STyLUX®

0.2 µm SM-grade Mini Capsule Filter (CM2/CK2 Model)

Description

The STyLUX® 0.2 µm is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and can be used to remove contaminants from a broad range 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 structure provides bacteria and particle removal at high flow rates and low pressure drops. STyLUX® has very low binding characteristics for preservatives commonly used in the pharmaceutical industry and is compatible with most cleaning chemicals, sanitizers and biocides.

Materials of Construction

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

Membrane:	Polyethersulfone	CFR Title 21, 177.2440
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
Capsule housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.2 µm

Minimum Bubble Point 44 psi (3.0 bar), water
16 psi (1.1 bar), 60% IPA / 40% water

Bacterial Retention >10^7 per cm^2 removal of *Brevundimonas diminuta* per ASTM F838

Operating Characteristics

Operating temperature range:	32 ºF to 122 ºF (0 °C to 50 °C)
Maximum operating pressure:	100 psig (6.9 bar)

Sterilization

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

Biological Safety

STyLUX® 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 STyLUX® filters are less than 0.5 EU/mL, as determined using the *Limulus* amebocyte lysate (LAL) test. No binders, adhesives or surfactants are used in the construction of STyLUX® filters. Filters comply with European Commission Regulation No 10/2011. STyLUX® CM2/CK2 capsules are TSE/BSE/animal component free (ACF).

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 serial number.

MEISSNER FILTRATION PRODUCTS

Ordering Guide

Capsule Options	
Standard capsule	C
Sterile capsule	G

Effective Filtration Area	
0.45 ft² (415 cm²)	K
0.36 ft² (334 cm²)	M

Housing Material Designator	
Gamma-stable polypropylene, animal component free (ACF)	2

Vent/Drain Ports	
0	No vent/drain port
1	One luer port with cap, inlet side
2	Standard; two luer ports with caps
4	Two sanitary valves with hose barbs
5	One sanitary valve with hose barb, inlet side
6	One sanitary valve with hose barb, outlet side

Inlet/Outlet Connections	
11	1/4" hose barb
1B	1/4" hose barb w/filling-bell
22	3/8" hose barb
2B	3/8" hose barb w/filling-bell
41	1/4" MNPT, 1/4" hose barb outlet
44	1/4" MNPT
71	3/4" sanitary flange inlet, 1/4" hose barb outlet
72	3/4" sanitary flange inlet, 3/8" hose barb outlet
77	3/4" sanitary flange

Product	Grade	Retention Rating
STyLUX® hydrophilic PES membrane	SM	0.2 µm

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

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