SteriLUX®

0.1 μm VTH-grade Large Capsule Filter (UltraCap® H.D. Model)

Description
SteriLUX® VTH0.1 filter capsule is a sterilizing grade hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for sterilizing filtration and mycoplasma removal 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 VTH0.1 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 SteriLUX® VTH0.1 capsule filter are either animal component free (ACF) or in compliance with EMEA/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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>CFR Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane</td>
<td>Polyvinylidene fluoride (PVDF)</td>
<td>21, 177.2510</td>
</tr>
<tr>
<td>Upstream support</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Downstream support</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Outer guard</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Core</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>End caps</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Capsule shell</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Sealing method</td>
<td>Thermal bonding</td>
<td></td>
</tr>
</tbody>
</table>

Pore Size
0.1 μm

Effective Filtration Area
7.9 ft² (0.73 m²) per 10”

Minimum Bubble Point
70 psi (4.8 bar), water
26 psi (1.8 bar), 60% IPA / 40% water
25 psi (1.7 bar), 70% IPA / 30% water

Maximum Diffusion Rate
20 mL/min per 10” (25 cm) @ 56 psi (3.86 bar), water

Bacterial Retention
>10⁷ per cm² 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: 140 °F @ 55 psig (60 °C @ 3.8 bar) liquid, @ 35 psig (2.4 bar) gas
Maximum Operating pressure: 90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service
Maximum Operating pressure: 60 psig @ 100 °F (4.1 bar @ 38 °C), gas service
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, ≥ 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® VTH0.1 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 and lot number, and serial number.
Ordering Guide

Sterile Filter Options
- Standard capsule: CR
- Sterile capsule: GR

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

Vent/Drain Ports
- Inline Configuration
  - 0: No vents/drains
  - 2: Vent/drain at inlet and outlet
  - 4: Two sanitary valves with hose barbs
  - K: SPD vent/drain at inlet and outlet
  - L: SPD vent/drain at outlet
- T-Style Configuration
  - 0: No vent; no drain
  - 1: No vent; standard 1/4" drain plug
  - 2: Standard vent valve; standard, drain plug
  - 3: Standard vent & drain plug; 3/4" sanitary gage port
  - 4: Standard vent; no drain
  - 5: Standard vent; no drain; gage port
  - 6: No vent; no drain; gage port
  - A: No vent; sanitary drain valve
  - B: Standard vent; sanitary drain valve
  - C: Standard vent; sanitary drain valve; gage port

Inlet/Outlet Connections
- 00: 1" sanitary flange
- 02: 1" sanitary flange in & 3/8" hose barb out
- 08: 1" sanitary flange in & 3/4" hose barb out
- 09: 1" sanitary flange in & 9/16" hose barb out
- 0C: 1" sanitary flange in & 1/2" hose barb out
- 0D: 1" sanitary flange in & 1" hose barb out
- 22: 3/8" hose barb
- 77: 3/4" sanitary flange
- 88: 3/4" hose barb
- 99: 9/16" hose barb
- CC: 1/2" hose barb
- DD: 1" hose barb

Body Style
- N: Inline configuration
- T: T-style configuration

Filter Length
- 10" 20" 30" 40" 50"

Product | Grade | Pore Size
--- | --- | ---
SteriLUX® hydrophilic | VTH | 0.1 µm
PVDF membrane

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

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