PPD Cartridge Filters Pleated Polypropylene Depth Media

CRITICAL PROCESS I I I I FILTRATION, INC.



PPD Depth Filter Cartridges are designed to be used as pre-filters in critical pharmaceutical systems. Special attention was given in the design of these cartridges to ensure long life as well as superior retention. PPD Depth Filter Cartridges are rated at 99.9% efficiencies at the rated pore size and have been flushed with high purity water (18+ megohm-cm) to remove any manufacturing debris and ensure particle-free filtrate.

Construction Materials

Filtration Media	Pleated Polypropylene Depth Media					
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					

Integrity Test Information

All PPD cartridge filter modules are factory tested for integrity before shipment. Field duplication of these tests is not practical because of the absence of commercial portable testing equipment.

Applications

- Diagnostics
- LVPs and SVPs
- Water
- Bulk Pharmaceutical Chemicals

Dimensions

Length	5 to 40 in. (12.7 to 101.6 cm) nominal
Outside Diameter	2.75 in. (7.0 cm) nominal
Filtration Area	5.8 ft ² (0.54 m ²) per 10 in. length (Average - area varies with media thickness and porosity)

Biologicals

Medications

Ophthalmics

Buffers and Other Media

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.

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.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical-grade PD cartridge 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. PPD cartridge 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 cartridge filters are below current USP limits as specified for water for injection.

Extractables

PPD cartridges are rinsed with high purity water (18+ megohmcm) to remove manufacturing debris and extractable substances. PPD cartridge filters typically exhibit low levels of non-volatile residues.

Quality Assurance and Standards

Critical Process Filtration filters are designed for use in cGMPcompliant 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, and 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.

Flow Rate

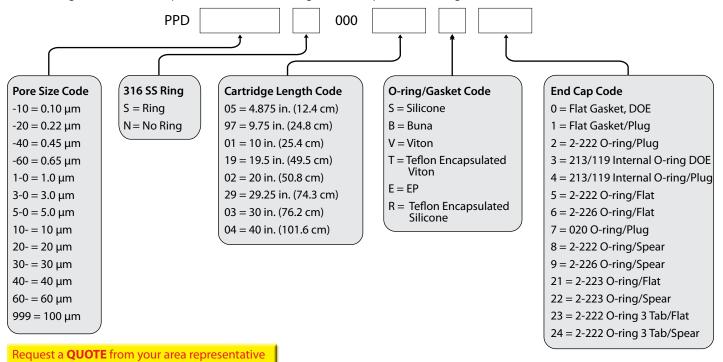
The Typical Flow Rates table represents typical water flow rates through a single 10-inch cartridge at 1 psid (69 mbard) pressure differential. These values are approximations because of the differences in pressure drop encountered in housings and piping systems. Extrapolation to multiple-length cartridges in multi-round housings can be done for sizing purposes. Exact flow rates will be installation dependent.

Typical Flow Rates

Pore Size	0.10 µm	0.22 μm	0.45 μm	0.65 µm	1.0 µm	3.0 µm	5.0 µm	10 µm	20 µm	30 µm	40 µm	60 µm	100 µm
GPM	1.0	3.0	5.0	6.0	8.0	12	16	18	> 20	> 20	> 20	> 20	> 20
LPM	3.79	11.35	18.92	22.71	30.28	45.42	60.56	68.13	75.70	75.70	75.70	75.70	75.70

Ordering Information

Cartridge order numbers have several variables from pore size to end cap type. For example, a 20 in. PPD cartridge with a 0.10 µm pore size, a 316 SS Ring, and a Teflon-encapsulated Viton 2-222 O-ring/Flat end cap would be designated PPD-10S00002T5.





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