



# HPPS Filters

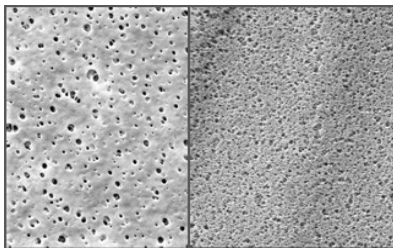
Dual Layered PES Membrane



For sterilizing products with high particle loads, HPPS filters offer a wide selection of validated, dual layer Polyethersulfone (PES) cartridge and capsule filters for aqueous liquids. Pore sizes range from 0.03 to 1.0  $\mu\text{m}$  and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

Designed with a High Capacity PES prefilter layer and Asymmetric PES final filter layer, HPPS 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 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.



High Capacity PES / Asymmetric PES

HPPS filters are recommended for:

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

## Sterilizing Filters



**CARTRIDGES – Nominal Dimensions**  
 Length: 5 to 40 in. (12.7 to 101.6 cm)  
 Outside Diameter: 2.75 in. (7.0 cm)



**CAPSULES – Nominal Dimensions**  
 Length: 2 to 30 in. (5.1 to 76.2 cm)  
 Outside Diameter: 3.50 in. (8.9 cm)

## Maximum Operating Parameters

	CARTRIDGES	CAPSULES
<b>Liquid Operational Pressure</b>	N/A	80 psi at 68 °F (5.51 bard at 20 °C)
<b>Gases Operational Pressure</b>	N/A	60 psi at 68 °F (4.14 bar at 20 °C)
<b>Operating Temperature (water)</b>	180 °F at 30 psid (82 °C at 2.07 bard)	110 °F at 30 psid (43 °C at 2.07 bard)
<b>Forward Differential Pressure</b>	80 psid at 68 °F (5.52 bard at 20 °C)	80 psid at 68 °F (5.52 bard at 20 °C)
<b>Reverse Differential Pressure</b>	50 psid at 68 °F (3.45 bard at 20 °C)	50 psid at 68 °F (3.45 bard at 20 °C)
<b>Recommended Changeout Pressure</b>	35 psid (2.41 bard)	35 psid (2.41 bard)

## Sanitization & Sterilization

<b>Filtered Hot Water*</b>	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow	N/A
<b>Inline Steam*</b>	275 °F (135 °C), 30 min, 25+ cycles	N/A
<b>Autoclave*</b>	250 °F (121 °C), 30 min, 25+ cycles	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.	

\*Cartridge Filters – For all elevated temperature procedures above, a stainless-steel support ring is required.

## Filtration Area (Nominal)

	CAPSULES	CARTRIDGES AND CAPSULES				CARTRIDGES
Length	2"	5"	10"	20"	30"	40"
	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	0.9 ft <sup>2</sup>	2.5 ft <sup>2</sup>	5.4 ft <sup>2</sup>	10.8 ft <sup>2</sup>	16.2 ft <sup>2</sup>	21.6 ft <sup>2</sup>
	0.08m <sup>2</sup>	0.23m <sup>2</sup>	0.50m <sup>2</sup>	1.00m <sup>2</sup>	1.51m <sup>2</sup>	2.01m <sup>2</sup>

## Integrity Testing

FINAL LAYER PORE SIZE	DIFFUSION TEST PRESSURE		BUBBLE POINT MINIMUM	
	PSIG	BARG	PSIG	BARG
0.03 µm	60	4.14	**	**
0.10	48	3.30	**	**
0.22	35	2.41	50	3.5
0.45	20	1.37	25	1.7
0.65	15	1.03	19	1.3
0.80	12	0.82	15	1.1
1.0	8	0.55	10	0.7

DIFFUSION SPECIFICATIONS* (Final Layer Pore Size)						
Length	2"	5"	10"	20"	30"	40"
mL/min (0.03µm, 0.10µm)	≤ 2.9	≤ 8.4	≤ 20	≤ 40	≤ 60	≤ 80
mL/min (All Other Pore Sizes)	≤ 2.1	≤ 6.3	≤ 15	≤ 30	≤ 45	≤ 60

\* For water-wetted membrane

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

## Construction Materials

<b>Filtration Media</b>	High Capacity PES membrane on polyester support prefilter layer and PES membrane final filter layer
<b>Media Support</b>	Polypropylene
<b>End Caps, Center Core, Outer Support Cage, Capsule Housing</b>	Polypropylene
<b>Sealing Method</b>	Thermal Bonding
<b>O-Rings/Gaskets Cartridges only</b>	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

## Validation

HPPS 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 filters are below current USP limits as specified for water for injection.

