

PNM Micro Capsule 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  $\mu m$ .

The PNM Micro Capsule 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, and 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.

# **Sterilizing Filters**

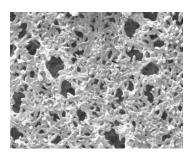


MICRO CAPSULES - Nominal Dimensions

Body Length: 1.9 in. (4.8 cm)

Overall Length: 2.8 to 3.8 in. (7.1 to 9.7 cm)

Outside Diameter: 2.6 in. (6.6 cm)



PNM Micro Capsule sterilizing filters are recommended for:

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

## **Maximum Operating Parameters**

	MICRO CAPSULES
Liquid Operational Pressure	80 psi at 68 °F (5.52 bard at 20 °C)
Gases Operational Pressure	60 psi at 68 °F (4.14 bar at 20 °C)
Operating Temperature (water)	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)
Reverse Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)
Recommended Changeout Pressure	35 psid (2.41 bard)

## Sanitization & Sterilization

Autoclave	250 °F (121 °C), 30 min, 5+ cycles
Chemical Sanitization	Performed using industry standard concentrations of hydrogen
	peroxide, peracetic acid, and other selected chemicals.

## **Integrity Testing**

PORE SIZE	BUBBLE POI	NT MINIMUM*
μm	PSIG	BARG
0.10	**	**
0.22	50	3.4
0.45	25	1.7
0.65	19	1.3

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

## Filtration Area (Nominal)

Area	0.58 ft²
	539 cm <sup>2</sup>

### **Construction Materials**

Filtration Media	Nylon 6,6 Membrane with polyester support
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Micro Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding

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

#### Validation

PNM Micro Capsule 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

Validation Guides available upon request.

#### **Endotoxins**

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

#### **Extractables**

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

#### **TOC** and Conductivity

PNM Micro Capsule 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 Micro 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.

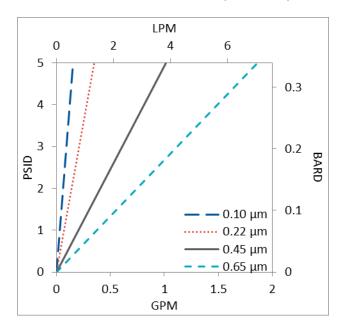
#### Non-Fiber Releasing

PNM Micro Capsule 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 Micro Capsules by Pore Size

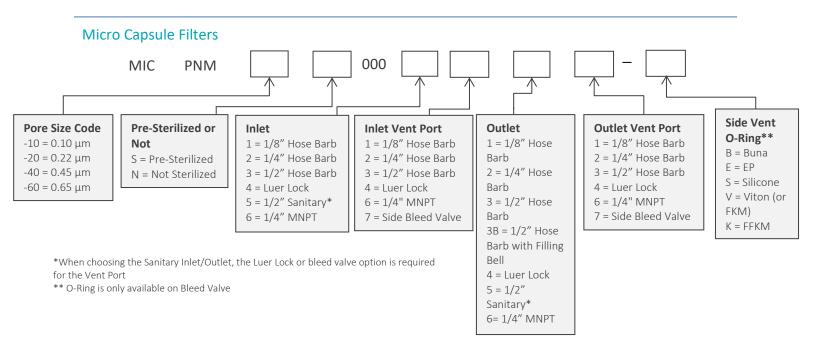


Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with ½" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

## PNM Micro Capsule 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) 880-4420 or contact us here.





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