



BPS Filters

Single and Dual Layer PES Membrane

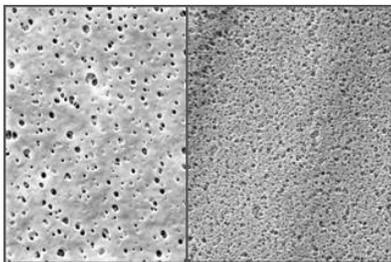


BPS filters offer single and dual layer Polyethersulfone (PES) cartridge and capsule filters for use with aqueous liquids. Pore sizes range from 0.03 to 1.2 μm and filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

These hydrophilic filters are designed to prevent bioburden contamination and reduce microbials when sterilizing is not required. They are also utilized in clarifying and prefiltering products with high proteins and preservatives. The BPS filter's low binding characteristics make them highly efficient, which is critical to protecting process quality and extending the life of sterilizing filters.

The BPS filters are designed with a single Asymmetric PES membrane and the option of adding a High Capacity PES prefilter layer. BPS filters deliver high flow and throughput across a wide pH range. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. BPS capsules 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 solution right the first time.



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 (5.51 bard at 20 °C)
Gases Operational Pressure	N/A	60 psi at 68 °F (4.13 bar at 20 °C)
Operating Temperature (water)	180 °F at 30 psid (82 °C at 2.06 bard)	110 °F at 30 psid (43 °C at 2.06 bard)
Forward Differential Pressure	80 psid at 68 °F (5.51 bard at 20 °C)	80 psid at 68 °F (5.51 bard at 20 °C)
Reverse Differential Pressure	50 psid at 68 °F (3.44 bard at 20 °C)	50 psid at 68 °F (3.44 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 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

	CAPSULES	CARTRIDGES AND CAPSULES					CARTRIDGES
	2"	5"	10"	20"	30"	40"	
Length	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm	
Area – Single Layer	1.2 ft ²	3.4 ft ²	7.3 ft ²	14.6 ft ²	21.9 ft ²	29.2 ft ²	
	0.11m ²	0.32m ²	0.68m ²	1.36m ²	2.04m ²	2.72m ²	
Area – Dual Layer	0.9 ft ²	2.5 ft ²	5.4 ft ²	10.8 ft ²	16.2 ft ²	21.6 ft ²	
	0.08m ²	0.23m ²	0.50m ²	1.00m ²	1.51m ²	2.01m ²	

Integrity Testing

FINAL LAYER PORE SIZE [‡]	DIFFUSION TEST PRESSURE*		BUBBLE POINT MINIMUM*		DIFFUSION SPECIFICATIONS*						
	PSIG	BARG	PSIG	BARG	Length	2"	5"	10"	20"	30"	40"
µm					mL/min	≤ 4.3	≤ 14	≤ 30	≤ 60	≤ 90	≤ 120
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							
0.8	12	0.82	15	1.1							
1.0	8	0.55	10	0.7							
1.2	7	0.48	9	0.6							

* For water wetted membrane
 ** Test pressure exceeds operational limits of capsule filters. Use the Diffusion Test method.

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

Construction Materials

Filtration Media	Asymmetric PES membrane OR High Capacity PES membrane with polyester support prefilter layer and Asymmetric 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.

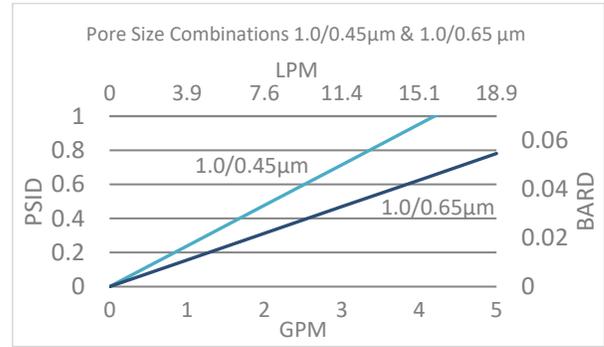
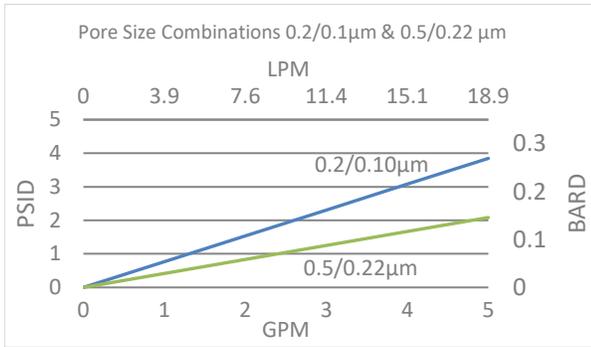
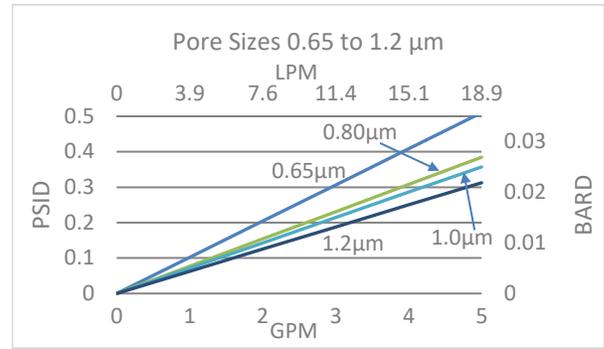
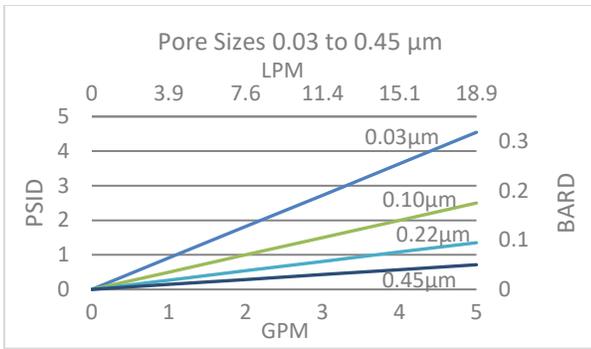
Non-Fiber Releasing

