Steridyne[®]

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

Description

The Steridyne[®] VTV0.2 is a hydrophobic PVDF membrane filter optimized for critical air and gas applications. This sterilizing grade filter is virus retentive and ideal for pharmaceutical gases, bioreactor air and sterile venting. Encapsulated Steridyne[®] filters withstand irradiation and are applicable for integration into single-use systems needing aeration or gas exhaust. 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 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: Upstream support: Downstream support: Outer guard: Core: End caps: Capsule shell: Sealing method:	Polyvinylidene fluoride (PVDF) Polypropylene Polypropylene Polypropylene Polypropylene Polypropylene Polypropylene Thermal bonding	CFR Title 21, 177.2510 CFR Title 21, 177.1520 CFR Title 21, 177.1520
Pore Size	0.2 μm	
Minimum Bubble Point	18 psi (1.24 bar), 60% IPA/40% water 17 psi (1.17 bar), 70% IPA/30% water	
Maximum Diffusion Rate	CS: 3.0 mL/min @ 15 psig (1.03 bar), 60% IPA/40% water CL: 6.3 mL/min @ 15 psig (1.03 bar), 60% IPA/40% water CJ: 9.8 mL/min @ 15 psig (1.03 bar), 60% IPA/40% water	
Maximum Water Intrusion Rate	CS: 0.1 mL/min water @ 20 psig (1.38 bar) CL: 0.2 mL/min water @ 20 psig (1.38 bar) CJ: 0.3 mL/min water @ 20 psig (1.38 bar) Specification can vary by instrumentation; consult factory.	
Typical Air Flow Rate	CS: 2.86 scfm @ 1 psid (3.52 Nm ³ /hr @ Δ P 50 mbar) CL: 5.51 scfm @ 1 psid (6.79 Nm ³ /hr @ Δ P 50 mbar) CJ: 9.50 scfm @ 1 psid (11.70 Nm ³ /hr @ Δ P 50 mbar)	
Bacterial Retention	>10 ⁷ per cm ² removal of <i>Brevundimonas diminuta</i> per ASTM F838	
Operating Characteristics Operating temperature range: Maximum temperature rating: Maximum operating pressure: Maximum operating pressure: Maximum reverse pressure:	32 °F to 100 °F (0 °C to 38 °C) 160 °F @ 35 psig (71 °C @ 2.4 bar) 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service 50 psig @ 100 °F (3.4 bar @ 38 °C), gas service 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, \geq 3 cycles. Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules. Capsules must not be in-line steam sterilized.

Biological Safety

Steridyne[®] filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and pyrogenicity tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No 10/2011.



Quality Assurance

Each Steridyne[®] VTV0.2 filter is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. Steridyne[®] 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 Steridyne[®] filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and serial number.



* CJ 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 Steridyne® Green Docs document at www.meissner.com/green-docs.

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