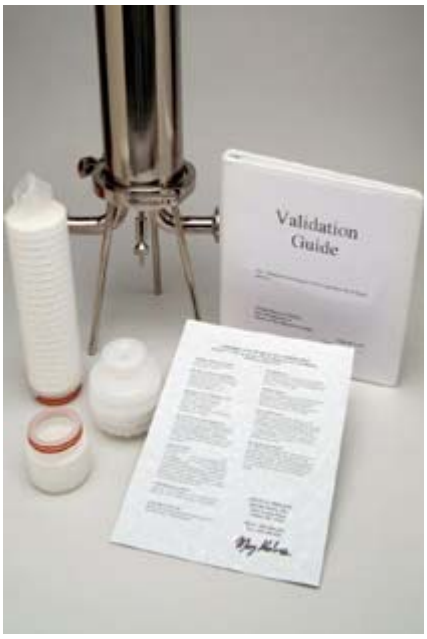
PHARMACEUTICAL FILTERS

These cartridge filters are manufactured for the specific needs of the Pharmaceutical industry:



- PTM grade Teflon Membrane Media Filter Cartridges

- PPM grade Polypropylene Membrane Media Filter Cartridges
  These cartridges are designed for use in the filtration of aggressive solvents, and as compressed gas and vent filters.

  PGD grade Fiber Glass Depth Media Filter Cartridges
  These high capacity cartridges are used in pre-filter applications as well as final filter applications where the goal is bioburdon reduction and not sterile product. The cartridge has the dual benefits of high containment holding as well as excellent retention.

- PPD grade Polypropylene Depth Media Filter Cartridges
  These cartridges are designed to be used as pre-filters and non-sterilization grade filters in the pharmaceutical industry Special attention was given in the design of these cartridges to ensure long life as well as superior retention.

  PPS grade Polyethersulfone Membrane Media Filter Cartridges(PDF*)
- Polyethersulfone cartridges see broad service in the sterile fill applications in SVPs and Biological products. Polyethersulfone is particularly suited for the filtration of products whose constituents, such as preservatives, can absorb 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.

  PNM grade Nylon Membrane Media Filter Cartridges (PDF*)
  Nylon cartridges see broad service in sterile fill applications in SVPs and as bio burden management filters in LVPs. Media and service liquid filtration are other common applications. Nylon is particularly suited for the filtration of solvents because of its broad compatibility and low level of extractables.

CRITICAL PROCESS FILTRATION, INC.

PTM grade

PTFE Membrane Media Filter Cartridges developed for the special needs of the pharmaceutical industry

Distributed by: John Mulhern Company
PO Box 6604, Santa Rosa, CA 95406
(800) 761-9201 (707) 578-5105 info@jmulhern.com

PTM sterilizing grade cartridge filters are manufactured for the specific needs of the pharmaceutical industry. Manufactured with inherently hydrophobic PTFE membrane, these cartridges are designed for use in the filtration of aggressive solvents, and as compressed gas and vent filters. Each cartridge module is individually bubble point tested using 60/40 IPA and water before it is released from manufacture. The cartridge surface area, filter core design, pleat configuration and pleat packing density have been optimized to provide increased cartridge life resulting in lower filtration operating costs. Rugged construction ensures repeatable steaming and testing. PTM grade cartridges are 100% integrity tested.

Construction Materials [1]

Filtration Media: ..... Dual Layered PTFE
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.

Dimensions

Length: ..... 5 to 40 inches (12.7 to 101.6 cm) nominal
Outside Diameter: ..... 2.75 inches (7.0 cm) nominal
Filtration Area: ..... 8.2 ft ² (0.76 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. PTM filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

Applications

Final Filtration of:

- Compressed Air
- Fermentation Air
- Solvents
- Pressurized Gases
- Tank Ventilation

Sanitization / Sterilization

Filtered Hot Water: ..... 194°F (90°C)
Autoclave: ..... 260°F (127°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 PTM cartridges are available from Critical Process Filtration, Inc.®.

Validation

PTM 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 diminuta)

Extractables

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

Flow Rate

The following table represents typical water flow and air flow rates. 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.

