# **SKL Series Dual Layer PES 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.

# **Application**

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

- Product Sterilization
- Bio Bags
- Biologics
- Ultrapure Water

- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- Serums

Part Number: SKLDS065S020SLFLM-PH-GP



SKL Series Capsule with Luer Loc Female Inlet and Luer Loc Male Outlet Connection

11070 Fleetwood St. Unit B, Sun Valley, CA 91352

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# **Technical Data Sheet**

# **Popular Configuration:**

Catalog Number	Micron	Inlet	Outlet	Vent	Sterilization
	Rating	Connection	Connection	Connection	
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

Find the complete list of available standard inlet and outlet fittings in page 5.

### **Micron Rating:**

Final Media: 0.2 µm PES [Sterilizing Grade]

Pre-Filter: Highly Asymmetric 0.65 µm PES

## **Effective Filtration Area:**

S-Size; 1.3  $ft^2$  (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

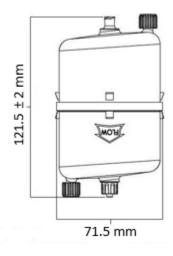
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#### **Nominal Dimension:**

Part Number: SKLDS065S020SLFLM-PH-GP



# **Hold-Up Volume (Approx.):**

Upstream Volume: 98 ml Downstream Volume: 11 ml

# **Typical Filtered Volume:**

30.0L - 60.0L

#### **Filter Integrity:**

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

#### Sterilization:

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

Autoclave: The filters can be autoclaved up to 10 cycles at 125°C (257°F) for 30 minutes.

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



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#### **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

### **USP Conductivity:**

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

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



# **SKL - Series PES Mid-Size Capsules**

(Pharmaceutical Grade)

# **Ordering Guide**

S K L [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 • S080020 : 0.8/0.2 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]	<ul> <li>LF: Luer Loc Female</li> <li>LM: Luer Loc Male</li> <li>2H: ½"-½" Tapered Hose Barb</li> <li>3H: 3/8" Hose Barb</li> <li>4H: 1/2" Hose Barb</li> <li>MT: 1/2" Tri-Clamp</li> <li>TC: 1 1/2" Tri-Clamp</li> </ul>	-GP Gamma Stable PP Construction				

## **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



# **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

## **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
- $2H = \frac{1}{4}$ "- $\frac{1}{2}$ " 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