SKV Series PES 0.8µm/0.2µm – Dual Layer 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 (up to 25%). 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 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. The filters are manufactured in accordance with GMP and comply with <USP 797> guidelines. The filters are flushed with pharmaceutical-grade purified pyrogens-free water, and 100% integrity tested prior to dispatch. Our filters and free from animal-derived components raw materials can be traced by Lot Number and strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

SKV Mid-Size Filter Capsules with various Inlet/Outlet Connections



- Buffers and Media
- > SVP (Small Volume Parenteral)
- Vaccines
- Scale up processing

Application

- Product Sterilization
- Bio Bags Compatible
- Biologics
- Ultrapure Water

- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- Serums



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Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 µm PES [Sterilizing Grade Membrane]

Pre-Filter: 0.8 µm PES

Effective Filtration Area:

H-Size; $0.73 ft^2$, $(680 cm^2)$

S-Size; 1.35 ft^2 , (1,250 cm^2)

L-Size; 2.74 ft^2 , (2,550 cm^2)

E-Size; 4.13 ft^2 , (3,840 cm^2)

K-Size; 5.47 ft^2 , (5,080 cm^2)

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

Membrane Feature: Hydrophilic, Low Protein Binding, High Flow Rate

Shell, Cage, Core, End Caps: Polypropylene

Valve O-Rings: Silicone (Standard)

Sealing: Thermally Bonded

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

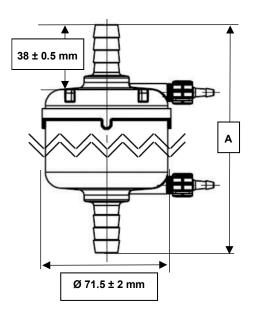
Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

Maximum Operating Temperature: 176°F/80°C



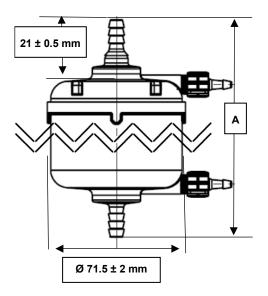


Nominal Dimension:



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
SKVS080020 H 4H4H-ETO	1.5"	½" Hose Barb	½" Hose Barb	1/8" Vent Valve	127 mm
SKVS080020 S 4H4H-ETO	2.5"	½" Hose Barb	½" Hose Barb	1/8" Vent Valve	155 mm
SKVS080020 L 4H4H-ETO	5.0"	½" Hose Barb	½" Hose Barb	1/8" Vent Valve	212 mm
SKVS080020 E 4H4H-ETO	7.5"	½" Hose Barb	½" Hose Barb	1/8" Vent Valve	276 mm
SKVS080020 K 4H4H-ETO	10.0"	½" Hose Barb	½" Hose Barb	1/8" Vent Valve	340 mm

4H4H Connections



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
SKVS080020 H 3H3H-ETO	1.5"	3/8" Hose Barb	3/8" Hose Barb	1/8" Vent Valve	120 mm
SKVS080020 \$ 3H3H-ETO	2.5"	3/8" Hose Barb	3/8" Hose Barb	1/8" Vent Valve	148 mm
SKVS080020 L 3H3H-ETO	5.0"	3/8" Hose Barb	3/8" Hose Barb	1/8" Vent Valve	205 mm
SKVS080020 E 3H3H-ETO	7.5"	3/8" Hose Barb	3/8" Hose Barb	1/8" Vent Valve	269 mm
SKVS080020 K 3H3H-ETO	10.0"	3/8" Hose Barb	3/8" Hose Barb	1/8" Vent Valve	333 mm

3H3H Connections





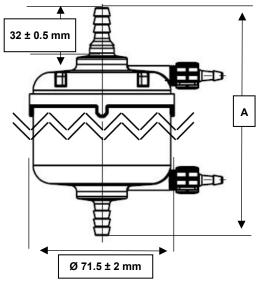






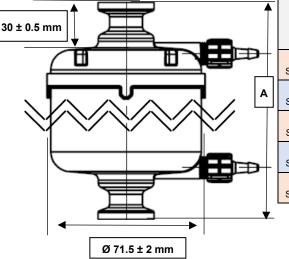
International Filter Products

Revolutionary systems for your industry



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
SKVS080020 H 2H2H-ETO	1.5"	1⁄4" Hose Barb	1/4" Hose Barb	1/8" Vent Valve	112 mm
SKVS080020 S 2H2H-ETO	2.5"	1/4" Hose Barb	1/4" Hose Barb	1/8" Vent Valve	140 mm
SKVS080020 L 2H2H-ETO	5.0"	1/4" Hose Barb	1/4" Hose Barb	1/8" Vent Valve	197 mm

