

BPS cartridge and capsule filters are multipurpose products that excel in bioburden reduction, clarification and the prefiltration of aqueous fluids when sterilizing is not the goal. They consist of a single layer of Polyethersulfone (PES) membrane and deliver high flow and throughput across a wide pH range. These filters have low binding characteristics which is necessary when filtering fluids with high proteins and preservatives. For fluids with heavy microbial and particle contamination, an optional high-capacity PES prefilter can be integrated. BPS final layer pore sizes range from 0.03 to 1.2 μm and the integrated prefilter pore sizes range from 0.2 to 1.0 μm . CPF filters are designed with flexible configurations so you can achieve targeted results.

When sterile filtrate is the goal, and bacteria loads are high, the BPS is a very efficient standalone prefilter. Installing the BPS Filter (single or dual layer) protects the final filter from premature fouling, and extends its useful life.

BPS Filters are 100% integrity tested. These high-quality filters are flushed to remove manufacturing debris and reduce extractables. CPF filter devices scale from laboratory to full production using identical materials to ensure consistent results. BPS Capsule filters are available pre-sterilized.

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

BPS filters are recommended for bioburden control in:

- SVPs & LVPs
- Diagnostics
- Buffers
- WFI, Water Purification
- Vaccines
- Ophthalmics

Bioburden Control Clarification & Prefiltration



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)

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)	80 psid at 68 °F (5.52 bard 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, 25+ cycles		
Chemical Sanitization	Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.		

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

Filtration Area (Nominal)

	CAPSULES	CARTRIDGES AND CAPSULES				CARTRIDGES
Lanath	2"	5"	10"	20"	30"	40"
Length	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area –	1.2 ft ²	3.4 ft ²	7.3 ft ²	14.6 ft ²	21.9 ft ²	29.2 ft ²
Single Layer	0.11m ²	0.32m ²	0.68m ²	1.36m ²	2.04m ²	2.72m ²
Area –	0.9 ft ²	2.5 ft ²	5.4 ft ²	10.8 ft ²	16.2 ft ²	21.6 ft ²
Dual Layer	0.08m ²	0.23m ²	0.50m ²	1.00m ²	1.50m ²	2.00m ²

Integrity Testing

	5.55.10			
FINAL LAYER PORE SIZE‡	DIFFUSION TEST PRESSURE*			E POINT MUM*
μm	PSIG	BARG	PSIG	BARG
0.03	60	4.13	**	**
0.10	48	3.30	**	**
0.22	35	2.41	50	3.5
0.45	20	1.37	25	1.7
0.65	15	1.03	19	1.3
0.80	12	0.82	15	1.1
1.0	8	0.55	10	0.7
1.2	7	0.48	9	0.6

[†] Integrity test values are the same for filters with and without a prefiltration layer

DIFFUSION SPECIFICATIONS*							
Length	2"	5"	10"	20"	30"	40"	
mL/min	≤ 4.3	≤ 12.9	≤ 30	≤ 60	≤ 90	≤ 120	

^{*} For water wetted membrane

^{**} Test pressure exceeds operational limits of capsule filters.
Use the Diffusion Test method.

Construction Materials

Filtration Media	PES membrane OR High Capacity PES membrane with polyester support prefilter layer and PES membrane final filter layer	
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)	

Validation

BPS 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 filters are challenged with the organisms listed below.

0.03μm: Acholeplasma laidlawii 0.10μm: Brevundimonas diminuta 0.22μm: Brevundimonas diminuta 0.45μm: Serratia marcescens 0.65μm: Saccharomyces cerevisiae

Validation Guides available upon request.

Endotoxins

The levels of bacterial endotoxins in aqueous extracts from BPS filters are below current USP limits as specified for water for injection.

Extractables

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

TOC and Conductivity

BPS 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 BPS 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.

