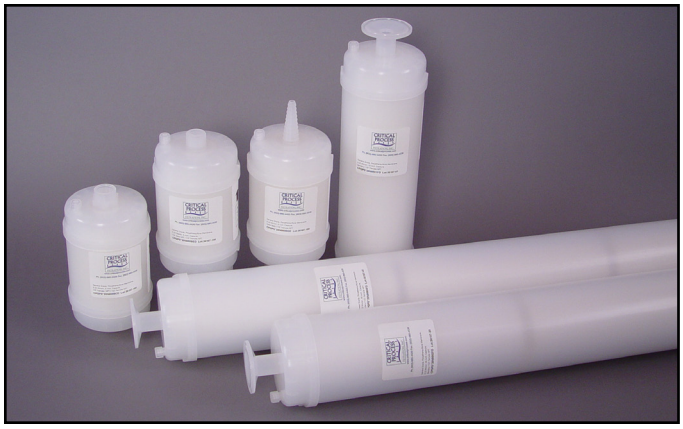
BTM Capsule Filters

PTFE Membrane

CRITICAL PROCESS FILTRATION, INC.



Optimized for maximum filter life

Filtration of air and process gases

Vent filtration for the protection of tank contents

Filtration of solvents, alcohols and other non-aqueous liquids

Applications

- Fermentation Air
- Solvent Filtration
- Non-Aqueous Solutions
- Process Gas
- Compressed Air Filtration
- Tank Vents

Biopharmaceutical grade TM capsules are manufactured for critical applications in biopharmaceutical processing. Made with highly hydrophobic polytetrafluoroethylene (PTFE) membrane, these capsules are used for filtration of fermentation air, solvents and alcohols, 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.

Biopharmaceutical Grade

BTM Capsule Filters - Filtration Area

Media	Capsule Length				
	2″	5″	10″	20″	30″
PTFE Membrane	1.0 ft^2 (930cm^2)	3.0 ft^2 (2788cm^2)	7.5 ft^2 (6967cm^2)	15.0 ft^2 (13934cm^2)	22.5 ft^2 (20901cm^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 (930 cm^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	**µm Rating**	0.10 µm	0.22 µm	0.45 µm	1.0 µm
SCFM	3.7	5.6	9	11	**GPM**	0.25	0.40	0.76	1.2
					LPM	0.95	1.51	2.87	4.54

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

(per 1.0 ft^2 (930 cm^2) 60/40 IPA/water wetted membrane)

Pore Size	Bubble Point
0.10 µm	21 psig (1.45 barg)
0.22 µm	15 psig (1.0 barg)
0.45 µm	9 psig (621 mbarg)
1.0 µm	6 psig (414 mbarg)

Sanitization/Sterilization

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

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

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

USP Biosafety and FDA Compliance

The materials used to construct biopharmaceutical grade BTM 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. BTM 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 biopharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

Extractables

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

Validation

Biopharmaceutical grade TM capsules are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. 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: Biopharmaceutical Grade PTFE Membrane, 0.22 Micron Rating, Non-Sterile, 10" Length, Sanitary Inlet, Sanitary Outlet = CPBTM-20N0001FF

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Micron Rating
-10 - .10 **-40** - .45
-20 - .22 **1-0** - 1.0

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 - Sanitary
G - Hose Barb*

Outlet
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 - Sanitary
G - Hose Barb*

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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