

PTM cartridge and capsule filters are constructed using a Polytetrafluoroethylene (PTFE) membrane and are validated for sterilizing filtration of gases and non-aqueous liquids. Pore sizes range from 0.10 to 5.0 μ m and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

The hydrophobic PTM filters resist wetting by airborne water droplets, making them ideal for air and gas applications. The broad chemical compatibility of the PTM filters makes them well suited for aggressive solvents and other non-aqueous liquids. 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 highperformance 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.

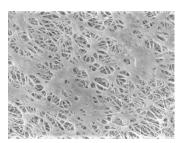
Sterilizing Filters Tank Vent & Process Gas



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



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



PTM sterilizing filters are recommended for:

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

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	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 concent hypochlorite and other selected chemicals.	rations of hydrogen peroxide, peracetic acid, sodium

*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	1.4 ft ²	3.8 ft ²	8.2 ft ²	16.4 ft ²	24.6 ft ²	32.8 ft ²
	0.13m ²	0.36 m ²	0.76m ²	1.52m ²	2.29m ²	3.05m ²

Integrity Testing

PORE SIZE		NTRUSION RESSURE	BUBBLE POINT MINIMUM*	
μm	PSIG	BARG	PSIG	BARG
0.10	35	2.41	22	1.52
0.22	35	2.41	18	1.24
0.45	N/A	N/A	9	0.62
1.0	N/A	N/A	6	0.41
3.0	N/A	N/A	2	0.14
5.0	N/A	N/A	1	0.07

WATER INTRUSION SPECIFICATIONS (mL/10 min)						
Length	2″	5″	10"	20"	30"	40"
0.10µm	≤1.4	≤ 4.3	≤ 10	≤ 20	≤ 30	≤ 40
0.22µm	≤ 1.9	≤ 5.6	≤ 13	≤ 26	≤ 39	≤ 52

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

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)

*High Temperature Cartridge configuration is available.

Validation

PTM 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 challenge level is a minimum of 10^7 organisms per cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.10µm and 0.22µm meet the FDA definition of sterilizing grade filters).

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 PTM filters are below current USP limits as specified for water for injection.

Extractables

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

Toxicity Compliance

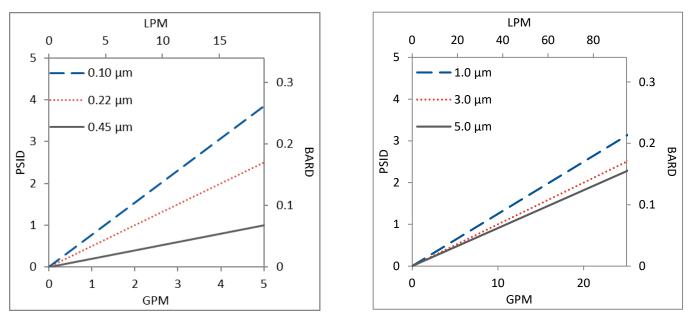
Materials used to construct the PTM filters are nontoxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

Non-Fiber Releasing

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

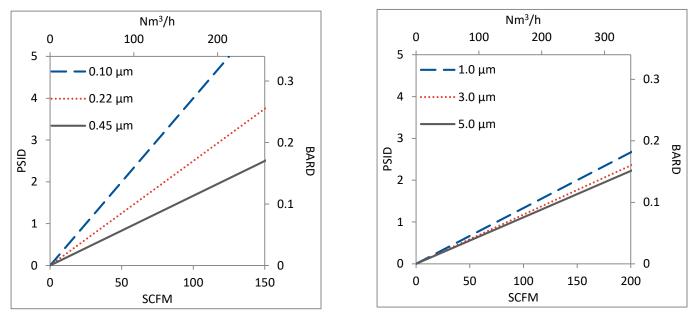
FDA Compliance

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.



