



# PNM Filters

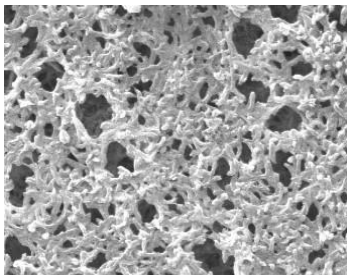
Nylon 6,6 Membrane



PNM filters are validated cartridge and capsule filters made using long-proven, absolute rated, Nylon 6,6 membrane. These filters are used for the sterilization of water, solvents and aqueous liquids. Pore sizes range from 0.10 to 0.65  $\mu\text{m}$  and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

The PNM filter's broad chemical compatibility makes it a good fit for the filtration of solvents and other harsh chemicals. These filters are optimized for flow, high retention and chemical compatibility. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. PNM capsules are available pre-sterilized.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration experts is how we deliver your company's solution right the first time.



PNM sterilizing filters are recommended for:

- SVPs & LVPs
- Diagnostics
- Buffers
- WFI, Water Purification
- Non-protein solutions
- Chemicals

## Sterilizing Filters



CARTRIDGES – Nominal Dimensions

Length: 5 to 40 in. (12.7 to 101.6 cm)

Outside Diameter: 2.75 in. (7.0cm)



CAPSULES – Nominal Dimensions

Length: 2 to 30 in. (5.1 to 76.2 cm)

Outside Diameter: 3.50 in. (8.9 cm)

## Maximum Operating Parameters

	CARTRIDGES	CAPSULES
<b>Liquid Operational Pressure</b>	N/A	80 psi at 68 °F (5.51 bard at 20 °C)
<b>Gases Operational Pressure</b>	N/A	60 psi at 68 °F (4.13 bar at 20 °C)
<b>Operating Temperature (water)</b>	180 °F at 30 psid (82 °C at 2.06 bard)	110 °F at 30 psid (43 °C at 2.06 bard)
<b>Forward Differential Pressure</b>	80 psid at 68 °F (5.51 bard at 20 °C)	80 psid at 68 °F (5.51 bard at 20 °C)
<b>Reverse Differential Pressure</b>	50 psid at 68 °F (3.44 bard at 20 °C)	50 psid at 68 °F (3.44 bard at 20 °C)
<b>Recommended Changeout Pressure</b>	35 psid (2.41 bard)	35 psid (2.41 bard)

## Sanitization & Sterilization

<b>Filtered Hot Water*</b>	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow	N/A
<b>Inline Steam*</b>	275 °F (135 °C), 30 min, 25+ cycles	N/A
<b>Autoclave*</b>	250 °F (121 °C), 30 min, 25+ cycles	250 °F (121 °C), 30 min, 5+ cycles
<b>Chemical Sanitization</b>	Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, and other selected chemicals.	

\*Cartridge Filters – For all elevated temperature procedures above, a stainless-steel support ring is required.

## Filtration Area

	CAPSULES	CARTRIDGES AND CAPSULES				CARTRIDGES
Length	2"	5"	10"	20"	30"	40"
	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	1.2 ft <sup>2</sup>	3.3 ft <sup>2</sup>	7.0 ft <sup>2</sup>	14.0 ft <sup>2</sup>	21.0 ft <sup>2</sup>	28.0 ft <sup>2</sup>
	0.11m <sup>2</sup>	0.30m <sup>2</sup>	0.65m <sup>2</sup>	1.30m <sup>2</sup>	1.95m <sup>2</sup>	2.60m <sup>2</sup>

## Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE*		BUBBLE POINT MINIMUM*	
	PSIG	BARG	PSIG	BARG
0.10	48	3.30	**	**
0.22	35	2.41	50	3.5
0.45	20	1.37	25	1.7
0.65	15	1.03	19	1.3

DIFFUSION SPECIFICATIONS*						
Length	2"	5"	10"	20"	30"	40"
mL/min	≤ 2.1	≤ 7.1	≤ 15	≤ 30	≤ 45	≤ 60

\* All specifications are for water wetted membrane  
 \*\* Test pressure exceeds operational limits of capsule filters. Use the Diffusion Test method.

