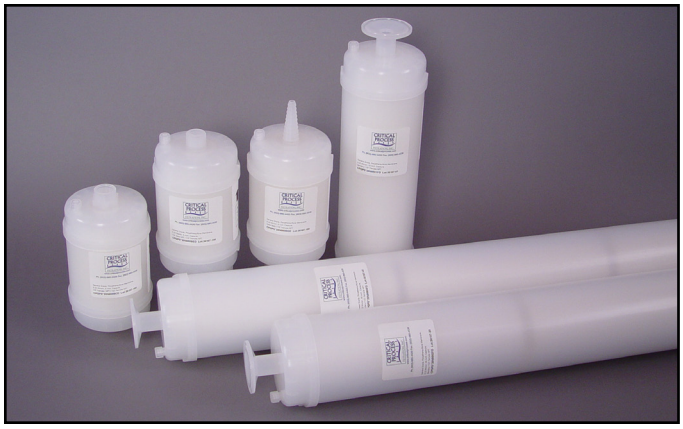
PGD Capsule Filters

Pleated Fiberglass Depth Media

CRITICAL PROCESS FILTRATION, INC.

Pharmaceutical Grade



Composite media filter rated at 99% retention at pore size

High contaminant holding capacity with excellent retention

Wide range of retention ratings

Prefiltration and bioburden reduction in bulk chemicals, LVPs, SVPs, water, buffers

Applications

- Bulk Pharmaceutical Chemicals
- LVPs and SVPs
- Buffers and Other Media
- Diagnostics
- Ophthalmics
- Water

PGD capsules are designed using composite media filter modules containing a fiberglass depth media and a final downstream layer of polypropylene depth media to ensure fiber free filtrate. They provide 99% retention at the rated pore size and have high contaminant holding capacity. These cartridges are used in pre-filter applications as well as bioburden reduction. Each capsule filtration module is tested for integrity before shipment.

Specific applications for PGD capsule filters include pre-filtration of bulk pharmaceutical chemicals, water, buffers, alcohols and other liquids. PGD capsules also are used for bioburden reduction in LVPs, SVPs, diagnostics, ophthalmics, and other final pharmaceutical products.

PGD Capsule Filters - Filtration Area*

Media	Capsule Length				
	2″	5″	10″	20″	30″
Pleated Fiberglass Depth	1.0 ft^2 (0.093m^2)	2.8 ft^2 (0.260m^2)	5.8 ft^2 (0.539m^2)	11.6 ft^2 (1.078m^2)	17.4 ft^2 (1.617m^2)

*Average – Filtration area varies with media thickness and porosity.

Flow Rate / Filtration Area

The following table represents typical water flow at a one psi (69 mbar) pressure differential across a single 2 inch capsule with 1.0 ft^2 (0.093 m^2) of media with 1/2″ FNPT ports. The test fluid is water at ambient temperature. Higher pressure drops are acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Pore Size	0.22 µm	0.30 µm	0.45 µm	0.65 µm	1 µm	2 µm	3 µm	5 µm	10 µm	20 µm	30 µm
GPM	0.50	0.60	1.0	1.2	1.6	2.0	2.4	3.2	3.6	4.0	>4.0
LPM	1.89	2.27	3.78	4.54	6.05	7.57	9.08	12.11	13.62	15.14	>15.14

* For approximate flow rates for 5″ through 30″ capsules, refer to the appropriate cartridge data sheet

Construction Materials

Housing	Polypropylene
Filtration Media	Pleated Fiberglass and Polypropylene Composite Depth Media
Media Support	Polypropylene
End Caps	Polypropylene
Center Core	Polypropylene
Outer Support Cage	Polypropylene
Sealing Method	Thermal Bonding

Maximum Operating Parameters

Liquid Operational Pressure	80 psi (5.5 bar) at 20 °C (68 °F)
Gases Operational Pressure	60 psi (4.1 bar) at 20 °C (68 °F)
Operating Temperature	43 °C (110 °F) at 30 psi (2.1 bar) in water
Forward Differential Pressure	50 psid (3.4 bard) at 20 °C (68 °F)
Reverse Differential Pressure	40 psid (2.7 bard) at 20 °C (68 °F)
Recommended Changeout Pressure	35 psid (2.4 bard)

Integrity Test Information

Representative sample capsule elements are factory tested for integrity before shipment. Field duplication of these tests is not practical because of the absence of commercial portable testing equipment.

Sanitization/Sterilization

Autoclave ..... 250° F (121° C), 30 min, 5+ cycles
Chemical Sanitization ..... Industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals.
Note ..... PGD capsules are not to be used in steam.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PGD capsule 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. PGD capsule 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 capsule filters are below current USP limits as specified for water for injection.

Extractables

PGD capsules are rinsed with high purity water to remove manufacturing debris and extractable substances. Pharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Quality Assurance and Standards

Critical Process Filtration uses state of the art computer controlled equipment to consistently produce high quality products as well as significantly reduce hand operations that can compromise quality. All manufacturing and testing is continuously monitored in real time so that data can be quickly and easily analyzed to facilitate improvements in both quality and cost.

The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled using a sophisticated manufacturing system that networks work stations, manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected in real time to allow continuous quality monitoring and full traceability of all materials and processes.

Each capsule assembly is integrity tested before release. Field duplication of these tests is not practical because of the absence of commercial portable testing equipment.

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.

Ordering Information

Capsule order number example: Pharmaceutical Grade Pleated Fiberglass/Polypropylene Composite Depth Media, 0.22 Micron Rating, Non-Sterile, 10" Length, Sanitary Inlet, Sanitary Outlet = CPPGD-20N0001FF.

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

Micron Rating
-20 - .22
-30 - .30
-40 - .45
-60 - .65
1-0 - 1.0
2-0 - 2.0
3-0 - 3.0
5-0 - 5.0
10 - 10.0
20 - 20.0
30 - 30.0

Pre Sterilized or Not
S - Pre- Sterilized
N - Not Sterilized

Length
A - 2"
B - 5"
1 - 10"
2 - 20"
3 - 30"

Inlet
A - 1/4" Female NPT
B - 1/4" Male NPT
C - 3/8" Female NPT
D - 1/2" Female NPT
E - 1/2" Male NPT
F - 1"-1½" Sanitary
G - Hose Barb*

Outlet
A - 1/4" Female NPT
B - 1/4" Male NPT
C - 3/8" Female NPT
D - 1/2" Female NPT
E - 1/2" Male NPT
F - 1"-1½" Sanitary
G - Hose Barb*

Hose Barb Diameter Ranges*

	Minimum	Maximum
Outer Diameters	11/32" (8.6mm)	9/16" (14.0mm)
Inner Diameters	5/32" (4.0mm)	13/32" (10.5mm)

Request a **QUOTE** from your area representative

Critical Process Filtration, Inc.
One Chestnut Street • Nashua, NH 03060
Tel: 603.880.4420 • Fax: 603.880.4536
criticalprocess.com • sales@criticalprocess.com