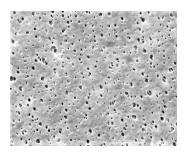


Employed in the most stringent and critical applications, PPS filters are constructed with a double layered Polyethersulfone (PES) membrane for sterilizing aqueous liquids. PPS filters are validated and available in cartridge and capsule models. Pore sizes range from 0.03 to 1.2  $\mu m$  and the filter 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. (7.0 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		
Liquid Operational Pressure	N/A	80 psi at 68 °F (5.52 bard at 20 °C)		
Gases Operational Pressure	N/A	60 psi at 68 °F (4.14 bar at 20 °C)		
Operating Temperature (water)	180 °F at 30 psid (82 °C at 2.07 bard)	110 °F at 30 psid (43 °C at 2.07 bard)		
Forward Differential Pressure 80 psid at 68 °F (5.52 bard at 20 °C) (Liquid and Gas)		Liquid - 80 psid at 68 °F (5.52 bard at 20 °C) Gas - 60 psi at 68 °F (4.14 bar at 20 °C)		
Reverse Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)	50 psid at 68 °F (3.45 bard at 20 °C)		
Recommended Changeout Pressure	35 psid (2.41 bard)	35 psid (2.41 bard)		

### Sanitization & Sterilization

Filtered Hot Water*	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow		
Inline Steam*	275 °F (135 °C), 30 min, 25+ cycles		
Autoclave*	250 °F (121 °C), 30 min, 25+ cycles	250 °F (121 °C), 30 min, 25+ cycles	
Chemical Sanitization	Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.		

<sup>\*</sup>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	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>	24.4ft²
	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>	2.28m²

## **Integrity Testing**

PORE SIZE	DIFFUSION TEST PRESSURE		BUBBLE POINT MINIMUM	
μm	PSIG	BARG	PSIG	BARG
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
0.80	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

<sup>\*</sup> For water wetted membrane

<sup>\*\*</sup> Test pressure exceeds operational limits of capsule filters.
Use the Diffusion Test method.

#### **Construction Materials**

Filtration Media	Double Layered Polyethersulfone (PES) Membrane
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding
O-Rings Cartridges only	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 cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03 $\mu$ m, 0.10 $\mu$ m and 0.22 $\mu$ 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

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.

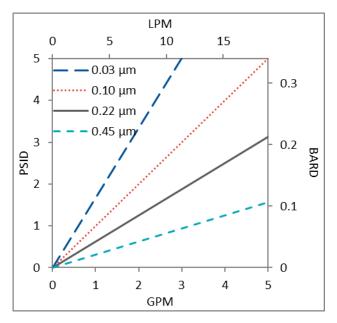
#### Non-Fiber Releasing

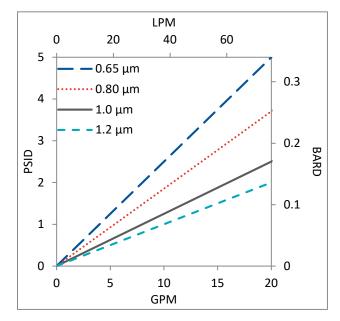
PPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

### **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.

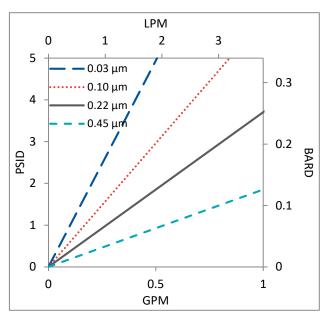
## Flow Rates for PPS Cartridges by Pore Size

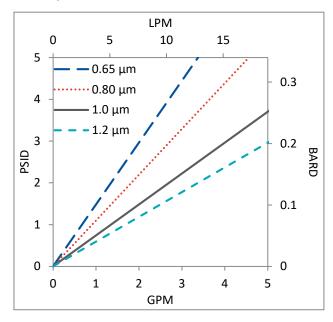




Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

## Flow Rates for PPS Capsules by Pore Size



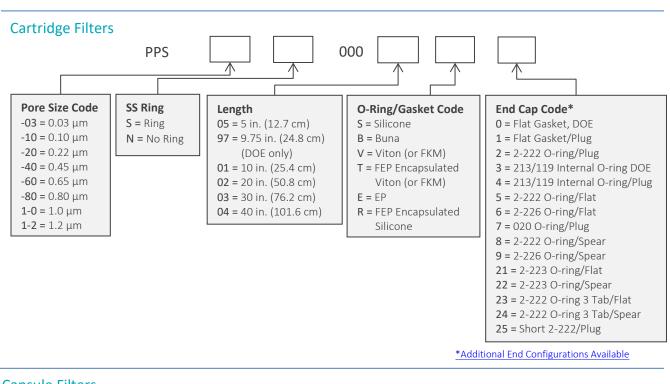


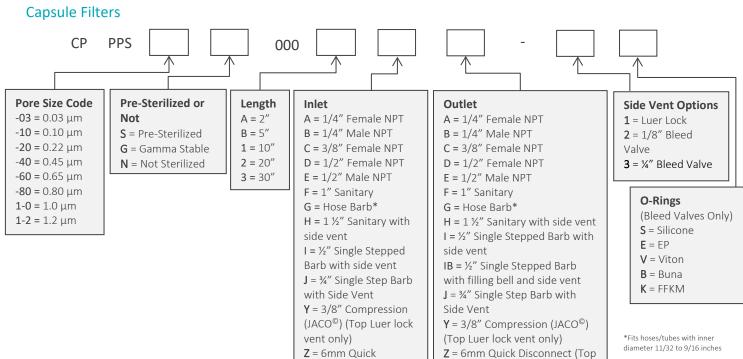
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

## **PPS 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.





Disconnect (Top Luer

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One Chestnut Street

Nashua, NH 03060 603.880.4420 FAX: 603.880.4536

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Data Sheet PPSDS Rev C