## Extractables

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

## TOC and Conductivity

HPPS 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 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.

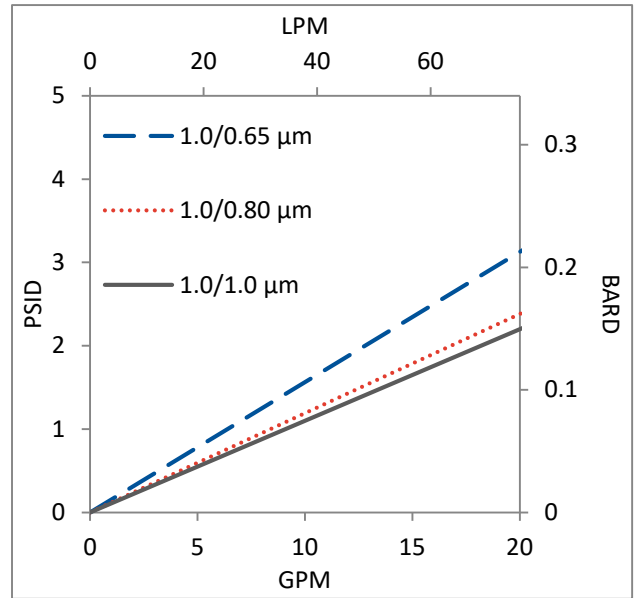
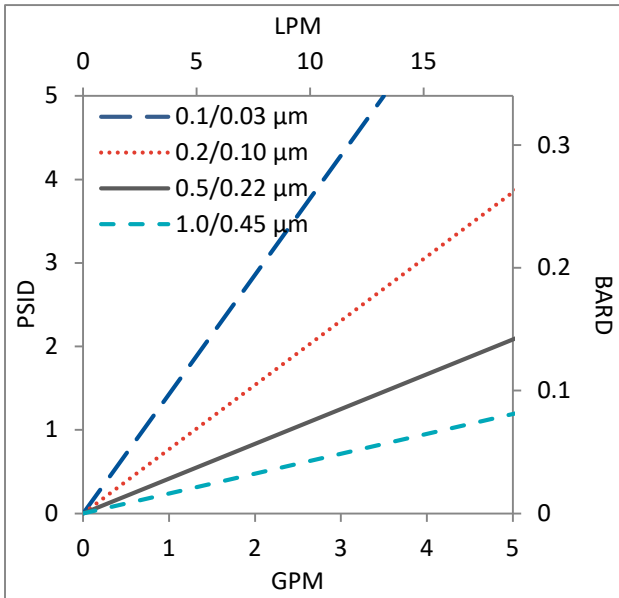
## Non-Fiber Releasing

