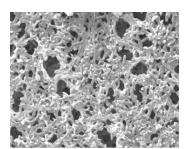


PNC Micro Capsule filters consist of a positively charged Nylon 6,6 membrane used for sterilizing aqueous and non-aqueous liquids that contain negatively charged contaminants. Available in 0.10, 0.22, 0.45 and 0.65  $\mu m$ , PNC Micro Capsule filters are validated for bacteria retention to provide reliable sterile filtration performance.

The positive charge in these filters removes negatively charged biological contaminants such as endotoxin, virus and other cell fragments. Depending on the level of contaminant and flow rate, PNC Micro Capsule filters will typically exhibit > 2-log removal of endotoxin. The combination of sterilizing and endotoxin removal functionality makes the PNC Micro Capsule filter an excellent choice for pharmaceutical and bioprocessing applications.

These laboratory filters are constructed with the same materials as our full-size filters to ensure consistent results throughout your process.

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.



PNC Micro Capsule filters are recommended for sterilizing and endotoxin removal in:

- Process Water
- Water for Injection (WFI)
- Serum
- Plasma
- Vitamins

# **Sterilizing Filters**

### **Endotoxin Removal**



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)

## **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	50 psid at 68 °F (3.45 bard at 20 °C)
Reverse Differential Pressure	40 psid at 68 °F (2.76 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, sodium hypochlorite and other selected chemicals.

# **Integrity Testing**

PORE SIZE	BUBBLE POI	NT MINIMUM*
μm	PSIG	BARG
0.10	**	**
0.22	50	3.5
0.45	25	1.7
0.65	19	1.3

<sup>\*</sup> For water wetted membrane

## Filtration Area (Nominal)

Area –	0.58 ft²
	539 cm <sup>2</sup>

## **Construction Materials**

Filtration Media	Positively Charged 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> Actual bubble point exceeds operational limits of Micro capsule filters

#### Validation

PNC 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

#### **Endotoxins**

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

#### Extractables

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

### **TOC** and Conductivity

PNC 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**

Materials used to construct PNC 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.

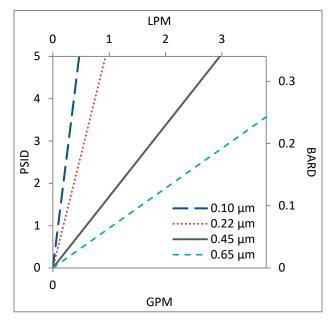
### Non-Fiber Releasing

PNC 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

## Flow Rates for PNC Micro Capsules by Pore Size



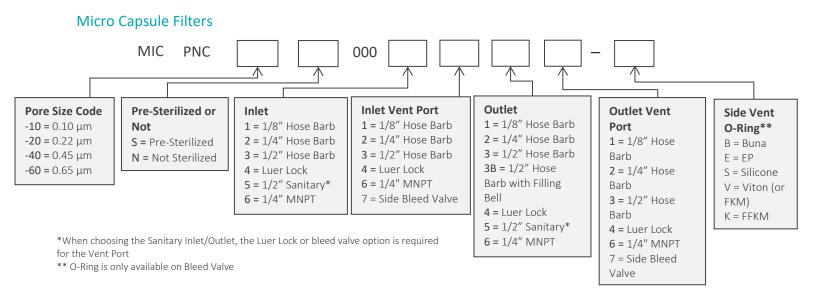
Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with ½" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

### **PNC 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.

\*\*Please note this product is not designed or approved for use in Hemodialysis applications\*\*





One Chestnut Street Nashua, NH 03060 603.880.4420 FAX: 603.880.4536

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