# PTM Filter Cartridges

# PTFE Membrane





PTM Membrane Filter Cartridges are sterilizing grade filters manufactured with inherently hydrophobic polytetrafluoroethylene (PTFE) membrane. These cartridges are designed for use in the filtration of aggressive solvents and as compressed gas and vent filters. 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

Construction	viateriais		
Filtration Media	Polytetrafluoroethylene (PTFE)		
<b>Media Support</b>	Polypropylene		
End Caps	Polypropylene		
Center Core	Polypropylene		
Outer Support Cage	Polypropylene		
<b>Sealing Method</b>	Thermal Bonding		
O-rings	Buna, Viton® (or FKM), EP, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)		

### **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.

# **Applications**

- ♦ Compressed Air
- ◆ Fermentation Air
- ♦ Solvents
- Pressurized Gases
- ♦ Tank Ventilation

### **Dimensions**

**Length** 5 to 40 in. (12.7 to 101.6 cm) nominal

Outside Diameter 2.75 in. (7.0 cm) nominal

**Filtration Area** 8.2 ft<sup>2</sup> (0.76 m<sup>2</sup>) per 10 in. length

# **Integrity Test Specifications**

Per 10 in. length

Pore Size (liquid)	Bubble Point 60/40 IPA/water wetted	Water Intrusion
0.10 μm	22 psig (1.52 barg)	10 cc/10 minutes @ 35 psi (2.4 bar)
0.22 μm	18 psig (1.24 barg)	13 cc/10 minutes @ 35 psi (2.4 bar)
0.45 μm	9 psig (621 mbarg)	N/A
1.0 μm	6 psig (414 mbarg)	N/A
3.0 µm	2 psig (138 mbarg)	N/A
5.0 μm	1 psig (69 mbarg)	N/A

# **Maximum Operating Parameters**

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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, 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.

# **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. 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 pharmaceutical grade TM 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. PTM 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 pharmaceutical grade filters are below current USP limits as specified for water for injection.

### Ordering Information

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

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### **Extractables**

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

### **Validation**

PTM cartridges are validated using test procedures that comply with the intent of both ASTM F 838-05 and HIMA protocols for the determination of bacterial retention in filters used for liquid filtration. The challenge level is  $10^7$  organisms per cm² of filter media: 0.22 µm challenged with *Brevundimonas diminuta*; 0.45 µm challenged with *Serratia marcescens*.

### 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. These values are approximations because of the differences in pressure drop encountered in housings and piping systems. Extrapolation to multiple length cartridges in multi-round housings can be done for sizing purposes. Exact flow rates will be installation dependent.

#### **Typical Flow Rates**

Typical Flott Hates								
Pore Size	0.10 μm	0.22 μm	0.45 μm	1.0 μm	3.0 μm	5.0 μm		
Liquid Flow Rates (gpm)	> 1.25	> 2.0	> 5.0	> 8.0	> 10.0	> 11.0		
Air/Gas Flow Rates (scfm)	> 25	> 40	> 60	> 75	> 85	> 85		

