

HPPC Micro Capsules are designed for laboratory use with their small filtration area and size. They are made from all the same materials as our larger HPPC filters to ensure consistent results at every scale. These validated, dual-layered PES membrane capsules are well suited for sterilizing products with high particle loads. Final layer pore sizes include 0.03, 0.10, 0.22, 0.45 µm.

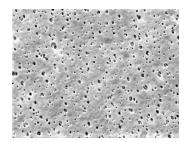
Designed with a High Capacity, Positively Charged, PES prefilter layer and an Asymmetric PES final filter layer, HPPC Micro Capsule filters deliver high flow across a wide pH range. The HPPC filter's low binding characteristics make them ideal for filtering products with preservatives and proteins that can adsorb to media. They are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. HPPC Micro Capsules are available pre-sterilized.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced highperformance 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 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)



HPPC Micro Capsule filters are recommended for:

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

# **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

Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.

## **Integrity Testing**

PORE SIZE	BUBBLE POIN	IT MINIMUM*
μm	PSIG	BARG
0.03	**	**
0.10	**	**
0.22	50	3.4
0.45	25	1.7

\* For water wetted membrane

\*\* Actual bubble point exceeds operational limits of Micro capsule filters.

# Filtration Area (Nominal)

Area —	0.5 ft <sup>2</sup>
	465 cm <sup>2</sup>

## **Construction Material**

Filtration Media	High Capacity, Positively Charged PES membrane on polyester support prefilter layer and Positively Charged PES membrane final filter layer	
Media Support	Polypropylene	
End Caps, Center Core, Outer Support Cage, Capsule Housing	Polypropylene	
Sealing Method	Thermal Bonding	
O-Rings/Gaskets Cartridges only	EEP Encapsulated Silicone, EEP	

#### Validation

HPPC 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 cm<sup>2</sup> of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03µm, 0.10µm and 0.22µm meet the FDA definition of sterilizing grade filters).

0.03μm: Acholeplasma laidlawii 0.10μm: Brevundimonas diminuta 0.22μm: Brevundimonas diminuta 0.45μm: Serratia marcescens

#### Endotoxins

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

#### Extractables

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

#### **TOC and Conductivity**

HPPC 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**

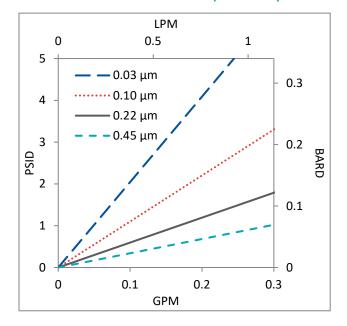
Materials used to construct HPPC Micro Capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

#### **Non-Fiber Releasing**

HPPC 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 HPPC 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  $\chi''$  Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

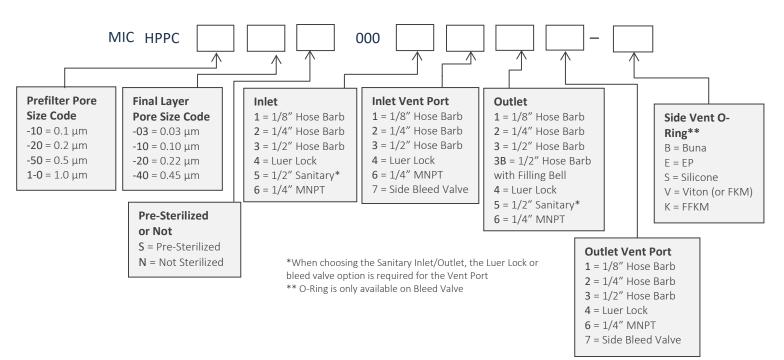
# HPPC Micro Capsule Filters Ordering Information

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\*\*

## **Micro Capsule Filters**





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Data Sheet HPPC Micro DS Rev -