

BPS Mini-Capsule Filters

Single and Dual Layer PES Membrane

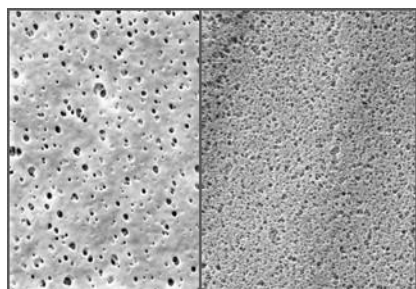


BPS Mini-Capsule filters offer single and dual layer Polyethersulfone (PES) media for use with aqueous liquids. Pore sizes range from 0.03 to 1.2 μm . These laboratory filters are constructed with the identical materials of our full-size filters to ensure consistent results in all areas of production.

These hydrophilic filters 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 Mini-Capsule filter's low binding characteristics make them highly efficient to protect process quality and extend the life of sterilizing filters.

BPS Mini-Capsules are designed with a single Asymmetric PES membrane and the option of adding a High Capacity PES prefilter layer. These 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 and 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 Mini-Capsule filters are recommended for bioburden control in:

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

Bioburden Control

Clarification & Prefiltration



MINI-CAPSULES – Nominal Dimensions

Body Length: 2.85 in. (7.2 cm)

Overall Length – 3.75 to 5.19 in. (9.5 to 13.2 cm)

Outside Diameter: 2.95 in. (7.5 cm)

Maximum Operating Parameters

MINI-CAPSULES	
Liquid Operational Pressure	80 psi at 68 °F (5.52 bard at 20 °C)
Gases Operational Pressure	60 psi at 68 °F (4.14 bar at 20 °C)
Operating Temperature (water)	110 °F at 30 psid (43 °C at 2.07 bard)
Forward Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)
Reverse Differential Pressure	40 psid at 68 °F (2.76 bard at 20 °C)
Recommended Changeout Pressure	35 psid (2.41 bard)

Sanitization & Sterilization

Autoclave	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.

Integrity Testing

FINAL LAYER PORE SIZE [‡]	BUBBLE POINT MINIMUM*	
	PSIG	BARG
μm		
0.03	**	**
0.10	**	**
0.22	50	3.5
0.45	25	1.7
0.65	19	1.3
0.80	15	1.1
1.0	10	0.7
1.2	9	0.6

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

* For water wetted membrane

** Test pressure exceeds operational limits of mini-capsule filters.

Filtration Area

	Single Layer	Dual Layer
Area – Single Layer	0.50 ft ²	0.45 ft ²
	468 cm ²	416 cm ²

Construction Materials

Filtration Media	Asymmetric PES membrane OR High Capacity PES membrane prefilter layer with polyester support and Asymmetric PES membrane final filter layer
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Mini-Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding

Validation

BPS Mini-Capsule filters are validated using test procedures that comply with ASTM F 838-15(æ1) 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 Mini-Capsule filters are below current USP limits as specified for water for injection.

Extractables

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

TOC and Conductivity

BPS Mini-Capsule 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 Mini-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.

