HPPS/HT Filters
High Temperature Dual Layered PES Membrane

For sterile applications at elevated temperatures (up to 203°F), HPPS/HT filters remove high particle loads from aqueous liquids. These validated dual layered PES cartridge filters are available in pore sizes that range from 0.03 µm to 1.0 µm.

Designed with a High Capacity PES prefilter layer and Asymmetric PES final filter layer, plus high temperature polypropylene membrane support and cartridge hardware, HPPS/HT filters deliver high flow across a wide pH range. The HPPS/HT filters’ low binding characteristics make them ideal for filtering products with preservatives and proteins that can adsorb to media. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested.

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.

HPPS/HT is recommended for:
- SVPs & LVPs
- Diagnostics
- Buffers
- WFI, Water Purification
- Vaccines
- Biologicals
- Ophthalmics

Sterilizing Filters

CARTRIDGES – Nominal Dimensions
Length: 5 to 40 in. (12.7 to 101.6 cm)
Outside Diameter: 2.75 in. (7.0 cm)
Maximum Operating Parameters

<table>
<thead>
<tr>
<th>CARTRIDGES</th>
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</thead>
<tbody>
<tr>
<td><strong>Length</strong></td>
</tr>
<tr>
<td>5&quot;</td>
</tr>
<tr>
<td>12.7 cm</td>
</tr>
<tr>
<td><strong>Area</strong></td>
</tr>
<tr>
<td>2.5 ft²</td>
</tr>
<tr>
<td>0.23 m²</td>
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Sanitization & Sterilization

<table>
<thead>
<tr>
<th>CARTRIDGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Filtered Hot Water</strong>*</td>
</tr>
<tr>
<td><strong>Inline Steam</strong>*</td>
</tr>
<tr>
<td><strong>Autoclave</strong>*</td>
</tr>
<tr>
<td><strong>Chemical Sanitization</strong></td>
</tr>
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</table>

*For all elevated temperature procedures above, a stainless-steel support ring is required.

Filtration Area (Nominal)

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Integrity Testing

<table>
<thead>
<tr>
<th>DIFFUSION TEST PRESSURE</th>
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</thead>
<tbody>
<tr>
<td><strong>PORE SIZE</strong></td>
</tr>
<tr>
<td>µm</td>
</tr>
<tr>
<td>0.1/0.03</td>
</tr>
<tr>
<td>0.2/0.10</td>
</tr>
<tr>
<td>0.5/0.22</td>
</tr>
<tr>
<td>1.0/0.22</td>
</tr>
<tr>
<td>1.0/0.45</td>
</tr>
<tr>
<td>1.0/0.65</td>
</tr>
<tr>
<td>1.0/0.80</td>
</tr>
<tr>
<td>1.0/1.0</td>
</tr>
</tbody>
</table>

*For water-wetted membrane
Validation

HPPS/HT 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 10⁷ organisms per cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03 μm, 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 HPPS/HT filters are below current USP limits as specified for water for injection.

Extractables

HPPS/HT filters typically exhibit low levels of non-volatile residues.

TOC and Conductivity

HPPS/HT 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 HPPS/HT 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

HPPS/HT 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 Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.
HPPS/HT 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.

Cartridge Filters

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Cartridge Filters

HPPS

OHT

S

Final Layer 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

Prefilter Pore Size Code
-10 = 0.1 μm
-20 = 0.2 μm
-50 = 0.5 μm
-80 = 0.8 μm
1-0 = 1.0 μm

SS Ring
S = Ring

O-Ring/Gasket Code
S = Silicone
B = Buna
V = Viton (or FKM)
T = FEP Encapsulated Viton (or FKM)
E = EPDM
R = FEP Encapsulated Silicone

End Cap Code
0 = Flat Gasket, DOE
2 = 2-222 O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear

Length
05 = 5 in. (12.7 cm)
01 = 10 in. (25.4 cm)
02 = 20 in. (50.8 cm)
03 = 30 in. (76.2 cm)
04 = 40 in. (101.6 cm)

Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.