



# PPS Filters

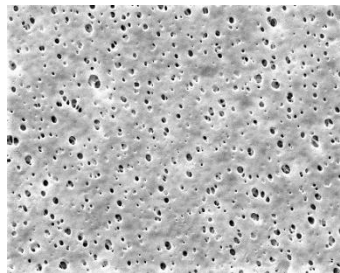
Double Layered PES Membrane



Employed in the most stringent and critical applications, PPS filters are constructed with a double layered Polyethersulfone (PES) membrane for sterilizing aqueous liquids. PPS filters are validated and available in cartridge and capsule models. Pore sizes range from 0.03 to 1.2  $\mu\text{m}$  and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

The PPS filter's low binding characteristics are well suited for filtering products with preservatives and protein solutions that can adsorb to media. These hydrophilic, double layered filters are optimized for retention and provide added security. PPS filters deliver high flow and throughput with compatibility across a wide pH range. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. PPS 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.



PPS is 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. (7.0cm)



**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 (4.13 bar at 20 °C)
<b>Operating Temperature (water)</b>	180 °F at 30 psid (82 °C at 2.06 bard)	110 °F at 30 psid (43 °C at 2.06 bard)
<b>Forward Differential Pressure</b>	80 psid at 68 °F (5.51 bard at 20 °C) (Liquid and Gas)	Liquid - 80 psid at 68 °F (5.51 bard at 20 °C) Gas - 60 psi at 68 °F (4.13 bar at 20 °C)
<b>Reverse Differential Pressure</b>	50 psid at 68 °F (3.44 bard at 20 °C)	50 psid at 68 °F (3.44 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	
<b>Inline Steam*</b>	275 °F (135 °C), 30 min, 25+ cycles	
<b>Autoclave*</b>	250 °F (121 °C), 30 min, 25+ cycles	250 °F (121 °C), 30 min, 5+ 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

	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	1.0 ft <sup>2</sup>	2.9 ft <sup>2</sup>	6.1 ft <sup>2</sup>	12.2 ft <sup>2</sup>	18.3 ft <sup>2</sup>	24.4ft <sup>2</sup>
	0.10m <sup>2</sup>	0.27m <sup>2</sup>	0.57m <sup>2</sup>	1.14m <sup>2</sup>	1.71m <sup>2</sup>	2.28m <sup>2</sup>

## Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE		BUBBLE POINT MINIMUM	
	PSIG	BARG	PSIG	BARG
μm				
0.03	60	4.13	**	**
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
0.8	12	0.82	15	1.1
1.0	8	0.55	10	0.7
1.2	7	0.48	9	0.6

DIFFUSION SPECIFICATIONS						
Length	2"	5"	10"	20"	30"	40"
mL/min	≤ 2.1	≤ 6.3	≤ 15	≤ 30	≤ 45	≤ 60

\*\* Test pressure exceeds operational limits of capsule filters.  
Use the Diffusion Test method.

## Construction Materials

<b>Filtration Media</b>	Double Layered Asymmetric Polyethersulfone (PES) Membrane
<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 Cartridges only</b>	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

## Validation

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

## Extractables

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

## TOC and Conductivity

PPS 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 PPS 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.

