BTM Filter Cartridges are manufactured with inherently hydrophobic polytetrafluoroethylene (PTFE) membrane. These cartridges are designed for use in the filtration of gases and non-aqueous liquids.

Applications include bioburden control in fermentation air, compressed gas filtration and tank vent filtration to protect the integrity of stored liquids.

Each cartridge module is individually tested using the water intrusion method before it is released from manufacture. The cartridge surface area, filter core design, pleat configuration, and pleat packing density have been optimized to provide increased cartridge life and lower filtration operating costs. Rugged construction ensures repeatable steaming and testing.

#### Construction Materials

<table>
<thead>
<tr>
<th>Filtration Media</th>
<th>PTFE Membrane (absolute rated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media Support</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>End Caps</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Center Core</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Outer Support Cage</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Sealing Method</td>
<td>Thermal Bonding</td>
</tr>
<tr>
<td>O-rings</td>
<td>Buna, Viton® (or FKM), EP, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)</td>
</tr>
</tbody>
</table>

#### Applications
- Fermentation Air
- Solvent Filtration
- Non-Aqueous Solutions
- Compressed Air Filtration
- Tank Vents
- Process Gas

#### Dimensions
- Length: 5 to 40 in. (12.7 to 101.6 cm) nominal
- Outside Diameter: 2.75 in. (7.0 cm) nominal
- Filtration Area: 7.0 ft² (0.65 m²) per 10 in. length

#### Integrity Test Specifications

60/40 IPA/water wetted membrane

<table>
<thead>
<tr>
<th>Pore Size (liquid)</th>
<th>Bubble Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.10 μm</td>
<td>21 psig (1.45 barg)</td>
</tr>
<tr>
<td>0.22 μm</td>
<td>15 psig (1.0 barg)</td>
</tr>
<tr>
<td>0.45 μm</td>
<td>9 psig (621 mbarg)</td>
</tr>
<tr>
<td>1.0 μm</td>
<td>6 psig (414 mbarg)</td>
</tr>
<tr>
<td>3.0 μm</td>
<td>2 psig (138 mbarg)</td>
</tr>
<tr>
<td>5.0 μm</td>
<td>1 psig (69 mbarg)</td>
</tr>
</tbody>
</table>

#### Maximum Operating Parameters

- **Differential Pressure**
  - Forward: 50 psid (3.4 bard) at 20 °C (68 °F)
  - Reverse: 40 psid (2.7 bard) at 20 °C (68 °F)

- **Operating Temperature**
  - 82 °C (180 °F) at 10 psid (0.69 bard)

- **Recommended Changeout Pressure**
  - 35 psid (2.4 bard)

#### Sanitization/Sterilization

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

- **In-line Steam**
  - 135 °C (275 °F), 30 min, multiple cycles

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

- **Chemical Sanitization**
  - Performed using industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite, and other selected chemicals.

#### 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.
Quality Assurance and Standards
Critical Process Filtration filters are designed for use in cGMP-compliant processes. Our state of the art manufacturing facility and quality management system both meet ISO 9001:2008 standards. Each operation from assembly and test to cleaning, drying, and packaging is done in appropriately rated clean rooms, and each filter is assigned a lot code to ensure the traceability of manufacturing data and materials. A sophisticated MRP system collects and processes real time data from manufacturing centers and inspection points. This allows variable and attribute data to be quickly and easily analyzed driving constant improvements in both quality and cost.

USP Biosafety and FDA Compliance
The materials used to construct biopharmaceutical grade TM cartridge 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. BTM 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 cartridge filters are below current USP limits as specified for water for injection.

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

Validation
Biopharmaceutical grade TM cartridges are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. The challenge level is 10⁷ organisms per cm² of filter media: 0.22 μm challenged with Brevundimonas diminuta; 0.45 μm challenged with Serratia marcescens; Critical Process Filtration can provide validation assistance.

Flow Rate
The Typical Flow Rates table represents typical water and air flows at ambient temperature and a 1 psid (69 mbard) pressure differential across a single 10 in. cartridge element. Extrapolation for housings with multiple elements and higher pressure drops is acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Typical Flow Rates

<table>
<thead>
<tr>
<th>Pore Size</th>
<th>0.1 μm</th>
<th>0.22 μm</th>
<th>0.45 μm</th>
<th>1.0 μm</th>
<th>3.0 μm</th>
<th>5.0 μm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid Flow Rates (gpm)</td>
<td>1.8</td>
<td>2.8</td>
<td>5.7</td>
<td>9.0</td>
<td>10.0</td>
<td>11.0</td>
</tr>
<tr>
<td>Air/Gas Flow Rates (scfm)</td>
<td>26</td>
<td>42</td>
<td>68</td>
<td>85</td>
<td>&gt;95</td>
<td>&gt;95</td>
</tr>
</tbody>
</table>

Ordering Information
Cartridge order numbers have several variables from pore size to end cap type. For example, Biopharmaceutical Grade PTFE Membrane, 0.22 Micron Rating, With SS Support Ring, 20” Length, Silicone O-Rings, 2-226/Spear End Cap Configuration = BTM-20S00002S9.

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Request a QUOTE from your area representative.