CRITICAL PROCESS FILTRATION, INC.

SPS/HT Filters

High Temperature Single Layer PES Membrane

SPS/HT filters provide a wide selection of validated, single layer Polyethersulfone (PES) cartridge filters used for the sterilizing of aqueous liquids at elevated temperatures (up to 203°F). Pore sizes range from 0.03 to 1.2 µm.

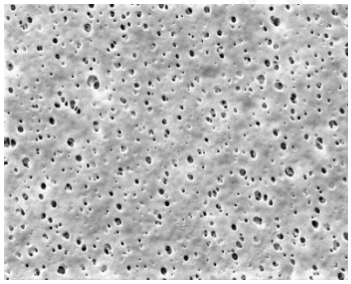
The hydrophilic SPS/HT filters have low binding characteristics that are ideal for filtering products with preservatives and high protein solutions that can adsorb to media, even at higher temperatures. SPS/HT filters deliver high flow and throughput with compatibility across a wide pH range.

SPS/HT filters 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.

Sterilizing Filters

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



SPS/HT is recommended for:

- SVPs & LVPs
- Diagnostics
- Buffers
- WFI
- Process Water
- 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	3.4 ft^2	7.3 ft^2	14.6 ft^2	21.9 ft^2	29.2 ft^2
	0.32m^2	0.68m^2	1.36m^2	2.04m^2	2.72m^2

Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE	
µm	PSIG	BARG
0.03	60	4.14
0.10	48	3.31
0.22	35	2.41
0.45	20	1.38
0.65	15	1.03
0.80	12	0.83
1.0	8	0.55
1.2	7	0.48

DIFFUSION SPECIFICATIONS*					
Length	5”	10”	20”	30”	40”
mL/min	≤ 8.6	≤ 20	≤ 40	≤ 60	≤ 80

* For water-wetted membrane

Construction Materials

Filtration Media	Single 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/Gaskets	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

Validation

SPS/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 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*
0.65µm: *Saccharomyces cerevisiae*

Endotoxins

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

Extractables

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

TOC and Conductivity

SPS/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 SPS/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.

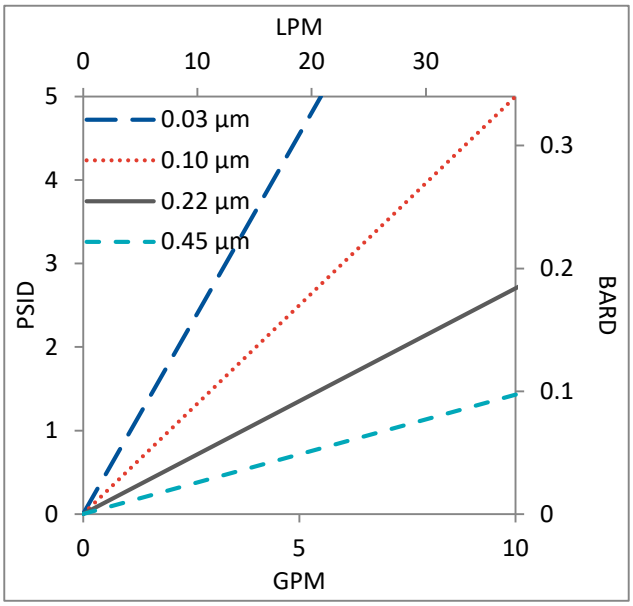
Non-Fiber Releasing

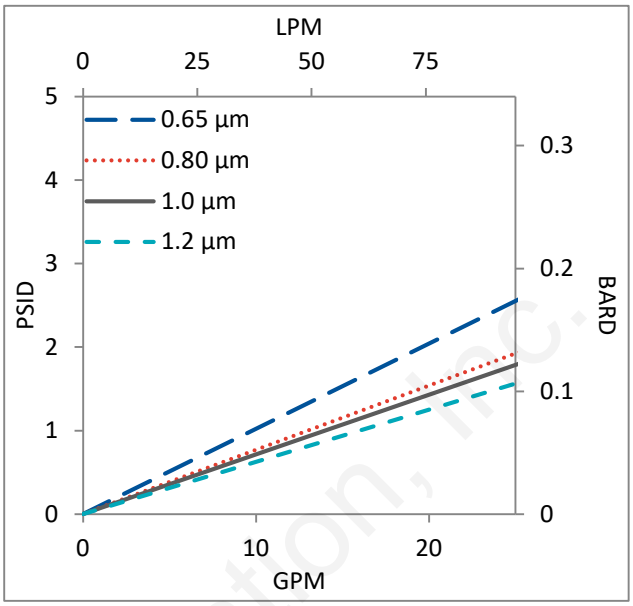
The SPS/HT filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

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 SPS/HT Cartridges by Pore Size





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

SPS/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 contact us here.

Cartridge Filters

SPS [ ] S 0HT [ ] [ ] [ ]

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
1-2 = 1.2 µm

Length
05 = 5 in. (12.7 cm)
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 = EPDM
R = FEP Encapsulated Silicone

End Cap Code
0 = Flat Gasket, DOE
2 = 2-222 O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear

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