSO-y



0.45μm BioPro KSO-γ



Specifications

Integrity Test (Bubble Point) Specifications (water wetted) 0.1 μ m: \geq 40psi, 0.2 μ m: \geq 30psi

Bacterial Retention

0.1μm: LRV> 6 for *B.diminuta* ATCC

19146 per cm² of filter area

0.2μm: LRV> 5 for *B.diminuta* ATCC 19146 per cm² of filter area

Material of Construction

Housing – Polypropylene Filter – Polyethersulfone Drainage Layer-Polyethylene

Maximum Differential Pressure

 \leq 4 Kg/cm² @ 30° C

Maximum Operating Temperature

 $80^{\circ} \text{ C } @ < 2 \text{ Kg/cm}^2$

Sterilization

Irradiation	Gamma irradiatable upto 50 kGy						
Autoclave	Autoclavable at 125° C for 30 minutes, 1 cycle after gamma Irradiation. Cannot be in-line steam sterilized.						

Oxidizable Matter

Passes test as per USP <1231>

Extractables

Passes NVR test as per USP <661>

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by LAL Test as per USP <85>

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

Toxicity: Passes Bioreactivity test, *In-vivo*, as per USP <88> for Class VI plastics

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

pH Compatibility:

Compatible with 1-14 pH

Ordering Information

Туре		Size		Pore Size		I/O Connection		Radiation Sterilizable		X	Sterility	Pack Size		c Size	
	Code		Code		Code		Code		Code			Code	Qty	Code	
BioPro KSO	DBKO	1″	51	0.1µm	36	1/4" SHB	Α	Yes	R		Non Sterile	1	1	01	
		2″	52	0.2μm	01	1/2"Hose Barb	D	No****	Х]	Gamma Sterile	3			
		5″	53	0.45µm	02	1½" Sanitary Flange	E	*C:I-	C+ 1/ // 1	D.		ded			
		8″	57			¾" Sanitary Flange	S	*Single Step ½"Hose Barb and 3/8" hose barb end connections are not available in 1" capsule filters **Male luer slip is available only in 1" capsule filter as outlet					s are not		
						Quick Connector	J								
						Single Step ½"Hose Barb*	Q	***3/16" hose barb end connection is available in:							
Female Lu							U		- 1" and 2" capsule filters as inlet and outlet						
						Male Luer Slip**	W		as outlet o						
3/16" Hose Barb*** N ****Gamma Sterile ca									e caps	sule filters cannot be gamma Irradiated again					
Example:						3/8" Hose Barb*	I								
DBK	0		57	0	1	EE		X X 3 01				01			

DST DBKORXX1500C