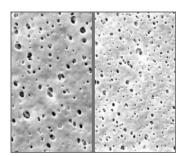


DPPS Micro Capsule Filters are bacteria retention filters consisting of two layers of Polyethersulfone (PES) membrane for the filtration of aqueous liquids where precision retention is the goal. The bioburden reduction prefilter and the sterilizing grade final filter each come in several pore sizes so you can configure the DPPS Micro Capsule 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 Micro Capsule Filter is available in all devices (cartridge, capsule and Micro capsules), which are all made using identical materials to ensure consistent results. 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 Micro Capsule 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 Micro 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 Micro Capsules are recommended for:

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

Sterilizing Filters



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)

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

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.	

Integrity Testing

PORE SIZE	BUBBLE POI	NT MINIMUM
μm	PSIG	BARG
0.03	**	**
0.10	**	**
0.22	50	3.5
0.45	25	1.7
0.65	19	1.3

^{**}Test pressure exceeds operational limits of Micro capsule filters

Filtration Area (Nominal)

Area	0.52 ft ²
	483 cm ²

Construction Materials

Filtration Media	Dual Layered Polyethersulfone (PES) Membrane
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Micro Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding

Validation

DPPS 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 $(0.03\mu\text{m}, 0.10\mu\text{m} \text{ and } 0.22\mu\text{m} \text{meet}$ 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 Micro Capsule filters are below current USP limits as specified for water for injection.

Extractables

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

TOC and Conductivity

DPPS 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 DPPS 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.

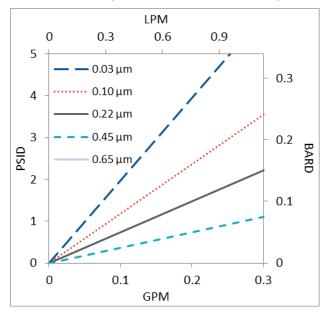
Non-Fiber Releasing

DPPS 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 Capsules by Pore Size

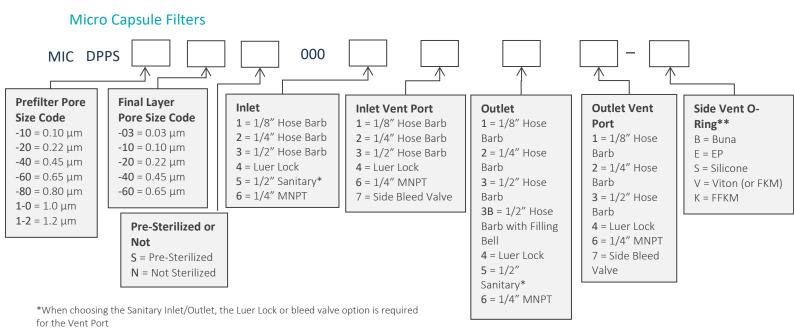


Flow rates for Micro Capsule filters are per filter. The test fluid is water at ambient temperature. Flows are tested using a Micro capsule filter with ½" Sanitary inlet and outlet ports. Rates will vary based on end configuration of the Micro capsule.

DPPS 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.







One Chestnut Street Nashua, NH 03060 603.880.4420 FAX: 603.880.4536

CriticalProcess.com

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