



# HPPS/HT Filters

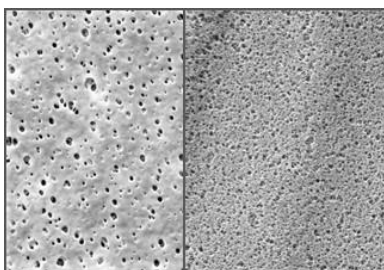
High Temperature Dual Layered  
PES Membrane



For sterile applications at elevated temperatures (up to 203°F), HPPS/HT filters remove high particle loads from aqueous liquids. These validated dual layered PES cartridge filters are available in pore sizes that range from 0.10  $\mu\text{m}$  to 1.0  $\mu\text{m}$ .

Designed with a High Capacity PES prefilter layer and Asymmetric PES final filter layer, plus high temperature polypropylene membrane support and cartridge hardware, HPPS/HT filters deliver high flow across a wide pH range. The HPPS/HT filters' 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.

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.



High Capacity PES / Asymmetric PES

HPPS/HT is recommended for:

- SVPs & LVPs
- Diagnostics
- Buffers
- WFI, Water Purification
- Vaccines
- Biologicals
- Ophthalmics

## Sterilizing Filters



CARTRIDGES – Nominal Dimensions

Length: 5 to 40 in. (12.7 to 101.6 cm)

Outside Diameter: 2.75 in. (7.0 cm)

## Maximum Operating Parameters

CARTRIDGES	
<b>Operating Temperature (water)</b>	203 °F at 30 psid (95 °C at 2.07 bard)
<b>Forward Differential Pressure</b>	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)
<b>Recommended Changeout Pressure</b>	35 psid (2.41 bard)

## Sanitization & Sterilization

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

\*For all elevated temperature procedures above, a stainless-steel support ring is required.

## Filtration Area (Nominal)

Length	CARTRIDGES				
	5"	10"	20"	30"	40"
	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	2.5 ft <sup>2</sup>	5.4 ft <sup>2</sup>	10.8 ft <sup>2</sup>	16.2 ft <sup>2</sup>	21.6 ft <sup>2</sup>
	0.23m <sup>2</sup>	0.50m <sup>2</sup>	1.00m <sup>2</sup>	1.51m <sup>2</sup>	2.01m <sup>2</sup>

## Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE		DIFFUSION SPECIFICATIONS* (Final Layer Pore Size)							
	µm	PSIG	BARG	Length	2"	5"	10"	20"	30"	40"
0.2/0.10	48		3.30							
0.5/0.22	35		2.41							
1.0/0.22	35		2.41							
1.0/0.45	20		1.37							
1.0/0.65	15		1.03							
1.0/0.80	12		0.82							
1.0/1.0	8		0.55							

\* For water-wetted membrane

## Construction Materials

<b>Filtration Media</b>	High Capacity PES membrane on polyester support prefilter layer and Asymmetric PES membrane final filter layer
<b>Media Support</b>	High Temperature Polypropylene
<b>End Caps, Center Core, Outer Support Cage</b>	High Temperature Polypropylene
<b>Sealing Method</b>	Thermal Bonding
<b>O-Rings/Gaskets Cartridges only</b>	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

## Validation

HPPS/HT 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  $\text{cm}^2$  of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.10 $\mu\text{m}$  and 0.22 $\mu\text{m}$  meet the FDA definition of sterilizing grade filters).

0.10 $\mu\text{m}$ : *Brevundimonas diminuta*

0.22 $\mu\text{m}$ : *Brevundimonas diminuta*

0.45 $\mu\text{m}$ : *Serratia marcescens*

0.65 $\mu\text{m}$ : *Saccharomyces cerevisiae*

Validation Guides available upon request.

## Endotoxins

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

## Extractables

HPPS/HT filters typically exhibit low levels of non-volatile residues.

## TOC and Conductivity

HPPS/HT 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 HPPS/HT 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.

