CRITICAL PROCESS FILTRATION, INC.

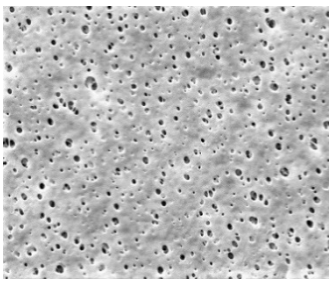
HPPC Filters

Positively Charged, Dual Layered PES Membrane

For sterilizing products with high particle loads, HPPC filters offer a wide selection of validated, dual-layer, positively charged Polyethersulfone (PES) cartridges and capsule filters. Available in 0.03, 0.10, 0.22, and 0.45 µm, HPPC filters are validated for absolute bacteria retention to provide reliable sterile filtration performance. The positive charge removes negatively charged biological contaminants such as endotoxins, viruses, and other cell fragments. Depending on the level of contaminant and flow rate, HPPC filters will typically exhibit > 3-log removal of endotoxin.

Designed with a High Capacity PES prefilter layer and an asymmetric PES final filter layer, HPPC filters deliver high flow across a wide pH range. The HPPC filter's low binding characteristics make it 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.
This combination of functionality makes the HPPC filter an excellent choice for pharmaceutical and biopharmaceutical applications.

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.



HPPC filters are recommended for sterilizing and endotoxin removal in:

- Process Water
- Water for Injection (WFI)

Sterilizing Filters

Endotoxin Removal

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
Liquid Operational Pressure	N/A	80 psi at 68 °F (5.52 bard at 20 °C)
Gases Operational Pressure	N/A	60 psi at 68 °F (4.14 bar at 20 °C)
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) (Liquid and Gas)	Liquid - 80 psid at 68 °F (5.52 bard at 20 °C) Gas - 60 psi at 68 °F (4.14 bar at 20 °C)
Reverse Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)	50 psid at 68 °F (3.45 bard at 20 °C)
Recommended Changeout Pressure	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, sodium hypochlorite and other selected chemicals.	

*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	0.9 ft^2	2.5 ft^2	5.4 ft^2	10.8 ft^2	16.2 ft^2	21.6 ft^2
	0.08 m^2	0.23 m^2	0.5 m^2	1.00 m^2	1.50 m^2	2.00 m^2

Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE*		BUBBLE POINT MINIMUM*	
µm	PSIG	BARG	PSIG	BARG
0.03	60	4.14	**	**
0.10	48	3.30	**	**
0.22	35	2.41	50	3.5
0.45	20	1.37	25	1.7

DIFFUSION SPECIFICATIONS* (Final Layer Pore Size)						
Length	2”	5”	10”	20”	30”	40”
mL/min (0.03µm, 0.10µm)	≤ 2.9	≤ 8.4	≤ 20	≤ 40	≤ 60	≤ 80
mL/min (All Other Pore Sizes)	≤ 2.1	≤ 6.3	≤ 15	≤ 30	≤ 45	≤ 60

* For water-wetted membrane
** Test pressure exceeds operational limits of capsule filters.

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	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

Validation

HPPC 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^2 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*

Validation Guides available upon request.

Endotoxins

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

Extractables

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

TOC and Conductivity

HPPC 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 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.

