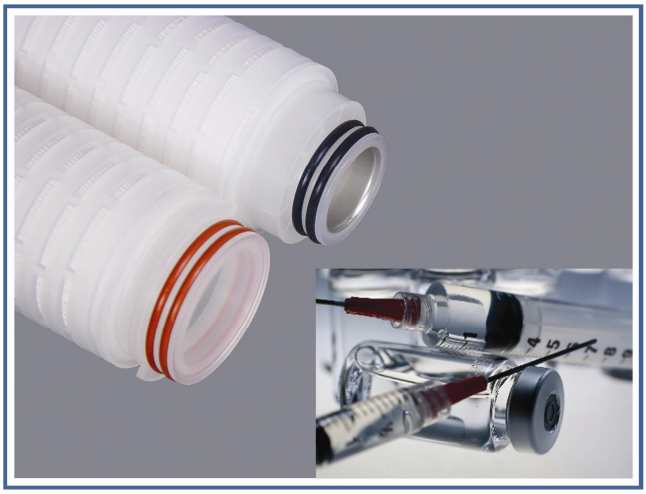
PPS grade

Polyethersulfone Membrane Media Filter Cartridges
Developed for the Special Needs of the Pharmaceutical Industry

Critical Process Filtration, Inc. • One Chestnut Street • Nashua, NH 03060
Telephone: 603-880-4420 • Fax: 603-880-4536
Web Site: www.criticalprocess.com • E-mail: sales@criticalprocess.com

PPS grade Polyethersulfone cartridges are designed to be used as sterilizing grade cartridges for the pharmaceutical industry. The PPS membrane utilized in these cartridges is optimized for retention and are 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, can adsorb to the media. The lower binding characteristics of Polyethersulfone make it a good choice for filtration of valuable protein solutions such as vaccines and other biologicals. PPS grade cartridges are 100% integrity tested.



Construction Materials

Filtration Media: ..... Dual Layered Polyethersulfone
Filtration Media Support: ..... Polypropylene
End Caps: ..... Polypropylene
Center Core: ..... Polypropylene
Outer support Cage: ..... Polypropylene
Sealing Method: ..... Thermal Bonding
O-rings: ..... Buna, Viton®, EP, Silicone, Teflon® Encapsulated Silicone, Teflon® Encapsulated Viton®

Maximum Operating Parameters

Forward Differential Pressure: ..... 50 psi (3.4 bar) at 20°C.
Reverse Differential Pressure: ..... 40 psi (2.7 bar) at 20°C.
Operating Temperature: ..... 180°F (82°C) at 10 psid (0.69 bar) in water.
Recommended Change Out Pressure: ..... 35 psid (2.4 bar)

Dimensions

Length: ..... 5 to 40 inches (12.7 to 101.6 cm) nominal
Outside Diameter: ..... 2.75 inches (7.0 cm) nominal
Filtration Area: ..... 7.0 ft² (0.65 m²) Per 10" length

USP Biosafety

The materials used to construct Pharmaceutical Grade filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and USP24 Plastic Class V1 121°C Test.

FDA Compliance

The materials used to construct Pharmaceutical Grade filters 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.

Applications

Final Filtration of:

- Diagnostics
- LVPs & SVPs
- WFI Water
- Vaccines
- Biologicals
- Medications

Sanitization / Sterilization

Filtered Hot Water: ..... 194°F (90°C)
Autoclave: ..... 250°F (121°C), 30 min, multiple cycles
In-line Steam: ..... 275°F (135°C), 30 min, multiple cycles
Chemical Sanitization: ..... Industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals. Sanitization protocols designed to extend the useful life of PPS cartridges are available from Critical Process Filtration, Inc.

Validation

PPS grade cartridges are validated using modified HIMA protocols at a challenge level of 10^7 organisms per cm² of filter media. (0.22 µm challenged with Brevundimonas diminutal) (0.45 µm challenged with Serratia marscecens) (0.65 µm challenged with Saccharomyces cerevisiae). Validation Guide is available for .22 micron to meet regulatory requirements.

Extractables

The levels of bacterial endotoxins in aqueous extracts from Pharmaceutical Grade Filters are below the USP24 limits defined in Water for Injection (≤0.5 EU/ml). Pharmaceutical Grade Filters typically exhibit low levels of non-volatile residues.

Flow Rate

The following table represents typical water flow at a one psi (69 mbar) pressure differential across a single 10-inch 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.

Pore Size	0.03 µm	0.10 µm	0.22 µm	0.45 µm	0.65 µm
GPM	1.1	1.8	3.2	5.0	6.0
LPM	4.16	6.81	12.11	18.92	22.71

Integrity Test Specifications

(per 10-inch length) (water wetted membrane)

Pore Size	Air Diffusion Rate
0.03 µm	≤ 15 cc/min at 60 psi (4137 mbar)
0.10 µm	≤ 15 cc/min at 48 psi (3307 mbar)
0.22 µm	≤ 15 cc/min at 35 psi (2412 mbar)
0.45 µm	≤ 15 cc/min at 20 psi (1378 mbar)
0.65 µm	≤ 15 cc/min at 15 psi (1044 mbar)

Quality Assurance

Pharmaceutical Grade Filters are manufactured using current Good Manufacturing Practices under a quality management system that has met ISO 9001 standards. Each Pharmaceutical Grade Filter is assigned a lot code to ensure traceability of the data and materials used in the manufacturing process. Our goal is to ensure our customers the greatest possible value for their filtration dollar. We achieve both low cost manufacture and high quality by employing state of the art manufacturing equipment. This computer controlled equipment is highly automated, reducing hand operations that compromise quality. Each operation including assembly, testing, cleaning, drying and packaging is done in appropriately rated clean rooms. Critical Process Filtration produces validated products to rigorous standards. Manufacturing is controlled using sophisticated MRP software that is networked to work stations in manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected "real time" from machinery and measuring instruments. This allows variable and attribute data to be quickly and easily analyzed to facilitate constant improvements in both quality and cost.

Total Performance

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

Ordering Information

The cartridge catalog number is made up of several variable characters i.e. pore size, length, O-ring material, and end cap code. For example: a 0.2 µm, 20 inch (50.8 cm) long cartridge with 2-222, Silicone O-rings, no spear (flat top) and no 316 SS Ring would be designated as: PPS*20N00002S5.

PPS ☐ ☐ **000** ☐ ☐ ☐

Pore size code
- ***03** = 0.03 µm
- ***10** = 0.10 µm
- ***20** = 0.22 µm
- ***40** = 0.45 µm
- ***60** = 0.65 µm

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

Cartridge Length
- **05** = 4.875 inches (12.4 cm)
- **97** = 9.75 inches (24.6 cm)
- **01** = 10 inches (25.4 cm)
- **19** = 19.5 inches (49.5 cm)
- **02** = 20 inches (50.8 cm)
- **29** = 29.25 inches (74.3 cm)
- **03** = 30 inches (76.2 cm)
- **04** = 40 inches (101.6 cm)

O-ring code
- **S** = Silicone
- **B** = Buna
- **V** = Viton®
- **T** = Teflon® Encapsulated Viton®
- **E** = EP
- **R** = Teflon® 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

CRITICAL PROCESS FILTRATION, INC.

Critical Process Filtration, Inc. • One Chestnut Street • Nashua, NH 03060
Telephone: 603-880-4420 • Fax: 603-880-4536
Web Site: www.criticalprocess.com • E-mail: sales@criticalprocess.com