

# 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

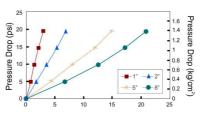
# **Applications**

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

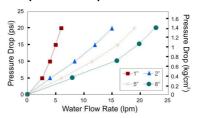


# **Typical Water Flow Rates**

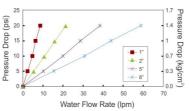
# 0.1μm BioPro KS-γ



0.2μm BioPro KS-y



0.45μm BioPro KS-γ



# **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 cm<sup>2</sup> of filter area

**0.2μm:** LRV> 5 for *B.diminuta* ATCC

19146 per cm<sup>2</sup> of filter area

#### **Material of Construction**

Housing – Polypropylene Filter – Polyethersulfone Drainage Layer-Polyester

# Maximum Differential Pressure

 $\leq$  4 Kg/cm<sup>2</sup> @ 30° C

# **Maximum Operating Temperature** 80° C @ < 2 Kg/cm<sup>2</sup>

Sterilization by Gamma Irradiation

Gamma Irradiatable upto 50 kGy. These filters should not be autoclaved or 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

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

- 5" as outlet only

**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

# **Ordering Information**

Type		Size		Pore Size		I/O Connection		Radiation Sterilizable		X	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 %" Sanitary Flange S *Single Step ½" Hose Barb and 3/8" Hose I					Barb con	nections	are not							
						Quick Connector	J	J 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:							
						Single Step ½"Hose Barb*	Q								

#### Example

DBKS

 p		
3/16" Hose Barb***	N	****Gamma Sterile Capsule Filters cannot be gamma Irradiated again
3/8" Hose Barb*	I	

Female Luer Lock

Male Luer Slip\*