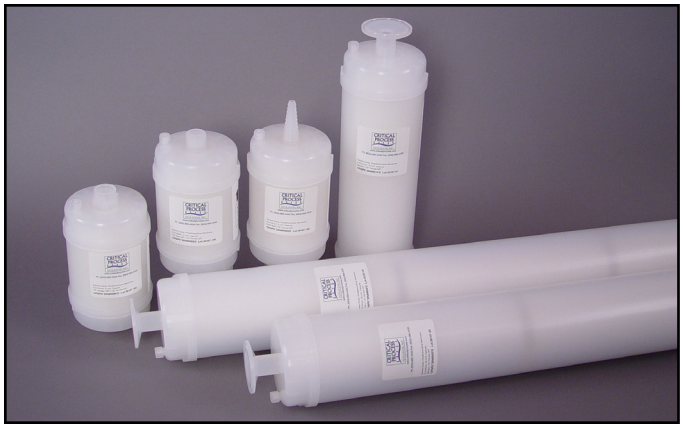
BPS Capsule Filters

PES Membrane

CRITICAL PROCESS FILTRATION, INC.



Validated for use in multiple biopharmaceutical applications

Excellent flow rates with high throughput

Designed for minimal leachables and extractables

Low adsorption of proteins and preservatives

Applications

- Buffers and Feedstocks
- WFI Water
- Solvents
- SVPs
- LVPs
- Vaccines

Biopharmaceutical grade PS capsules are hydrophilic and manufactured with the highest quality asymmetric polyethersulfone (PES) membrane. PES membrane exhibits excellent flow rates with high throughput. BPS capsule filters are used for bioburden reduction applications in the biologicals industry. Specific applications for BPS capsule filters are bacteria removal in buffers, USP Water for Injection (WFI), SVPs, LVPs and other biological products. The filter elements are 100% integrity tested during production.

Polyethersulfone is particularly suited for the filtration of products that contain elements that can adsorb to the media, such as preservatives and proteins. The lower binding characteristics of PES make it a good choice for filtration of valuable protein solutions such as vaccines and other biologicals.

Biopharmaceutical Grade

Flow Rate / Filtration Area

The following table represents typical 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 test fluid is water at ambient temperature. Higher pressure drops are acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Pore Size	0.03 µm	0.10 µm	0.22 µm	0.45 µm	0.65 µm	0.8 µm	1.0 µm	1.2 µm
GPM	0.16	0.26	0.46	0.71	0.86	0.91	0.97	1.0
LPM	0.61	0.98	1.74	2.69	3.26	3.44	3.67	3.78

* For approximate flow rates for 5" through 30" capsules, refer to the appropriate cartridge data sheet

BPS Capsule Filters - Filtration Area

Media	Capsule Length				
	2"	5"	10"	20"	30"
PES Membrane	1.0 ft^2 (0.093m^2)	3.0 ft^2 (0.279m^2)	7.0 ft^2 (0.650m^2)	14.0 ft^2 (1.301m^2)	21.0 ft^2 (1.951m^2)

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.....BPS capsules are not to be used in steam.
Pre-Sterilized.....BPS capsules are offered in both non- and pre-sterilized forms.

Construction Materials

Housing	Polypropylene
Filtration Media	Polyethersulfone (PES) 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

Pore Size	Test Pressure (psi)	Max Diffusion Rate (cc/min -water wetted membrane)				
		2"	5"	10"	20"	30"
0.03	60	4.3	12.9	30	60	90
0.10	48	4.3	12.9	30	60	90
0.22	35	4.3	12.9	30	60	90
0.45	20	4.3	12.9	30	60	90
0.65	15	4.3	12.9	30	60	90
0.80	12	4.3	12.9	30	60	90
1.00	8	4.3	12.9	30	60	90
1.20	7	4.3	12.9	30	60	90

Integrity Test Specifications - Bubble Point

Pore Size	Bubble Point (water wetted membrane)
0.03 µm	**
0.10 µm	**
0.22 µm	50 psig (3.5 barg)
0.45 µm	25 psig (1.7 barg)
0.65 µm	19 psig (1.3 barg)
0.8 µm	15 psig (1.1 barg)
1.0 µm	10 psig (0.7 barg)
1.2 µm	9 psig (0.6 barg)

** Test pressure exceeds operational limits of capsule filters. Use the diffusion test method.

Validation

BPS cartridges 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 in filters used for liquid filtration. The challenge level is 10^7 organisms per cm^2 of filter media:

0.10 µm challenged with *Acholeplasma laidlawii*;
0.22 µm challenged with *Brevundimonas diminuta*;
0.45 µm challenged with *Serratia marcescens*;
0.65 µm challenged with *Saccharomyces cerevisiae*.

Critical Process Filtration can provide validation assistance.

Extractables

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

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 filter assembly is integrity tested before release.

USP Biosafety and FDA Compliance

The materials used to construct biopharmaceutical grade PS 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. BPS 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.

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 PES Membrane, 0.22 Micron Rating, Pre-Sterilized, 10" Length, Sanitary Inlet, Sanitary Outlet = CPBPS-20S0001FF.

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Micron Rating
-03 - .03 **-60** - .65
-10 - .10 **-80** - .80
-20 - .22 **1-0** - 1.0
-40 - .45 **1-2** - 1.2

Pre-Sterilized or Not
S - Pre-Sterilized
N - Not Sterilized

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
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*

Request a **QUOTE** from your area representative

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)

CRITICAL PROCESS FILTRATION, INC.

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