## Construction Materials

<b>Filtration Media</b>	Nylon 6,6 Membrane with polyester support
<b>Media Support</b>	Polypropylene
<b>End Caps, Center Core, Outer Support Cage, Capsule Housing</b>	Polypropylene
<b>Sealing Method</b>	Thermal Bonding
<b>O-Rings/Gaskets Cartridges only</b>	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

## Validation

PNM filters are validated using test procedures that comply with ASTM F 838-15(ae1) protocols for the determination of bacterial retention in filters used for liquid filtration. The challenge level is a minimum of  $10^7$  organisms per  $\text{cm}^2$  of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.10 $\mu\text{m}$  and 0.22 $\mu\text{m}$  meet the FDA definition of sterilizing grade filters).

0.10 $\mu\text{m}$ : *Brevundimonas diminuta*

0.22 $\mu\text{m}$ : *Brevundimonas diminuta*

0.45 $\mu\text{m}$ : *Serratia marcescens*

0.65 $\mu\text{m}$ : *Saccharomyces cerevisiae*

Validation Guides available upon request.

## Endotoxins

The levels of bacterial endotoxins in aqueous extracts from PNM filters are below current USP limits as specified for water for injection.

## Extractables

PNM filters typically exhibit low levels of non-volatile residues.

## TOC and Conductivity

PNM filters conform with TOC standards of USP <643> and the water conductivity standards of USP <645> after an appropriate flush with purified water.

## Toxicity Compliance

The materials used to construct PNM 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.

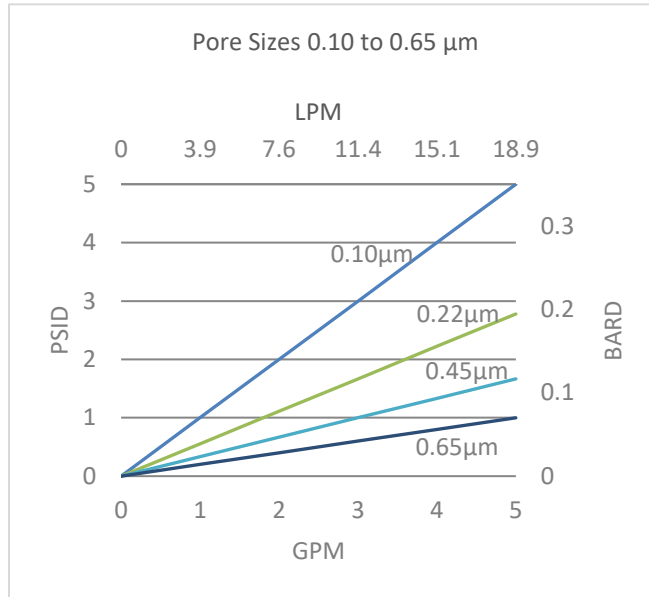
## Non-Fiber Releasing

PNM filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

## FDA Compliance

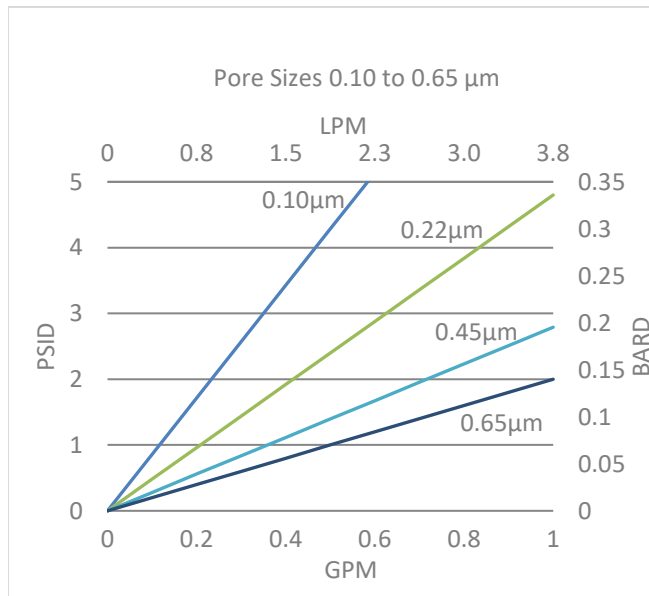
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