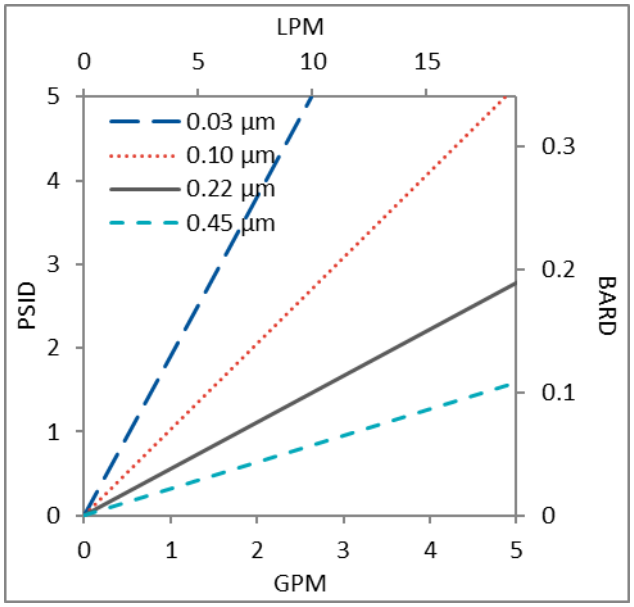
Non-Fiber Releasing

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

FDA Compliance

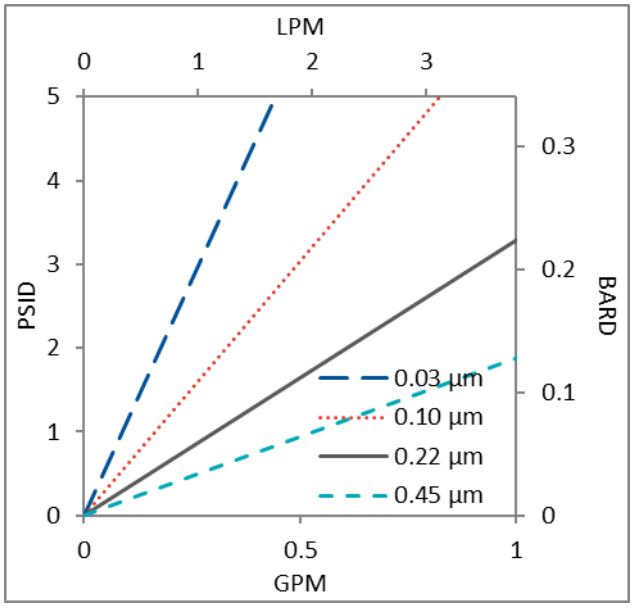
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

Flow Rates for HPPC 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 HPPC 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.

HPPC 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.

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

Cartridge Filters

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Prefilter Pore Size Code
-10 = 0.1 µm
-20 = 0.2 µm
-50 = 0.5 µm
-80 = 0.8 µm
1-0 = 1.0 µm

Final Layer Pore Size Code
-03 = 0.03 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm
-60 = 0.65 µm
-80 = 0.80 µm
1-0 = 1.0 µm

SS Ring
S = Ring
N = No Ring

Length
05 = 5 in. (12.7 cm)
97 = 9.75 in. (24.8 cm) (DOE only)
01 = 10 in. (25.4 cm)
02 = 20 in. (50.8 cm)
03 = 30 in. (76.2 cm)
04 = 40 in. (101.6 cm)

O-Ring/Gasket Code
S = Silicone
B = Buna
V = Viton (or FKM)
T = FEP Encapsulated Viton (or FKM)
E = EP
R = FEP Encapsulated Silicone

End Cap Code*
0 = Flat Gasket, DOE
1 = Flat Gasket/Plug
2 = 2-222 O-ring/Plug
3 = 213/119 Internal O-ring DOE
4 = 213/119 Internal O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
7 = 020 O-ring/Plug
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear
21 = 2-223 O-ring/Flat
22 = 2-223 O-ring/Spear
23 = 2-222 O-ring 3 Tab/Flat
24 = 2-222 O-ring 3 Tab/Spear
25 = Short 2-222/Plug

Capsule Filters

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Prefilter Pore Size Code
-10 = 0.1 µm
-20 = 0.2 µm
-50 = 0.5 µm
-80 = 0.8 µm
1-0 = 1.0 µm

Final Layer Pore Size Code
-03 = 0.03 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm
-60 = 0.65 µm
-80 = 0.80 µm
1-0 = 1.0 µm

Length
A = 2”
B = 5”
1 = 10”
2 = 20”
3 = 30”

Pre-Sterilized or Not
S = Pre-Sterilized
G = Gamma Stable
N = Not Sterilized

Inlet
A = 1/4” Female NPT
B = 1/4” Male NPT
C = 3/8” Female NPT
D = 1/2” Female NPT
E = 1/2” Male NPT
F = 1” Sanitary
G = Hose Barb*
H = 1 ½” Sanitary with side vent
I = ½” Single Stepped Barb with side vent
J = ¾” Single Step Barb with Side Vent
Y = 3/8” Compression (JACO©) (Top Luer lock vent only)
Z = 6mm Quick Disconnect (Top Luer lock vent only)

Outlet
A = 1/4” Female NPT
B = 1/4” Male NPT
C = 3/8” Female NPT
D = 1/2” Female NPT
E = 1/2” Male NPT
F = 1” Sanitary
G = Hose Barb*
H = 1 ½” Sanitary with side vent
I = ½” Single Stepped Barb with side vent
IB = ½” Single Stepped Barb with filling bell and side vent
J = ¾” Single Step Barb with Side Vent
Y = 3/8” Compression (JACO©) (Top Luer lock vent only)
Z = 6mm Quick Disconnect (Top Luer lock vent only)

Side Vent Options
1 = Luer Lock
2 = 1/8” Bleed Valve
3 = ¼” Bleed Valve

O-Rings
(Bleed Valves Only)
S = Silicone
E = EP
V = Viton
B = Buna
K = FFKM

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

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Data Sheet HPPC DS Rev -