

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  $\mu m$  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 presterilized.

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. (7.0 cm)



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		
	CARTRIDGES	CAPSOLES		
Liquid Operational Pressure	N/A	80 psi at 68 °F (5.52 bard at 20 °C)		
Gases Operational Pressure	ases Operational Pressure N/A 60 psi at 68 °F (4			
Operating Temperature (water)	180 °F at 30 psid (82 °C at 2.07 bard)	110 °F at 30 psid (43 °C at 2.07 bard)		
Forward Differential Pressure	80 psid at 68 °F (5.52 bard at 20 °C) 80 psid at 68 °F (5.52 bard at 20 °C			
<b>Reverse Differential Pressure</b> 50 psid at 68 °F (3.45 bard at 20 °C)		50 psid at 68 °F (3.45 bard at 20 °C)		
<b>Recommended Changeout Pressure</b>	35 psid (2.41 bard)	35 psid (2.41 bard)		

### Sanitization & Sterilization

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

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

### Filtration Area (Nominal)

	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>	0.31m <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*			E POINT MUM*
μm	PSIG	BARG	PSIG	BARG
0.10	48	3.31	**	**
0.22	35	2.41	50	3.4
0.45	20	1.38	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

<sup>\*</sup> All specifications are for water wetted membrane

<sup>\*\*</sup> Test pressure exceeds operational limits of capsule filters.
Use the Diffusion Test method.

#### **Construction Materials**

Filtration Media	Nylon 6,6 Membrane with polyester support		
Media Support	Polypropylene		
End Caps, Center Core, Outer Support Cage, Capsule Housing	Polypropylene		
Sealing Method	Thermal Bonding		
O-Rings/Gaskets Cartridges only	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 cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.10 $\mu$ m and 0.22 $\mu$ m meet the FDA definition of sterilizing grade filters).

0.10μm: Brevundimonas diminuta 0.22μm: Brevundimonas diminuta 0.45μm: Serratia marcescens 0.65μm: Saccharomyces cerevisiae

#### **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.

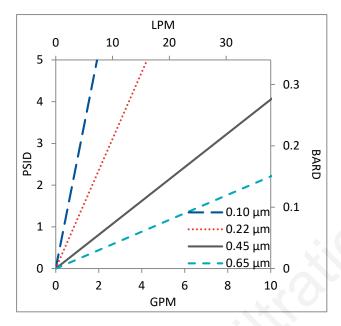
#### Non-Fiber Releasing

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

#### **FDA Compliance**

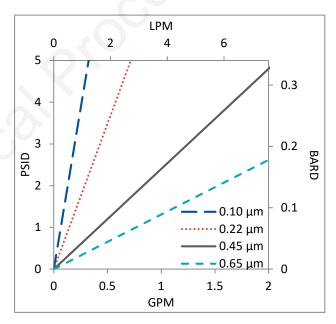
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

### Flow Rates for PNM Cartridges by Pore Size



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

## Flow Rates for PNM Capsules by Pore Size

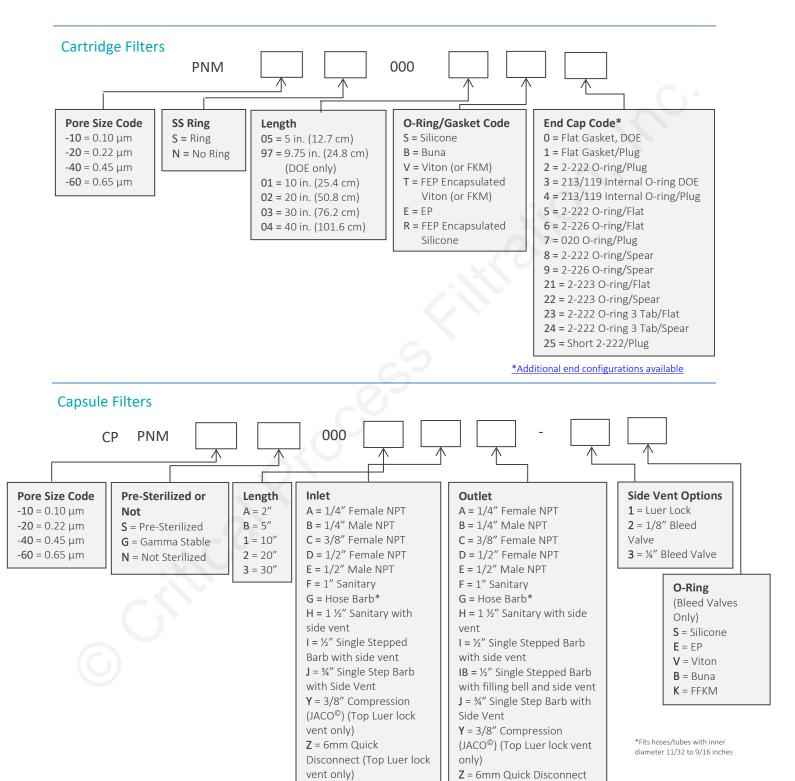


Flow rates for Capsule filters are tested using a 2'' capsule filter with 1'' sanitary inlet and outlet ports. The test fluid is water at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

### **PNM Filters Ordering Information**

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) 880-4420 or contact us here.





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