

SPS Micro Capsule Filters are single layer Polyethersulfone (PES) filters used for the sterilizing of aqueous liquids. Pore sizes range from 0.03 to 1.2  $\mu m$ . These validated laboratory filters are constructed with the identical materials of our full-size filters to ensure consistent results in all areas of production.

The hydrophilic SPS Micro Capsule filters have low binding characteristics that are ideal for filtering products with preservatives and high protein solutions that can adsorb to media. SPS Micro Capsule filters deliver high flow and throughput with compatibility across a wide pH range.

SPS Micro Capsule filters are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. SPS Micro 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.

# **Sterilizing Filters**

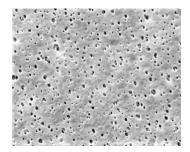


MICRO CAPSULES - Nominal Dimensions

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)



SPS Micro Capsule filters are recommended for:

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

## **Maximum Operating Parameters**

MICRO CAPSULES	
80 psi at 68 °F (5.52 bard at 20 °C)	
60 psi at 68 °F (4.14 bar at 20 °C)	
110 °F at 30 psid (43 °C at 2.07 bard)	
50 psid at 68 °F (3.45 bard at 20 °C)	
40 psid at 68 °F (2.76 bard at 20 °C)	
35 psid (2.41 bard)	
	80 psi at 68 °F (5.52 bard at 20 °C) 60 psi at 68 °F (4.14 bar at 20 °C) 110 °F at 30 psid (43 °C at 2.07 bard) 50 psid at 68 °F (3.45 bard at 20 °C) 40 psid at 68 °F (2.76 bard at 20 °C)

## Sanitization & Sterilization

250 °F (121 °C), 30 min, 5+ cycles
Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected

chemicals.

## **Integrity Testing**

PORE SIZE	BUBBLE POIN	NT MINIMUM*
μm	PSIG	BARG
0.03	**	**
0.10	**	**
0.22	50	3.4
0.45	25	1.7
0.65	19	1.3
0.80	15	1.0
1.0	10	0.7
1.2	8	0.6

Filtration Area (Nominal)

Area	0.575 ft <sup>2</sup>
	533 cm <sup>2</sup>

<sup>\*</sup> For water wetted membrane
\*\* Test pressure exceeds operational limits of Micro capsule filters.

#### **Construction Materials**

Filtration Media	PES membrane
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Micro Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding

#### Validation

SPS 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 challenge level is a minimum of  $10^7$  organisms per cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below  $(0.03\mu\text{m}, 0.10\mu\text{m})$  and  $0.22\mu\text{m}$  meet the FDA definition of sterilizing grade filters).

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 SPS Micro Capsule filters are below current USP limits as specified for water for injection.

#### **Extractables**

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

### **TOC and Conductivity**

SPS 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 SPS 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.

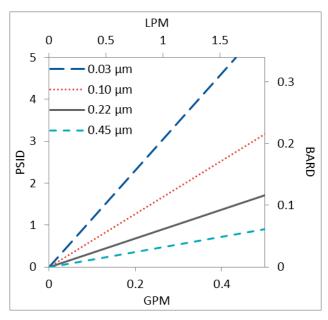
### Non-Fiber Releasing

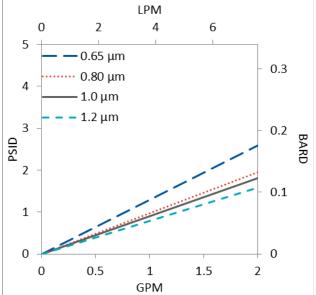
The SPS Micro Capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

### **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 SPS Micro Capsules by Pore Size



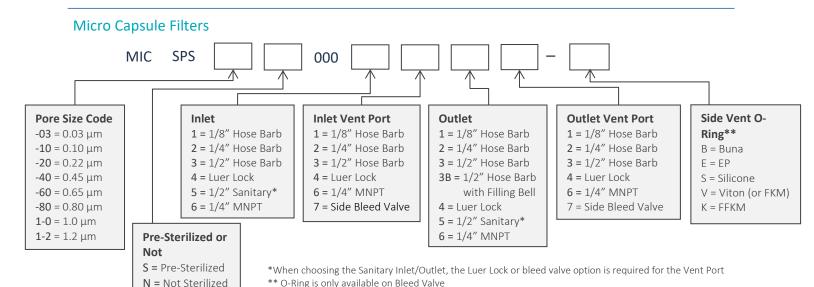


Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with ½" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

## SPS 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.





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Data Sheet SPS Micro DS Rev -