STyLUX[®] 0.2 µm SM-grade Medium Capsule Filter (CF/CF2 Model)

Description

The STyLUX[®] SM0.2 capsule filter is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and is recommended for sterilizing filtration and bioburden reduction of pharmaceutical preparations, antibiotics, vaccines, protein solutions, virus suspensions, enzymes, buffers, ophthalmic solutions, reagents, salt solutions, nutrients, serum and blood-based products, biologicals, and wine and beverages. The filter's asymmetric membrane provides absolute retention, superior flow rates and contaminant capacity.

Materials of Construction

All components of the filter are either animal component free (ACF) or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Filter membrane: Up/downstream support: Core, outer guard, end caps: Capsule shell: Sealing method:	Polyethersulfone (PES) Polypropylene Polypropylene Polypropylene Thermal bonding	CFR Title 21, 177.2440 CFR Title 21, 177.1520 CFR Title 21, 177.1520 CFR Title 21, 177.1520
Pore Size	0.2 μm	
Minimum Bubble Point	44 psi (3.03 bar) in water, with air or nitrogen 16 psi (1.10 bar) in 60% IPA/40% water, with air or nitrogen 15 psi (1.03 bar) in 70% IPA/30% water, with air or nitrogen	
Maximum Diffusion Rate	3 mL/min @ 35 psi (2.41 bar), water with air	
Typical Water Flow Rate	1.2 psid @ 1 L/min (0.12 L/min @ ∆p 10 mbar)	
Bacterial Retention	>10 ⁷ per cm ² removal of <i>Brevundimonas diminuta</i> per ASTM F838	
Operating Characteristics Operating temperature range: Maximum temperature rating: Maximum operating pressure:	32 °F to 100 °F (0 °C to 38 °C) 160 °F @ 35 psig (71 °C @ 2.4 bar) 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service	

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, \geq 3 cycles. Water wet membrane prior to autoclaving. Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules. Capsules must not be in-line steam sterilized.

50 psig @ 100 °F (3.4 bar @ 38 °C), gas service

15 psig @ 100 °F (1.0 bar @ 38 °C)

Biological Safety

Maximum operating pressure:

Maximum reverse pressure:

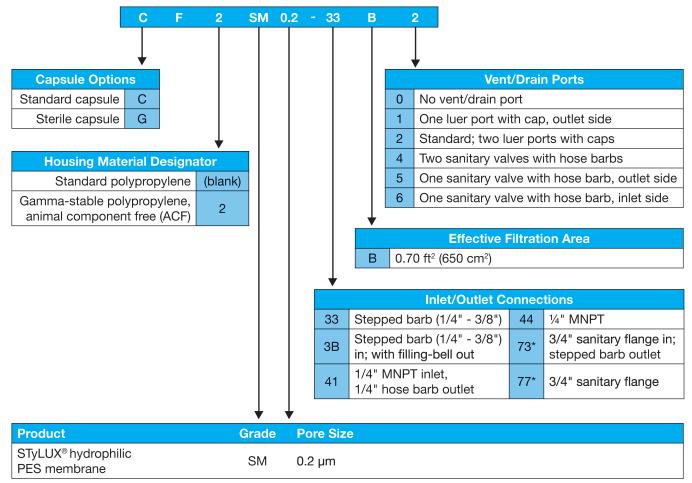
STyLUX[®] filters meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity, physicochemical, and USP 43 oxidizable substances tests. Bacterial endotoxin levels in aqueous extracts of STyLUX[®] filters are less than 0.5 EU/mL, as determined using the current USP <85> *Limulus* amebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of STyLUX[®] filters. Filters comply with Commission Regulation (EU) No. 10/2011.

Quality Assurance

STyLUX[®] 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 STyLUX[®] filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and unique serial number.



Ordering Guide



*3/4 sanitary flange fitting option is only available for CF2 Capsules.

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



1001 Flynn Road • Camarillo, CA 93012 • USA +1.805.388.9911 • +1.805.388.5948 Fax www.meissner.com