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

## FDA Compliance

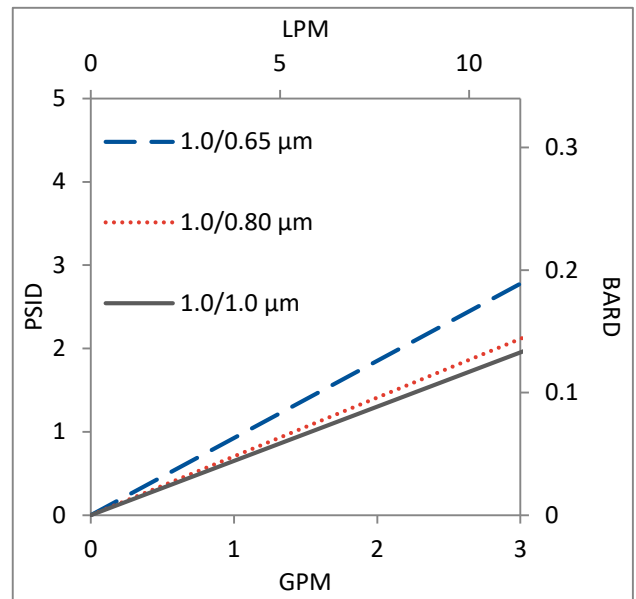
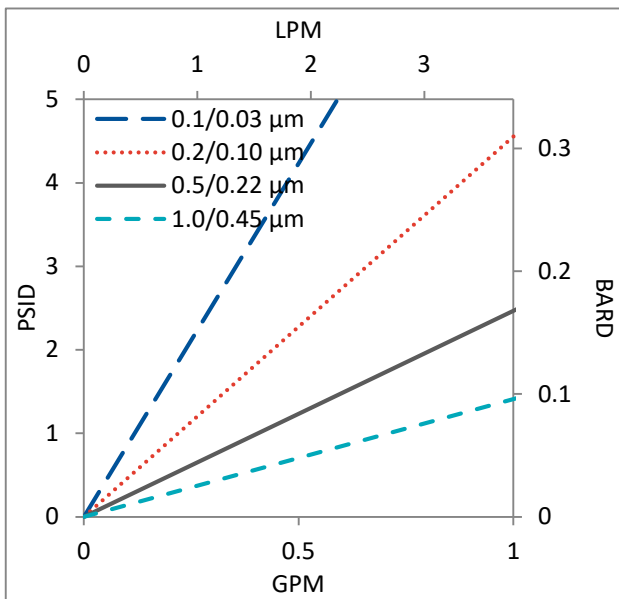
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

## Flow Rates for HPPS Cartridges by Pore Size



Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

## Flow Rates for HPPS Capsules by Pore Size



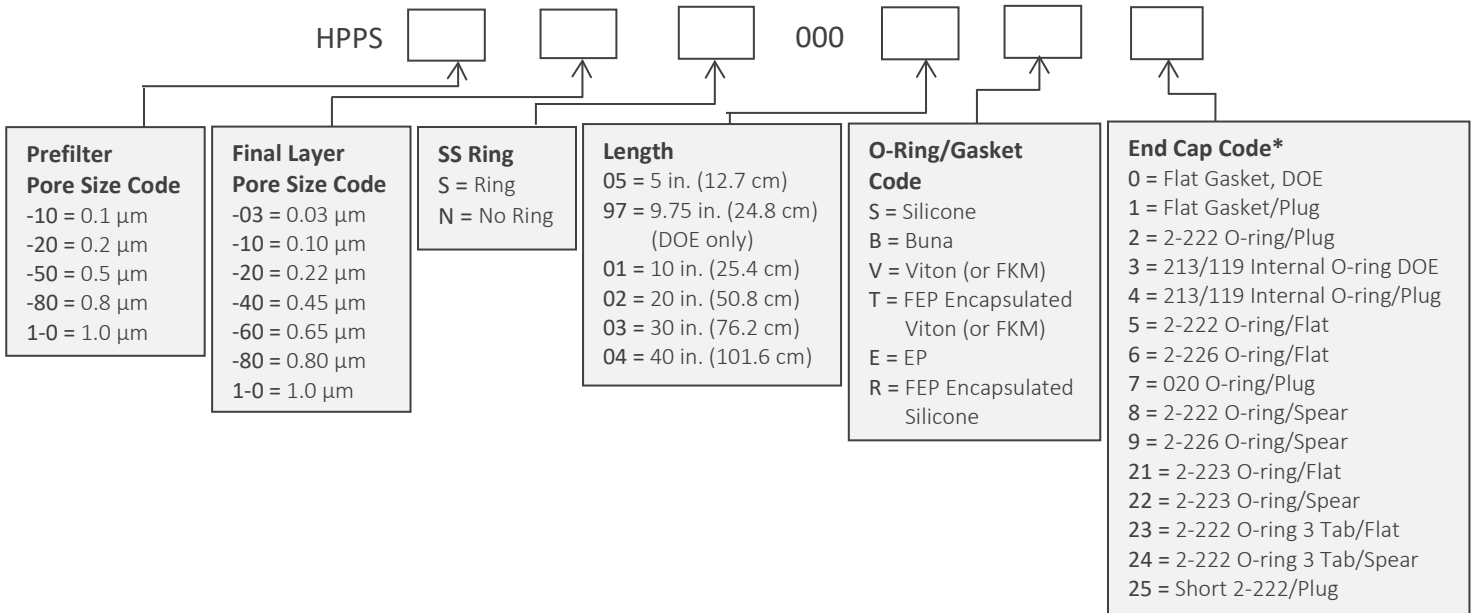
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

# HPPS Filters Ordering Information

Fill in the corresponding codes in the boxes below to build your Part Number.

