SepraPor®

500 kDa Hollow Fiber Tangential Flow Filter Cartridge

Description

SepraPor® XFM500 is a tangential flow filtration (TFF) cartridge containing hollow fiber membranes. It is ideal for use in a variety of biopharmaceutical applications including ultrafiltration, diafiltration, and purification. This TFF cartridge is available in a range of sizes from bench through production scale for ease of scalability. The SepraPor® filter cartridge is 100% integrity tested during manufacture and meets the critical demands of the pharmaceutical, biotechnology, and related industries.

Materials of Construction

All components of the filter are animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Hollow fibers:	Polysulfone	CFR Title 21, 177.1655
Fiber bundle netting:	Polypropylene	CFR Title 21, 177.1520
Outer sleeve:	Polysulfone	CFR Title 21, 177.1655
Fiber encapsulation:	Epoxy	CFR Title 21, 175.300
O-rings:	Silicone	CFR Title 21, 177.2600

Retention Rating	500 kDa
Typical Fiber Lumen	1.0 mm
Fluid Path Length (Nominal)	12 in (30 cm) 24 in (60 cm)
Maximum Diffusive Flow Rate	2.79 mL/min/m^2 @ 30 psig (2.07 bar), water with air
Minimum Permeate Flux	465 - 1,200 LMH/bar (Liters/m^2/h/bar) @ 25 °C

Operating Characteristics

Operating temperature range:	32 ºF to 100 ºF (0 ºC to 38 ºC)
Maximum operating temperature:	122 ºF (50 ºC) for short-term operations such as cleaning
Maximum feed pressure:	65 psig @ 77 °F (4.48 bar @ 25 °C)
Maximum transmembrane pressure:	45 psig @ 77 °F (3.10 bar @ 25 °C)

Sterilization

Autoclave or steam in place (SIP): 121 °C to 123 °C (15 psi, 1.03 bar), 30 minutes.
Apply a validated sterilization cycle that increases and decreases temperature gradually.
Consult sterilization instructions in the SepraPor® Green Docs document for further guidance.

Biological Safety

SepraPor® filters meet the requirements as specified in the USP 43 Biological Reactivity Tests, *in vitro* <87> (cytotoxicity), and polysulfone and epoxy meet *in vivo* <88> (Class VI Plastics).

Quality Assurance

SepraPor® filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each SepraPor® filter is labeled with filter type, lot number, and unique serial number. The serial number for all cartridge filters can be found on the product packaging.

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Ordering Guide

Part Number	Filter Diameter	Fluid Path Length (Nominal)	Effective Filtration Area	Housing Seal Configuration	O-ring Seal Material
XFM500C412-AAS	2" (5.1 cm)	12" (30 cm)	4.3 ft^2 (0.4 m^2)	AA	Silicone
XFM500C424-AAS		24" (60 cm)	8.6 ft^2 (0.8 m^2)		
XFM500C512-AAS	3" (7.6 cm)	12" (30 cm)	9.7 ft^2 (0.9 m^2)		
XFM500C524-AAS		24" (60 cm)	22.6 ft^2 (2.1 m^2)		

Additional information about this filter product is available in the SepraPor® Green Docs document at www.meissner.com/green-docs.

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