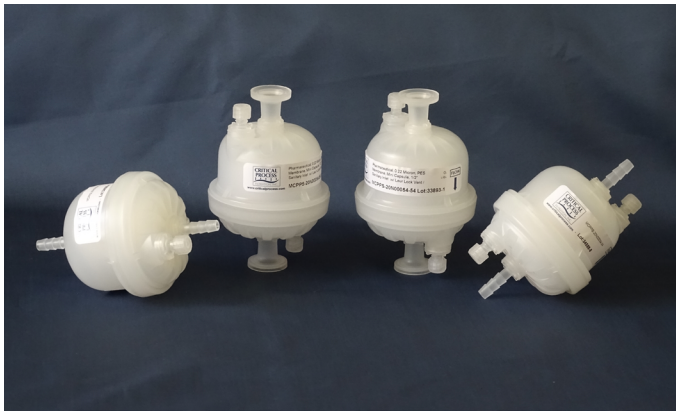
PPS Mini-Capsule Filters

Asymmetric Polyethersulfone (PES) Membrane

CRITICAL PROCESS FILTRATION, INC.

Pharmaceutical Grade



Validated for use in multiple pharmaceutical applications

Excellent flow rates with high throughput

Integrity testable

Designed for minimal leachables and extractables

Low adsorption of proteins and preservatives

Applications

- Diagnostics
- Vaccines
- LVPs and SVPs
- Biologicals
- WFI Water
- Ophthalmics

PPS Mini-Capsules are hydrophilic and manufactured with the highest quality asymmetric polyethersulfone membrane, double layered for extra security. Polyethersulfone (PES) membrane exhibits excellent flow rates with high throughput. PPS capsule elements are 100% integrity tested during production.

Specific laboratory and pilot scale applications for PPS mini-capsule filters are final, sterilizing filtration of USP Water for Injection (WFI), diagnostic solutions, vaccines, ophthalmics, SVPs, LVPs and biological products.

Polyethersulfone is particularly suited for the filtration of products containing elements that can adsorb to media, such as preservatives and proteins. The lower binding characteristics of polyethersulfone (PES) make it a good choice for of protein solutions such as vaccines and biologicals and ophthalmics.

PPS Mini-Capsule Filters - Dimensions

Diameter	Length	Filtration Area
75 mm (2.95")	Body Length = 2.85" (72.4mm) Overall Length = 3.75" to 5.19" (Varies with Choice of Inlet/Outlet)	500 cm^2 (0.5 ft^2) (nominal)

Sanitization/Sterilization

Autoclave ..... 250° F (121° C), 30 min, 5+ cycles
Chemical Sanitization ..... Industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.
Note ..... PPS mini-capsules are not to be used in steam.

Pre-Sterilized .... PPS mini-capsules are offered in both non- and pre-sterilized forms.

Flow Rates

The following table represents typical water flow at a one psi (69 mbar) pressure differential through a mini-capsule filter with 1/4" hose barb inlet and outlet ports. The test fluid is water at ambient temperature. Higher pressure drops are acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Pore Size	0.03 µm	0.10 µm	0.22 µm	0.45 µm	0.65 µm	0.80 µm	1.0 µm	1.2 µm
GPM	0.03	0.05	0.11	0.21	0.40	0.66	0.82	0.85
LPM	0.1	0.2	0.4	0.8	1.5	2.5	3.1	3.2

Construction Materials

Housing	Polypropylene
Filtration Media	Double Layer Asymmetric Polyethersulfone (PES) Membrane
Media Support	Polypropylene
End Caps	Polypropylene
Center Core	Polypropylene
Outer Support Cage	Polypropylene
Sealing Method	Thermal Bonding

