CRITICAL PROCESS FILTRATION, INC.

BPS Filters

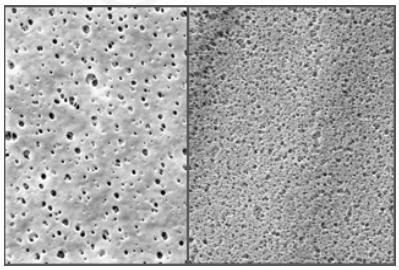
Single Layer PES Membrane with Optional Prefilter

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
Length	2”	5”	10”	20”	30”	40”
	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	1.50m^2	2.00m^2

Integrity Testing

FINAL LAYER PORE SIZE‡	DIFFUSION TEST PRESSURE*		BUBBLE POINT MINIMUM*	
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.

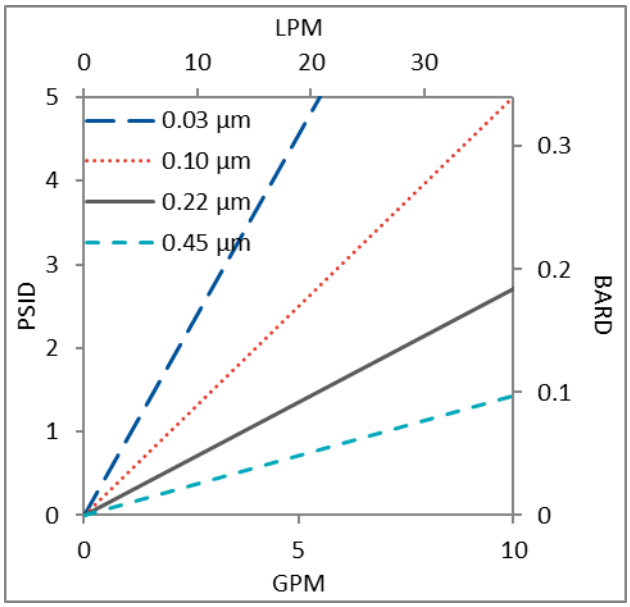
Non-Fiber Releasing

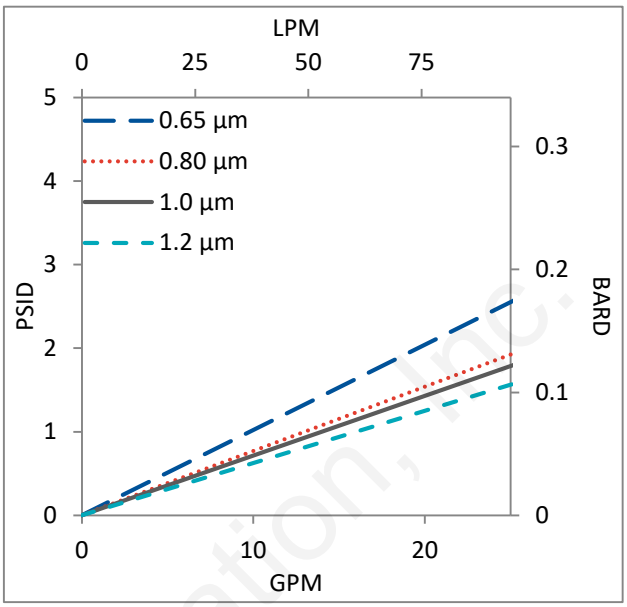
BPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

