

BTM cartridge and capsule filters are constructed with a Polytetrafluoroethylene (PTFE) membrane and are used for bioburden control in non-aqueous liquids, process gases and tank vent filtration. Pore sizes range from 0.10 to 5.0  $\mu m$  and filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

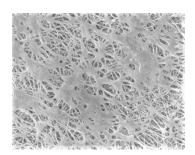
These single layer, hydrophobic filters are optimized for flow and throughput, and resist wetting by airborne water droplets, making them ideal for air and gas applications. BTM bioburden control filters protect processes and extend the life of sterilizing filters. Each cartridge module is individually tested using the water intrusion method before it is released from manufacture.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration experts is how we deliver your company's solution right the first time.

# Bioburden Control Tank Vent & Process Gas



CARTRIDGES – Nominal Dimensions Length: 5 to 40 in. (12.7 to 101.6 cm) Outside Diameter: 2.75 in. (7.0 cm)



BTM bioburden control filters are recommended for:

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



CAPSULES – Nominal Dimensions Length: 2 to 30 in. (5.1 to 76.2 cm) Outside Diameter: 3.50 in. (8.9 cm)

# **Maximum Operating Parameters**

	CARTRIDGES	CAPSULES
Liquid Operational Pressure	N/A	80 psi at 68 °F (5.52 bard at 20 °C)
Gases Operational Pressure	N/A	60 psi at 68 °F (4.14 bar at 20 °C)
Operating Temperature (water)	180 °F at 30 psid (82 °C at 2.07 bard)	110 °F at 30 psid (43 °C at 2.07 bard)
Forward Differential Pressure	80 psid at 68 °F (5.52 bard at 20 °C) (Liquid and Gas)	Liquid - 80 psid at 68 °F (5.52 bard at 20 °C) Gas - 60 psi at 68 °F (4.14 bar at 20 °C)
Reverse Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)	50 psid at 68 °F (3.45 bard at 20 °C)
Recommended Changeout Pressure	mended Changeout Pressure 35 psid (2.41 bard) 35 psid (2.41 bard)	

## Sanitization & Sterilization

Filtered Hot Water*	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow	N/A	
Inline Steam*	275 °F (135 °C), 30 min, 25+ cycles	N/A	
Autoclave*	250 °F (121 °C), 30 min, 25+ cycles	250 °F (121 °C), 30 min, 5+ cycles	
Chemical Sanitization	,	Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.	

<sup>\*</sup>Cartridge Filters – For all elevated temperature procedures above, a stainless-steel support ring is required.

### Filtration Area (Nominal)

	CAPSULES	CARTRIDGES AND CAPSULES			CARTRIDGES	
Length	2"	5"	10"	20"	30"	40"
	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	1.2 ft <sup>2</sup>	3.3 ft <sup>2</sup>	7.0 ft <sup>2</sup>	14.0 ft <sup>2</sup>	21.0 ft <sup>2</sup>	28.0 ft <sup>2</sup>
	0.11m <sup>2</sup>	0.31m <sup>2</sup>	0.65m <sup>2</sup>	1.30m <sup>2</sup>	1.95m²	2.60m <sup>2</sup>

## **Integrity Testing**

PORE SIZE	BUBBLE POINT MINIMUM*		
μm	PSIG	BARG	
0.10	21	1.45	
0.22	15	1.03	
0.45	9	0.62	
1.0	6	0.41	
3.0	2	0.14	
5.0	1	0.07	

<sup>\*</sup> Bubble Point for membrane wetted with 60% IPA / 40% water solution.

#### **Construction Materials**

Polytetrafluoroethylene (PTFE)	
Polytetrafluoroethylene (PTFE) Membrane	
Polypropylene	
Polypropylene	
Thermal Bonding	
Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)	

High Temperature cartridge configuration is available.

#### Validation

BTM filters are validated using test procedures that comply with ASTM F 838-15(ae1) protocols for the determination of bacterial retention in filters used for liquid filtration. The filters are challenged with the organisms listed below.

0.10μm: *Brevundimonas diminuta* 0.22μm: *Brevundimonas diminuta* 0.45μm: *Serratia marcescens* 

#### **Endotoxins**

The levels of bacterial endotoxins in aqueous extracts from BTM filters are below current USP limits as specified for water for injection.

#### Extractables

BTM filters typically exhibit low levels of non-volatile residues.

#### **Toxicity Compliance**

The materials used to construct BTM 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.

#### Non-Fiber Releasing

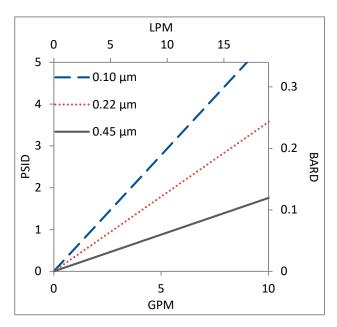
BTM filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

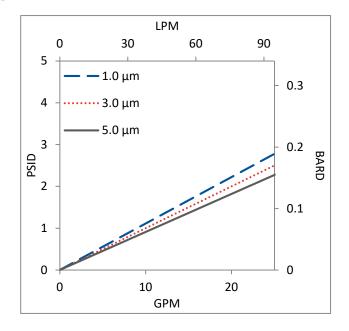
#### **FDA Compliance**

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 applicable.

