

PTR filters are validated Polytetrafluoroethylene (PTFE) membrane cartridge and capsule filters used for sterilizing process gas applications and tank vents. The PTR membrane has a pore size of 0.22  $\mu m$  and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

These hydrophobic PTR filters have high air flow and low pressure drops. Each cartridge module is individually integrity 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.

PTR filters are recommended for:

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

# Sterilizing Filters

### 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)



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	
Gases Operational Pressure	N/A	60 psi at 68 °F (4.14 bar at 20 °C)	
Operating Temperature	180 °F at 30 psid (82 °C at 2.07 bard)	110 °F at 30 psid (43 °C at 2.07 bard)	
rward Differential Pressure 80 psid at 68 °F (5.52 bard at 20		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 35 psid (2.41 bard)		35 psid (2.41 bard)	

### Sanitization & Sterilization

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	1.5 ft <sup>2</sup>	4.1 ft <sup>2</sup>	8.7 ft <sup>2</sup>	17.4 ft <sup>2</sup>	26.0 ft <sup>2</sup>	34.7 ft <sup>2</sup>
	0.14m <sup>2</sup>	0.38m <sup>2</sup>	0.81m <sup>2</sup>	1.62m <sup>2</sup>	2.43m <sup>2</sup>	3.24m <sup>2</sup>

### **Integrity Testing**

PORE SIZE	WATER INTRUSION TEST PRESSURE		BUBBLE POINT MINIMUM*	
μm	PSIG	BARG	PSIG	BARG
0.22	35	2.41	18	1.24

WATER INTRUSION SPECIFICATIONS (mL/10 min)

Length 2" 5" 10" 20" 30" 40"

0.22μm  $\leq 1.9 \leq 5.6 \leq 13 \leq 26 \leq 39 \leq 52$ 

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

#### **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)	

<sup>\*</sup>High Temperature Cartridge configurations are also available.

#### Validation

PTR cartridges 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 cm² of filter media of Brevundimonas diminuta (ATCC 19146).

PTR 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 cm² of filter media. CPF filters have > 7-log removal when challenged with the Brevundimonas diminuta (0.22 $\mu$ m meets the FDA definition of sterilizing grade filters).

Validation Guides available upon request.

#### **Endotoxins**

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

#### **Extractables**

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

#### **TOC and Conductivity**

The PTR 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 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.

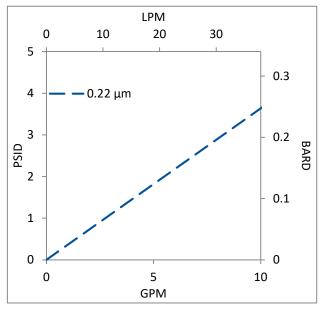
#### Non-Fiber Releasing

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

### **FDA Compliance**

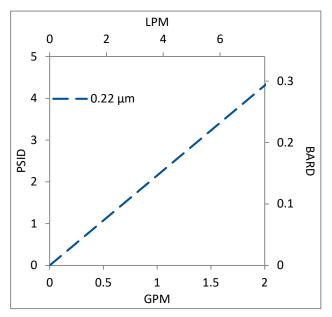
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

## Water Flow Rates for PTR Cartridges by Pore Size



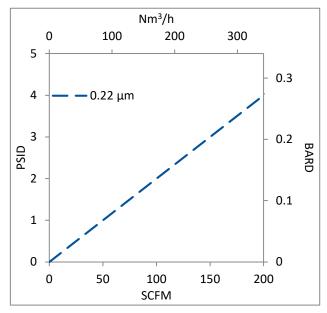
Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

# Water Flow Rates for PTR Capsules by Pore Size



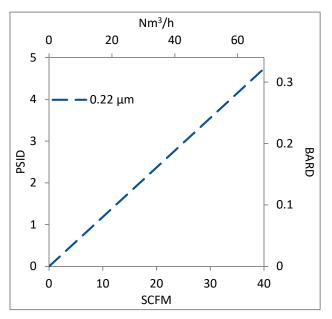
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water or compressed air at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

## Air/Gas Flow Rates for PTR Cartridges by Pore Size



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

# Air/Gas Flow Rates for PTR Capsules by Pore Size

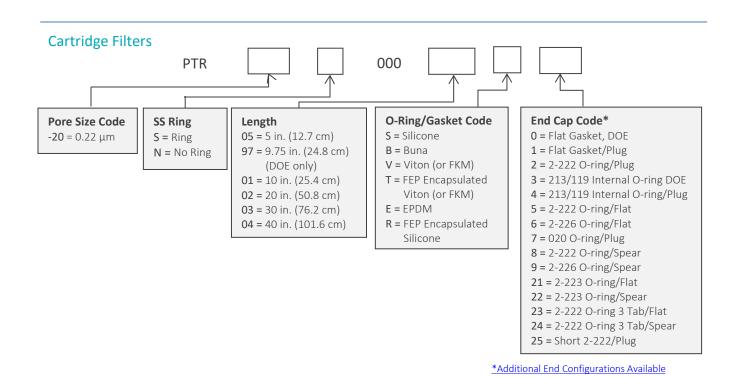


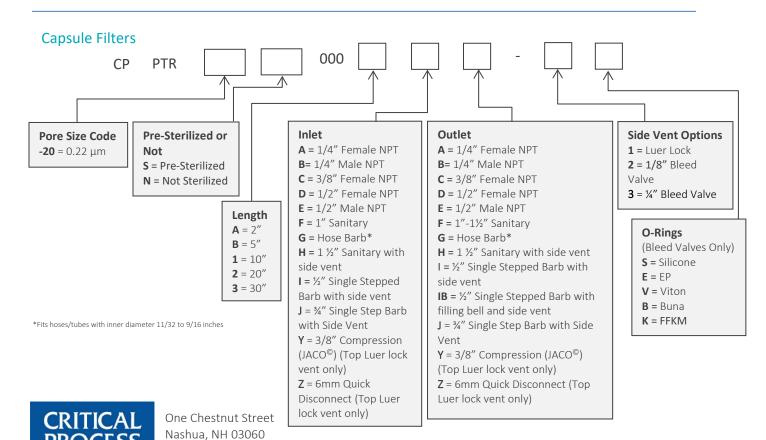
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water or compressed air at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

### PTR 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.





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