PPS Mini-Capsule Filters
Double Layered PES Membrane

Employed in the most stringent and critical applications, PPS Mini-Capsule filters are constructed with a double layered Polyethersulfone (PES) membrane for sterilizing aqueous liquids. PPS Mini-Capsule filters are validated and pore sizes range from 0.03 to 1.2 µm. These laboratory filters are constructed with the identical materials of our full-size filters to ensure consistent results in all areas of production.

The PPS Mini-Capsule filter’s low binding characteristics are well suited for filtering products with preservatives and protein solutions that can adsorb to media. These hydrophilic, double layered filters are optimized for retention and provide added security. PPS Mini-Capsule filters deliver high flow and throughput with compatibility across a wide pH range. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested and are available pre-sterilized.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration experts is how we deliver your company’s solution right the first time.

PPS Mini-Capsule filters are recommended for:
- SVPs & LVPs
- Diagnostics
- Buffers
- WFI, Water Purification
- Vaccines
- Biologicals
- Ophthalmics

Sterilizing Filters

MINI-CAPSULES – Nominal Dimensions
Body Length: 2.85 in. (7.2 cm)
Overall Length – 3.75 to 5.19 in. (9.5 to 13.2 cm)
Outside Diameter: 2.95 in. (7.5 cm)
Maximum Operating Parameters

<table>
<thead>
<tr>
<th></th>
<th>MINI-CAPSULES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid Operational Pressure</td>
<td>80 psi at 68 °F (5.52 bar at 20 °C)</td>
</tr>
<tr>
<td>Gases Operational Pressure</td>
<td>60 psi at 68 °F (4.14 bar at 20 °C)</td>
</tr>
<tr>
<td>Operating Temperature (water)</td>
<td>110 °F at 30 psid (43 °C at 2.07 bar)</td>
</tr>
<tr>
<td>Forward Differential Pressure</td>
<td>50 psid at 68 °F (3.45 bar at 20 °C)</td>
</tr>
<tr>
<td>Reverse Differential Pressure</td>
<td>40 psid at 68 °F (2.76 bar at 20 °C)</td>
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<tr>
<td>Recommended Changeout Pressure</td>
<td>35 psid (2.41 bar)</td>
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Sanitization & Sterilization

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<table>
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<tr>
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<tbody>
<tr>
<td>Autoclave</td>
<td>250 °F (121 °C), 30 min, 5+ cycles</td>
</tr>
<tr>
<td>Chemical Sanitization</td>
<td>Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.</td>
</tr>
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Integrity Testing

<table>
<thead>
<tr>
<th>PORE SIZE</th>
<th>BUBBLE POINT MINIMUM*</th>
</tr>
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<tbody>
<tr>
<td>µm</td>
<td>PSIG</td>
</tr>
<tr>
<td>0.03</td>
<td>**</td>
</tr>
<tr>
<td>0.10</td>
<td>**</td>
</tr>
<tr>
<td>0.22</td>
<td>50</td>
</tr>
<tr>
<td>0.45</td>
<td>25</td>
</tr>
<tr>
<td>0.65</td>
<td>19</td>
</tr>
<tr>
<td>0.80</td>
<td>15</td>
</tr>
<tr>
<td>1.0</td>
<td>10</td>
</tr>
<tr>
<td>1.2</td>
<td>9</td>
</tr>
</tbody>
</table>

* For water wetted membrane
** Test pressure exceeds operational limits of mini-capsule filters.

Filtration Area (Nominal)

<table>
<thead>
<tr>
<th>Area</th>
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<tbody>
<tr>
<td>0.45 ft²</td>
</tr>
<tr>
<td>416 cm²</td>
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</table>

Construction Materials

<table>
<thead>
<tr>
<th>Filtration Media</th>
<th>Double Layer Asymmetric PES Membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media Support</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>End Caps, Center Core, Outer Support Cage, Mini-Capsule Housing</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Sealing Method</td>
<td>Thermal Bonding</td>
</tr>
</tbody>
</table>

Critical Process Filtration, Inc.   2
Validation
PPS Mini-Capsule filters are validated using test procedures that comply with ASTM F 838-15(ae1) protocols for the determination of bacterial retention in filters used for liquid filtration. The challenge level is a minimum of $10^7$ organisms per cm$^2$ of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03μm, 0.10μm and 0.22μm meet the FDA definition of sterilizing grade filters).

0.03μm: *Acholeplasma laidlawii*
0.10μm: *Brevundimonas diminuta*
0.22μm: *Brevundimonas diminuta*
0.45μm: *Serratia marcescens*
0.65μm: *Saccharomyces cerevisiae*

Validation Guides available upon request.

Endotoxins
The levels of bacterial endotoxins in aqueous extracts from PPS Mini-Capsule filters are below current USP limits as specified for water for injection.

Extractables
PPS Mini-Capsule filters typically exhibit low levels of non-volatile residues.

TOC and Conductivity
PPS Mini-Capsule filters conform with TOC standards of USP <643> and the water conductivity standards of USP <645> after an appropriate flush with purified water.

Toxicity Compliance
Materials used to construct PPS Mini-Capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

Non-Fiber Releasing
PPS Mini-Capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

FDA Compliance
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

Flow Rates for PPS Mini-Capsules by Pore Size

Flow rates for Mini-Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a mini-capsule filter with ½” Sanitary inlet and outlet ports. Rates will vary based on end configuration of the mini-capsule.
PPS Mini-Capsule Filters Ordering Information

All Critical Process filters are configurable to meet customer specifications. Fill in the corresponding codes in the boxes below to build your Part Number.

To consult with one of our technical team members, request a quote or place an order: call (603) 880-4420 Ext. 106, or send an email to sales@criticalprocess.com

Mini-Capsule Filters

Pore Size Code
-03 = 0.03 μm
-10 = 0.10 μm
-20 = 0.22 μm
-40 = 0.45 μm
-60 = 0.65 μm
-80 = 0.80 μm
1.0 = 1.0 μm
1.2 = 1.2 μm

Pre-Sterilized or Not
S = Pre-Sterilized
N = Not Sterilized

Inlet
1 = 1/8” Hose Barb
2 = 1/4” Hose Barb
3 = 1/2” Hose Barb
4 = Luer Lock
5 = 1/2” Sanitary*
6 = 1/4” MNPT

Outlet
1 = 1/8” Hose Barb
2 = 1/4” Hose Barb
3 = 1/2” Hose Barb
3B = 1/2” Hose Barb with Filling Bell
4 = Luer Lock
5 = 1/2” Sanitary*
6= 1/4” MNPT

Inlet Vent Port
1 = 1/8” Hose Barb
2 = 1/4” Hose Barb
3 = 1/2” Hose Barb
4 = Luer Lock
6 = 1/4” MNPT

Outlet Vent Port
1 = 1/8” Hose Barb
2 = 1/4” Hose Barb
3 = 1/2” Hose Barb
4 = Luer Lock
6 = 1/4” MNPT

*When choosing the Sanitary Inlet/Outlet, the Luer Lock option is required for the Vent Port