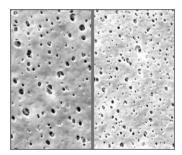


DPPS Filters are bacteria retention filters consisting of two layers of Polyethersulfone (PES) membrane for the filtration of aqueous liquids where precision retention is the goal. The bioburden reduction prefilter and the sterilizing grade final filter each come in several pore sizes so you can configure the DPPS product to meet your unique requirements based on bacteria size and load. The prefilter retains large amounts of bacteria and other particulates which can extend the life of final filter, reduce changeouts and ultimately lower costs.

The DPPS Filter is available in all devices, which are all made using identical materials to ensure consistent results. Bioburden prefilter pore sizes range from 0.10 to 1.2  $\mu$ m. Final filter pore sizes range from 0.03 to 0.65  $\mu$ m.

The DPPS Filter's low binding characteristics are well suited for filtering products with preservatives and protein solutions that can adsorb to media. These filters are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. DPPS Capsule Filters are available pre-sterilized.

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.



DPPS Filters are recommended for:

- SVPs & LVPs
- Diagnostics
- WFI, Water Purification
- Cell Culture Media
- Buffers, Serum, Plasma
- Vaccines
  - Biologicals

# **Sterilizing Filters**



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 Pressure50 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	,	
Inline Steam*	275 °F (135 °C), 30 min, 25+ cycles		
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	1.0 ft <sup>2</sup>	2.9 ft <sup>2</sup>	6.1 ft <sup>2</sup>	12.2 ft <sup>2</sup>	18.3 ft <sup>2</sup>	24.4ft <sup>2</sup>
	0.10m <sup>2</sup>	0.27m <sup>2</sup>	0.57m <sup>2</sup>	1.14m <sup>2</sup>	1.71m <sup>2</sup>	2.28m <sup>2</sup>

### **Integrity Testing**

DIFFUSION TEST PRESSURE		BUBBLE POINT MINIMUM	
PSIG	BARG	PSIG	BARG
60	4.13	**	**
48	3.30	**	**
35	2.41	50	3.5
20	1.37	25	1.7
15	1.03	19	1.3
	PRESS   PSIG   60   48   35   20	PRESSURE   PSIG BARG   60 4.13   48 3.30   35 2.41   20 1.37	PRESSURE MININ   PSIG BARG PSIG   60 4.13 **   48 3.30 **   35 2.41 50   20 1.37 25

DIFFUSION SPECIFICATIONS*						
Length	2″	5″	10"	20"	30″	40"
mL/min	≤ 2.9	≤8.6	≤ 20	≤ 40	≤ 60	≤ 80

\* For water wetted membrane

\*\* Test pressure exceeds operational limits of capsule filters. Use the Diffusion Test method.

### **Construction Materials**

Filtration Media	Dual Layered Polyethersulfone (PES) Membrane
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding
<b>O-Rings</b> Cartridges only	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

#### Validation

DPPS 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 (0.03 $\mu$ m, 0.10 $\mu$ m and 0.22 $\mu$ 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 DPPS filters are below current USP limits as specified for water for injection.

#### Extractables

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

#### **TOC and Conductivity**

DPPS 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 DPPS 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.

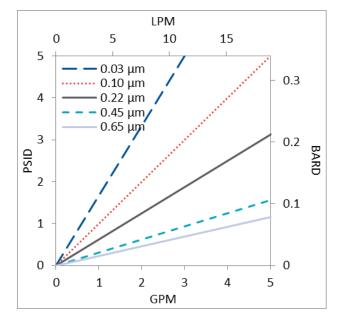
#### **Non-Fiber Releasing**

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

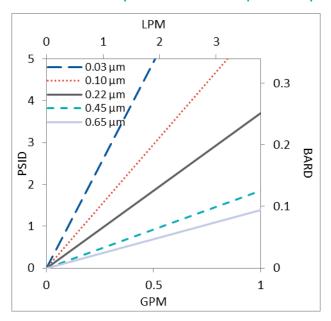
#### FDA Compliance

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 of Final Layers for DPPS Cartridges by Pore Size



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



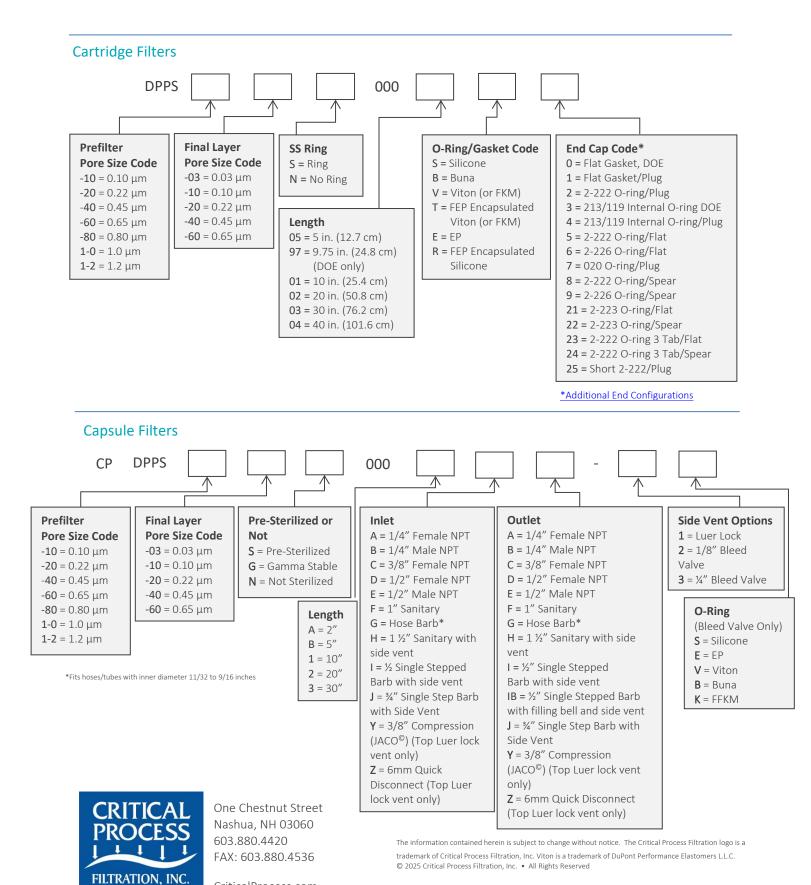
### Flow Rates of Final Layers for DPPS Capsules by Pore Size

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.

## **DPPS 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>.



Critical Process.com

Data Sheet DPPSDS Rev B