## Flow Rates for PNM Cartridges



Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

## Flow Rates for PNM Capsules

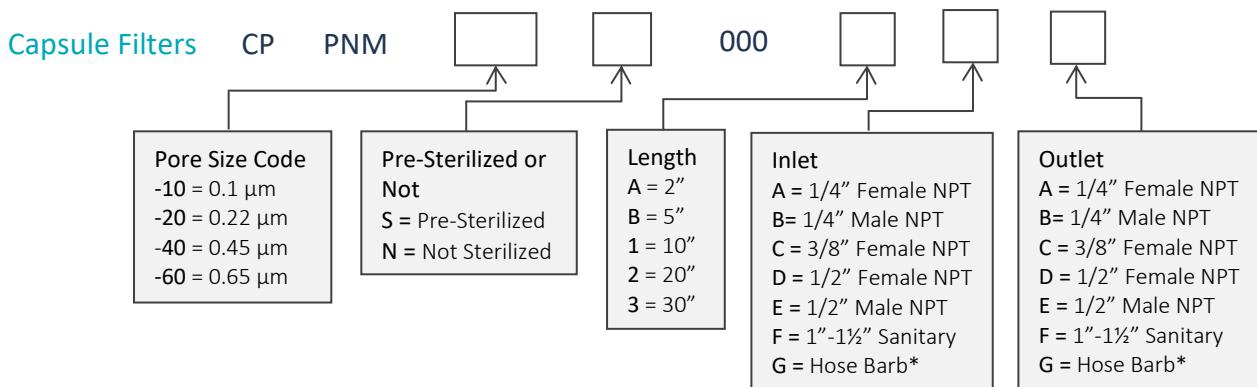
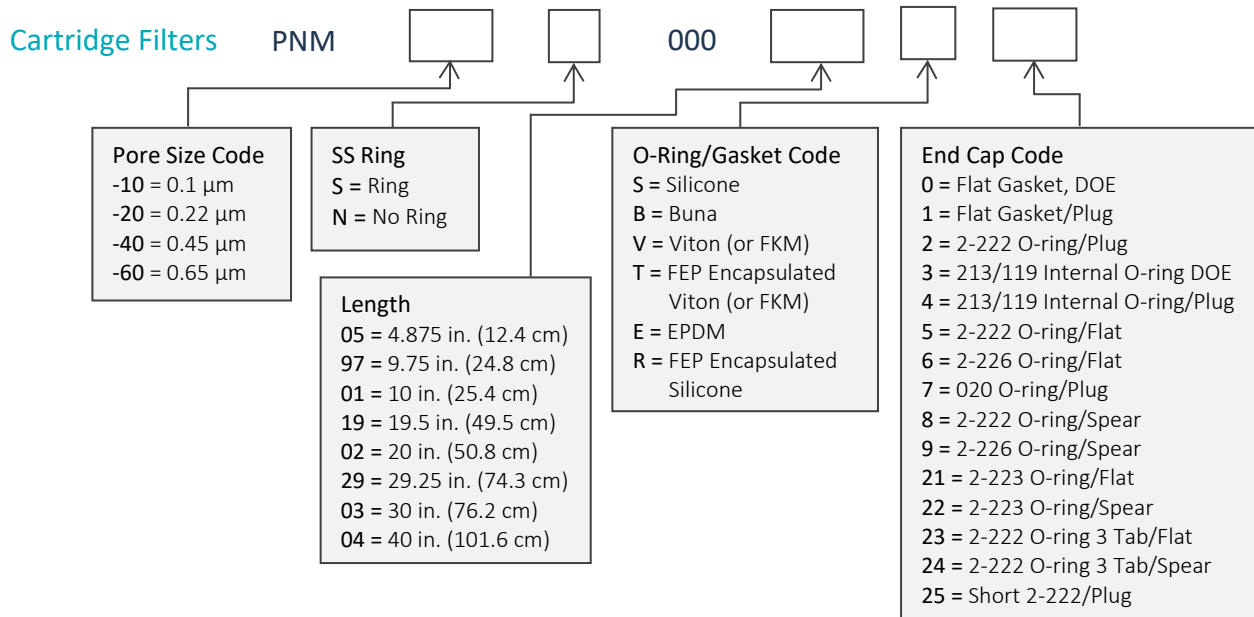


Flow rates for Capsule filters are per square foot of membrane area. The test fluid is water at ambient temperature. Flows are tested using a 2" capsule filter with  $\frac{1}{2}$ " FNPT inlet and outlet ports. Rates will vary based on end configuration of the capsule.

## PNM Filters Ordering Information

All Critical Process filters are configurable to meet customer specifications.  
Fill in the corresponding codes in the boxes below to build your Part Number.

To consult with one of our technical team members, request a quote or place an order:  
call (603) 880-4220 Ext. 106, or send an email to [sales@criticalprocess.com](mailto:sales@criticalprocess.com)



\*Fits hoses/tubes with inner diameter 11/32 to 9/16 inches

### Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.



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