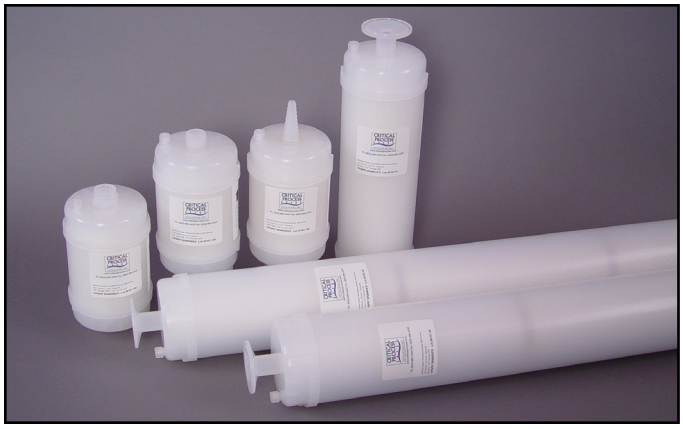
PTM Capsule Filters

PTFE Membrane

CRITICAL PROCESS FILTRATION, INC.

Pharmaceutical Grade



Optimized for maximum filter life

Designed for filtration of air and process gases

Vent filtration for the protection of tank contents

Final filtration of solvents, alcohols and other non-aqueous liquids

Applications

- Solvent Filtration
- Fermentation Air
- Tank Vent Filters
- Process Gas
- Compressed Air Filtration

Pharmaceutical grade TM capsules are manufactured for the critical needs of the pharmaceutical industry. Made with highly hydrophobic polytetrafluoroethylene (PTFE) membrane, these capsules are used for filtration of non-aqueous liquids, aggressive solvents, compressed gases, and as vent filters. Each module is individually tested using the water intrusion method before it is released from manufacture.

The capsule media surface area, filter core design, pleat configuration and pleat packing density have been optimized to provide increased life resulting in lower filtration operating costs.

PTM Capsule Filters - Filtration Area

Media	Capsule Length				
	2″	5″	10″	20″	30″
PTFE Membrane	1.0 ft^2 (0.093m^2)	3.0 ft^2 (0.279m^2)	8.2 ft^2 (0.763m^2)	16.4 ft^2 (1.525m^2)	24.6 ft^2 (2.288m^2)

Flow Rate / Filtration Area

The following table represents typical air and water flow at a one psi (69 mbar) pressure differential across a single 2 inch capsule with 1.0 ft^2 (0.093 m^2) of media with 1/2″ FNPT ports. The liquid test fluid is water at ambient temperature. The gas test fluid is compressed air at ambient temperature. Higher pressure drops are acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Air/Gas Flow Rates							Liquid Flow Rates						
µm Rating	0.10 µm	0.22 µm	0.45 µm	1.0 µm	3.0 µm	5.0 µm	**µm Rating**	0.10 µm	0.22 µm	0.45 µm	1.0 µm	3.0 µm	5.0 µm
SCFM	3.0	4.9	9	11	>11	>11	**GPM**	0.15	0.24	0.76	1.2	1.4	1.6
							LPM	0.57	0.91	2.87	4.54	5.30	6.06

Construction Materials

Housing	Polypropylene
Filtration Media	PTFE Membrane
Media Support	Polypropylene
End Caps	Polypropylene
Center Core	Polypropylene
Outer Support Cage	Polypropylene
Sealing Method	Thermal Bonding

Maximum Operating Parameters

Liquid Operational Pressure	80 psi (5.5 bar) at 20 °C (68 °F)
Gases Operational Pressure	60 psi (4.1 bar) at 20 °C (68 °F)
Operating Temperature	43 °C (110 °F) at 30 psi (2.1 bar) in water
Forward Differential Pressure	50 psid (3.4 bard) at 20 °C (68 °F)
Reverse Differential Pressure	40 psid (2.7 bard) at 20 °C (68 °F)
Recommended Changeout Pressure	35 psid (2.4 bard)

Integrity Test Specifications

60/40 IPA/water wetted membrane

Pore Size	Bubble Point
0.10 µm	22 psig (1.52 barg)
0.22 µm	18 psig (1.2 barg)
0.45 µm	9 psig (621 mbarg)
1.0 µm	6 psig (414 mbarg)
3.0 µm	2 psig (138 mbarg)
5.0 µm	1 psig (69 mbarg)

Sanitization/Sterilization

Autoclave.....250° F (121° C), 30 min, 5+ cycles

Chemical Sanitization..... Industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals.

Note..... PTM capsules are not to be used in steam.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PTM 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. In addition, the 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 appropriate. PTM capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

Extractables

Pharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Validation

PTM capsules are validated using test procedures that comply with the intent of both ASTM F 838-05 and HIMA protocols for the determination of bacterial retention. The challenge level is 10^7 organisms per cm^2 of filter media; 0.22 µm challenged with *Brevundimonas diminuta*; 0.45 µm challenged with *Serratia marcescens.*

Critical Process Filtration can provide validation assistance.

Quality Assurance and Standards

Critical Process Filtration uses state of the art computer controlled equipment to consistently produce high quality products as well as significantly reduce hand operations that can compromise quality. All manufacturing and testing is continuously monitored in real time so that data can be quickly and easily analyzed to facilitate improvements in both quality and cost.

The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled using a sophisticated manufacturing system that networks work stations, manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected in real time to allow continuous quality monitoring and full traceability of all materials and processes.

Each capsule assembly is integrity tested before release.

Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products to industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Ordering Information

Capsule order number example: Pharmaceutical Grade PTFE Membrane, 0.22 Micron Rating, Non-Sterile, 10" Length, Sanitary Inlet, Sanitary Outlet = CPPTM-20N0001FF.

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Micron Rating
-10 - .10 **1-0** - 1.0
-20 - .22 **3-0** - 3.0
-40 - .45 **5-0** - 5.0

N - Non-Sterile

Length
A - 2"
B - 5"
1 - 10"
2 - 20"
3 - 30"

Inlet
A - 1/4" Female NPT
B - 1/4" Male NPT
C - 3/8" Female NPT
D - 1/2" Female NPT
E - 1/2" Male NPT
F - 1"-1½" Sanitary
G - Hose Barb*

Outlet
A - 1/4" Female NPT
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C - 3/8" Female NPT
D - 1/2" Female NPT
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Hose Barb Diameter Ranges*

	Minimum	Maximum
Outer Diameters	11/32" (8.6mm)	9/16" (14.0mm)
Inner Diameters	5/32" (4.0mm)	13/32" (10.5mm)

Request a QUOTE from your area representative

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