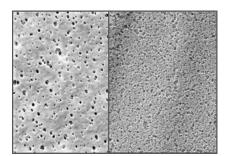


BPS Mini-Capsule filters are multipurpose products that excel in bioburden reduction, clarification and the prefiltration of aqueous fluids when sterilizing is not the goal. They consist of a single layer of Polyethersulfone (PES) membrane and deliver high flow and throughput across a wide pH range. 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  $\mu$ m and the integrated prefilter pore sizes range from 0.2 to 1.0  $\mu$ m. 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 Mini-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 Mini-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 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 <sup>‡</sup>	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

<sup>†</sup> Integrity test values are the same for filters with and without a prefiltration layer

## Filtration Area

	Single Layer	Dual Layer
Area	0.50 ft <sup>2</sup>	0.45 ft²
	468 cm <sup>2</sup>	416 cm <sup>2</sup>

<sup>\*</sup> For water wetted membrane

<sup>\*\*</sup> Test pressure exceeds operational limits of mini-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, 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(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 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.

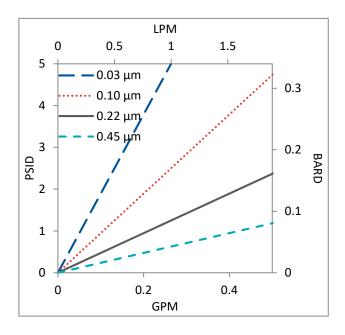
#### Non-Fiber Releasing

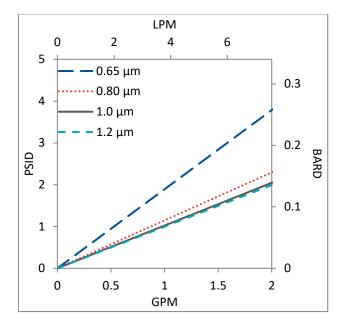
BPS Mini-Capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

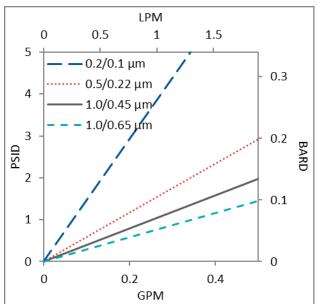
#### **FDA Compliance**

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







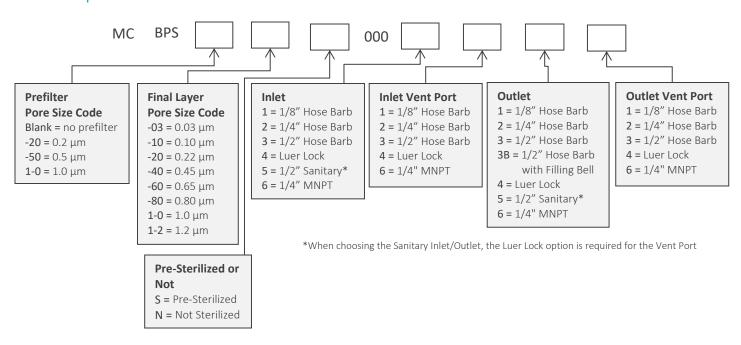
Flow rates for Mini-Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a mini-capsule filter with  $\chi''$  Sanitary inlet and outlet ports. Rates will vary based on end configuration of the mini-capsule.

# **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 or contact us here.

## Mini-Capsule Filters





One Chestnut Street Nashua, NH 03060 603.880.4420 FAX: 603.880.4536

CriticalProcess.com

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