

# BPVWL Capsule Filters

High Capacity PVDF Membrane



**Bioburden reduction in multiple biologicals applications**

**Excellent flow rates with high throughput**

**Designed for minimal leachables and extractables**

**Low adsorption of proteins and preservatives**

## Applications

- ◆ Buffers and Feedstocks
- ◆ WFI Water
- ◆ Serum
- ◆ Plasma Products
- ◆ SVPs
- ◆ LVPs
- ◆ Vaccines

BPVWL capsules are made using high capacity hydrophilic polyvinylidene fluoride (PVDF) membrane. The proprietary membrane casting process creates a thick membrane with a high capacity to hold contaminants, excellent retention characteristics, high flow rates and low protein binding. BPVWL capsules are used for critical applications in the processing of a wide range of liquids in biopharmaceutical production.

Applications for BPVWL capsule filters are bioburden reduction in buffers and media, water for injection (WFI), solvents, alcohols and other liquids. Our capsules provide high efficiency, validatable performance to protect downstream processes and sterilizing filters.

PVDF is particularly suited for the filtration of products containing elements that can adsorb to the media, such as preservatives and proteins. The very low binding nature of PVDF makes it a good choice for filtration of valuable protein solutions as well as products that contain low amounts of preservatives.

Biopharmaceutical Grade

## BPVWL Capsule Filters - Filtration Area

Media	Capsule Length				
	2"	5"	10"	20"	30"
<b>High Capacity PVDF Membrane</b>	1.0 ft <sup>2</sup> (0.093m <sup>2</sup> )	3.0 ft <sup>2</sup> (0.279m <sup>2</sup> )	6.0 ft <sup>2</sup> (0.557m <sup>2</sup> )	12.0 ft <sup>2</sup> (1.115m <sup>2</sup> )	18.0 ft <sup>2</sup> (1.672m <sup>2</sup> )

## Flow Rate / Filtration Area

The following table represents typical water flow at a one psi (69 mbar) pressure differential across a single 2 inch capsule with 1.0 ft<sup>2</sup> (0.093 m<sup>2</sup>) of media with 1/2" FNPT 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	0.22 μm	0.45 μm	0.65 μm	0.85 μm	1.0 μm
<b>GPM</b>	0.18	0.23	0.42	0.67	1.17
<b>LPM</b>	0.68	0.87	1.59	2.54	4.43

\* For approximate flow rates for 5" through 30" capsules, refer to the appropriate cartridge data sheet

## Construction Materials

<b>Housing</b>	Polypropylene
<b>Filtration Media</b>	High Capacity Polyvinylidene fluoride (PVDF) Membrane
<b>Media Support</b>	Polypropylene
<b>End Caps</b>	Polypropylene
<b>Center Core</b>	Polypropylene
<b>Outer Support Cage</b>	Polypropylene
<b>Sealing Method</b>	Thermal Bonding

## Maximum Operating Parameters

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

## Sanitization/Sterilization

**Autoclave**..... 250° F (121° C), 30 min, 5+ cycles

**Chemical Sanitization** ..... Industry standard concentrations of hydrogen peroxide, paracetic acid, sodium hypochlorite and other selected chemicals.

**Note** ..... BPVWL capsules are not to be used in steam.

**Pre Sterilized**.....BPVWL capsules are offered in both non- and pre-sterilized forms.

## Extractables

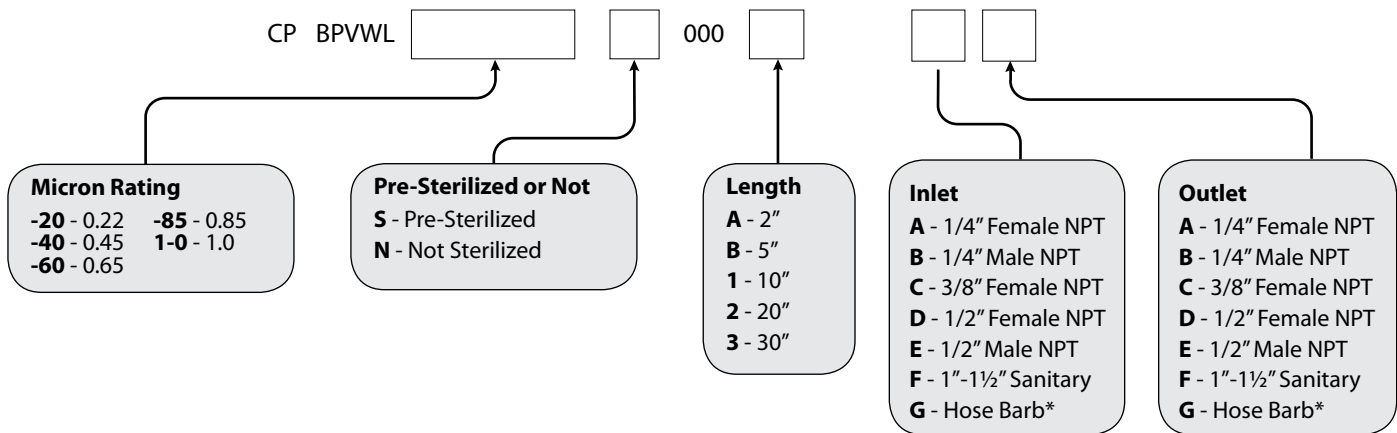
Biopharmaceutical grade filters typically exhibit low levels of non-volatile residues.

## USP Biosafety and FDA Compliance

The materials used to construct BPVWL 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. BPVWL 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 biopharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

## Ordering Information

Capsule order number example: Biopharmaceutical Grade High Capacity PVDF Membrane, 0.22 Micron Rating, Pre-Sterilized, 10" Length, Sanitary Inlet, Sanitary Outlet = CPBPVWL-20S0001FF.



Hose Barb Diameter Ranges\*

	Minimum	Maximum
<b>Outer Diameters</b>	11/32" (8.6mm)	9/16" (14.0mm)
<b>Inner Diameters</b>	5/32" (4.0mm)	13/32" (10.5mm)

## Quality Assurance and Standards

Critical Process Filtration uses state of the art computer controlled equipment to consistently produce high quality products as well as significantly reduce hand operations that can compromise quality. All manufacturing and testing is continuously monitored in real time so that data can be quickly and easily analyzed to facilitate improvements in both quality and cost.

The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled using a sophisticated manufacturing system that networks work stations, manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected in real time to allow continuous quality monitoring and full traceability of all materials and processes.

Representative capsule filter assemblies from each manufacturing lot are integrity tested before lot release.

## Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products to industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Request a QUOTE from your area representative



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