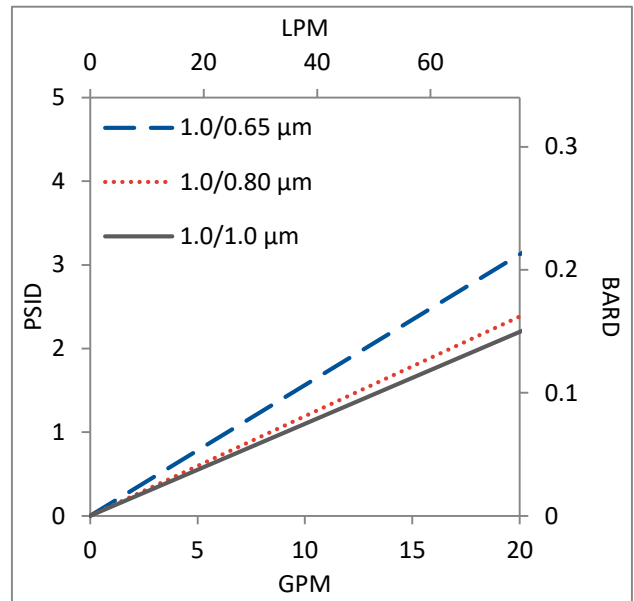
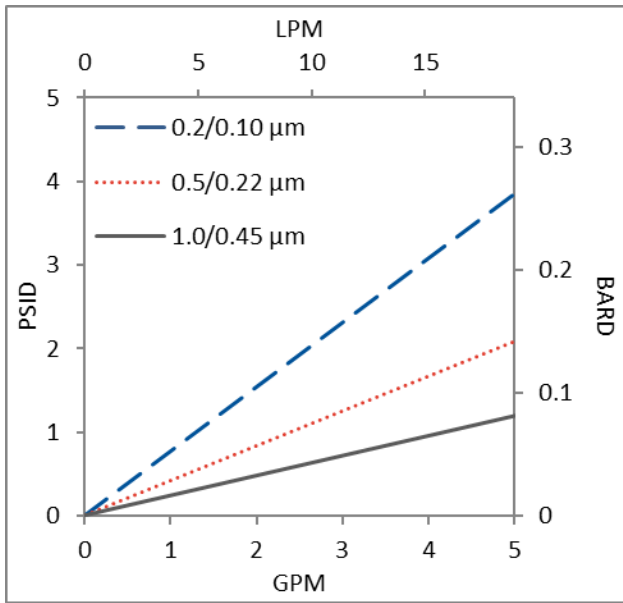
## Non-Fiber Releasing

HPPS/HT 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 HPPS/HT Cartridges by Pore Size



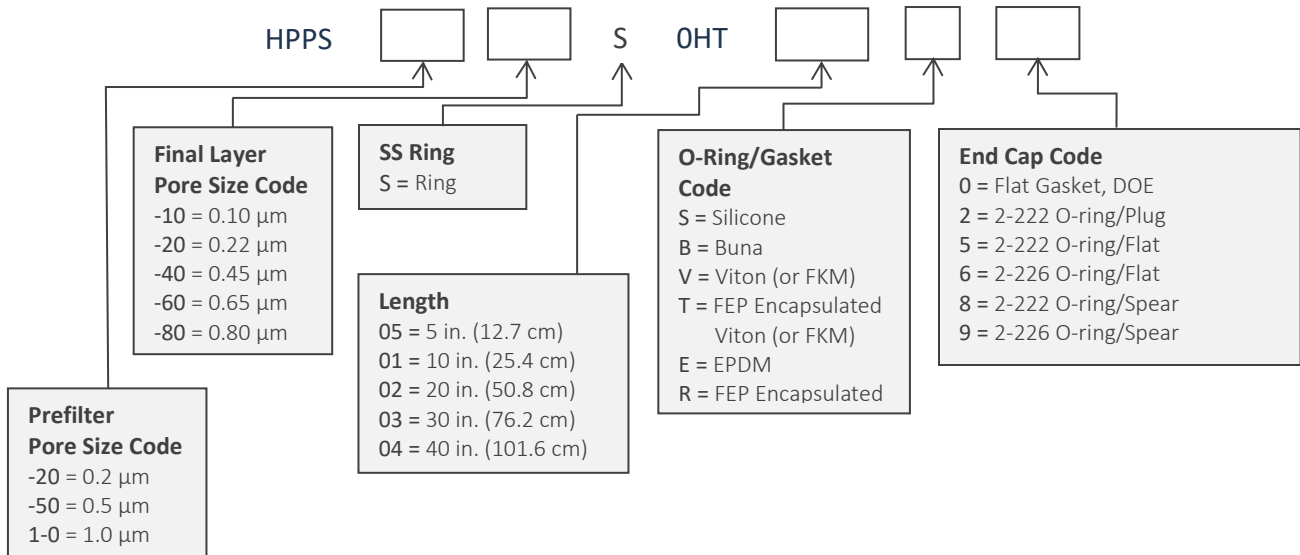
Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

## HPPS/HT 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.

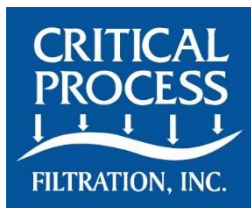
To consult with one of our technical team members, request a quote or place an order: call (603) 880-4220 Ext. 106, or send an email to [sales@criticalprocess.com](mailto:sales@criticalprocess.com)

### Cartridge Filters



### Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.



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