PTM/ HT grade

PTFE Membrane Media Filter Cartridges Developed for the Special Needs of the Pharmaceutical Industry

PTM sterilizing grade cartridge filters are manufactured for the specific needs of the pharmaceutical industry. Manufactured with inherently hydrophobic 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 bubble point 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.

High temperature polypropylene support material and rugged construction ensures repeatable steaming and testing. PTM grade cartridges are 100% integrity tested.

Applications

Final Filtration of:

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

Maximum Operating Parameters

Forward Differential Pressure: 50 psi (3.4 bar) at 20°C.
Reverse Differential Pressure: 40 psi (2.7 bar) at 20°C.
Maximum Continues Air Temperature: 221°F (105°C), recommended maximum service life 1 year.

Integrity Test Specifications

(per 10 inch length) (60/40, IPA/water wetted membrane)

Pore Size	Bubble Point
0.22 µm	18 psig

Dimensions

Length: ..... 5 to 40 inches (12.7 to 101.6 cm) nominal
Outside Diameter: ..... 2.75 inches (7.0 cm) nominal
Filtration Area: ..... 8.2 ft ² (0.76 m²) Per 10" length

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Construction Materials

Filtration Media: ..... Dual Layered PTFE
Filtration Media Support: ..... Polyester
End Caps: ..... HT Polypropylene
Center Core: ..... HT Polypropylene
Outer support Cage: ..... HT Polypropylene
Sealing Method: ..... Thermal Bonding
O-rings: ..... Buna, Viton®, EP, Silicone, Teflon® Encapsulated Silicone, Teflon® Encapsulated Viton®

Sanitisation/ Sterilisation

Filtered Hot Water: ..... 194°F (90°C)
Autoclave: ..... 250°F (121°C), 30 min, multiple cycles
In-line Steam: ..... 275°F (135°C), 30 min, multiple cycles
Chemical Sanitization: Industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals. Sanitization protocols designed to extend the useful life of PTM cartridges are available from Critical Process Filtration, Inc..

Total Performance

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

USP Biosafety

The materials used to construct Pharmaceutical Grade filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and USP24 Plastic Class V1 121°C Test.

FDA Compliance

The materials used to construct Pharmaceutical Grade filters 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.

Extractables

The levels of bacterial endotoxins in aqueous extracts from Pharmaceutical Grade Filters are typically below the USP24 limits defined in Water for Injection. Pharmaceutical Grade Filters typically exhibit low levels of non-volatile residues.

Validation

PTM grade cartridges are validated using modified HIMA protocols at a challenge level of 10^7 organisms per cm^2 of filter media. (0.22 µm challenged with Brevundimonas diminuta).

Quality Assurance

Pharmaceutical Grade Filters are manufactured using current Good Manufacturing Practices under a quality management system that has met ISO 9001 standards. Each Pharmaceutical Grade Filter is assigned a lot code to ensure traceability of the data and materials used in the manufacturing process. Our goal is to ensure our customers the greatest possible value for their filtration dollar. We achieve both low cost manufacture and high quality by employing state of the art manufacturing equipment. This computer controlled equipment is highly automated, reducing hand operations that compromise quality. Each operation including assembly, testing, cleaning, drying and packaging is done in appropriately rated clean rooms. Critical Process Filtration produces validated products to rigorous standards. Manufacturing is controlled using sophisticated MRP software that is networked to work stations in manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected "real time" from machinery and measuring instruments. This allows variable and attribute data to be quickly and easily analyzed to facilitate constant improvements in both quality and cost.

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Flow Rate / Retention Ratings

The following table represents typical water flow and air flow rates. 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.

Pore Size	0.22 µm
SCFM	> 40 SCFM/psid/10 inch cartridge length>
GPM	2.0 gpm/psid/10 inch cartridge length
Liquids	0.22 µm, sterilizing grade
Air/Gases	<0.003µm, particulate

Ordering Information

The cartridge catalog number is made up of several variable characters i.e. pore size, length, O-ring material, and end cap code. For example: a 0.20 µm, 20 inch (50.8 cm) long cartridge with 2-226, Silicone O-rings, with spear and 316 SS Ring would be designated as: PTM*20S0HT02S9.

PTM ☐ **S** ☐ **0HT** ☐ ☐ ☐

Pore size code
***20** = 0.22 µm

316 SS Ring
S = Ring

Cartridge Length
05 = 4.875 inches (12.4 cm)
97 = 9.75 inches (24.6 cm)
01 = 10 inches (25.4 cm)
19 = 19.5 inches (49.5 cm)
02 = 20 inches (50.8 cm)
29 = 29.25 inches (74.3 cm)
03 = 30 inches (76.2 cm)
04 = 40 inches (101.6 cm)

O-ring code
S = Silicone
B = Buna
V = Viton®
T = Teflon® Encapsulated Viton®
E = EP
R = Teflon® Encapsulated Silicone

End cap code
5 = 2-222 O-ring / Flat
6 = 2-226 O-ring / Flat
8 = 2-222 O-ring / Spear
9 = 2-226 O-ring / Spear

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