

0.4 µm VTH-grade Large Capsule Filter (UltraCap® Model)

Description

The SteriLUX® VTH0.4 capsule filter is a hydrophilic PVDF membrane filter with low protein binding properties and broad chemical compatibility. It is recommended for sterile filtration and bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, and ophthalmic and other dilute preservative solutions.

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 are either animal component free (ACF) 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 shell: Polypropylene CFR Title 21, 177.1520

Sealing method: Thermal bonding

Pore Size 0.4 μm

Effective Filtration Area7.9 ft² (0.73 m²) per 10"Minimum Bubble Point28 psi (1.93 bar), water

10 psi (0.69 bar) 60% IPA/40% water 9 psi (0.62 bar) 70% IPA/30% water

Maximum Diffusion Rate 15 mL/min per 10" (25 cm) @ 22 psi (1.52 bar), water

Bacterial Retention >10⁷ cfu per cm² removal of Serratia marcescens per modified ASTM F838

Operating Characteristics

Opertating temperature range: 32 °F to 100 °F (0 °C to 38 °C)

Maximum Temperature rating: 140 °F @ 45 psig (60 °C @ 3.1 bar) liquid, @ 30 psig (2.1 bar) gas

Maximum operating pressure: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid Maximum operating pressure: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, \geq 3 cycles.

Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules. Capsules must not be in-line steam sterilized.

Biological Safety

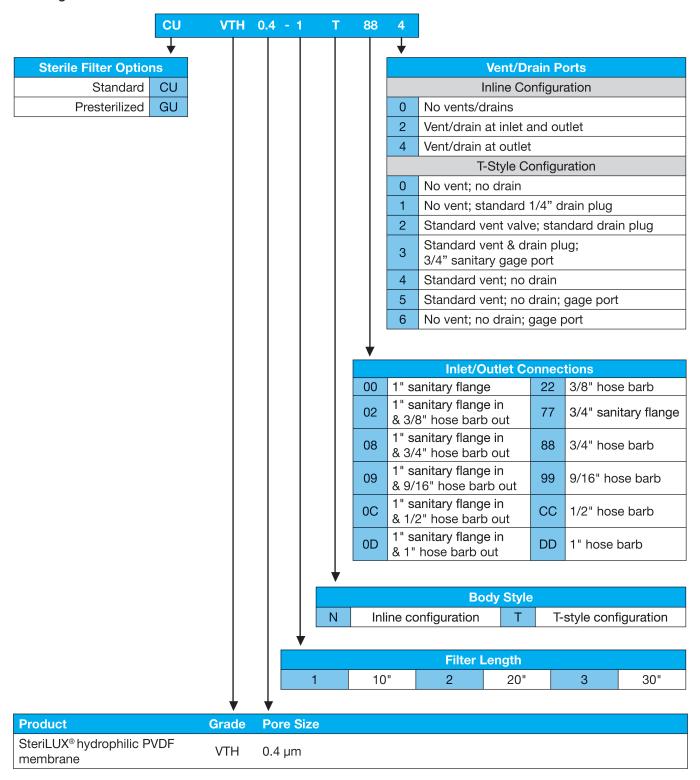
SteriLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of SteriLUX® filters are less than 0.5 EU/mL,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

Quality Assurance

SteriLUX® VTH0.4 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 serial number.



Ordering Guide



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

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