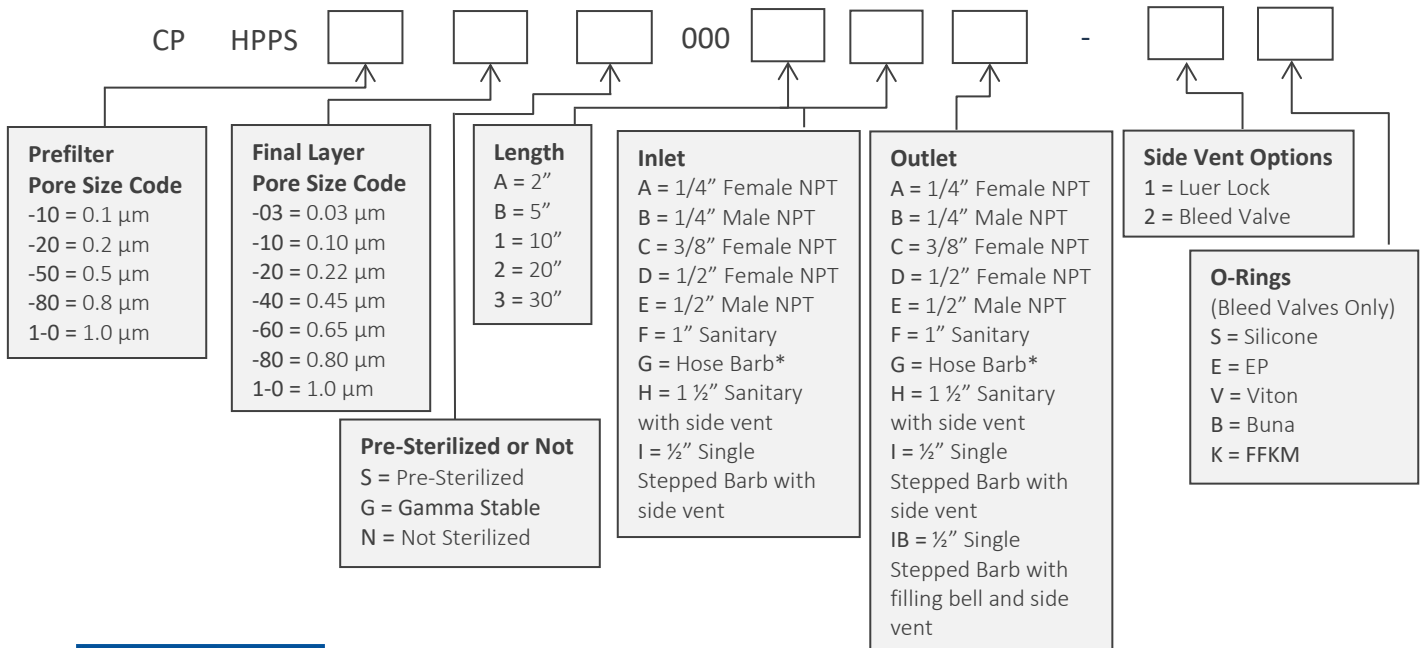
To consult with one of our technical team members, request a quote or place an order:  
call (603) 880-4420 or [contact us here](#).

## Cartridge Filters



\*Additional End Configurations are available

## Capsule Filters



**Pre-Sterilized or Not**  
 S = Pre-Sterilized  
 G = Gamma Stable  
 N = Not Sterilized

\*Fits hoses/tubes with inner diameter 11/32 to 9/16



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Data Sheet HPPSDS Rev C