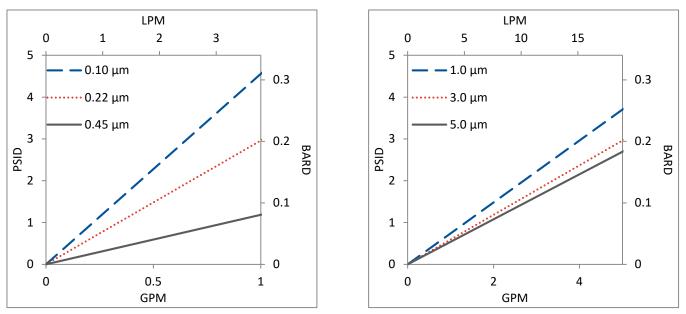
Water Flow Rates for PTM Cartridges by Pore Size

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



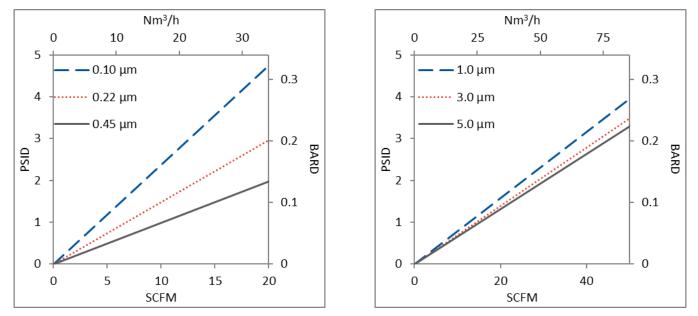
Air/Gas Flow Rates for PTM Cartridges by Pore Size

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



Water Flow Rates for PTM 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.



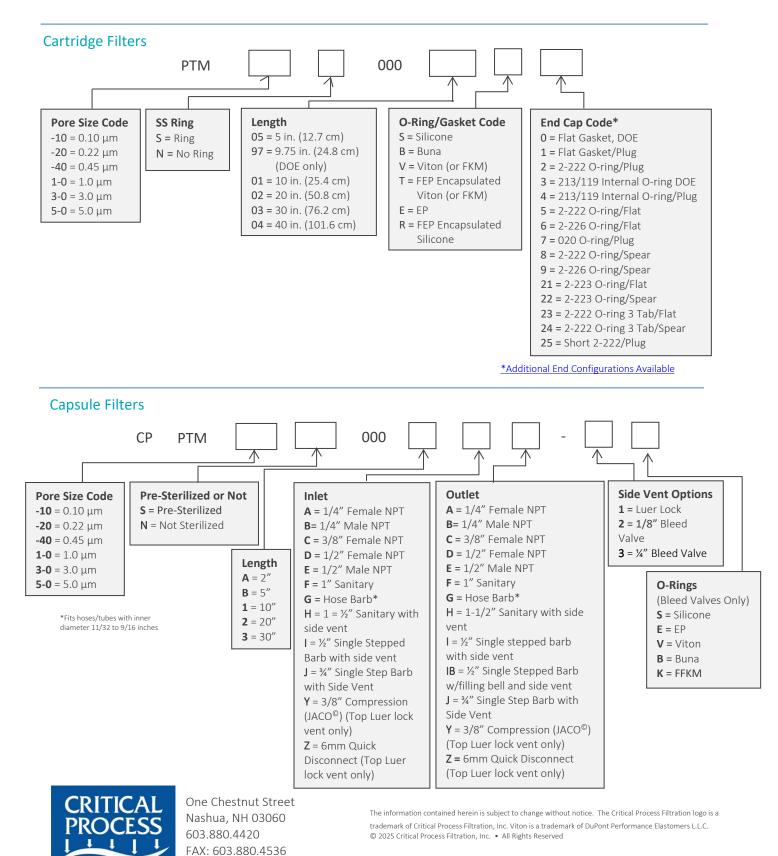
Air/Gas Flow Rates for PTM Capsules by Pore Size

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.

PTM 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 Ext. 106, or send an email to <u>sales@criticalprocess.com</u>



CriticalProcess.com

FILTRATION, INC.

Data Sheet PTMDS Rev C