Pore Size	0.1 µm
SCFM	›25 SCFM/psid/10 inch cartridge length
GPM	1.25 gpm/psid/10 inch cartridge length
Pore Size	**0.22 µm**
SCFM	›40 SCFM/psid/10 inch cartridge length›
GPM	2.0 gpm/psid/10 inch cartridge length

Integrity Test Specifications (per 10 inch length)

(60/40, IPA/water wetted membrane)

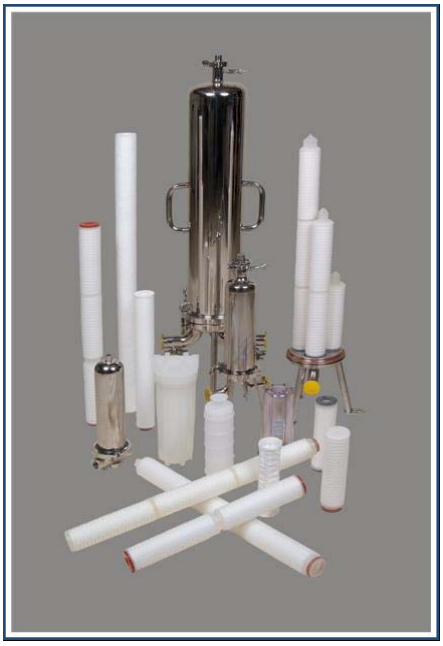
Pore Size	Bubble Point
0.1 µm	18 psig
0.22 µm	14 psig

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.

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.



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 2-226, Silicone O-rings, with spear and 316 SS Ring would be designated as: PTM*20S00092S9.

PTM [ ] [S] 000 [ ] [ ] [ ]

Pore size code
- ***10** = 0.10 µm
- ***20** = 0.22 µm

316 SS Ring
- **S** = 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
- **5** - 2-222 O-Ring / Flat
- **6** - 2-226 O-Ring / Flat
- **8** - 2-222 O-ring / Spear
- **9** - 2-226 O-ring / Spear

CRITICAL PROCESS FILTRATION, INC.

CRITICAL PROCESS FILTRATION, INC.

PPM grade

Polypropylene Membrane Media Filter Cartridges
Developed for the special needs of the pharmaceutical industry

Distributed by: John Mulhern Company info@jmulhern.com
PO Box 6604, Santa Rosa, Ca 95406
800 761-9201 707 578-5105 fx 707 578-8692

PPM cartridges filters are manufactured for the specified needs of the pharmaceutical industry. Manufactured with inherently hydrophobic Polypropylene Membrane, these cartridges are designed for use in the filtration of aggressive solvents, and as compressed gas and vent filters. Each cartridge module is individually diffusion tested using 60/40 IPA and water before it is released from manufacture. The cartridge surface area, filter core design, pleat configuration and pleat packing density have been optimized to provide increased cartridge life resulting in lower filtration operating costs. Rugged construction ensures repeatable steaming and testing.

Construction Materials [1]

Filtration Media: ..... Polypropylene
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

[1]All materials of construction are FDA accepted. Final assemblies have been validated to pass USP class 6 Toxicology extractable tests, oxidizable substances for plastics, endotoxin level and other quality tests.

Applications

Filtration of:

- Gases
- Chemicals
- Compressed Air
- Tank Vents
- Solvents

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 ft ² (0.65 m²) Per 10" length

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)

Validation

PPM 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)

Sanitization / Sterilization

Filtered Hot Water: ..... 194^{0}F (90^{0}C)

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 PPM cartridges are available from Critical Process Filtration, Inc.®.

Integrity Test Specifications (per 10 inch length) (water wetted membrane)

Pore Size	Air Diffusion Rate
0.1 µm	‹ 30 cc/min at 40 psi (2756 mbar)
0.22 µm	‹ 30 cc/min at 35 psi (2412 mbar)

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	0.1 µm	0.22 µm
GPM	0.75	2.75
SCFM	›20 SCFM/psid/10 inch cartridge length	›30 SCFM/psid/10 inch cartridge length
Gas Retention	0.01 µm	0.02 µm

Quality Standards

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 0.10 µm , 20 inch (50.8 cm) long cartridge with 2-222, Teflon® Encapsulated Viton O-rings no spear (flat top) and no 316 SS Ring would be designated as: PPM*10N00002T5.