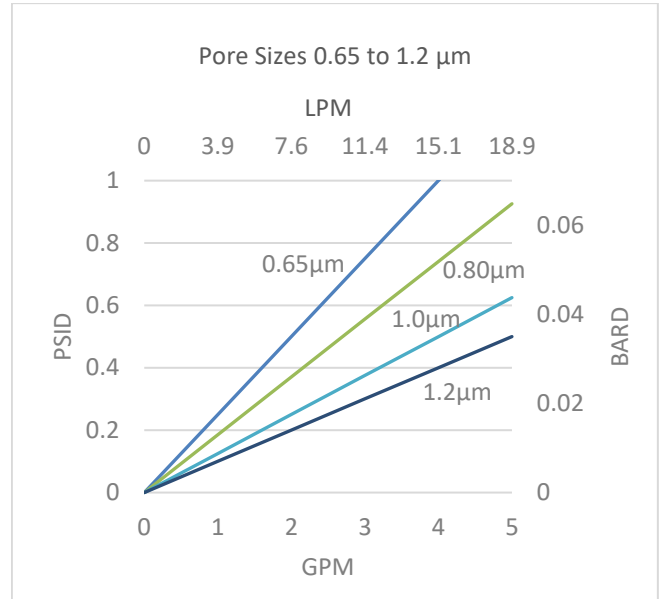
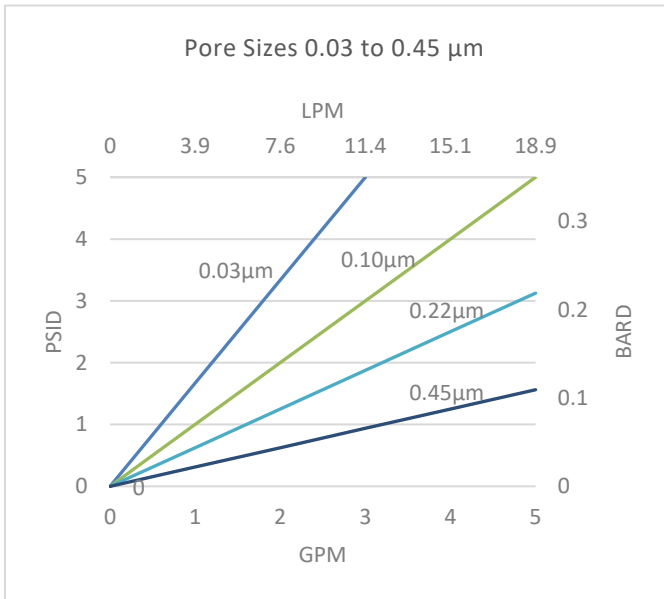
## Non-Fiber Releasing

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

## FDA Compliance

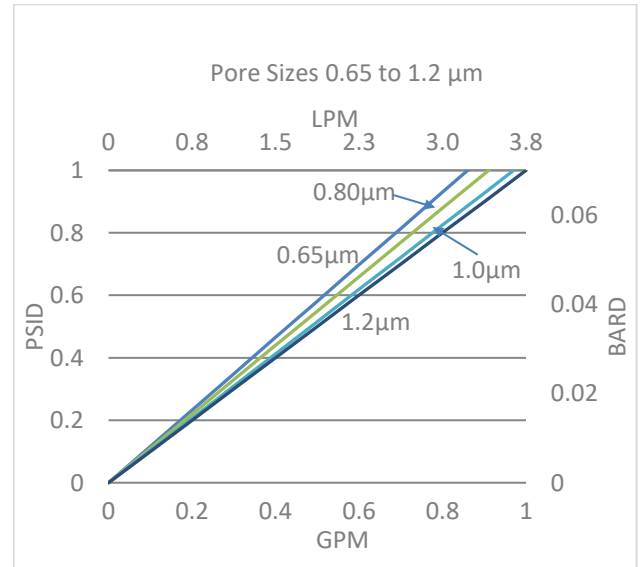
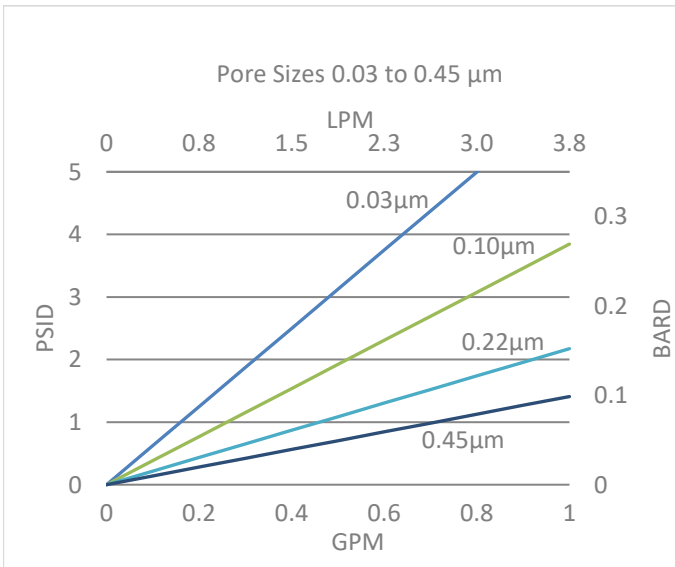
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