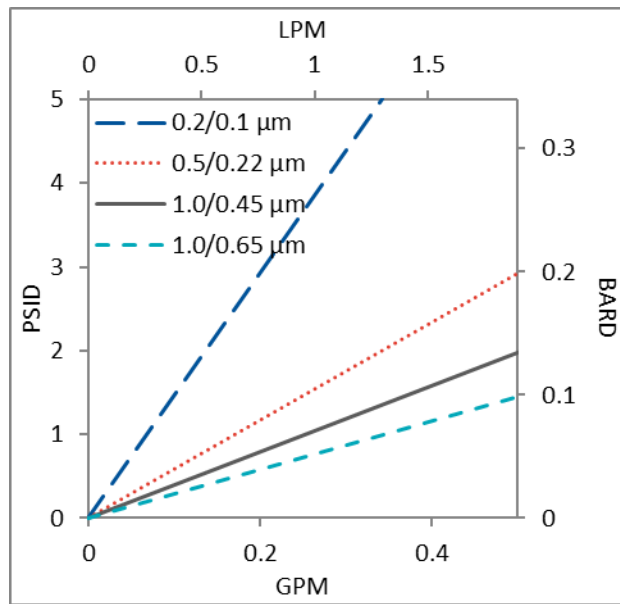
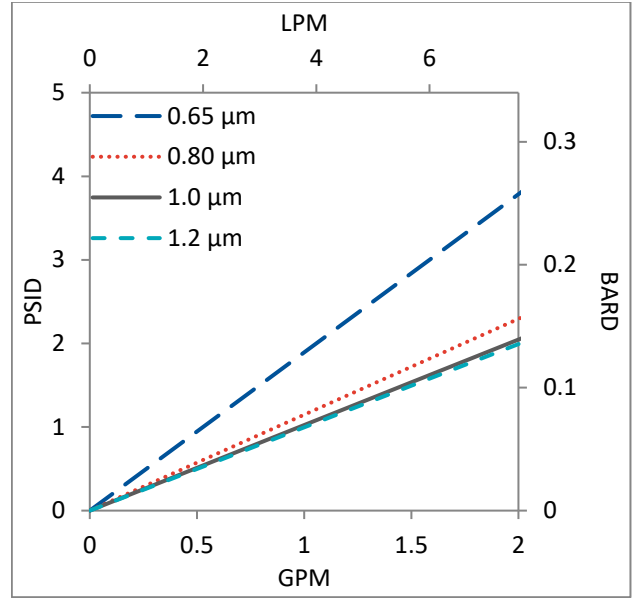
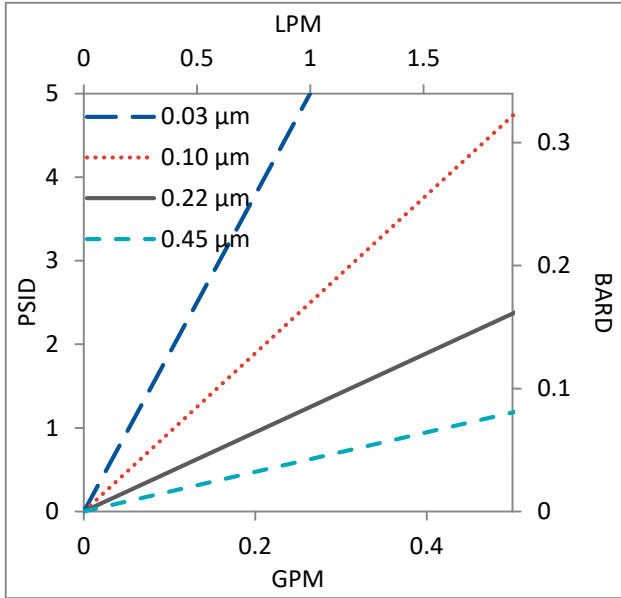
Non-Fiber Releasing

BPS Mini-Capsule 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 Mini-Capsules by Pore Size



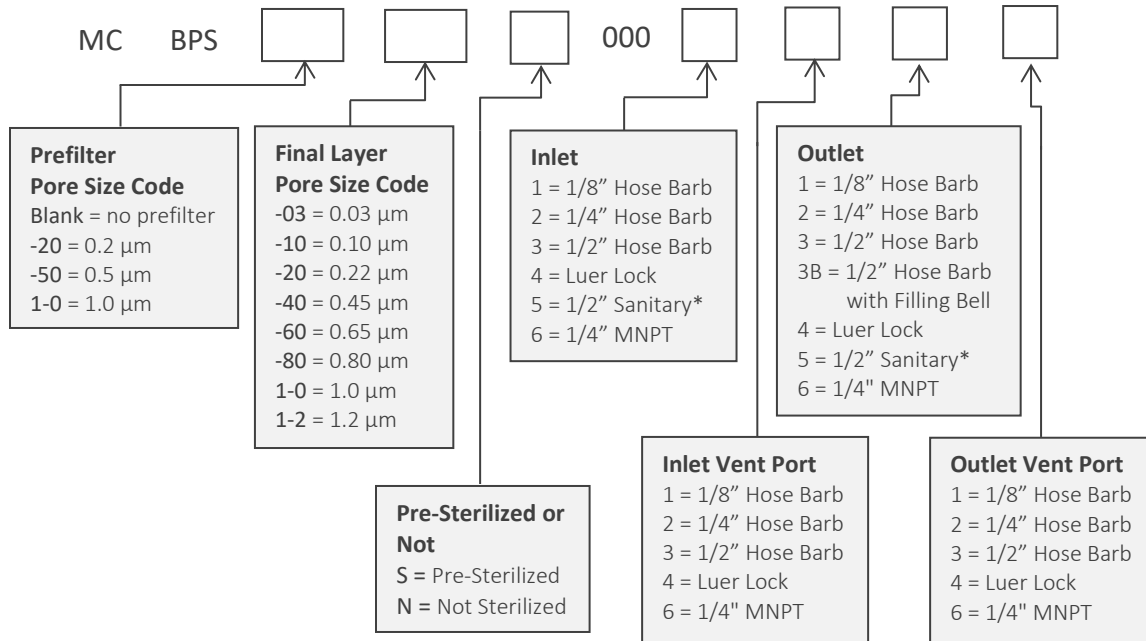
Flow rates for Mini-Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a mini-capsule filter with 1/2" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the mini-capsule.

BPS Mini-Capsule 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) 880-4420 Ext. 106, or send an email to sales@criticalprocess.com

Mini-Capsule Filters



*When choosing the Sanitary Inlet/Outlet, the Luer Lock option is required for the Vent Port



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Data Sheet BPSMiniDS Rev B