

PTR Micro Capsule filters consist of a single layer of validated Polytetrafluoroethylene (PTFE) membrane and are used for sterilizing process gas applications and tank vents. The PTR Micro Capsule's membrane has a pore size of 0.22  $\mu$ m.

PTR Micro Capsule filters are hydrophobic and have high air flow and low pressure drops. Each Micro capsule is individually integrity tested using the bubble point 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.

# Sterilizing Filters 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)



PTR Micro Capsule filters are recommended for:

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

# Maximum Operating Parameters

MICRO CAPSULES	
60 psi at 68 °F (4.14 bar at 20 °C)	
110 °F at 30 psid (43 °C at 2.07 bard)	
Gas - 60 psi at 68 °F (4.14 bar at 20 °C)	
50 psid at 68 °F (3.45 bard at 20 °C)	
35 psid (2.41 bard)	
-	60 psi at 68 °F (4.14 bar at 20 °C) 110 °F at 30 psid (43 °C at 2.07 bard) Gas - 60 psi at 68 °F (4.14 bar at 20 °C) 50 psid at 68 °F (3.45 bard at 20 °C)

### Sanitization & Sterilization

Autoclave	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**

#### Filtration Area (Nominal)

PORE SIZE	BUBBLE POI	NT MINIMUM*
μm	PSIG	BARG
0.22	18	1.24

Area	0.59 ft <sup>2</sup>
	548 cm <sup>2</sup>

### **Construction Materials**

Filtration Media	Polytetrafluoroethylene (PTFE) Membrane
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Micro Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding

### $\ast$ Bubble Point for membrane wetted with 60% IPA / 40% water

### Validation

PTR Micro Capsules are validated using test procedures that comply with the intent of BFE protocols for the determination of bacterial retention in filters used for air and gas filtration. The challenge level for the 0.22  $\mu$ m filter membrane is 7.5 x 10<sup>7</sup> organisms per cm<sup>2</sup> of filter media of Brevundimonas diminuta (ATCC 19146).

PTR Micro Capsule filters are also 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 challenge level is a minimum of  $10^7$  Brevundimonas diminuta organisms per cm<sup>2</sup> of filter media. CPF filters have > 7-log removal when challenged with the Brevundimonas diminuta (0.22µm meets the FDA definition of sterilizing grade filters).

Validation Guides available upon request.

#### Endotoxins

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

#### Extractables

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

### **TOC and Conductivity**

The PTR Micro Capsule filters conform with TOC standards of USP <643> and the water conductivity standards of USP <645> after an appropriate flush with purified water.

#### **Toxicity Compliance**

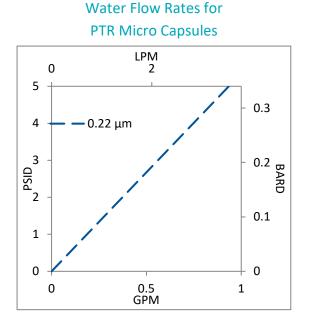
Materials used to construct the PTR Micro Capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

#### **Non-Fiber Releasing**

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

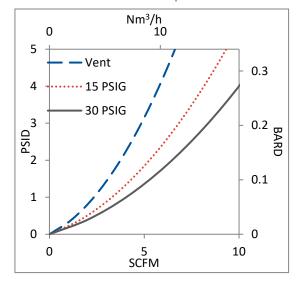
#### **FDA Compliance**

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

## Air Flow Rates for PTR Micro Capsules



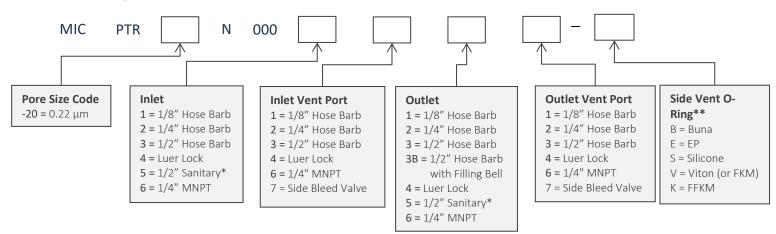
Flow rates for Micro Capsule filters are per filter. The test fluid is air at ambient temperature. Flows are tested using a Micro capsule filter with  $\frac{1}{2}$ " Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

# PTR 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 or <u>contact us here</u>.

### **Micro Capsule Filters**



\*When choosing the Sanitary Inlet/Outlet, the Luer Lock or bleed valve option is required for the Vent Port \*\* O-Ring is only available on Bleed Valve



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Data Sheet PTR Micro DS Rev -