## Flow Rates for PPS Cartridges



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

## Flow Rates for PPS Capsules



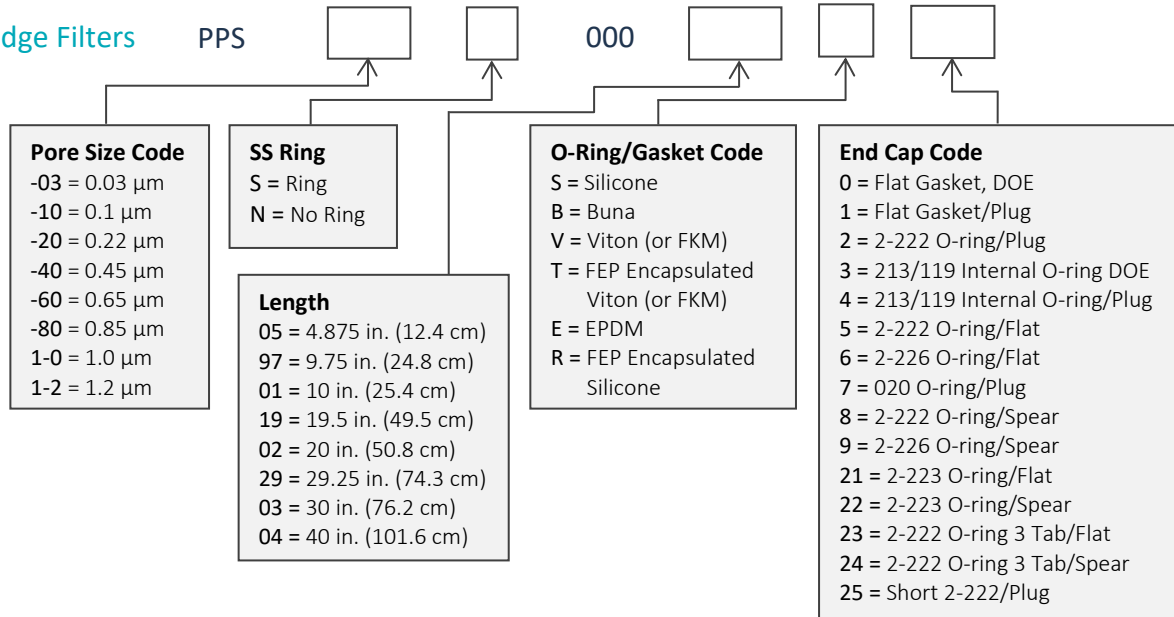
Flow rates for Capsule filters are per square foot of membrane area. The test fluid is water at ambient temperature. Flows are tested using a 2" capsule filter with 1/2" FNPT inlet and outlet ports. Rates will vary based on end configuration of the capsule.

## PPS Filters Ordering Information

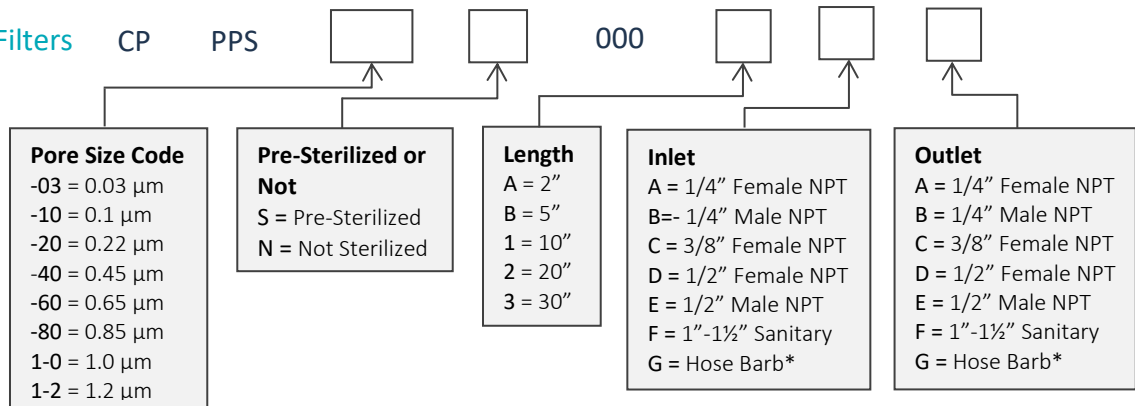
All Critical Process filters are configurable to meet customer specifications.  
Fill in the corresponding codes in the boxes below to build your Part Number.

To consult with one of our technical team members, request a quote or place an order:  
call (603) 880-4220 Ext. 106, or send an email to [sales@criticalprocess.com](mailto:sales@criticalprocess.com)

### Cartridge Filters



### Capsule Filters



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

### Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.



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