

# HPPS Mini-Capsule Filters

Dual Layered PES Membrane



HPPS Mini-Capsules are designed for laboratory use with their small filtration area and size. They are made from all the same materials as our larger HPPS filters to ensure consistent results at every scale. These validated, dual-layered PES membrane capsules are well suited for sterilizing products with high particle loads. Pore sizes range from 0.03 to 1.0  $\mu\text{m}$ .

Designed with a High Capacity PES prefilter layer and Asymmetric PES final filter layer, HPPS Mini-Capsule filters deliver high flow across a wide pH range. The HPPS filter's low binding characteristics make them ideal for filtering products with preservatives and proteins that can adsorb to media. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. HPPS Mini-Capsules are available pre-sterilized.

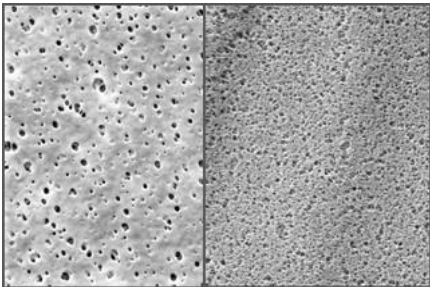
Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration experts is how we deliver your company's solution right the first time.

## Sterilizing Filters



### 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)



High Capacity PES / Asymmetric PES

HPPS filters are recommended for:

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

## Maximum Operating Parameters

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

## Sanitization & Sterilization

<b>Autoclave</b>	250 °F (121 °C), 30 min, 25+ cycles
<b>Chemical Sanitization</b>	Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.

## Filtration Area (Nominal)

	Dual Layer
Area	0.45 ft <sup>2</sup> 416 cm <sup>2</sup>

## 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

\* For water wetted membrane

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

## Construction Materials

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

## Validation

HPPS 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  $\text{cm}^2$  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).

0.03 $\mu\text{m}$ : *Acholeplasma laidlawii*  
0.10 $\mu\text{m}$ : *Brevundimonas diminuta*  
0.22 $\mu\text{m}$ : *Brevundimonas diminuta*  
0.45 $\mu\text{m}$ : *Serratia marcescens*  
0.65 $\mu\text{m}$ : *Saccharomyces cerevisiae*

Validation Guides available upon request.

## Endotoxins

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

## Extractables

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

## TOC and Conductivity

HPPS 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 HPPS 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.

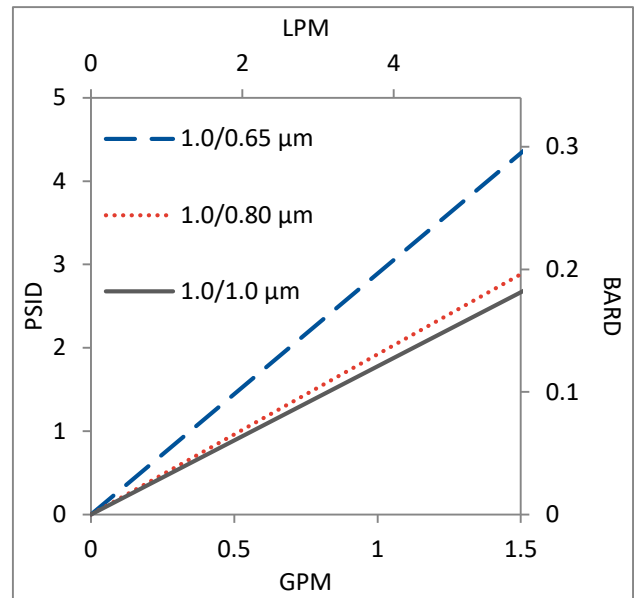
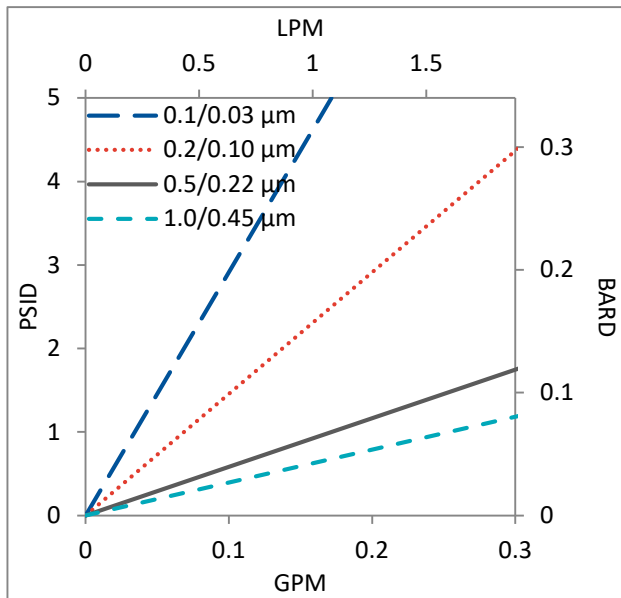
## Non-Fiber Releasing

HPPS 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 HPPS Mini-Capsules by Pore Size



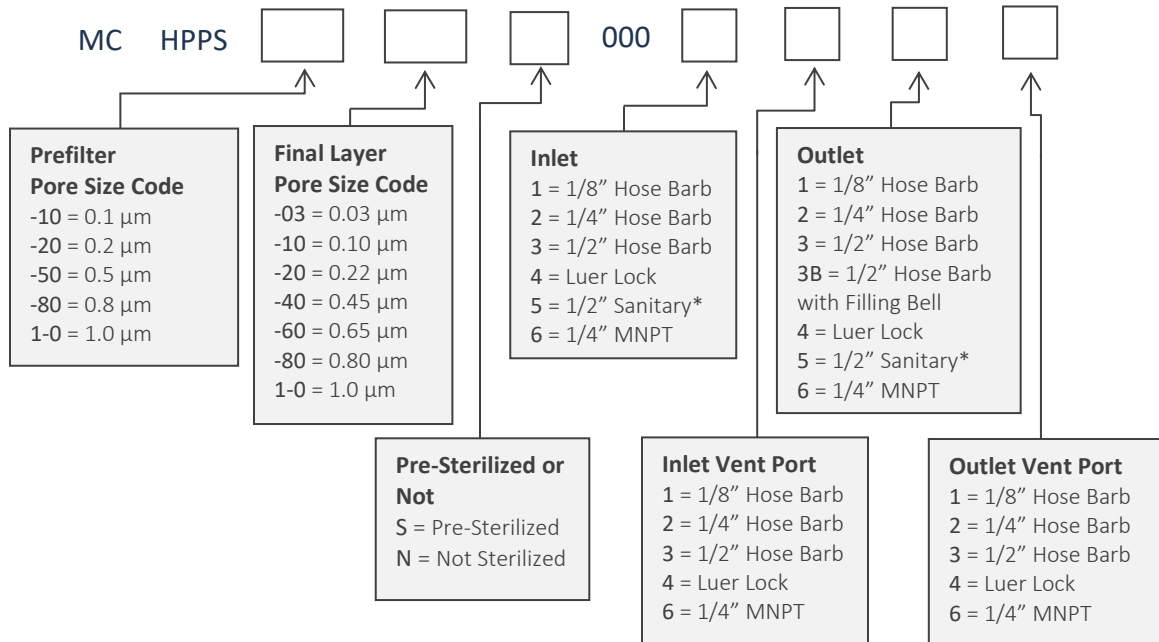
Flow rates for Mini-Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a mini-capsule filter with 1/2" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the mini-capsule.

## HPPS 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](mailto:sales@criticalprocess.com)

### HPPS Mini-Capsule Filters



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



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