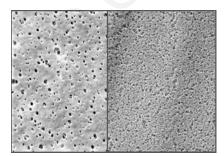


BPS Micro Capsule filters are multipurpose products that excel in bioburden reduction, clarification and the prefiltration of aqueous fluids when sterilizing is not the goal. They consist of a single layer of Polyethersulfone (PES) membrane and deliver high flow and throughput across a wide pH range. 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, BPS is an efficient standalone prefilter. Installing the BPS Filter protects the final filter from premature fouling, and extends its useful life.

BPS Micro Capsule 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 Micro 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 solution right the first time.



BPS Micro Capsule filters are recommended for bioburden control in:

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

Bioburden Control Clarification & Prefiltration



MICRO CAPSULES – Nominal Dimensions
Body Length: 1.9 in. (4.8 cm)
Overall Length: 2.8 to 3.8 in. (7.1 to 9.7 cm)
Outside Diameter: 2.6 in. (6.6 cm)

Maximum Operating Parameters

	MICDO CADCILIEC		
	MICRO 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)	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*	
μm	PSIG	BARG
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

Filtration Area

	Single Layer	Dual Layer
Area	0.575 ft ²	0.5 ft ²
	533 cm ²	465 cm ²

^{*} For water wetted membrane

 $[\]ensuremath{^{**}}$ Test pressure exceeds operational limits of Micro capsule filters.

Construction Materials

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

Validation

BPS Micro Capsule 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

Endotoxins

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

Extractables

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

TOC and Conductivity

BPS Micro 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 Micro 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.

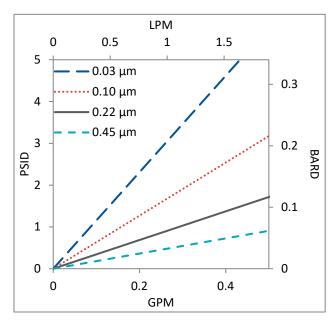
Non-Fiber Releasing

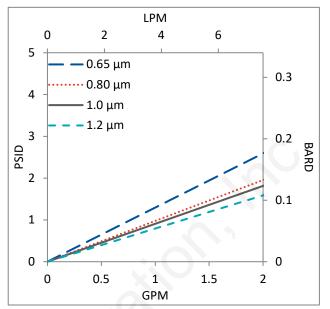
BPS Micro Capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

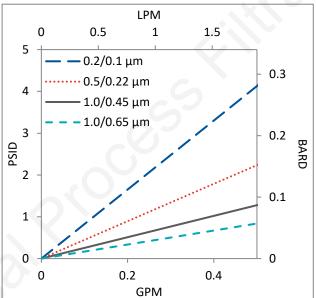
FDA Compliance

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 Micro Capsules by Pore Size





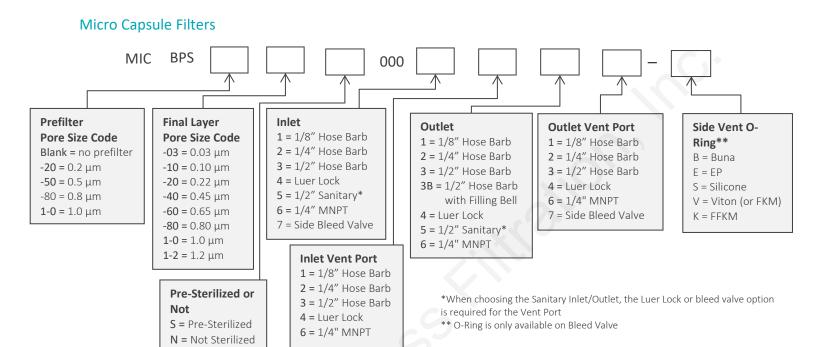


Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with $\frac{1}{2}$ " Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

BPS Micro 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 or contact us here.





One Chestnut Street Nashua, NH 03060 603.880.4420 FAX: 603.880.4536

CriticalProcess.com

The information contained herein is subject to change without notice. The Critical Process Filtration logo is a trademark of Critical Process Filtration, Inc. Viton is a trademark of DuPont Performance Elastomers L.L.C.

Data Sheet BPS Micro DS Rev -