PureFlo® MKP Series PES 0.2µm – Single Layer Filter Capsules

MKP pharma-grade capsules were designed for small-scale filtration, clarification, and filling applications in the pharmaceutical and biotechnology industries worldwide. This family of products is particularly suitable for scale-up testing where a full-size capsule or cartridge would be excessive. The all-polypropylene construction provides excellent compatibility with a wide range of chemicals. The capsules are thermally sealed, and 100% integrity tested. 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 are strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

PureFlo® MKP Filter Capsules

2H2H Connections

Inlet:
1/4" Hose Barb
Outlet:
1/4" Hose Barb

7914 Ajay Drive, Sun Valley, CA 91352
www.internationalfilterproducts.com
sales@internationalfilterproducts.com
Phone: (818) 504-8115

Application

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

Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 µm PES [Sterilizing Grade Membrane]

Effective Filtration Area:

Junior Capsule; 77.5 in^2 (500 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

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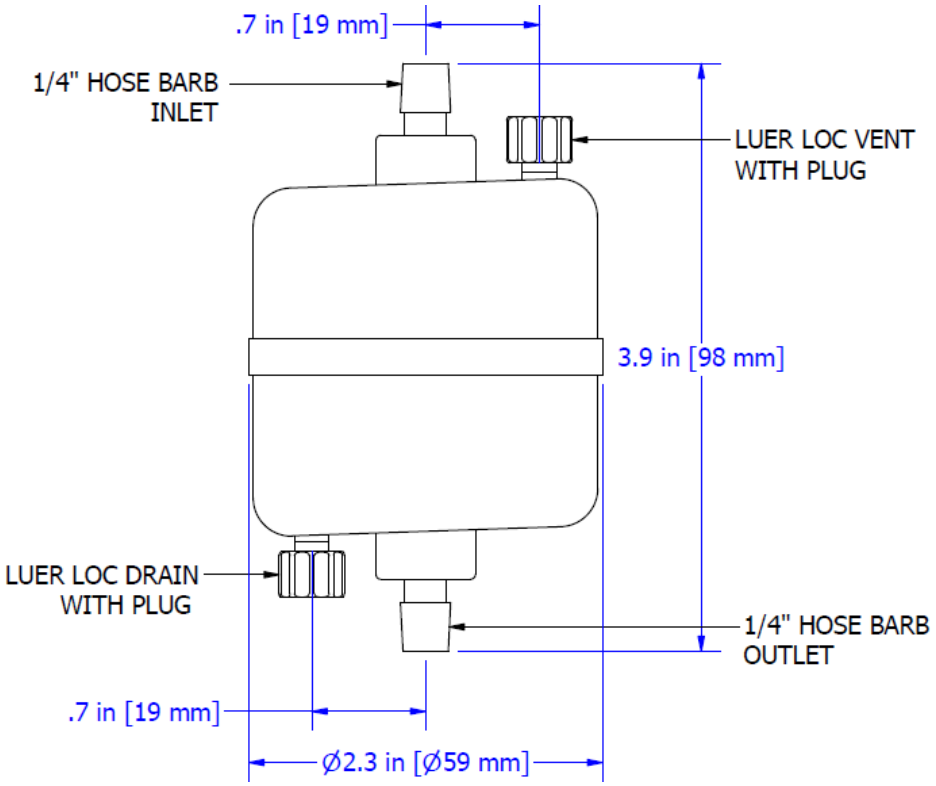
Nominal Dimension:



Typical Filtered Volume:

4.5L - 24.5L

[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: 38 ml

Downstream Volume: 13 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℃).

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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:

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}.

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 MKP 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 product's distribution, handling, and 3-year shelf life.

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MKP- Series PES Mini Capsules (Pharmaceutical Grade)

Ordering Guide

M	K	P	[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 Note: All final membranes are sterilizing grade.	• D [Filtration Area: 500 cm^2]	• LF : Luer Loc Female • LM : Luer Loc Male	-ETO Ethylene Oxide Sterilization

Example:

Part Number	Description
MKPS020DLFLM-ETO	PureFlo® MKP Series Mini Capsule, Single Layer 0.2µm PES membrane (Sterilizing Grade), Filtration Area 500 cm^2, Luer Loc Female (Inlet) and Luer Loc Make (Outlet), ETO Sterilized (Factory Sterilized)

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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

Inlet Fitting Option:

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barbs
- 2H-FB : 1/4" Hose barbs with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : ¼" MNPT
- 3H : 3/8" Hose Barbs
- LF : Luer Loc Female
- MT : 1/2" Tri clamps

Outlet Fitting Option:

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barbs
- 2H-FB : 1/4" Hose barbs with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : ¼" MNPT
- 3H : 3/8" Hose Barbs
- LM : Luer Loc Male
- MT : 1/2" Tri clamps

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