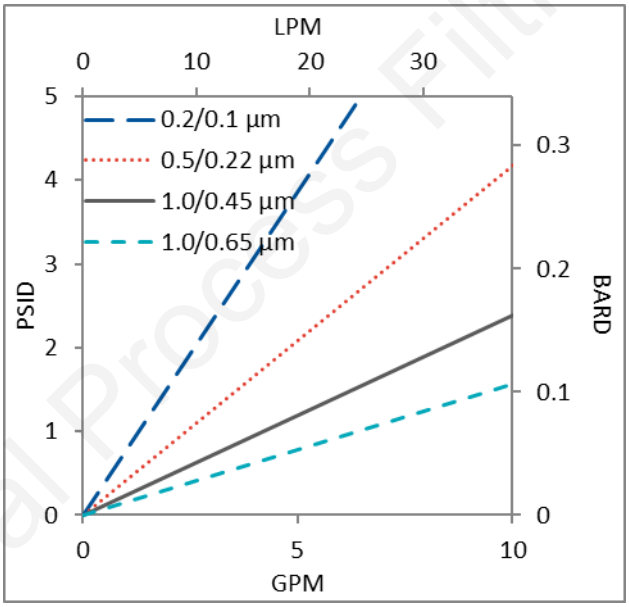
FDA Compliance

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

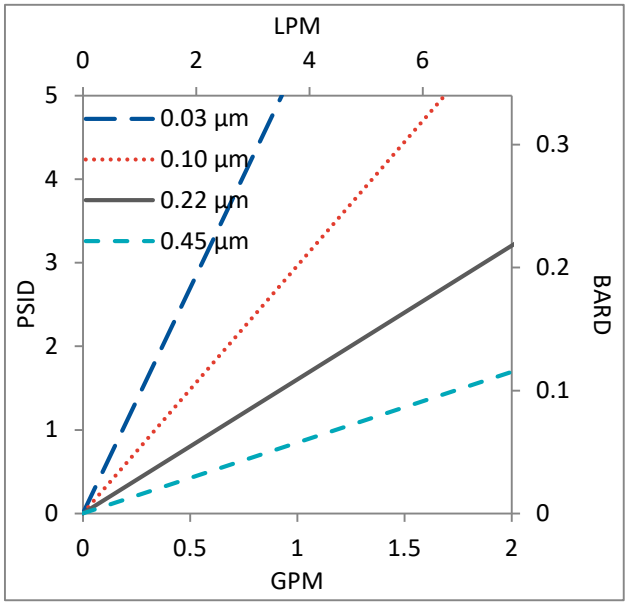


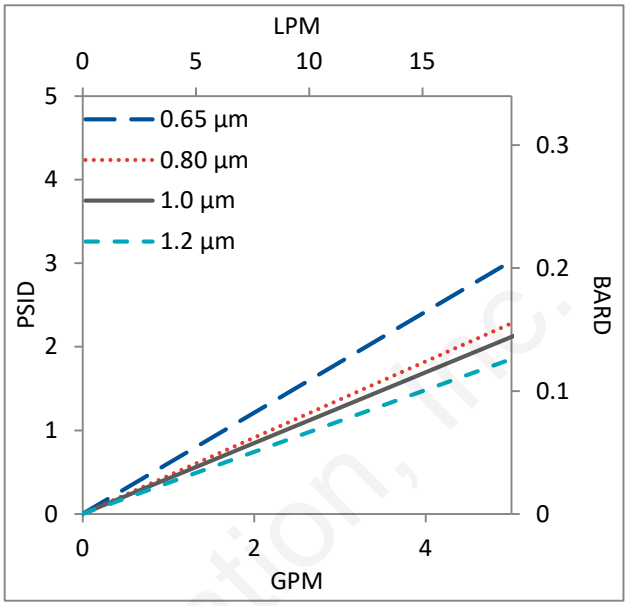


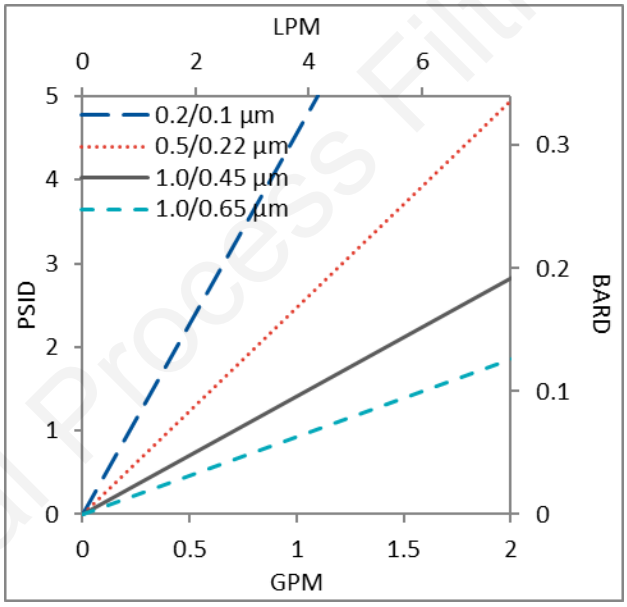


Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

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.

