

# PNM Capsule Filters

Nylon 6,6 Membrane



## Applications

- ◆ Bulk Pharmaceutical Chemicals
- ◆ Solvents
- ◆ SVPs and LVPs
- ◆ WFI Water
- ◆ Buffers and Other Media
- ◆ Feedstock

PNM capsules are designed to be used for sterilizing grade filtration. The high quality nylon membrane is optimized for retention. PNM capsule filter elements are 100% integrity tested during production.

Nylon capsules see broad service in sterile fill applications in SVPs and as bioburden management filters in LVPs. Media and service liquid filtration are other common applications for this membrane.

Additional applications for PNM capsule filters include final filtration of bulk pharmaceutical chemicals, USP Purified Water, Water for Injection (WFI), buffers, solvents, alcohols and other excipients. Nylon is particularly suited for the filtration of solvents because of its broad compatibility and low level of extractables.

Designed for sterilizing filtration

Optimized for retention

Final filtration of bulk chemicals, USP Purified Water and WFI, buffers

Bioburden reduction in LVPs

Broad solvent compatibility

## PNM Capsule Filters - Filtration Area

Media	Capsule Length				
	2"	5"	10"	20"	30"
Nylon 6,6 Membrane	1.0 ft <sup>2</sup> (930cm <sup>2</sup> )	3.0 ft <sup>2</sup> (2788cm <sup>2</sup> )	7.0 ft <sup>2</sup> (6503cm <sup>2</sup> )	14.0 ft <sup>2</sup> (13006cm <sup>2</sup> )	21.0 ft <sup>2</sup> (19509cm <sup>2</sup> )

## 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<sup>2</sup> (930 cm<sup>2</sup>) 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	0.10 µm	0.22 µm	0.45 µm	0.65 µm
GPM	0.14	0.25	0.43	0.60
LPM	0.53	0.95	1.63	2.27

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

## Construction Materials

Housing	Polypropylene
Filtration Media	Nylon 6,6 Membrane
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 Specifications

Pore Size	Test Pressure (psi)	Max Diffusion Rate (cc/min -water wetted membrane)				
		2"	5"	10"	20"	30"
0.10	48	2.1	6.3	15	30	45
0.22	35	2.1	6.3	15	30	45
0.45	20	2.1	6.3	15	30	45
0.65	15	2.1	6.3	15	30	45

## Integrity Test Specifications - Bubble Point

Pore Size	Bubble Point (water wetted membrane)
0.10 µm	**
0.22 µm	50 psig (3.5 barg)
0.45 µm	25 psig (1.7 barg)
0.65 µm	19 psig (1.3 barg)

\*\* Test pressure exceeds operational limits of capsule filters. Use the diffusion test method.

## Quality Assurance and Standards

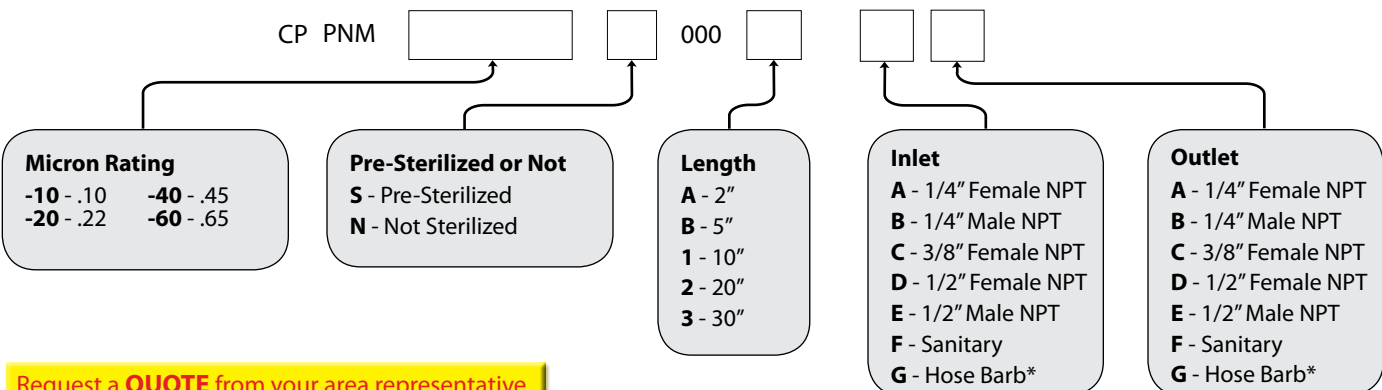
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The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled 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.

## Ordering Information

Capsule order number example: Pharmaceutical Grade Nylon 6,6 Membrane, 0.22 Micron Rating, Pre-Sterilized, 10" Length, Sanitary Inlet, Sanitary Outlet = CPPNM-20S0001FF.



Request a **QUOTE** from your area representative



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## Validation

PNM capsule filters are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. The challenge level is 10<sup>7</sup> organisms per cm<sup>2</sup> of filter media:

0.22 µm challenged with *Brevundimonas diminuta*;

0.45 µm challenged with *Serratia marcescens*;

0.65 µm challenged with *Saccharomyces cerevisiae*.

Critical Process Filtration can provide validation assistance.

## Sanitization/Sterilization

**Autoclave**..... 250° F (121° C), 30 min, multiple cycles

**Chemical Sanitization** .....

Nylon does not tolerate aggressive chemical sanitization protocols. Nylon membrane cartridges are best sanitized with 1% hydrogen peroxide or 1% hydrogen peroxide and peracetic acid. Follow the manufacturers instructions for use on nylon filter devices.

**Note**.....PNM capsules are not to be used in steam.

**Pre-Sterilized**.....PNM capsules are offered in both non- and pre-sterilized forms.

## USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PNM capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the 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. PNM 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

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

## 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.

Hose Barb Diameter Ranges\*

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