

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 .22 μ 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.

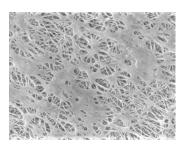
Sterilizing Filters Tank Vent & Process Gas



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



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



PTR filters are recommended for:

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

Maximum Operating Parameters

	CARTRIDGES	CAPSULES
Gases Operational Pressure	N/A	60 psi at 68 °F (4.13 bar at 20 °C)
Operating Temperature	180 °F at 30 psid (82 °C at 2.06 bard)	110 °F at 30 psid (43 °C at 2.06 bard)
Forward Differential Pressure	80 psid at 68 °F (5.51 bard at 20 °C)	Gas - 60 psi at 68 °F (4.13 bar at 20 °C)
Reverse Differential Pressure	50 psid at 68 °F (3.44 bard at 20 °C)	50 psid at 68 °F (3.44 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 con acid, sodium hypochlorite and other sel	centrations of hydrogen peroxide, peracetic lected chemicals.

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

Filtration Area

	CAPSULES		CARTRIDGES A	AND CAPSULES		CARTRIDGES
Length	2″	5″	10"	20"	30"	40"
	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	1.0 ft ²	3.0 ft ²	8.68 ft ²	17.36 ft ²	26.04 ft ²	34.72 ft ²
	0.10m ²	0.28m ²	0.76m ²	1.52m ²	2.29m ²	3.05m ²

Integrity Testing

PORE SIZE		NTRUSION RESSURE	-	E POINT MUM*	WATER IN	RUSION	SPECIFIC	ATIONS	(mL/10	min)	
μm	PSIG	BARG	PSIG	BARG	Length	2″	5″	10"	20"	30"	40"
0.22	35	2.41	18	1.24	- 0.22μm	≤ 1.6	≤ 4.8	≤ 13	≤ 26	≤ 39	≤ 52

 * Bubble Point for membrane wetted with 60% IPA / 40% water

Construction Materials

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

*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 μ m filter membrane is 7.5 x 10⁷ 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* (0.22µm meets the FDA definition of sterilizing grade filters).

Validation Guides available upon request.

Endotoxins

The levels of bacterial endotoxins in aqueous extracts from PTR 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.

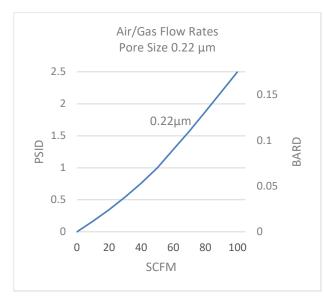
Non-Fiber Releasing

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

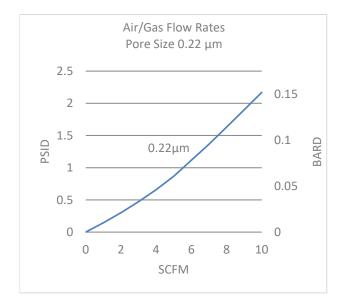
FDA Compliance

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.

Flow Rates for PTR Cartridges



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



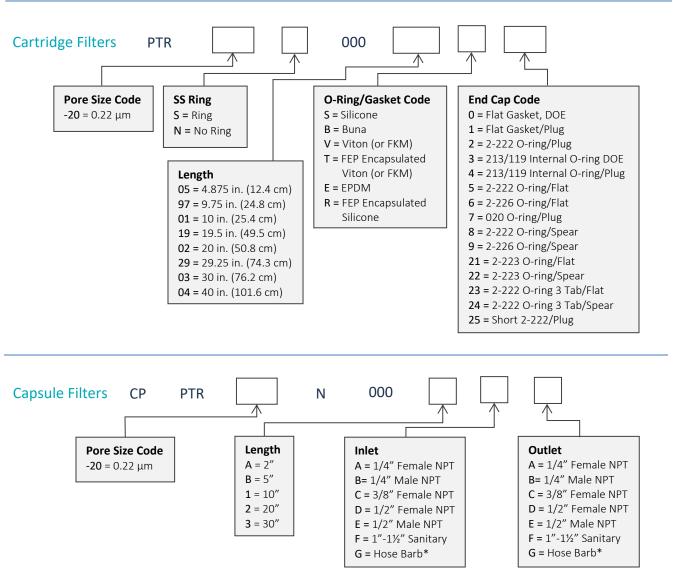
Flow Rates for PTR Capsules

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

PTR 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) 880-4220 Ext. 106, or send an email to <u>sales@criticalprocess.com</u>



*Fits hoses/tubes with inner diameter 11/32 to 9/16 inches

Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.



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