SZV Series Dual Layer PES Filter Capsules

SKV Series Dual Layer PES filter capsule with all polypropylene construction provides excellent chemical compatibility and superior flow per unit area as compared to other membrane capsules. The PES filter capsules have been specially designed for sterilizing in biopharmaceutical applications. The filters come with pre layer configuration, which increases the filtration volume significantly. The hydrophilic PES membrane does not require pre-wetting agents, thereby eliminating a potential source of contamination. The PES membrane is a low protein binding media. The capsules were designed with built-in bleed valves for simple and efficient evacuation of air and liquid. The units are used for filtration of small to medium volumes used in production, laboratory, and pilot runs. No adhesives, binders, or surfactants are used in the manufacturing process of these capsules. All filter capsules are 100% integrity tested to ensure filter performance.

Application

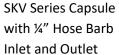
Buffers and Media Product Sterilization Fermentation Broths

SVP (Small Volume Parenteral) Bio Bags Pharmaceuticals

Vaccines Biologics Antibiotics

Scale up processing Water Serums





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Technical Data Sheet

Popular Configuration:

Catalog Number	Micron Rating	Inlet	Outlet	Vent Connection	Sterilization
		Connection	Connection		
SKVS045020_TCTC-ETO	0.45 μm / 0.2	½" Tri-Clamp	½" Tri-Clamp	Bleed Valve with	ETO
	μm			1/8" Hose Barb	Sterilized
	(Dual Layer)				
SKVDS065020_TCTC-ETO	0.65 μm / 0.2	½" Tri-Clamp	½" Tri-Clamp	Bleed Valve with	ETO
	μm			1/8" Hose Barb	Sterilized
	(Dual Layer)				
SKVS080020_TCTC-ETO	0.8 μm / 0.2 μm	½" Tri-Clamp	½" Tri-Clamp	Bleed Valve with	ETO
	(Dual Layer)			1/8" Hose Barb	Sterilized

- ❖ The blank space is for filter size code. Find the codes below.
- Find the complete list of available standard inlet and outlet fittings in page 4.

Filter Size Codes:

Filter Size Code	Filtration area (cm²)	Body Length Without Fittings (mm)	Body Diameter (mm)
Н	680	56	73
S	1300	84	73
L	2600	141	73
E	3900	210	73
К	5200	265	73

Materials of Construction

Media: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade - Hydrophilic

Media Supports: Polypropylene

Cage, Core, End Caps: Polypropylene

Valve O-Rings: Silicon (Standard)

Sealing: Thermally End Capping

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point (at 22° C) of 50 psi (3.5 bar) in water.



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Operating Conditions:

Maximum Forward Differential Pressure: Liquid: 5.5 bar (80psi) at 77°F/25°C

Gas: 4.1 bar (60psi) at 77°F/25°C

Minimum Burst Pressure: 8.3 bar (120psi) at 77°F/25°C

Maximum Forward Differential Pressure: 5 bar (72psi) at 68°F/20°C Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

Maximum Operating Temperature: 176°F/80°C

Regulatory Compliance:

The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological Test for Plastic.

Filter Integrity:

The finished product was sampled and shown to exhibit a bubble point of 3.5 bar (50 psi) using air at 22°C.

USP Bacterial Endotoxins:

The filters were tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test

USP Conductivity:

Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

Bacterial Retention:

The filters are quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of 10^7 CFU per cm^2 of filtration area, consistent with ASTM F838-05

Sterilization:

Capsules can be autoclaved 25 times at 125 °C (257°F) for 30 minutes or chemically sanitized in situ using common sanitizing agents or hot water at 90 °C (194°F) for a limited time (dependent on time and temperature). *Waring:* The filters cannot be sterilized by steam-in-place (SIP)

ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic

ASTM Hemolysis:

Extract from this product is non-Hemolytic

Shelf Life:

The SKV capsules have a shelf life of 3 years from the date of manufacture.

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Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

Micron Rating Option:

- 0.04 Micron
- 0.1 Micron
- 0.2 Micron
- 0.45 Micron
- 0.65 Micron
- 0.8 Micron
- 1.2 Micron

Seal Option:

- Silicone
- EPDM
- Nitrile
- Viton

Inlet Fitting Option:

- 1H = 1/8" Hose Barb
- 1Q = 1/8" Male Quick Coupling with Metal Latch
- 2H = 1/4" Hose Barbs
- 2HS = 1/4" to 3/8 " Hose Barb
- 2Q = 1/4" Male Quick Coupling for Metal Latch
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 4Q = 1/2" Male Quick Coupling for Plastic latch
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

Outlet Fitting Option:

- 1H = 1/8" Hose Barb
- 1Q = 1/8" Male Quick Coupling with Metal Latch
- 2H = 1/4" Hose Barbs
- 2HS = 1/4" to 3/8 " Hose Barb
- 2Q = 1/4" Male Quick Coupling for Metal Latch
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 4Q = 1/2" Male Quick Coupling for Plastic latch
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