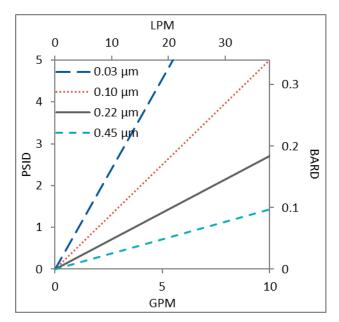
Non-Fiber Releasing

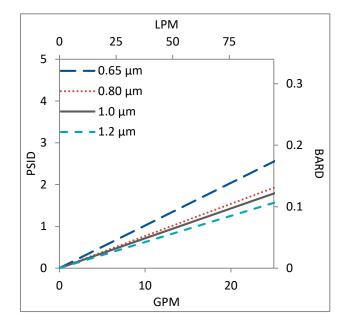
BPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

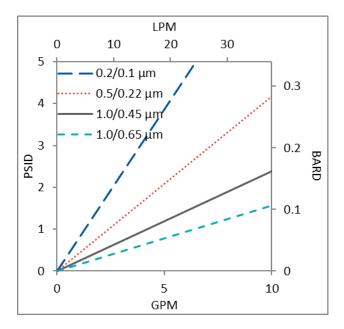
FDA Compliance

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 BPS Cartridges by Pore Size

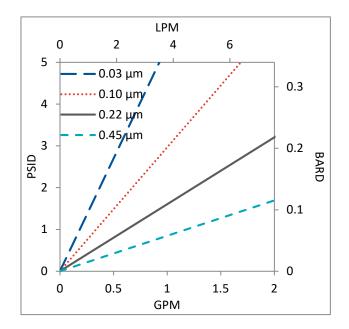


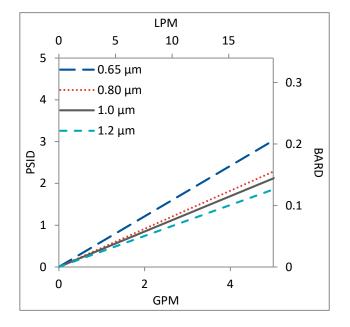


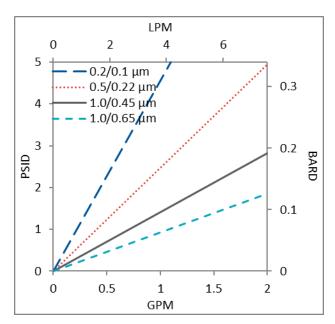


Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

Flow Rates for BPS Capsules by Pore Size





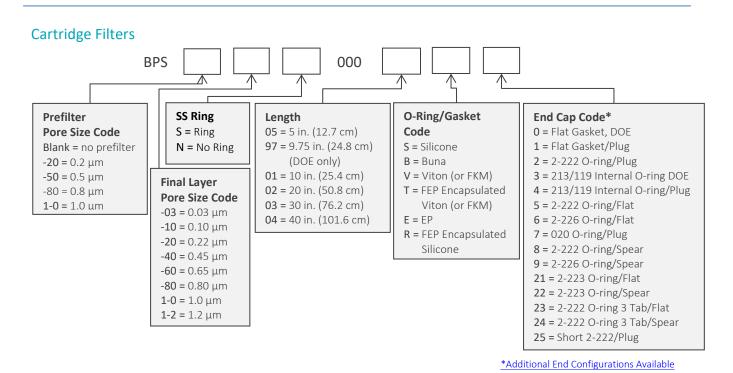


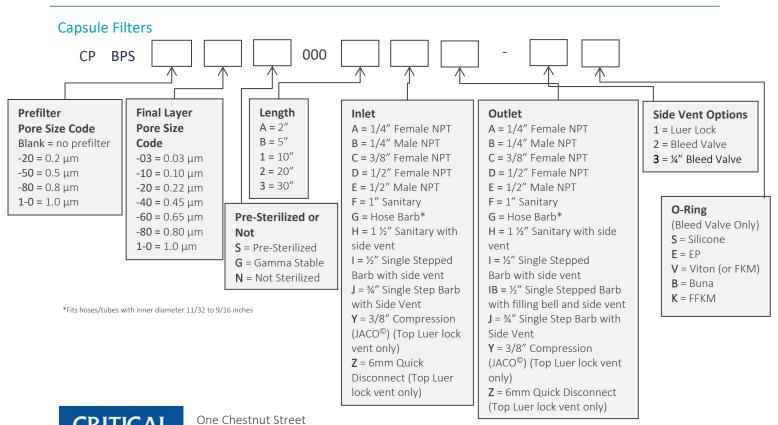
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

BPS 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 or contact us here.





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