2H2H Connections



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
SKVS080020 H MTMT-ETO	1.5"	0.5" Tri-Clamp	0.5" Tri-Clamp	1/8" Vent Valve	98 mm
SKVS080020 S MTMT-ETO	2.5"	0.5" Tri-Clamp	0.5" Tri-Clamp	1/8" Vent Valve	126 mm
SKVS080020 L MTMT-ETO	5.0"	0.5" Tri-Clamp	0.5" Tri-Clamp	1/8" Vent Valve	183 mm
SKVS080020 E MTMT-ETO	7.5"	0.5" Tri-Clamp	0.5" Tri-Clamp	1/8" Vent Valve	247 mm
SKVS080020 K MTMT-ETO	10.0"	0.5" Tri-Clamp	0.5" Tri-Clamp	1/8" Vent Valve	311 mm

MTMT Connections





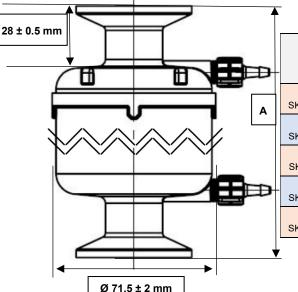






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	Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
	SKVS080020 H TCTC-ETO	1.5"	1-1/2" Tri-Clamp	1-1/2" Tri-Clamp	1/8" Vent Valve	110 mm
1	SKVS080020 S TCTC-ETO	2.5"	1-1/2" Tri-Clamp	1-1/2" Tri-Clamp	1/8" Vent Valve	138 mm
	SKVS080020 L TCTC-ETO	5.0"	1-1/2" Tri-Clamp	1-1/2" Tri-Clamp	1/8" Vent Valve	195 mm
۲	SKVS080020 E TCTC-ETO	7.5"	1-1/2" Tri-Clamp	1-1/2" Tri-Clamp	1/8" Vent Valve	259 mm
	SKVS080020 K TCTC-ETO	10.0"	1-1/2" Tri-Clamp	1-1/2" Tri-Clamp	1/8" Vent Valve	323 mm

MTMT Connections

Typical Filtered Volume:

Filter Size	Filter Area	Volume to be Filtered (Thru-Put in Liters)
SKV-H	680 cm ²	17.5 to 40
SKV-S	1250 cm ²	25 to 60
SKV-L	2550 cm ²	40 to 120
SKV-E	3840 cm ²	60 to 175
SKV-K	5080 cm ²	90 to 220

*Volume Filtered is an estimated range for Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by your solution's viscosity, active ingredients, etc., properties. The best way to determine the exact filtration volume per filter is to try it with your solution.







Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of ≥18 psi (1.2 bar) in 60%IPA / 40% water and ≥ 50 psi (3.5 bar) in DI Water (at 22%).

Sterilization:

International Filter Products Inc. mostly stocks ETO Sterilized (Factory Sterilized) Filter Capsules.

Ethylene Oxide (ETO) Sterilization Process complies with ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7. Each filter is subjected to a validated ETO process. Sterilization of the fluid path has been validated per ANSI/AAMI/ISO 11135 which provides a minimum sterility assurance level (SAL) of 10-6.

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).

Warning: The filters cannot be sterilized by steam-in-place (SIP)

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.

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

ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic

ASTM Hemolysis:

Extract from this product is non-Hemolytic

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, additional requirement of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

Animal-Derived Components & TSE/BSE Risk:

No animal-derived material is intentionally added or used during the manufacture of this product.

Shelf Life:

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

Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the distribution, handling, and 3-year shelf life of the product.









SKV - Series PES Mid-Size Capsules

(Pharmaceutical Grade)

Ordering Guide

S	[1] [2	[3] [4] [5]	
[1]	[2]	[3] Inlet and [4] Outlet	[5]
Micron Rating [Pre-Filter/Final Filter]	Filter Size Code [Filtration Area]	Inlet and Outlet Connection	Sterilization
 S020: 0.2 µm DS065S020: Highly Asymmetric 0.65/0.2 µm DS045S020: Highly Asymmetric 0.45/0.2 µm DS045S010: Highly Asymmetric 0.45/0.1 µm S080020: 0.8/0.2 µm S020010: 0.2/0.1 µm Note: All final membranes are sterilizing grade. 	• H [Filtration Area: 720 cm²] • S [Filtration Area: 1380 cm²] • L [Filtration Area: 2600 cm²] • E [Filtration Area: 3980 cm²] • K [Filtration Area: 5200 cm²]	 1H: 1/8" Hose Barb 2H: 1/4" Hose Barb 3H: 3/8" Hose Barb 4H: 1/2" Hose Barb 5H: 9/16" Hose Barb MT: 1/2" Tri-Clamp TC: 1 1/2" Tri-Clamp 	-ETO Ethylene Oxide Sterilization

Example:

SKVS080020S4H4H-ETO

PureFlo SKV Series Capsule, Dual Layer PES 0.8µm / 0.2µm PES membrane (Sterilizing Grade), 2.5", S-Size, Filtration Area 1,250 cm², ½" Hose Barb (Inlet/Outlet), ETO Sterilized (Factory Sterilized)

Part Number Description







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

Bleed Valve 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





