



# International Filter Products

*Revolutionary systems for your industry*

## MKP Series PES Dual 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. They are also very suitable for disposable Bio-bag applications. The all-polypropylene construction provides excellent compatibility with a wide range of chemicals. The capsules are thermally sealed, and 100% integrity tested.

### 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# **MKPDS065S020DMTMT-ETO**: MKP Filter Capsule with 1/2" TC Inlet/outlet Connection





## Technical Data Sheet

### Popular Configuration:

Catalog Number	Micron Rating	Inlet Connection	Outlet Connection	Vent Connection	Sterilization
MKPDS065S020DMTMT-ETO	0.65 µm / 0.2 µm (Dual Layer)	½" Tri-Clamp	½" Tri-Clamp	Luer Loc Cap	ETO Sterilized

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

### Micron Rating:

**Final Membrane:** 0.2 µm PES [Sterilizing Grade Membrane]

**Pre-Filter:** Highly Asymmetric 0.65 µm PES

### Effective Filtration Area:

Mini Capsule; 77.5 in<sup>2</sup> (500 cm<sup>2</sup>)

### Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

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

Media Supports: Polypropylene

Shell, Cage, Core, End Caps: 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



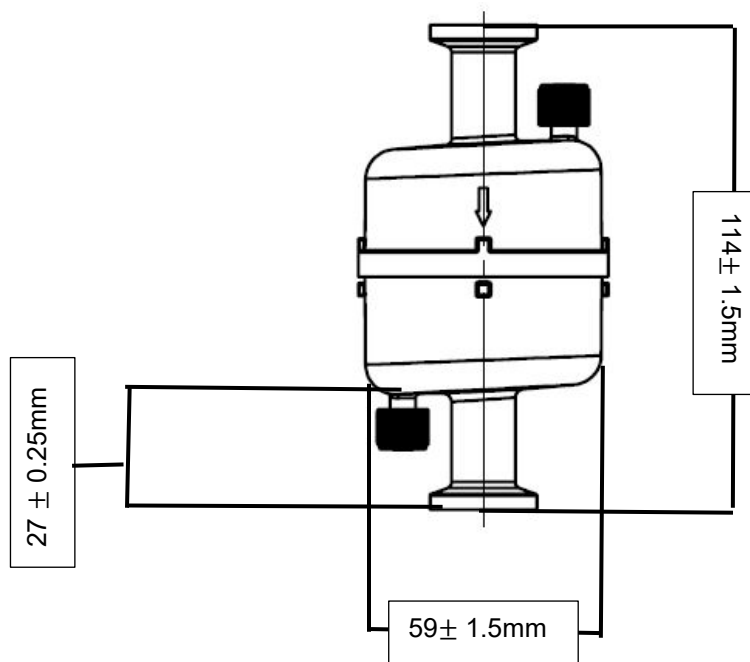


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## Nominal Dimension:

**Part Number:** MKPDS065S020DMTMT-ETO



## Hold-Up Volume (Approx.):

Upstream Volume: 40 ml

Downstream Volume: 16 ml

## Typical Filtered Volume:

10.0L – 28.0L

## 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:

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)



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## **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.

## **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

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





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## MKP- Series PES Mini 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"> <li>S020 : 0.2 µm</li> <li>DS065S020 : Highly Asymmetric 0.65/0.2 µm</li> <li>DS045S020 : Highly Asymmetric 0.45/0.2 µm</li> <li>DS045S010 : Highly Asymmetric 0.45/0.1 µm</li> <li>S080020 : 0.8/0.2 µm</li> <li>S020010: 0.2/0.1 µm</li> </ul> <p>Note: All final membranes are sterilizing grade.</p>	<ul style="list-style-type: none"> <li>B [Filtration Area: 360 cm<sup>2</sup>]</li> <li>C [Filtration Area: 420 cm<sup>2</sup>]</li> <li>D [Filtration Area: 500 cm<sup>2</sup>]</li> </ul>	<ul style="list-style-type: none"> <li>1H : 1/8" Hose Barb</li> <li>1Q : 1/8" Male Quick Coupling with Metal Latch</li> <li>2H : 1/4" Hose Barbs</li> <li>2H-FB : 1/4" Hose barbs with Filling Bell</li> <li>2Q : 1/4" Male Quick Coupling for Metal Latch</li> <li>2N : 1/4" MNPT</li> <li>3H : 3/8" Hose barbs</li> <li>LF : Luer Loc Female</li> <li>LM : Luer Loc Male</li> <li>MT : 1/2" Tri clamps</li> </ul>	<p>-ETO</p> <p>Ethylene Oxide Sterilization</p>

#### Example:

**MKPD065S020D3H3H-ETO**

PureFlo MKP Series Mini Capsule, Highly Asymmetric Dual Layer PES 0.65µm / 0.2µm PES membrane (Sterilizing Grade), Filtration Area 500 cm<sup>2</sup>, 3/8" Hose Barb (Inlet/Outlet), ETO Sterilized (Factory Sterilized)

Part Number

Description





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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 : 1/4" 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 : 1/4" MNPT
- 3H : 3/8" Hose Barbs
- LM : Luer Loc Male
- MT : 1/2" Tri clamps

