

Biofil™ 3

Polyethersulfone Membrane Cartridge Filters

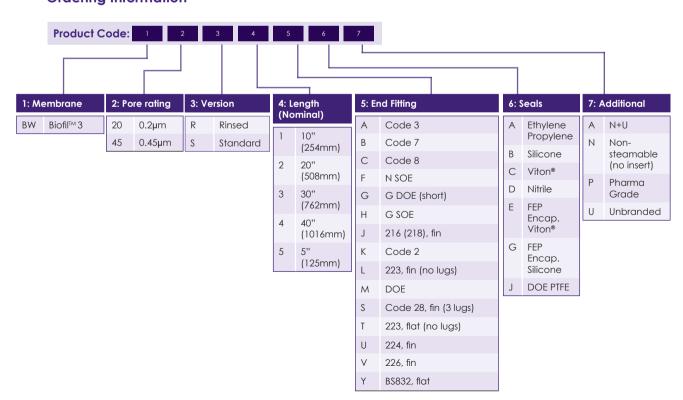


Porvair Biofil™3 cartridges utilise a single layer of polyethersulfone (PES) membrane, providing a filter with effective bioburden reduction properties (LRV ≥ 7) to support the manufacture of pharmaceutical, food & beverage and other life science products. The inherently hydrophilic and highly asymmetric nature of the PES membrane facilitates high flux rates and enhances the wettability characteristics of the cartridges. By combining this membrane with quality all-polypropylene support components and high integrity manufacturing techniques, Biofil™3 filter cartridges are ideally suited to the most demanding process conditions.

Ordering Information

Typical Applications

- Biopharmaceuticals
- · Opthalmic solutions
- Electronics and semiconductors
- Fine chemicals
- Beverages
- Pure water supply



Features and Benefits

- Guaranteed microbial ratings
- · Low protein binding
- Excellent hydrolysis resistance
- · Excellent chemical compatibility
- Suitable for steam sterilising
- Full traceability
- · Controlled manufacturing environment

Specifications

Materials of Manufacture

Filter membrane: Polyethersulfone Membrane support: Polypropylene Irrigation mesh (support): Polypropylene Drainage layer: Polypropylene Inner core: Polypropylene Outer support: Polypropylene End fittings: Polypropylene Stainless steel Support ring:

All polymeric materials used in the manufacture of BiofilTM 3 are USP Class VI-121, FDA CFR 21 & EC 10/2011 compliant. The finished device has also been tested and proven to show compliance with USP Class VI-121.

Cartridge Dimensions (Nominal)

Effective Filtration Area: 0.69m² (7.4ft²)

(per 10" module)

Diameter: 70mm (2.8")
Length: 1 module: 254mm (10")
2 modules: 508mm (20")

2 modules: 508mm (20") 3 modules: 762mm (30") 4 modules: 1016mm (40")

Cartridge Treatment

Standard: Cleaned and flushed with pyrogen-free water Rinsed: Ultra-clean, pulse flushed to give a system

resistivity of 18MΩ.cm

Gaskets and O-Rings

FDA approved Ethylene Propylene, FEP encapsulated, Silicone, Viton® or Nitrile.

Maximum Differential Pressure

Normal flow direction at:

20°C (68°F): 6.0bar (87psi) 80°C (176°F): 4.0bar (58psi)

Reverse flow direction at:

20°C (68°F): 2.1bar (30psi) 80°C (176°F): 1.0bar (15psi)

Operating Temperature

Maximum continuous: 80°C (176°F)

Sterilisation

In situ steam 20 x 30 minute cycles at 135°C (275°F) Hot water 100 x 30 minute cycles at 90°C (194°F)

Integrity Testing

Each Biofil[™] 3 module of every cartridge is individually integrity tested using the Diffusive Flow Test, which correlates to the HIMA and ASTM F838-20 bacterial challenge tests. Non-destructive integrity tests, such as Pressure Hold, Diffusive Flow and Bubble Point, can be performed by customers. Please contact us for procedural detail.

Filtrate Quality

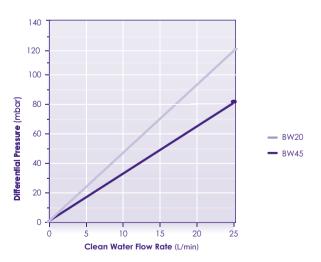
Cartridges have been validated to give high levels of effluent cleanliness, in accordance with USP guidance for:

- Extractables
- TOC & Conductivity
- Particulates & Non-Fibre Release
- Bacterial Endotoxins

Please refer to the Biofil $^{\text{IM}}$ 3 Validation Guide for full supporting data.

Clean Water Flow Rates

 A 254mm (10") Biofil™ 3 single cartridge exhibits the flow-ΔP characteristics indicated below, for solutions with a viscosity of 1 centipoise.



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