

DPPC Micro Capsule filters consist of two layers of positively charged Polyethersulfone (PES) membrane. The bioburden reduction prefilter and the sterilizing grade final filter each come in several pore sizes so you can configure to your system's needs. Available in 0.03, 0.10, 0.22, and 0.45 µm, DPPC Micro Capsules are validated for absolute bacteria retention to provide reliable sterile filtration performance. The positive charge removes negatively charged biological contaminants such as endotoxins, viruses, and other cell fragments. Depending on the level of contaminant and flow rate, DPPC filters will typically exhibit > 3-log removal of endotoxin.

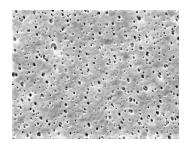
This combination of functionality makes the DPPC filter an excellent choice for pharmaceutical and biopharmaceutical applications.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and 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 Endotoxin Removal



MICRO CAPSULES – Nominal Dimensions Body Length: 1.9 in. (4.8 cm) Overall Length: 2.8 to 3.8 in. (7.1 to 9.7 cm) Outside Diameter: 2.6 in. (6.6 cm)



DPPC Micro Capsule filters are recommended for:

- Water Purification
- Water for Injection (WFI)
- Serum
- Plasma
- Vitamins

Maximum Operating Parameters

| | MICRO CAPSULES | |
|--------------------------------|--|--|
| Liquid Operational Pressure | 80 psi at 68 °F (5.52 bard at 20 °C) | |
| Gases Operational Pressure | 60 psi at 68 °F (4.14 bar at 20 °C) | |
| Operating Temperature (water) | 110 °F at 30 psid (43 °C at 2.07 bard) | |
| Forward Differential Pressure | 50 psid at 68 °F (3.45 bard at 20 °C) | |
| Reverse Differential Pressure | 40 psid at 68 °F (2.76 bard at 20 °C) | |
| Recommended Changeout Pressure | 35 psid (2.41 bard) | |

Sanitization & Sterilization

| Autoclave | 250 °F (121 °C), 30 min, 5+ cycles | |
|-----------------------|--|--|
| Chemical Sanitization | Performed using industry standard concentrations of hydrogen peroxide peracetic acid, sodium hypochlorite and other selected | |

peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.

Integrity Testing

| PORE SIZE | BUBBLE POINT MINIMUM* | |
|-----------|-----------------------|------|
| μm | PSIG | BARG |
| 0.03 | ** | ** |
| 0.10 | ** | ** |
| 0.22 | 50 | 3.4 |
| 0.45 | 25 | 1.7 |

* For water wetted membrane

** Actual bubble point exceeds operational limits of Micro capsule filters.

Filtration Area (Nominal)

| Area – | 0.52 ft ² |
|--------|----------------------|
| | 483 cm ² |

Construction Materials

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Validation

DPPC Micro Capsule 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 (0.03µm, 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

Endotoxins

The levels of bacterial endotoxins in aqueous extracts from DPPC Micro Capsule filters are below current USP limits as specified for water for injection.

Extractables

DPPC Micro Capsule filters typically exhibit low levels of non-volatile residues.

TOC and Conductivity

DPPC Micro Capsule 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 DPPC Micro Capsule 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.

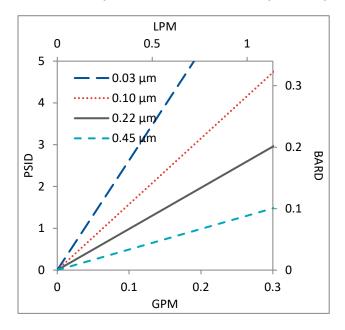
Non-Fiber Releasing

DPPC Micro Capsule 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 Micro Capsule by Pore Size



Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with ½" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

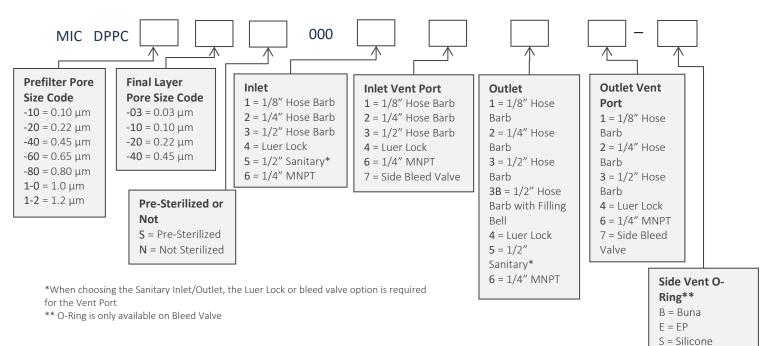
DPPC Micro Capsule Filters Ordering Information

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) 880-4420 or contact us here.

Please note this product is not designed or approved for use in Hemodialysis applications

Micro Capsule Filters





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V = Viton (or FKM) K = FFKM

Data Sheet DPPC Micro DS Rev -