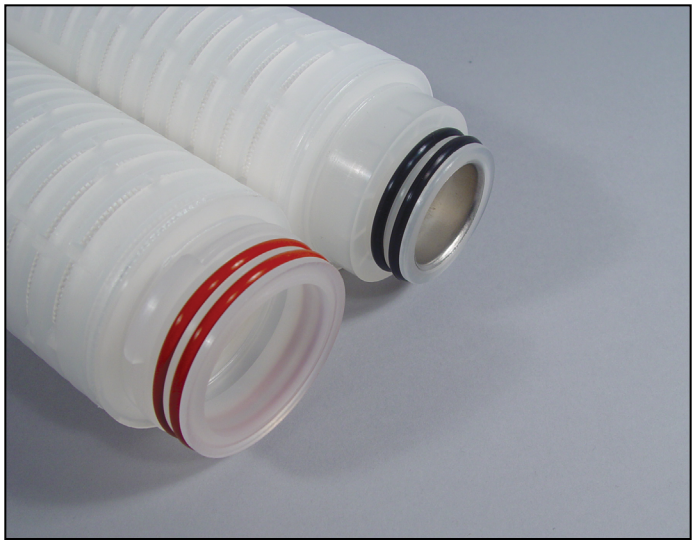
BTM/HT Cartridge Filters

PTFE Membrane

CRITICAL PROCESS FILTRATION, INC.



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

Filtration Media	PTFE Membrane (absolute rated)
Media Support	High Temperature Polypropylene
End Caps	High Temperature Polypropylene
Center Core	High Temperature Polypropylene
Outer Support Cage	High Temperature Polypropylene
Sealing Method	Thermal Bonding
O-rings	Buna,Viton® (or FKM), EP, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

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

Applications

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

Integrity Test Specifications

60/40 IPA/water wetted membrane

Pore Size (liquid)	Bubble Point
0.10 µm	21 psig (1.45 barg)
0.22 µm	15 psig (1.0 barg)
0.45 µm	9 psig (621 mbarg)
1.0 µm	6 psig (414 mbarg)
3.0 µm	2 psig (138 mbarg)
5.0 µm	1 psig (69 mbarg)

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)
Maximum Continuous Air Temperature	105 °C (221 °F)
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, peracetic acid, sodium hypochlorite, and other selected chemicals.

We Do It Right the First Time

We solve filtration challenges where filters are a critical part of your manufacturing process. Our Technical Team works with you to engineer filtration solutions that fit your needs. Then we manufacture the filters in our ISO 9001 certified facility and deliver them fast, so you have the right filters when you need them.

Biopharmaceutical Grade

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 are certified to meet ISO 9001 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 and serial number 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, allowing quick and easy analysis driving constant improvements in quality.

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

Bioharmaceutical grade filters typically exhibit low levels of non-volatile residues. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade filters are below current USP limits as specified for water for injection.

Validation

Biopharmaceutical grade TM cartridges are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. The filters are validated to remove 10^7 organisms per cm^2 of filter media:
0.10 µm challenged with Acholeplasma laidlawii;
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

Pore Size	0.1 µm	0.22 µm	0.45 µm	1.0 µm	3.0 µm	5.0 µm
Liquid Flow Rates (gpm)	1.8	2.8	5.7	9.0	10.0	11.0
Air/Gas Flow Rates (scfm)	26	42	68	85	>95	>95

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, High Temperature, 20" Length, Silicone O-Rings, 2-226/Spear End Cap Configuration = BTM-20S0HT02S9.

BTM [ ] S 0HT [ ] [ ] [ ]

Pore Size Code
-05 = 0.05 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm
1-0 = 1.0 µm
3-0 = 3.0 µm
5-0 = 5.0 µm

316 SS Ring
S = 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
E = EP
V = Viton (or FKM)
T = PTFE Gasket or FEP Encapsulated Viton (or FKM) - O-rings
R = FEP Encapsulated Silicone - O-rings only

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

Request a **QUOTE** from your area representative

CRITICAL PROCESS FILTRATION, INC.

Critical Process Filtration, Inc.
One Chestnut Street • Nashua, NH 03060
Tel: 603.880.4420 • Fax: 603.880.4536

criticalprocess.com • sales@criticalprocess.com