Cartridge Filters

BPS [ ] [ ] [ ] 000 [ ] [ ] [ ]

Prefilter Pore Size Code
Blank = no prefilter
-20 = 0.2 µm
-50 = 0.5 µm
-80 = 0.8 µm
1-0 = 1.0 µm

SS Ring
S = Ring
N = No Ring

Final Layer Pore Size Code
-03 = 0.03 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm
-60 = 0.65 µm
-80 = 0.80 µm
1-0 = 1.0 µm
1-2 = 1.2 µm

Length
05 = 5 in. (12.7 cm)
97 = 9.75 in. (24.8 cm) (DOE only)
01 = 10 in. (25.4 cm)
02 = 20 in. (50.8 cm)
03 = 30 in. (76.2 cm)
04 = 40 in. (101.6 cm)

O-Ring/Gasket Code
S = Silicone
B = Buna
V = Viton (or FKM)
T = FEP Encapsulated Viton (or FKM)
E = EP
R = FEP Encapsulated Silicone

End Cap Code*
0 = Flat Gasket, DOE
1 = Flat Gasket/Plug
2 = 2-222 O-ring/Plug
3 = 213/119 Internal O-ring DOE
4 = 213/119 Internal O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
7 = 020 O-ring/Plug
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear
21 = 2-223 O-ring/Flat
22 = 2-223 O-ring/Spear
23 = 2-222 O-ring 3 Tab/Flat
24 = 2-222 O-ring 3 Tab/Spear
25 = Short 2-222/Plug

*Additional End Configurations Available

Capsule Filters

CP BPS [ ] [ ] [ ] 000 [ ] [ ] [ ] - [ ] [ ]

Prefilter Pore Size Code
Blank = no prefilter
-20 = 0.2 µm
-50 = 0.5 µm
-80 = 0.8 µm
1-0 = 1.0 µm

Final Layer Pore Size Code
-03 = 0.03 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm
-60 = 0.65 µm
-80 = 0.80 µm
1-0 = 1.0 µm

Length
A = 2”
B = 5”
1 = 10”
2 = 20”
3 = 30”

Pre-Sterilized or Not
S = Pre-Sterilized
G = Gamma Stable
N = Not Sterilized

*Fits hoses/tubes with inner diameter 11/32 to 9/16 inches

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” Sanitary
G = Hose Barb*
H = 1 ½” Sanitary with side vent
I = ½” Single Stepped Barb with side vent
J = ¾” Single Step Barb with Side Vent
Y = 3/8” Compression (JACO©) (Top Luer lock vent only)
Z = 6mm Quick Disconnect (Top Luer lock vent only)

Outlet
A = 1/4” Female NPT
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C = 3/8” Female NPT
D = 1/2” Female NPT
E = 1/2” Male NPT
F = 1” Sanitary
G = Hose Barb*
H = 1 ½” Sanitary with side vent
I = ½” Single Stepped Barb with side vent
IB = ½” Single Stepped Barb with filling bell and side vent
J = ¾” Single Step Barb with Side Vent
Y = 3/8” Compression (JACO©) (Top Luer lock vent only)
Z = 6mm Quick Disconnect (Top Luer lock vent only)

Side Vent Options
1 = Luer Lock
2 = Bleed Valve
3 = ¼” Bleed Valve

O-Ring
(Bleed Valve Only)
S = Silicone
E = EP
V = Viton (or FKM)
B = Buna
K = FFKM

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