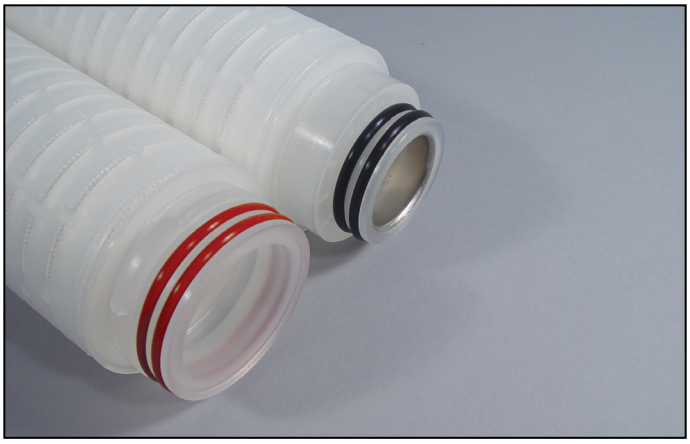
PPS Cartridge Filters

Double Layered PES Membrane

CRITICAL PROCESS FILTRATION, INC.

Pharmaceutical Grade



Pharmaceutical grade polyethersulfone PPS Filter Cartridges are sterilizing grade cartridges. The polyethersulfone (PES) membrane used in these cartridges is optimized for retention and is double layered for extra security. Polyethersulfone cartridges see broad service in sterile fill applications in SVPs and biological products. Polyethersulfone is particularly suited for the filtration of products whose constituents, such as preservatives and proteins, can adsorb to the media. The low binding characteristics of polyethersulfone make it a good choice for filtration of ophthalmics and valuable protein solutions such as vaccines and other biologicals. PPS Membrane Filter Cartridges are 100% integrity tested.

Construction Materials

Filtration Media	Double Layered Asymmetric Polyethersulfone (PES) Membrane
Media Support	Polypropylene
End Caps	Polypropylene
Center Core	Polypropylene
Outer Support Cage	Polypropylene
Sealing Method	Thermal Bonding
O-rings	Buna, Viton® (or FKM), EP, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products to industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Applications

- Diagnostics
- LVPs and SVPs
- Water for Injection
- Vaccines
- Biologicals
- Ophthalmics

Dimensions

Length	5 to 40 in. (12.7 to 101.6 cm) nominal
Outside Diameter	2.75 in. (7.0 cm) nominal
Filtration Area	7.0 ft^2 (0.65 m^2) per 10 in. length

Integrity Test Specifications

Per 10-in. length, water wetted membrane

Pore Size	Air Diffusion Rate
0.03 µm	< 15 cc/min at 60 psig (4.1 barg)
0.10 µm	< 15 cc/min at 48 psig (3.3 barg)
0.22 µm	< 15 cc/min at 35 psig (2.4 barg)
0.45 µm	< 15 cc/min at 20 psig (1.4 barg)
0.65 µm	< 15 cc/min at 15 psig (1.0 barg)
0.80 µm	< 15 cc/min at 12 psig (0.8 barg)
1.0 µm	< 15 cc/min at 8 psig (552 mbarg)
1.2 µm	< 15 cc/min at 7 psig (483 mbarg)

Maximum Operating Parameters

Differential Pressure	
• **Forward**	50 psid (3.4 bard) at 20 °C (68 °F)
• **Reverse**	40 psid (2.7 bard) at 20 °C (68 °F)
Operating Temperature	82 °C (180 °F) at 10 psid (0.69 bard) in water
Recommended Changeout Pressure	35 psid (2.4 bard)

Sanitization/Sterilization

Filtered Hot Water	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow
Autoclave	121 °C (250 °F), 30 min, multiple cycles
In-line Steam	135 °C (275 °F), 30 min, multiple cycles

For all elevated temperature procedures above, a stainless steel support ring is required.

Chemical Sanitization

Performed using industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals.

