

PPS/HT cartridge filters are constructed with a double layered Polyethersulfone (PES) membrane, high temperature polypropylene membrane support and high temperature cartridge hardware. They are for the critical sterilizing filtration of aqueous liquids. PPS/HT cartridge filters are validated for bacteria removal. Pore sizes range from 0.03 to 1.2 μ m.

The PPS/HT filter's low binding characteristics are well suited for filtering elevated temperature liquids (up to 203°F) that might contain preservatives and proteins that can adsorb to media. These hydrophilic, double layered filters are optimized for retention and provide added security. PPS/HT filters deliver high flow and throughput at higher temperatures with compatibility across a wide pH range. 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 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



CARTRIDGES – Nominal Dimensions Length: 5 to 40 in. (12.7 to 101.6 cm) Outside Diameter: 2.75 in. (7.0 cm)



PPS/HT is recommended for:

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

Maximum Operating Parameters

	CARTRIDGES	
Operating Temperature (water)	203 °F at 30 psid (95 °C at 2.07 bard)	
Forward Differential Pressure	80 psid at 68 °F (5.52 bard at 20 °C) (Liquid and Gas)	
Reverse Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)	
Recommended Changeout Pressure	35 psid (2.41 bard)	
Sanitization & Sterilization		
Filtered Hot Water*	90 °C (194 °F), 30 minutes	
Inline Steam*	275 °F (135 °C), 30 min, 25+ cycles	
Autoclave*	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.	

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

Filtration Area (Nominal)

	CARTRIDGES				
Length	5″	10"	20"	30"	40"
	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	2.9 ft ²	6.1 ft ²	12.2 ft ²	18.3 ft ²	24.4ft ²
	0.27m ²	0.57m ²	1.14m ²	1.71m ²	2.28m ²

Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE	
μm	PSIG	BARG
0.03	60	4.13
0.10	48	3.30
0.22	35	2.41
0.45	20	1.37
0.65	15	1.03
0.80	12	0.82
1.0	8	0.55
1.2	7	0.48

DIFFUSION SPECIFICATIONS*					
Length	5″	10"	20"	30"	40"
mL/min	≤ 6.3	≤ 15	≤ 30	≤ 45	≤ 60

* For water-wetted membrane

Construction Materials

Filtration Media	Double Layered Polyethersulfone (PES) Membrane
Media Support	High Temperature Polypropylene
End Caps, Center Core, Outer Support Cage	High Temperature Polypropylene
Sealing Method	Thermal Bonding
O-Rings	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

Validation

PPS/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 cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03 μ m, 0.10 μ m and 0.22 μ m meet the FDA definition of sterilizing grade filters).

0.03μm: Acholeplasma laidlawii 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 PPS/HT filters are below current USP limits as specified for water for injection.

Extractables

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

TOC and Conductivity

PPS/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 PPS/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

PPS/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 PPS/HT Cartridges by Pore Size

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

PPS/HT 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 <u>contact us here.</u>





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