Steridyne[®]

0.2 µm VMV-grade 50 mm Vent Filter (CB2 Model)

Description

Steridyne[®] is hydrophobic PVDF membrane filter optimized for critical air and gas applications. Designed for bidirectional flow, this filter is well suited for applications requiring complete removal of bacteria and viruses from air and gas streams, such as fermenter inlet air and exhaust, sterile process air, and sterile venting of carboys, filling vessels, bioreactors and small product or intermediate tanks. Steridyne[®] capsule filters are manufactured using gamma irradiation tolerant materials and are ideal for integration into single-use systems needing aeration or gas exhaust.

Materials of Construction

All components of the encapsulated discs are animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

| Membrane: Downstream support: Capsule housing: Sealing method: | Polyvinylidene fluoride Polypropylene Polypropylene Thermal bonding | CFR Title 21, 177.2510 CFR Title 21, 177.1520 CFR Title 21, 177.1520 |
|---|---|--|
| Pore Size | 0.2 µm | |
| EFA | 19.6 cm ² | |
| Bacterial Retention | $>10^7$ cfu/cm ² retention of Brevundimonas diminuta per ASTM F838 | |
| Minimum Bubble Point | 18 psi (1.24 bar), 60% IPA/40% water 17 psi (1.17 bar), 70% IPA/30% water | |

Operating Characteristics

Normal operating temperature range: 32 °F to 100 °F (0 °C to 38 °C) Maximum operating pressure: 80 psig @ 100 °F (5.5 bar @ 38 °C)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, \ge 3 cycles. Capsules must not be in-line steam sterilized.

Biological Safety

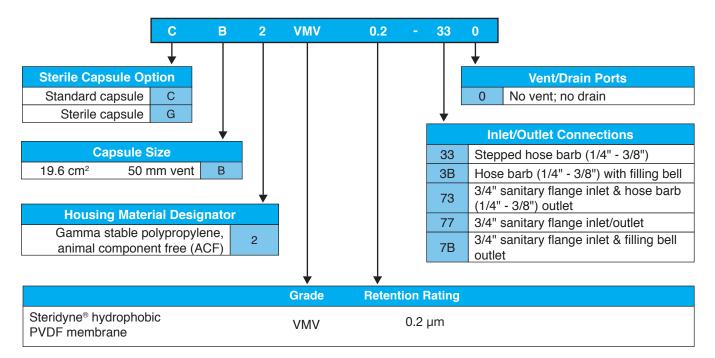
Steridyne[®] filters meet the requirements as specified in the current USP <88> Class VI plastics, physicochemical, oxidizable substances, and USP <87> cytotoxicity tests. No adhesives or surfactants are used in the construction of the filters. Filters comply with European Commission Regulation No 10/2011. Capsules are TSE/BSE/animal component free (ACF).

Quality Assurance

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 filter is clearly marked with filter type and lot number.



Ordering Guide



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

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