CRITICAL PROCESS FILTRATION, INC.

# DPPS/HT Filters

## High Temperature, Dual Layered PES Membrane

DPPS/HT Filters are bacteria retention cartridge filters designed for elevated temperature liquids up to 203° F. They consist 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.

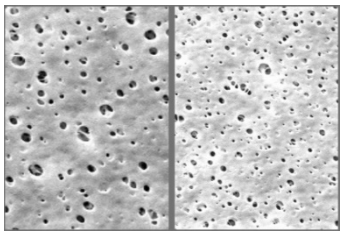
The DPPS/HT is a cartridge filter ranging from 5 – 40 inches in length. Bioburden prefilter pore sizes range from 0.10 to 1.2 µm. Final filter pore sizes range from 0.03 to 0.65 µm.

The DPPS Filter's low binding characteristics are well suited for filtering products with preservatives and protein solutions that can adsorb to media. These hydrophilic filters are optimized for retention and compatible across a wide pH range. DPPS/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)



DPPS/HT is recommended for:

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

## 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) |
| **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, 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 |
| **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 $ft^2$ | 2.9 $ft^2$ | 6.1 $ft^2$ | 12.2 $ft^2$ | 18.3 $ft^2$ | 24.4$ft^2$ |
| | 0.10$m^2$ | 0.27$m^2$ | 0.57$m^2$ | 1.14$m^2$ | 1.71$m^2$ | 2.28$m^2$ |

## 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 |

| DIFFUSION SPECIFICATIONS* | | | | | | |
|---|---|---|---|---|---|---|
| Length | 2” | 5” | 10” | 20” | 30” | 40” |
| mL/min | ≤ 2.9 | ≤8.6 | ≤ 20 | ≤ 40 | ≤ 60 | ≤ 80 |

* For water wetted membrane

## Construction Materials

| | |
|---|---|
| **Filtration Media** | Dual 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

DPPS/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 DPPS/HT filters are below current USP limits as specified for water for injection.

## Extractables

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

## TOC and Conductivity

DPPS/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 DPPS/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.

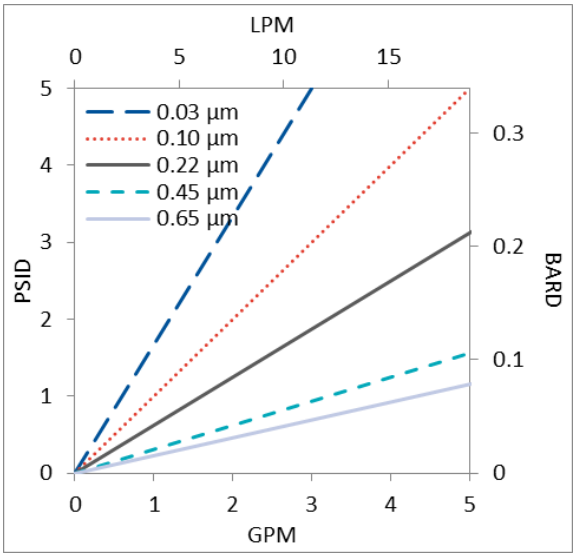
## Non-Fiber Releasing

DPPS/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 of Final Layer for DPPS/HT Cartridges by Pore Size




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

## DPPS/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

DPPS [ ] [ ] S 0HT [ ] [ ] [ ] [ ] [ ]

**Prefilter Pore Size Code**
-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

**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

**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

**Side Vent Options**
1 = Luer Lock
2 = Bleed Valve

**O-Ring (Bleed Valve Only)**
S = Silicone
E = EP
V = Viton
B = Buna
T = FKM

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