



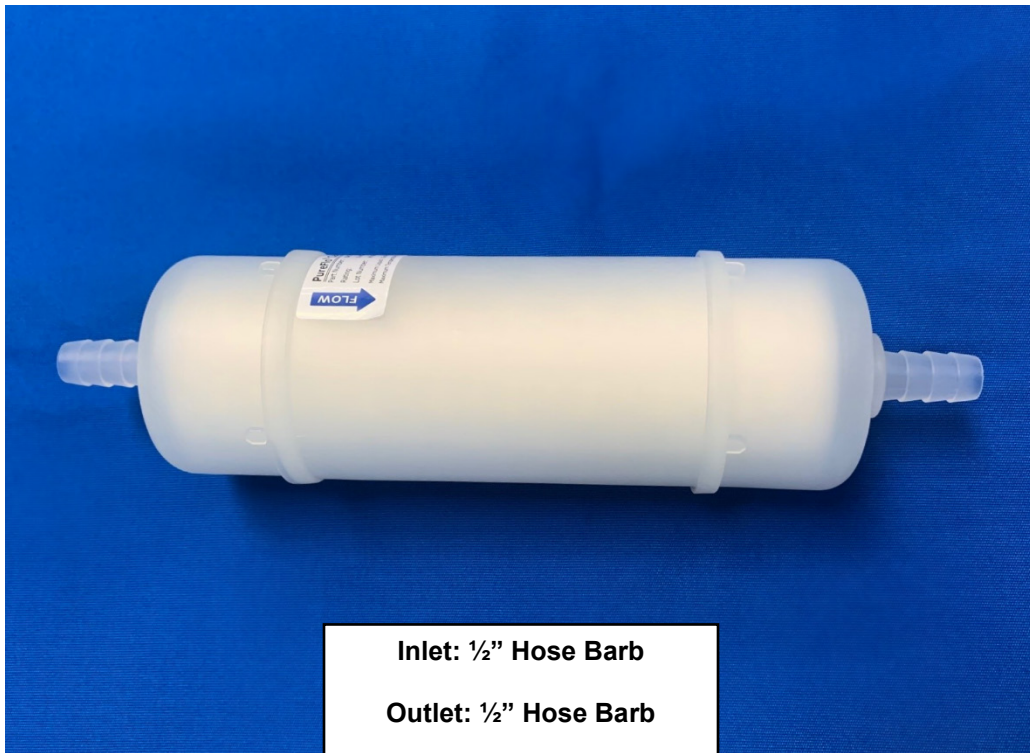
SKL Dual Layer Series PES Filter Capsules

SKL Dual Layer Series PES filters are designed for applications where sterility of the affluent is mandatory. The PES filter capsules have been specially designed for sterilizing in biopharmaceutical applications. The filters come with pre layer configuration. 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

SKL Series L-size Capsule with 1/2" Inlet & Outlet Connection





Technical Data Sheet

Popular Configuration:

Catalog Number	Internal Filter Length	Inlet Connection	Outlet Connection	Sterilization
SKLDS065S020L4H4H-PH-ETO	5.0"	1/2" Hose Barb	1/2" Hose Barb	ETO

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

Micron Rating:

Final Media: 0.2 µm

Pre-Filter: 0.65 µm Asymmetric PES

Effective Filtration Area:

2.8 ft² (2600 cm²)

Nominal Dimensions:

Lengths: 8.4" (215mm) with fittings

Diameter: 2.75" (70mm)

Operating Conditions:

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

Minimum Burst Pressure: >3.5 bar (50 psi) at 77°F/25°C

Recommended Replacement Pressure: 2.4 bar (35.3 psi)

Maximum Forward Differential Pressure: 4.1 bar (60psi) at 77°F/25°C

Maximum Reverse Differential Pressure: 2.1 bar (30psi) at 77°F/25°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.

Capsule Integrity:

The capsules meet the minimum burst pressure of 8.3 bar (120 psi) at 72°F/22°C

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.



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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:

The filters can be autoclaved up to 25 cycles at 125°C (257°F) for 30 minutes.

Warning: 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 SKL capsules have a shelf life of 3 years from the date of sterilization

Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

Size Option:

- H = 1.5" [Filtration Area: 720 cm^2]
- S = 2.5" [Filtration Area: 1380 cm^2]
- L = 5.0" [Filtration Area: 2600 cm^2]

Seal Option:

- EPDM
- Buna-N
- Viton

Micron Rating Option:

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





Inlet Fitting Option:

- 1H = 1/8" Hose barbs
- 1Q = 1/8" Male Quick Coupling with Metal latch
- 1QF = 1/8" Female Quick Coupling with Metal latch
- 2H = 1/4" to 1/2" Hose barbs
- 2HS = 1/4" to 3/8" Hose barbs
- 2P = 1/4" Push to Connect
- 2Q = 1/4" Male Quick Coupling for Metal latch
- 2QF = 1/4" Female Quick Coupling with Metal latch
- 3H = 3/8" Hose Barb
- 3H-FB = 3/8" Hose Barb with filling bell
- 4H = 1/2" Hose Barb
- 4Q = 1/2" Male Quick Coupling for Plastic latch
- LF = Luer Lock Female
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

Outlet Fitting Option:

- 1H = 1/8" Hose barbs
- 1Q = 1/8" Male Quick Coupling with Metal latch
- 1QF = 1/8" Female Quick Coupling with Metal latch
- 2H = 1/4" to 1/2" Hose barbs
- 2HS = 1/4" to 3/8" Hose barbs
- 2P = 1/4" Push to Connect
- 2Q = 1/4" Male Quick Coupling for Metal latch
- 2QF = 1/4" Female Quick Coupling with Metal latch
- 3H = 3/8" Hose Barb
- 3H-FB = 3/8" Hose Barb with filling bell
- 4H = 1/2" Hose Barb
- 4Q = 1/2" Male Quick Coupling for Plastic latch
- LM = Luer Lock Male
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

