

SPS Mini-Capsule Filters are single layer Polyethersulfone (PES) filters used for the sterilizing of aqueous liquids. Pore sizes range from 0.03 to 1.2 μm . 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 Mini-Capsule filters have low binding characteristics that are ideal for filtering products with preservatives and high protein solutions that can adsorb to media. SPS Mini-Capsule filters deliver high flow and throughput with compatibility across a wide pH range.

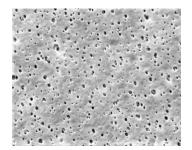
SPS Mini-Capsule filters are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. SPS Mini-Capsules are available pre-sterilized.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced highperformance 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



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)



SPS Mini-Capsule filters are recommended for:

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

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

Filtration Area (Nominal)

PORE SIZE	BUBBLE POI	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

	Single Layer	
Area	0.50 ft ²	
	468 cm ²	

* For water wetted membrane

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

Construction Materials

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

Validation

SPS 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 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 (0.03µm, 0.10µm and 0.22µm 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

Validation Guides available upon request.

Endotoxins

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

Extractables

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

TOC and Conductivity

SPS 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

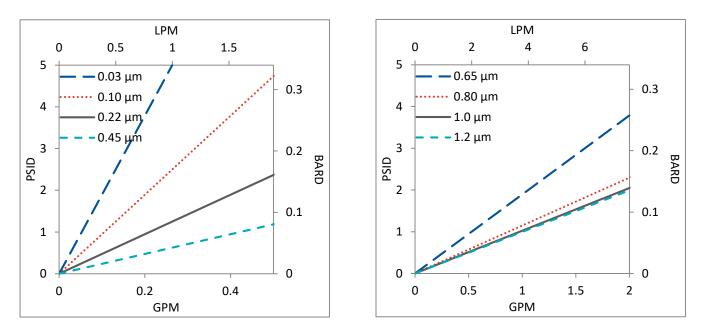
Materials used to construct SPS Mini-Capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

Non-Fiber Releasing

The SPS 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 SPS Mini-Capsules by Pore Size

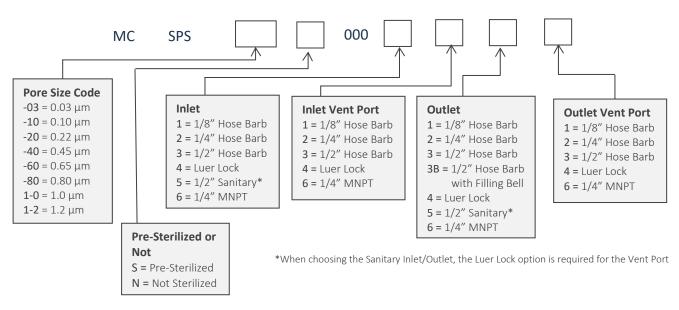
Flow rates for Mini-Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a mini-capsule filter with $\frac{1}{2}$ " Sanitary inlet and outlet ports. Rates will vary based on end configuration of the mini-capsule.

SPS 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 <u>sales@criticalprocess.com</u>

Mini-Capsule Filters





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