



International Filter Products

Revolutionary systems for your industry

PureFlo® SKL Series PES 0.65 µm/0.2 µm – Dual Layer Filter Capsules

SKL Series Dual Layer PES filter capsule with gamma stable polypropylene construction provides excellent chemical compatibility and superior flow per unit area as compared to other membrane capsules. The filters can be Gamma Sterilized up to 50kGy. 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 35%). 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 luer loc caps for simple and efficient evacuation of air and liquid. The units are used for the 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. All filters are USP <797> compliant, manufactured in a Class 7 Cleanroom, following ISO 13485 standards, and include a **Complete Certificate of Conformance**.

PureFlo® SKL Filter Capsules



Catalog Number	Micron Rating	Inlet Connection	Outlet Connection	Vent Connection	Sterilization
SKLDS065S020SLFLM-PH-GP	0.65 µm / 0.2 µm (Dual Layer)	Luer Loc Female (Sterile Connection)	Luer Loc Male (Sterile Connection)	Luer Loc Cap	Can be Gamma Sterilized



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Application

- Buffers and Media
- SVP (Small Volume Parenteral)
- Vaccines
- Scale up processing
- Product Sterilization
- Bio Bags
- Biologics
- Ultrapure Water
- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- Serums

Technical Data Sheet

Micron Rating:

Final Media: 0.2 μm PES [Sterilizing Grade]

Pre-Filter: Highly Asymmetric 0.65 μm PES

Effective Filtration Area:

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

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

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

Media Supports: Polyester

Shell, Cage, Core, End Caps: Gamma Stable Polypropylene

Valve O-Rings: Silicon (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



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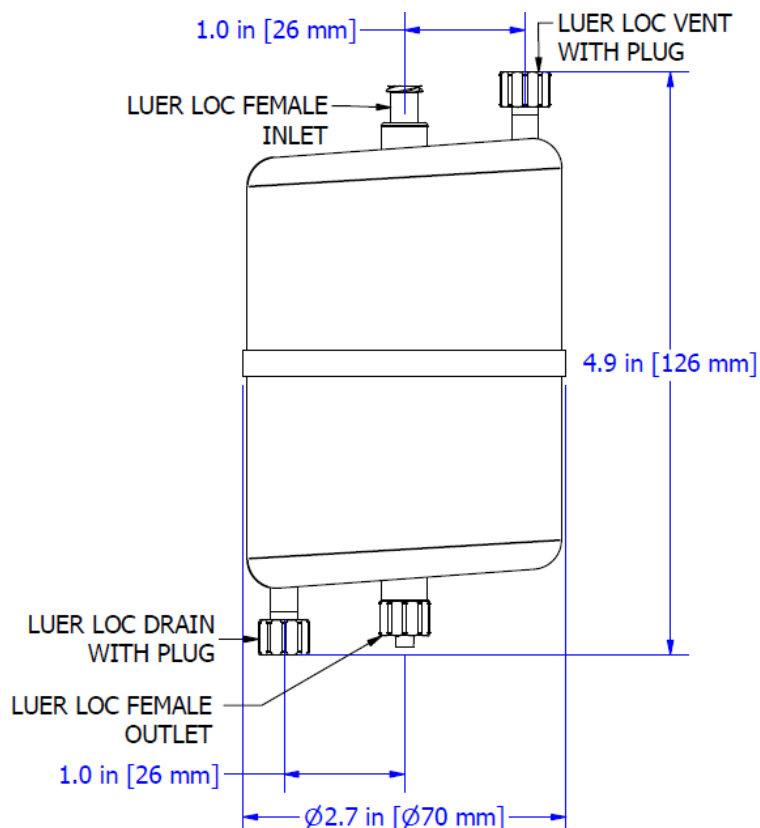
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Nominal Dimension:



Typical Filtered Volume:

16.0L – 68.5L

[Aqueous and alcohol base solutions]

*Volume Filtered is an estimated range for Sterile Compounding, 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.

Hold-Up Volume (Approx.):

Upstream Volume: 98 ml

Downstream Volume: 11 ml

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°C).



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Bacterial Retention ASTM F838-05:

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:

Gamma Irradiation: The filters can be Gamma Sterilized up to 50kGy.

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

Regulatory Compliance 21CFR Part 177 & USP <88>:

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 USP <88> Test for Plastic.

USP <85> 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 <645> Conductivity USP:

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

USP <87> / ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic.

Hemolysis ASTM F756-17:

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 requirements 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 SKL capsules have a shelf life of 3 years from the date of sterilization.



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SKL - Series PES Mid-Size Capsules (Pharmaceutical Grade)

Ordering Guide



[1]	[2]	[3] Inlet and [4] Outlet	[5]
Micron Rating [Pre-Filter/Final Filter]	Filter Size Code [Filtration Area]	Inlet and Outlet Connection	Sterilization
<ul style="list-style-type: none">• DS065S020 : Highly Asymmetric 0.65/0.2 µm <p>Note: All final membranes are sterilizing grade.</p>	<ul style="list-style-type: none">• S <p>[Filtration Area: 1,250 cm²]</p>	<ul style="list-style-type: none">• LF : Luer Loc Female• LM : Luer Loc Male	<ul style="list-style-type: none">• -GP <p>Gamma Stable PP Construction</p>

Example:

SKLDS065S020SLFLM-PH-GP

PureFlo SKL Series Capsule, Highly Asymmetric Dual Layer PES 0.65µm / 0.2µm PES membrane (Sterilizing Grade), Internal Filter Length 2.5", S-Size, Filtration Area 1,250 cm², Luer Loc Female Inlet and Luer Loc Male Outlet, Gamma Stable PP Construction

Part Number

Description



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Special Configuration:

Layer Option:

- 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

Inlet Fitting Option:

- LF : Luer Loc Female
- LM : Luer Loc Male
- 1H = 1/8" Hose Barb
- 1Q = 1/8" Male Quick Coupling with Metal Latch
- 2H = 1/4"-1/2" Tapered Hose Barb
- 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:

- LF : Luer Loc Female
- LM : Luer Loc Male
- 1H = 1/8" Hose Barb
- 1Q = 1/8" Male Quick Coupling with Metal Latch
- 2H = 1/4"-1/2" Tapered Hose Barb
- 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



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