

0.1 µm STC-grade Standard Capsule Filter (CS/CL Model)

Description

The EverLUX® STC0.1 features two serially layered, highly asymmetric and asymmetric polyethersulfone (PES) membranes designed for 100% removal of mycoplasma. The coarser upstream layer is optimized for prefiltration. The filter is 100% integrity tested and DI flushed during manufacture, and it has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology and related industries.

Materials of Construction

All components of the EverLUX® filter capsule are either animal component free or in compliance with EMEA/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 membranes:	Polyethersulfone	CFR Title 21, 177.2440
Up/downstream support:	Polypropylene	CFR Title 21, 177.1520
Core, outer guard, end caps:	Polypropylene	CFR Title 21, 177.1520
Capsule shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.1 µm

Maximum Diffusion Rate 1.2 ft²: 5.3 mL/min per 10" (25 cm) @ 40 psi (2.76 bar), water
2.6 ft²: 11 mL/min per 10" (25 cm) @ 40 psi (2.76 bar), water

Operating Characteristics

Operating temperature range: 32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating: 160 °F @ 35 psig (72 °C @ 2.4 bar)
Maximum operating pressure: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service
Maximum operating pressure: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas service
Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)

Bacterial Retention >10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838
>10⁷ per cm² removal of *Acholeplasma laidlawii* per modified F838

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles. Water wet membrane first.
Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in-line steam sterilized.

Biological Safety

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

Quality Assurance

Each EverLUX® STC0.1 is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. EverLUX® 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 EverLUX® filter is clearly marked with filter type, lot number and serial number.

Ordering Guide

C		S		2		STC		0.1 - 00		2		
Capsule Options									Vent/Drain Ports			
Standard capsule	C							0	No vent/drain port			
Sterile capsule	G							1	One luer port with cap, outlet side			
Opaque capsule	O							2	Standard; two luer ports with caps			
									4	Two sanitary valves with hose barsbs		
									5	One sanitary valve with hose barb, outlet side		
									6	One sanitary valve with hose barb, inlet side		
Effective Filtration Area									Inlet/Outlet Connections			
2.6 ft ² (0.24 m ²)	L							00	1" sanitary flange	44	1/4" MNPT	
1.2 ft ² (0.11 m ²)	S							02	1" sanitary flange in; 3/8" hose barb out	55	3/8" FNPT	
									0C	1" sanitary flange in; 1/2" hose barb out	66	3/8" MNPT
									CC	1/2" hose barb (rigid tubing)	77*	3/4" sanitary flange
									LL	1" sanitary flange, long neck	88	3/4" hose barb
									22	3/8" hose barb	99	1/2" hose barb (flexible tubing)
									2B	3/8" hose barb w/filling-bell		
Housing Material Designator												
Standard polypropylene	(blank)											
Gamma-stable polypropylene, animal component free (ACF)	2											
Product		Grade		Retention Rating								
EverLUX [®] hydrophilic PES membrane		STC		0.1 µm								

*3/4" sanitary flange fitting option is only available for CS2 and CL2 Capsules.

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

EverLUX[®] is a registered trademark of Meissner Filtration Products.

© 2021 Meissner Filtration Products, Inc. All rights reserved.