PPM [ ] [ ] 000 [ ] [ ] [ ]

Pore size code
- ***10** - 0.10 µm
- ***20** - 0.22 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.

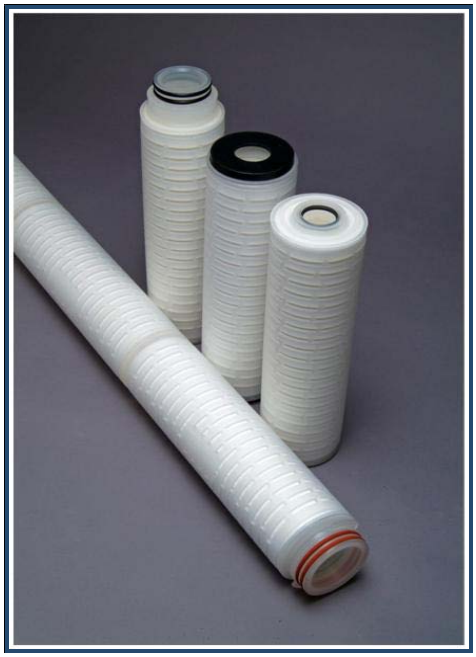
PGD grade

Fiber Glass Depth Media Filter Cartridges

Developed for the special needs of the pharmaceutical industry

Distributed by: John Mulhern Company
PO Box 6604, Santa Rosa, CA 95406
(800) 761-9201 (707) 578-5105 info@jmulhern.com

PGD grade Fiber Glass Depth cartridges are designed as required by the FDA, our pharmaceutical grade Fiber Glass Depth media cartridges are composite media cartridges containing a final downstream layer of Polypropylene media to ensure fiber free effluent. This means they can be used without the addition of membrane cartridge downstream in the filter train. The cartridge has the dual benefits of high contaminant holding as well as excellent retention. These high capacity cartridges are used in pre-filter applications as well as final filter applications where the goal is bioburden reduction and not sterile product. Each cartridge module is tested for integrity before shipment.



Construction Materials [1]

Filtration Media: ..... Fiber Glass / Polypropylene
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

[1]All materials of construction are FDA accepted. Final assemblies have been validated to pass USP class 6 Toxicology extractable tests, oxidizable substances for plastics, endotoxin level and other quality tests.

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: ..... Up to 5.8 ft² (0.54 m²) Per 10" length

Sanitization / Sterilization

Filtered Hot Water: ..... 194^0F (90^0C)
Autoclave: ..... 260^0F (127^0C), 30 min, multiple cycles
In-line Steam: ..... 275^0F (135^0C), 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 PGD cartridges are available from Critical Process Filtration, Inc.®.

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	0.22 µm	0.30 µm	0.45 µm	0.65 µm	1.0 µm	2.0 µm	3.0 µm	5.0 µm	10 µm	20 µm	30 µm
GPM	2.6	3.0	5.0	6.0	8.0	10	12	14	› 15	›15	›15
LPM	9.84	11.35	18.92	22.71	30.28	37.85	45.42	52.99	›56.78	›56.78	›56.78

Integrity Test Information

Cartridges are factory tested for integrity before shipment. Field Duplication of these tests is not practical because of the complexity of the testing process and absence of commercial portable testing equipment.

Quality Standards

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 manages an ISO 9000 facility that 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

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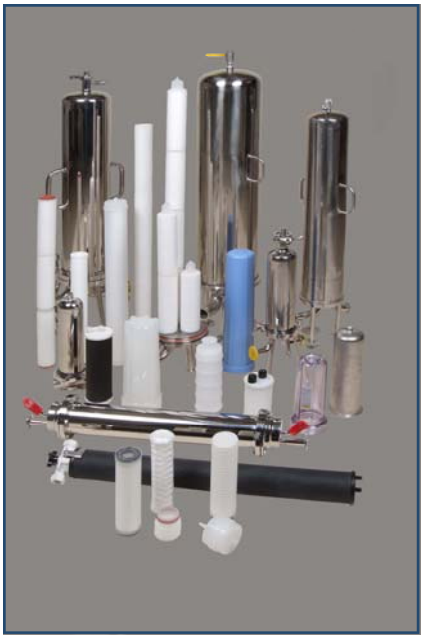


Ordering Information

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 1.0 µm , 20 inch (50.8 cm) long cartridge with 2-222, Teflon® Encapsulated Viton O-rings, no spear (flat top) and no 316 SS Ring would be designated as: PGD1*0N00002T5.

