BCWPS Capsule Filters
High Capacity PES Membrane

Applications

- Buffers and Feedstocks
- WFI Water
- Solvents
- SVPs
- LVPs
- Vaccines

BCWPS capsule filters are hydrophilic and manufactured with high capacity polyethersulfone membrane. The proprietary membrane casting process creates a thick membrane with high contaminant holding capacity, excellent retention characteristics and high flow rates.

BCWPS capsule filters are used for bioburden reduction applications in the biopharmaceutical industry. Applications for BCWPS capsule filters include bacteria removal in buffers, USP Water for Injection (WFI), SVPs, LVPs and other products. Filter elements from each manufacturing lot are integrity tested during production. BCWPS capsules also see service in removing organic and other contaminants from wash water and clean in place solutions used in piping and other systems.

High capacity polyethersulfone is particularly suited for the filtration of products that contain elements that can adsorb to media, such as preservatives and proteins. The lower binding characteristics of PES make it a good choice for filtration of valuable protein solutions such as vaccines and other biotech products.

Excellent flow rates with excellent retention characteristics
Remove organic contaminants from liquid streams
Protect processes by removing organic contaminants from wash water, CIP solutions
Low product adsorption for protein solutions

Flow Rate / Filtration Area
The following table represents typical water flow at a one psi (69 mbar) pressure differential across a single 2 inch capsule with 0.9 ft² (836 cm²) of media with 1/2" FNPT ports. The test fluid is water at ambient temperature. Higher pressure drops are acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

<table>
<thead>
<tr>
<th>Pore Size</th>
<th>0.22 μm</th>
<th>0.45 μm</th>
<th>0.65 μm</th>
<th>1.2 μm</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPM</td>
<td>0.18</td>
<td>0.21</td>
<td>0.68</td>
<td>1.05</td>
</tr>
<tr>
<td>LPM</td>
<td>0.68</td>
<td>0.79</td>
<td>2.57</td>
<td>3.97</td>
</tr>
</tbody>
</table>

* For approximate flow rates for 5” through 30” capsules, refer to the appropriate cartridge data sheet

Construction Materials

- Housing: Polypropylene
- Filtration Media: High Capacity Polyethersulfone (PES) Membrane
- Media Support: Polypropylene
- End Caps: Polypropylene
- Center Core: Polypropylene
- Outer Support Cage: Polypropylene
- Sealing Method: Thermal Bonding

Maximum Operating Parameters

- Liquid Operational Pressure: 80 psi (5.5 bar) at 20 °C (68 °F)
- Gases Operational Pressure: 60 psi (4.1 bar) at 20 °C (68 °F)
- Operating Temperature: 43 °C (110 °F) at 30 psi (2.1 bar) in water
- Forward Differential Pressure: 50 psid (3.4 bard) at 20 °C (68 °F)
- Reverse Differential Pressure: 40 psid (2.7 bard) at 20 °C (68 °F)
- Recommended Changeout Pressure: 35 psid (2.4 bard)
Sanitization/Sterilization

**Autoclave** .......................... 250° F (121° C), 30 min, multiple cycles

**Chemical Sanitization** ........ Industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals.

**Note** ............................ BCWPS capsules are not to be used in steam.

**Pre-Sterilized** ........... BCWPS capsules are offered in both non- and pre-sterilized forms.

Integrity Test Information

Representative samples from each manufacturing lot are tested for integrity to ensure consistent performance.

USP Biosafety and FDA Compliance

The materials used to construct biopharmaceutical grade CWPS 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. In addition, the 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 appropriate. BCWPS capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters. The levels of bacterial endotoxins in aqueous extracts from biopharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

Extractables

Biopharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Quality Assurance and Standards

Critical Process Filtration uses state of the art computer controlled equipment to consistently produce high quality products as well as significantly reduce hand operations that can compromise quality. All manufacturing and testing is continuously monitored in real time so that data can be quickly and easily analyzed to facilitate improvements in both quality and cost.

The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled using a sophisticated manufacturing system that networks work stations, manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected in real time to allow continuous quality monitoring and full traceability of all materials and processes.

Representative capsule filter assemblies are integrity tested before manufacturing lot release.

Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products to industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Ordering Information

Capsule order number example: Biopharmaceutical Grade High Capacity PES Membrane, 0.22 Micron Rating, Pre-Sterilized, 10" Length, Sanitary Inlet, Sanitary Outlet = CPBCWPS-20S0001FF.

<table>
<thead>
<tr>
<th>Micron Rating</th>
<th>Pre-Sterilized or Not</th>
<th>Length</th>
<th>Inlet</th>
<th>Outlet</th>
</tr>
</thead>
<tbody>
<tr>
<td>-20 - .22</td>
<td>S - Pre-Sterilized</td>
<td>A - 2&quot;</td>
<td>A - 1/4&quot; Female NPT</td>
<td>A - 1/4&quot; Female NPT</td>
</tr>
<tr>
<td>-40 - .45</td>
<td>N - Not Sterilized</td>
<td>B - 5&quot;</td>
<td>B - 1/4&quot; Male NPT</td>
<td>B - 1/4&quot; Male NPT</td>
</tr>
<tr>
<td>-60 - .65</td>
<td></td>
<td>1 - 10&quot;</td>
<td>C - 3/8&quot; Female NPT</td>
<td>C - 3/8&quot; Female NPT</td>
</tr>
<tr>
<td>-80 - .85</td>
<td></td>
<td>2 - 20&quot;</td>
<td>D - 1/2&quot; Female NPT</td>
<td>D - 1/2&quot; Female NPT</td>
</tr>
<tr>
<td>-100 - 1.2</td>
<td></td>
<td>3 - 30&quot;</td>
<td>E - 1/2&quot; Male NPT</td>
<td>E - 1/2&quot; Male NPT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>F - Sanitary</td>
<td>F - Sanitary</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>G - Hose Barb*</td>
<td>G - Hose Barb*</td>
</tr>
</tbody>
</table>

Hose Barb Diameter Ranges*

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Maximum</th>
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</thead>
<tbody>
<tr>
<td>Outer Diameters</td>
<td>11/32&quot; (8.6mm)</td>
<td>9/16&quot; (14.0mm)</td>
</tr>
<tr>
<td>Inner Diameters</td>
<td>5/32&quot; (4.0mm)</td>
<td>13/32&quot; (10.5mm)</td>
</tr>
</tbody>
</table>

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