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

FDA Compliance

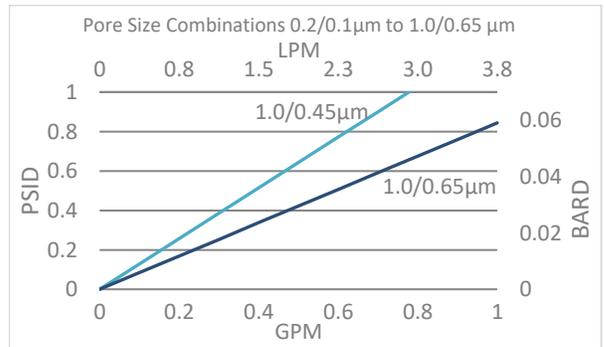
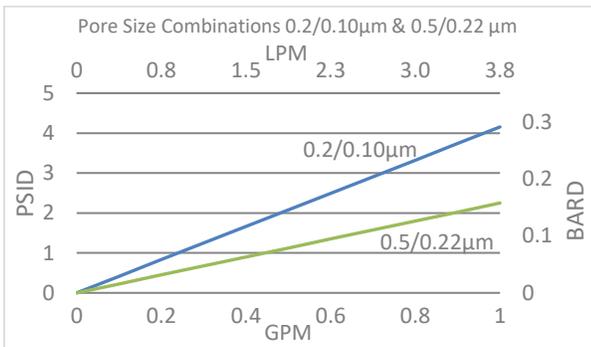
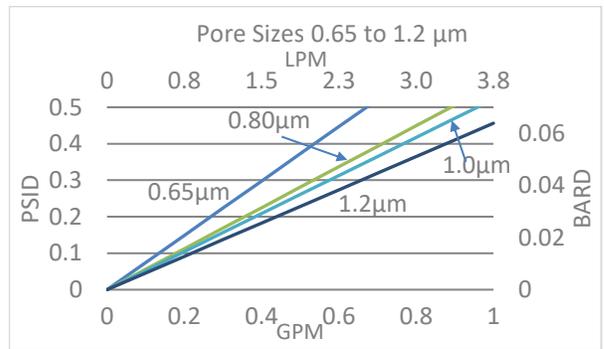
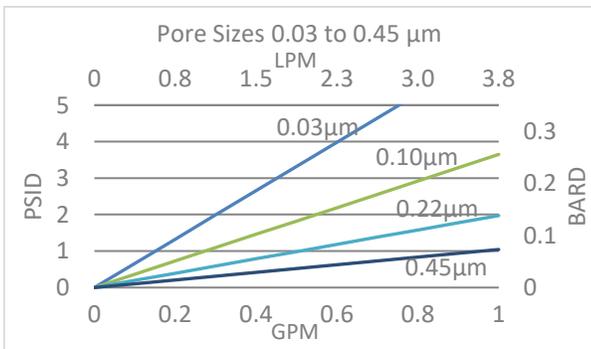
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