PGD [ ] [ ] 000 [ ] [ ] [ ]

Pore size code

- ***20** = 0.22 µm
- ***30** = 0.30 µm
- ***40** = 0.45 µm
- ***60** = 0.65 µm
- **1*0** = 1.0 µm
- **2*0** = 2.0 µm
- **3*0** = 3.0 µm
- **5*0** = 5.0 µm
- **10*** = 10.0 µm
- **20*** = 20.0 µm
- **30*** = 30.0 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.

PPD grade

Polypropylene Depth Media Filter Cartridges

Developed for the special needs of the pharmaceutical industry

Distributed by: John Mulhern Company info@jmulhern.com
PO Box 6604, Santa Rosa, Ca 95406
800 761-9201 707 578-5105 fx 707 578-8692

PPD Grade Polypropylene Depth Media cartridges are designed to be used as pre-filters and non-sterilization grade Filters in the pharmaceutical industry. Special attention was give in the design of these cartridges to ensure long life as well as superior retention. PPD Grade cartridges are rated at 99.9% efficiencies at the rated pore size and have been flushed to remove any manufacturing debris and ensure particle free filtrate.

Construction Materials [1]

Filtration Media: ..... Polypropylene
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

[1]All materials of construction are FDA accepted. Final assemblies have been validated to pass USP class 6 Toxicology extractable tests, oxidizable substances for plastics, endotoxin level and other quality tests.

Dimensions

Length: ..... 5 to 40 inches (12.7 to 101.6 cm) nominal
Outside Diameter: ..... 2.75 inches (7.0 cm) nominal
Filtration Area: ..... Up to 7.2 ft² (0.67 m²) Per 10" length

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)

Sanitization / Sterilization

Filtered Hot Water: ..... 194^{0}F (90^{0}C)
Autoclave: ..... 260^{0}F (127^{0}C), 30 min, multiple cycles
In-line Steam: ..... 275^{0}F (135^{0}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 PPD cartridges are available from Critical Process Filtration, Inc.®.

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	0.10	0.22	0.45	0.65	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

Integrity Test Information

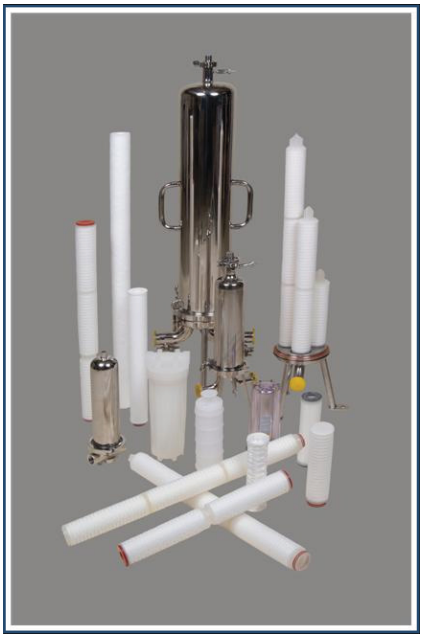
Cartridges are factory tested for integrity before shipment. Field Duplication of these tests is not practical because of the complexity of the testing process and absence of commercial portable testing equipment.

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.

Quality Standards

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.



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 0.10 µm , 20 inch (50.8 cm) long cartridge with 2-222, Teflon® Encapsulated Viton O-rings, no spear (flat top) and no 316 SS Ring would be designated as: PPD*10N00002T5.

PPD □□□ □ 000 □ □ □

Pore size code

- ***10** = 0.10 µm
- ***20** = 0.22 µm
- ***40** = 0.45 µm
- ***60** – 0.65 µm
- **1*0** – 1.0 µm
- **3*0** – 3.0 µm
- **5*0** – 5.0 µm
- **10*** – 10.0 µm
- **20*** – 20.0 µm
- **30*** – 30.0 µm
- **40*** – 40.0 µm
- **60*** – 60.0 µm
- **999** – 100.0 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.