Quality Assurance and Standards

Critical Process Filtration filters are designed for use in cGMP-compliant processes. Our state of the art manufacturing facility and quality management system both meet ISO 9001:2008 standards. Each operation from assembly and test to cleaning, drying, and packaging is done in appropriately rated clean rooms. Each filter is assigned a lot code to ensure the traceability of manufacturing data and materials. A sophisticated MRP system collects and processes real time data from manufacturing centers and inspection points. This allows variable and attribute data to be quickly and easily analyzed driving constant improvements in both quality and cost.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PS 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. In addition, the 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 appropriate. PPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade filters are below current USP limits as specified for water for injection.

Extractables

Pharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Validation

PPS cartridges are validated using test procedures that comply with the intent of both ASTM F 838-05 and HIMA protocols for the determination of bacterial retention in filters used for liquid filtration. The challenge level is 10^7 organisms per cm^2 of filter media: 0.10 µm challenged with *Acholeplasma laidlawii*; 0.22 µm challenged with *Brevundimonas diminuta*; 0.45 µm challenged with *Serratia marcescens*; 0.65 µm challenged with *Saccharomyces cerevisiae*.

Flow Rate

The Typical Flow Rates table represents typical water flow at a 1 psid (69 mbard) pressure differential across a single 10 in. cartridge element. The test fluid is water at ambient temperature. Extrapolation for housings with multiple elements and higher pressure drops is acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Typical Flow Rates

Pore Size	0.03 µm	0.10 µm	0.22 µm	0.45 µm	0.65 µm	0.8 µm	1.0 µm	1.2 µm
GPM	1.1	1.8	3.2	5.0	6.0	6.4	6.8	7.0
LPM	4.16	6.81	12.11	18.92	22.71	24.22	25.74	26.50

Ordering Information

Cartridge order numbers have several variables from pore size to end cap type. For example, Pharmaceutical Grade, Double Layered Asymmetric PES Membrane, 0.22 Micron Rating, With SS Support Ring, 20" Length, Silicone O-Rings, 2-226/Spear End Cap Configuration = PPS-20S00002S9.

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Pore Size Code
- **-03** = 0.03 µm
- **-10** = 0.10 µm
- **-20** = 0.22 µm
- **-40** = 0.45 µm
- **-60** = 0.65 µm
- -80 = .80 µm
- 1-0 = 1.0 µm
- 1-2 = 1.2 µm

316 SS Ring
- S = Ring
- N = No Ring

Cartridge Length Code
- **05** = 4.875 in. (12.4 cm)
- **97** = 9.75 in. (24.8 cm)
- **01** = 10 in. (25.4 cm)
- **19** = 19.5 in. (49.5 cm)
- **02** = 20 in. (50.8 cm)
- **29** = 29.25 in. (74.3 cm)
- **03** = 30 in. (76.2 cm)
- **04** = 40 in. (101.6 cm)

O-ring/Gasket Code
- **S** = Silicone
- **B** = Buna
- **V** = Viton (or FKM)
- **T** = FEP Encapsulated Viton (or FKM)
- **E** = EP
- **R** = FEP Encapsulated Silicone

End Cap Code
- **0** = Flat Gasket, DOE
- **1** = Flat Gasket/Plug
- **2** = 2-222 O-ring/Plug
- **3** = 213/119 Internal O-ring DOE
- **4** = 213/119 Internal O-ring/Plug
- **5** = 2-222 O-ring/Flat
- **6** = 2-226 O-ring/Flat
- **7** = 020 O-ring/Plug
- **8** = 2-222 O-ring/Spear
- **9** = 2-226 O-ring/Spear
- **21** = 2-223 O-ring/Flat
- **22** = 2-223 O-ring/Spear
- **23** = 2-222 O-ring 3 Tab/Flat
- **24** = 2-222 O-ring 3 Tab/Spear
- 25 = Short 2-222/Plug