Maximum Operating Parameters

Liquid Operational Pressure	80 psi (5.5 bar) at 20 °C (68 °F)
Gases Operational Pressure	60 psi (4.1 bar) at 20 °C (68 °F)
Operating Temperature	43 °C (110 °F) at 30 psi (2.1 bar) in water
Forward Differential Pressure	50 psid (3.4 bard) at 20 °C (68 °F)
Reverse Differential Pressure	40 psid (2.7 bard) at 20 °C (68 °F)
Recommended Changeout Pressure	35 psid (2.4 bard)

Integrity Test Specifications - Bubble Point

Pore Size	Bubble Point (water wetted membrane)
0.03 µm	**
0.10 µm	**
0.22 µm	50 psig (3.5 barg)
0.45 µm	25 psig (1.7 barg)
0.65 µm	19 psig (1.3 barg)
0.8 µm	15 psig (1.1 barg)
1.0 µm	10 psig (0.7 barg)
1.2 µm	9 psig (0.6 barg)

** Test pressure exceeds operational limits of capsule filters. Use the diffusion test method.

Validation

PPS filters are validated using test procedures that comply with the intent of both ASTM F 838-05 and HIMA protocols for the determination of bacterial retention in filters used for liquid filtration. The filters are validated to remove 10^7 organisms per cm^2 of filter media:

0.10 µm challenged with *Acholeplasma laidlawii*;
0.22 µm challenged with *Brevundimonas diminuta*;
0.45 µm challenged with *Serratia marcescens*;
0.65 µm challenged with *Saccharomyces cerevisiae*.

Critical Process Filtration can provide validation assistance.

We Do It Right the First Time

We solve filtration challenges where filters are a critical part of your manufacturing process. Our Technical Team works with you to engineer filtration solutions that fit your needs. Then we manufacture the filters in our ISO 9001 certified facility and deliver them fast, so you have the right filters when you need them.

Extractables

Pharmaceutical grade filters typically exhibit low levels of non-volatile residues. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade filters are below current USP limits as specified for water for injection.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PPS mini-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. In addition, the 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 appropriate. PPS mini-capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

Quality Assurance and Standards

Critical Process Filtration filters are designed for use in cGMP-compliant processes. Our state of the art manufacturing facility and quality management system are certified to meet ISO 9001 standards. Each operation from assembly and test to cleaning, drying, and packaging is done in appropriately rated clean rooms. Each filter is assigned a lot code and serial number to ensure the traceability of manufacturing data and materials. A sophisticated MRP system collects and processes real time data from manufacturing centers and inspection points, allowing quick and easy analysis driving constant improvements in quality.

Ordering Information

Mini-Capsule order number example: Pharmaceutical Grade Asymmetric Polyethersulfone (PES) Membrane, 0.22 Micron Rating, Non-Sterile, 1/2" Sanitary Inlet, Luer Lock Inlet Vent, 1/2" Sanitary Outlet, Luer Lock Outlet Vent = MCPPS-20N0005454.

MC PPS [ ] [ ] 000 [ ] [ ] [ ] [ ]

Micron Rating
-03 - .03
-10 - .10
-20 - .22
-40 - .45
-60 - .65
-80 - .80
1-0 - 1.0
1-2 - 1.2

Pre-Sterilized or Not
S - Pre- Sterilized (gamma irradiated)
N - Not Sterilized

Inlet
1 - 1/8" Hose Barb
2 - 1/4" Hose Barb
3 - 1/2" Hose Barb
4 - Luer Lock
5 - 1/2" Sanitary

Inlet Vent Port
1 - 1/8" Hose Barb
2 - 1/4" Hose Barb
3 - 1/2" Hose Barb
4 - Luer Lock
5 - 1/2" Sanitary

Outlet
1 - 1/8" Hose Barb
2 - 1/4" Hose Barb
3 - 1/2" Hose Barb
4 - Luer Lock
5 - 1/2" Sanitary

Outlet Vent Port
1 - 1/8" Hose Barb
2 - 1/4" Hose Barb
3 - 1/2" Hose Barb
4 - Luer Lock
5 - 1/2" Sanitary

Request a **QUOTE** from your area representative

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