PPS grade

Polyethersulfone Membrane Media Filter Cartridges developed for the special needs of the pharmaceutical industry

Distributed by: John Mulhern Company
PO Box 6604, Santa Rosa, CA 95406
(800) 761-9201 (707) 578-5105 info@jmulhern.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 [1]

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 ft ² (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: ..... 260°F (127°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 typically below the USP24 limits defined in Water for Injection. 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	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

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.

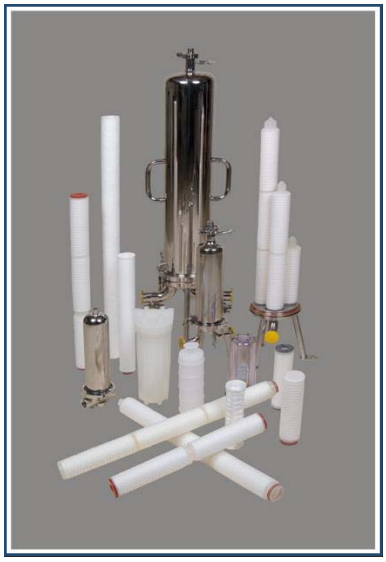
Integrity Test Specifications (per 10 inch length)

(water wetted membrane)

Pore Size	Air Diffusion Rate
0.03 µm	≤ 15 cc/min at 60 psi (4137 mbar)
0.1 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)

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.

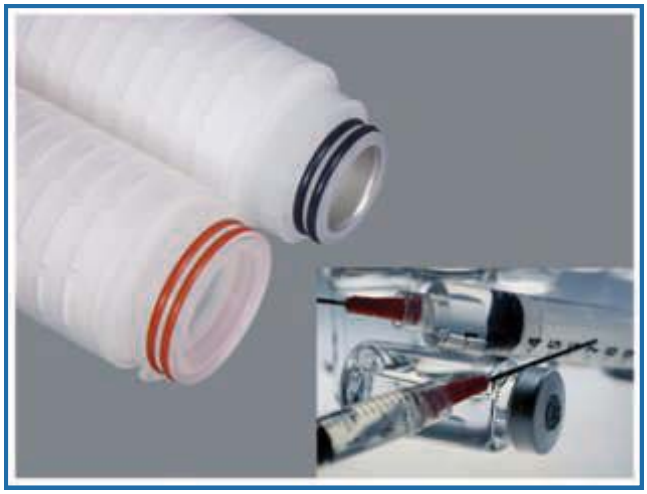
CRITICAL PROCESS FILTRATION, INC.

PNM grade

Nylon Membrane Media Filter Cartridges developed for the special needs of the pharmaceutical industry

Distributed by: John Mulhern Company
PO Box 6604, Santa Rosa, CA 95406
(800) 761-9201 (707) 578-5105 info@jmulhern.com

PNM grade Nylon cartridges are designed to be used as sterilizing grade cartridges for the pharmaceutical industry. The higher quality nylon membrane utilized in these cartridges is optimized for retention so that it need not be double layered for extra security. Nylon cartridges see broad service in sterile fill applications in SVPs and as bio burden management filters in LVPs. Media and service liquid filtration are other common applications for this cartridge. Nylon is particularly suited for the filtration of solvents because of it's broad compatibility and low level of extractables.



Construction Materials

Filtration Media: ..... Nylon
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
- Solvents

Sanitization / Sterilization

Filtered Hot Water: ..... 194°F (90°C)
Autoclave: ..... 260°F (127°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 PNM cartridges are available from Critical Process Filtration, Inc.

Validation

PNM 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).

Extractables

The levels of bacterial endotoxins in aqueous extracts from Pharmaceutical Grade Filters are typically below the USP24 limits defined in Water for Injection. 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 (1034 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 2-226, Silicone O-rings, with spear (fin top) and 316 SS Ring would be designated as: PNM*20S00002S9.

PNM [ ] [ ] **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.