



0.04 µm ST-grade Filter Cartridge

Description

STyLUX® ST0.04 filter cartridge 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 in the sterile filtration of 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, and biologicals. 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.

STyLUX® ST0.04 capsule filter is sterilizing filter designed specifically for the 100% removal of Mycoplasma. It 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 5.2.8 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:

Membrane:	Polyethersulfone (PES)	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
O-rings:	Typically Silicone	CFR Title 21, 177.2600
Sealing method:	Thermal bonding	

Pore Size 0.04 µm

Effective Filtration Area 8.1 ft² (0.75 m²) per 10" (25 cm)

Minimum Bubble Point
115 psi (7.93 bar) in water, with air
38 psi (2.62 bar) in 60% IPA/40% water, with air
37 psi (2.55 bar) in 70% IPA/30% water, with air

Maximum Diffusion Rate 30 mL/min per 10" (25 cm) @ 45 psi (3.10 bar), water with air

Typical Water Flow Rate 0.9 psid/gpm per 10" (0.6 L/min @ Δp 10 mbar per 25 cm)

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

Operating Characteristics

Operating temperature range:	32 °F to 180 °F (0 °C to 82 °C)
Maximum temperature rating:	180 °F @ 30 psid (82 °C @ 2.07 bar)
Maximum operating pressure:	80 psid @ 100 °F (5.52 bar @ 38 °C)
Maximum reverse pressure:	15 psid @ 100 °F (1.03 bar @ 38 °C)

Sterilization

Autoclave: 121 °C to 135 °C (250 °F to 275 °F) @ 15 to 30 psi (1.03 to 2.07 bar), 30 to 60 min, ≥ 3 cycles.

Steam-in-place (SIP): 121 °C to 135 °C (250 °F to 275 °F) @ 15 to 30 psi (1.03 to 2.07 bar), 30 to 60 min, ≥ 3 cycles.

Water wet membrane before steaming or autoclaving if filter is to be integrity tested post sterilization.

Biological Safety

STyLUX® filters meet the requirements as specified in USP 43 <88> Biological Reactivity Tests, *In Vivo*, <87> Biological Reactivity Tests, *In Vitro* and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of STyLUX® filters are less than 0.5 EU/mL, as determined using the current USP <85> *Limulus* amoebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of STyLUX® filters. Filters comply with European Commission Regulation (EU) No. 10/2011.



StyLUX® ST0.04 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. StyLUX® filter cartridges comply with the Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA current Good Manufacturing Practice Practices (cGMP). 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 labeled with filter type, lot number, and unique serial number. The serial number for all cartridge filters can be found on the product packaging.

ST	0.04 - 1	C2	R	S														
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