SteriLUX®

0.2 µm VTH-grade Standard Capsule Filter — CS(2), CL(2), CJ2 Model

Description

The SteriLUX® VTH0.2 capsule filter is a hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for sterilizing filtration of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols, and sanitizing agents. The filter is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology, and related industries.

Materials of Construction

All components of the filter capsule are either animal component free or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.807/2011:50208), 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:

Membrane:	Polyvinylidene fluoride (PVDF)	CFR Title 21, 177.2510
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 (sterilizing grade)

Minimum Bubble Point

50 psi (3.44 bar) in water, with air or nitrogen
18 psi (1.24 bar) in 60% IPA/40% water, with air or nitrogen
17 psi (1.17 bar) in 70% IPA/30% water, with air or nitrogen

Maximum Diffusion Rate

CS: 2.7 mL/min @ 40 psi (2.76 bar), water with air
CS: 2.3 mL/min @ 40 psi (2.76 bar), water with nitrogen
CL: 5.7 mL/min @ 40 psi (2.76 bar), water with air
CL: 4.8 mL/min @ 40 psi (2.76 bar), water with nitrogen
CJ: 8.8 mL/min @ 40 psi (2.76 bar), water with air
CJ: 7.5 mL/min @ 40 psi (2.76 bar), water with nitrogen

Typical Water Flow Rate

CS: 0.24 gpm @ 1 psid (0.13 L min^{-1} at Δp 10 mbar)
CL: 0.51 gpm @ 1 psid (0.28 L min^{-1} at Δp 10 mbar)
CJ: 0.88 gpm @ 1 psid (0.48 L min^{-1} at Δp 10 mbar)
Capsule inlet/outlet selection may affect pressure drop and flow rate.

Bacterial Retention

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

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	160 °F @ 35 psig (71 °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
Reverse operating pressure:	15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

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

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Biological Safety

SteriLUX® filters meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of SteriLUX® 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 SteriLUX® filters. Filters comply with European Commission Regulation (EU) No. 10/2011.

Quality Assurance

SteriLUX® VTH0.2 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. SteriLUX® 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 SteriLUX® filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and unique serial number.

Ordering Guide

C	S	2	VTH	0.2	-	00	2

Capsule Options	
Standard capsule	C
Sterile capsule	G

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

Effective Filtration Area	
1.6 ft² (0.15 m²)	S
3.3 ft² (0.31 m²)	L
5.2 ft² (0.48 m²)	J

Inlet/Outlet Connections			
00	1" sanitary flange	2B	3/8" hose barb with filling bell
02	1" sanitary flange in; 3/8" hose barb out	72**	¾" sanitary flange; 3/8" hose barb out
09	1" sanitary flange in; ½" hose barb out (flexible tubing)	77**	¾" sanitary flange
LL	1" sanitary flange, long neck	88	¾" hose barb
22	3/8" hose barb	99	½" hose barb

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

Product	Grade	Pore Size
SteriLUX® hydrophilic PVDF membrane	VTH	0.2 µm

** CJ2 filters are animal component free (ACF) and only available with a gamma-stable polypropylene housing.*
***3/4 sanitary flange fitting option is only available for CS2, CL2, and CJ2 capsules.*
Additional information about this filter product is available in the SteriLUX® Green Docs document at www.meissner.com/green-docs.

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