

BTM Micro 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 μ m and filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

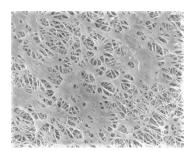
These single layer, hydrophobic filters are optimized for flow and throughput, and resist wetting by airborne water droplets, making them ideal for air and gas applications. BTM Micro Capsule bioburden control filters protect processes and extend the life of sterilizing filters. Each module is individually 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



MICRO CAPSULES – Nominal Dimensions Body Length: 1.9 in. (4.8 cm) Overall Length: 2.8 to 3.8 in. (7.1 to 9.7 cm) Outside Diameter: 2.6 in. (6.6 cm)



BTM Micro Capsule bioburden control filters are recommended for:

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

Maximum Operating Parameters

_	MICRO CAPSULES	
Liquid Operational Pressure	80 psi at 68 °F (5.52 bard at 20 °C)	
Gases Operational Pressure	60 psi at 68 °F (4.14 bar at 20 °C)	
Operating Temperature (water)	110 °F at 30 psid (43 °C at 2.07 bard)	
Forward Differential Pressure	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)	
Recommended Changeout Pressure	nmended Changeout Pressure 35 psid (2.41 bard)	

Sanitization & Sterilization

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.	

Integrity Testing

PORE SIZE	BUBBLE POI	NT 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

 $^{^{\}ast}$ Bubble Point for membrane wetted with 60% IPA / 40% water solution.

Filtration Area (Nominal)

Area	0.51 ft ²
	474 cm ²

Construction Materials

Filtration Media	Polytetrafluoroethylene (PTFE) Membrane
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding
O-Rings/Gaskets Cartridges only	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

Validation

BTM Micro Capsule 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

Validation Guides available upon request.

Endotoxins

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

Extractables

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

Toxicity Compliance

The materials used to construct BTM Micro Capsule 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.

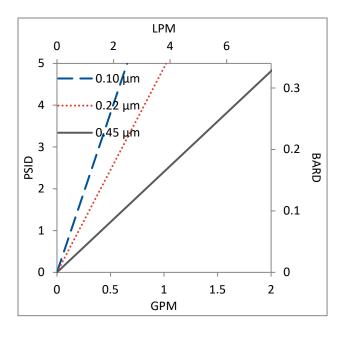
Non-Fiber Releasing

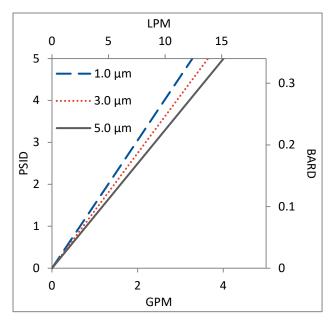
BTM Micro Capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

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 Micro Capsules by Pore Size



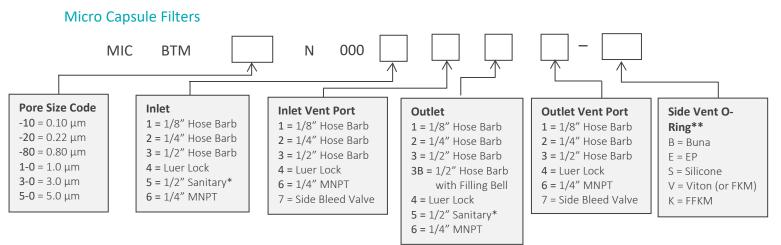


Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with ½" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

BTM Micro Capsule Filters Ordering Information

All Critical Process filters are configurable to meet customer specifications. 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 Ext. 106, or send an email to sales@criticalprocess.com



^{*}When choosing the Sanitary Inlet/Outlet, the Luer Lock or bleed valve option is required for the Vent Port



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Data Sheet BTM Micro DS Rev -

^{**} O-Ring is only available on Bleed Valve