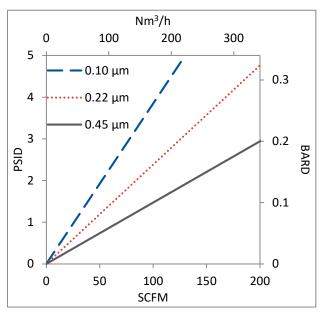
# Flow Rates for BTM Cartridges by Pore Size

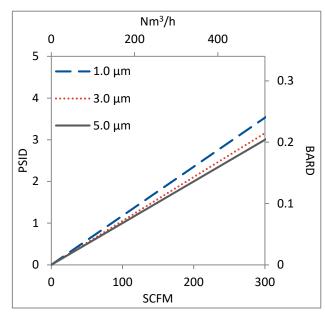
# Water





## Air

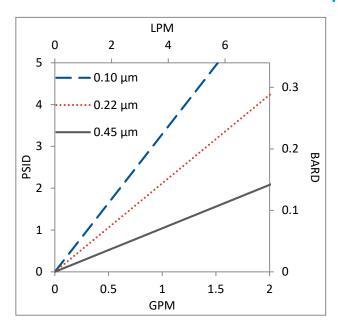


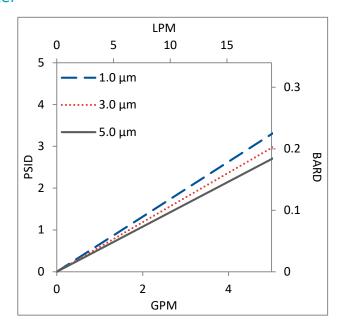


Flow rates for Cartridge filters are per 10-inch length. The test fluid is water or compressed air at ambient temperature.

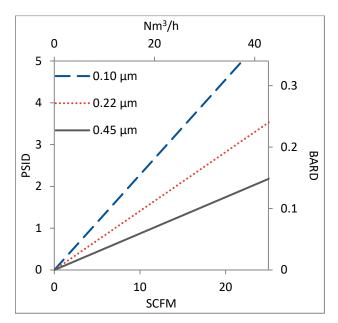
# Flow Rates for BTM Capsules by Pore Size

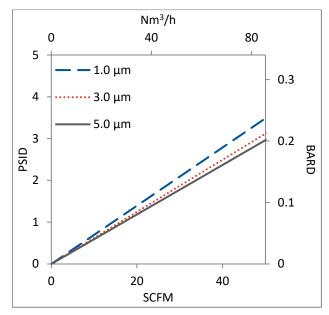
## Water





## Air



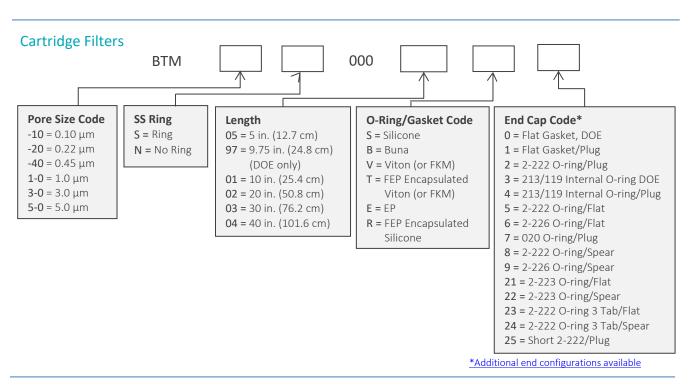


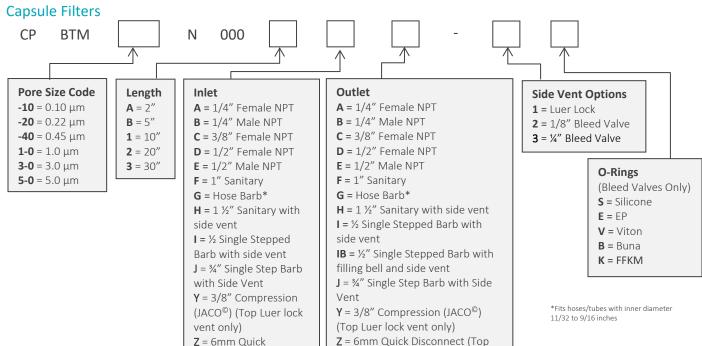
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water or compressed air at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

# **BTM Filters Ordering Information**

Fill in the corresponding codes in the boxes below to build your Part Number.

To consult with one of our technical team members, request a quote or place an order: call (603) 880-4420 or contact us here.







One Chestnut Street Nashua, NH 03060 603.880.4420

Disconnect (Top Luer lock vent only)

FAX: 603.880.4536

CriticalProcess.com

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Data Sheet BTMDS Rev C

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