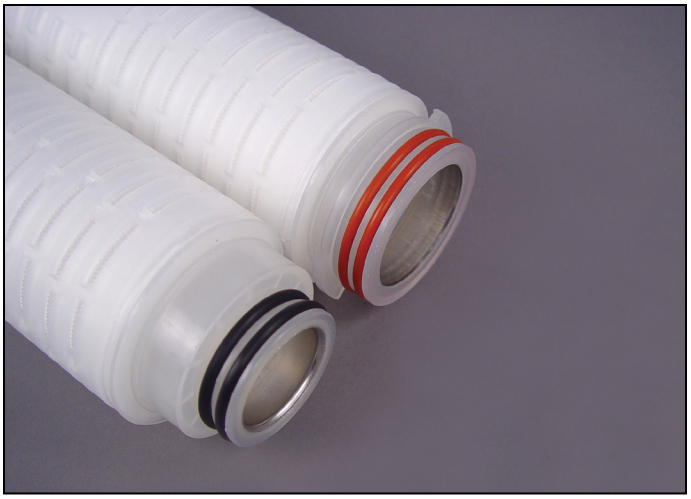
PPM Cartridge Filters

Pleated Polypropylene Membrane

CRITICAL PROCESS FILTRATION, INC.

Pharmaceutical Grade



PPM Membrane Filter Cartridges are manufactured for the specified needs of the pharmaceutical industry. Manufactured with inherently hydrophobic polypropylene 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 diffusion tested using 60/40 IPA and water 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 resulting in lower filtration operating costs. Rugged construction ensures repeatable steaming and testing.

Construction Materials

Filtration Media	Polypropylene Membrane
Media Support	Polypropylene
End Caps	Polypropylene
Center Core	Polypropylene
Outer Support Cage	Polypropylene
Sealing Method	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

- Gases
- Tank Vents
- Solvents
- Compressed Air
- Chemicals
- Bulk Pharmaceutical Chemicals

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 ft^2 (0.65 m^2) per 10 in. length

Integrity Test Specifications

Per 10 in. length, 60/40 IPA/water wetted membrane

Pore Size	Air Diffusion Rate
0.10 µm	< 30 cc/min at 40 psig (2.89 barg)
0.22 µm	< 30 cc/min at 35 psig (2.4 barg)

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) in water
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.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PM 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. PPM cartridge 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 cartridge filters are below current USP limits as specified for water for injection.

Extractables

PPM cartridge filters typically exhibit low levels of non-volatile residues.

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.

Validation

PPM 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 cm^2 of filter media: 0.10 µm challenged with *Acholeplasma laidlawii*; 0.22 µm challenged with *Brevundimonas diminuta*.

Flow Rate

The Typical Flow Rate table represents typical water and air flow rates at ambient temperature for a single 10-inch cartridge at 1 psid (69 mbard) pressure differential. 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

Rated Pore Size	0.10 µm	0.22 µm
Liquid Flow Rates (gpm)	.75	2.75
Air/Gas Flow Rates (scfm)	> 20	> 30

Ordering Information

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

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Pore Size Code
-10 = 0.10 µm
-20 = 0.22 µm

316 SS Ring
S = Ring
N = No Ring

Cartridge Length Code
05 = 4.875 in. (12.4 cm)
97 = 9.75 in. (24.8 cm)
01 = 10 in. (25.4 cm)
19 = 19.5 in. (49.5 cm)
02 = 20 in. (50.8 cm)
29 = 29.25 in. (74.3 cm)
03 = 30 in. (76.2 cm)
04 = 40 in. (101.6 cm)

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

End Cap Code
0 = Flat Gasket, DOE
1 = Flat Gasket/Plug
2 = 2-222 O-ring/Plug
3 = 213/119 Internal O-ring DOE
4 = 213/119 Internal O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
7 = 020 O-ring/Plug
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear
21 = 2-223 O-ring/Flat
22 = 2-223 O-ring/Spear
23 = 2-222 O-ring 3 Tab/Flat
24 = 2-222 O-ring 3 Tab/Spear
25 = Short 2-222/Plug