Flow Rates for BPS Cartridges



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

Flow Rates for BPS Capsules

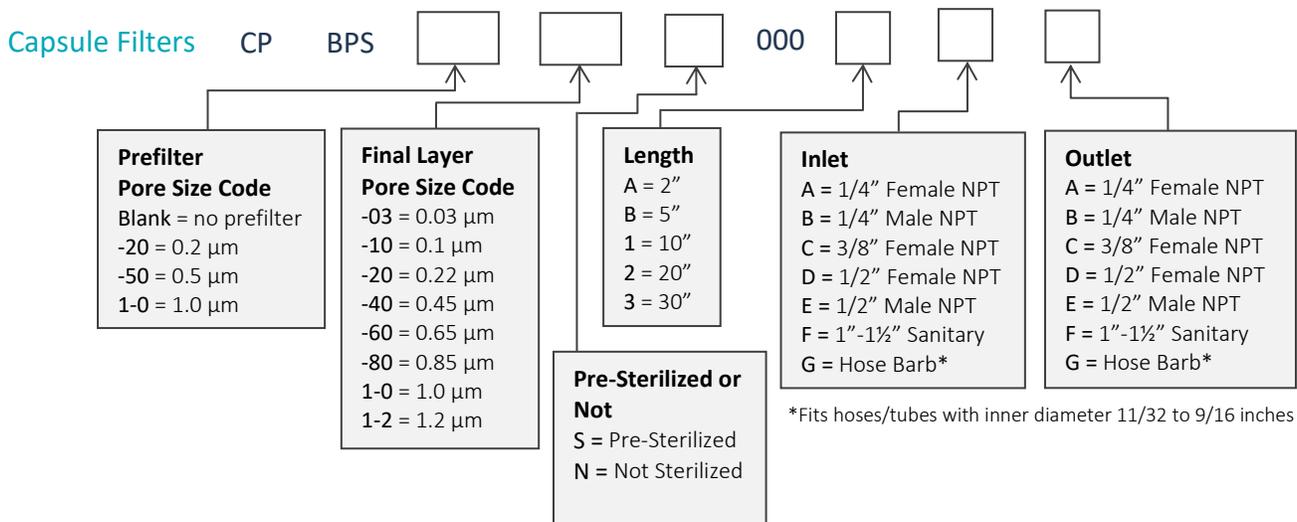
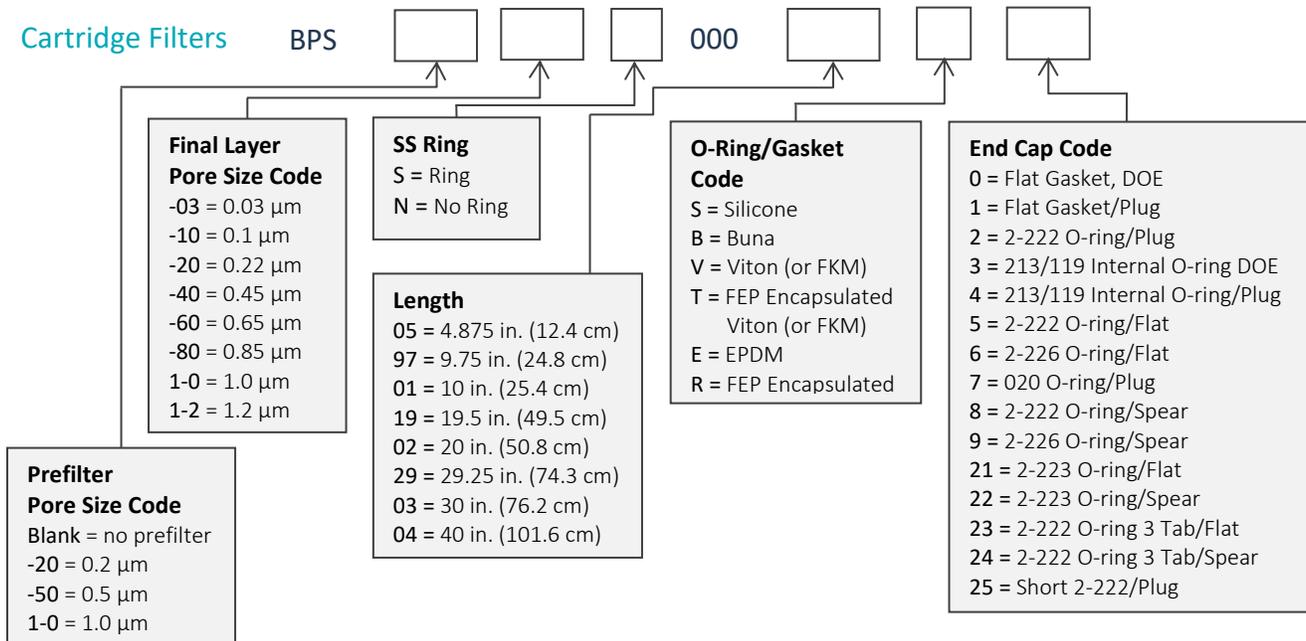


Flow rates for Capsule filters are per square foot of membrane area. The test fluid is water at ambient temperature. Flows are tested using a 2" capsule filter with 1/2" FNPT inlet and outlet ports. Rates will vary based on end configuration of the capsule.

BPS Filters Ordering Information

All Critical Process filters are configurable to meet customer specifications.
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) 880-4220 Ext. 106, or send an email to sales@criticalprocess.com



Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.



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