

Polyethersulfone Membrane Bioburden Reduction Small Capsule Filters

The *BioPro KS-y* 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

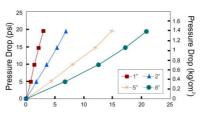
Applications

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

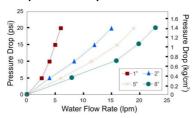


Typical Water Flow Rates

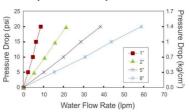
0.1μm BioPro KS-y



0.2μm BioPro KS-y



0.45μm BioPro KS-y



Specifications

Integrity Test (Bubble Point)
Specifications (water wetted)
0.1µm: ≥ 40psi, 0.2µm: ≥ 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-Polyester

Maximum Differential Pressure < 4 Kg/cm² @ 30° C

Maximum Operating Temperature 80° C @ < 2 Kg/cm²

Sterilization by Gamma IrradiationGamma irradiatable upto 50 kGy

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, *Invivo*, as per USP <88> for Class VI plastics

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

Ordering Information

Туре		Size		Pore Size		I/O Connection		Radiation Sterilizable		х	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code	Qty	Code
BioPro KS	DBKS	1″	51	0.1µm	36	1⁄4" SHB	Α	Yes	R		Non Sterile	1	1	01
		2"	52	0.2µm	01	½″Hose Barb	D	No****	Х		Gamma Sterile	3		
		5"	53	0.45µm	02	1½" Sanitary Flange	E							
		8″	57			¾" Sanitary Flange	S			Hose Barb and 3/8" Hose Barb connections are not				
						Quick Connector	J		available in 1" capsule filters **Male luer slip is available only in 1" capsule filter as outlet					
						Single Step ½"Hose Barb*	Q				connection is availab		itiet	

			Single Step /2 mose bank	٧.	"""3/16 nose parb end connection is available in:					
			Female Luer Lock	U	- 1" and 2" capsule filters as inlet and outlet - 5" as outlet only					
Example:				Male Luer Slip**						
			3/16" Hose Barb***	N	****Gamma Sterile	****Gamma Sterile Capsule Filters cannot be gamma Irradiated again				
				3/8" Hose Barb*	I					
	DBKS	57	01	EE		Х	Х	3	01	