Ultradyne®

0.2 µm TT-grade Large Capsule Filter (UltraCap® Model)

Description

The Ultradyne® TT0.2 capsule filter is a hydrophobic PTFE membrane filter offering maximum chemical compatibility with minimal extractables in a wide range of fluids and applications. This sterilizing grade filter provides reliable removal of particles and microorganisms from aggressive liquids, including strong acids and bases, and organic solvents. Ultradyne® is optimized for applications requiring complete removal of contaminant bacteria and viruses from air and gas streams, such as fermenter inlet air and exhaust, sterile process air and sterile venting of tanks, and lyophilizers.

The Ultradyne® filter provides sterility assurance, high flow rates and throughput under demanding conditions. 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 5.2.807/2011:50208), 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:	Polytetrafluoroethylene (PTFE)	CFR Title 21, 177.1550
	Polytetralidoroetriylerie (PTPE)	· · · · · · · · · · · · · · · · · · ·
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
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Sealing method: Thermal bonding

Pore Size 0.2 μm

Effective Filtration Area 6.0 ft² (0.56 m²) per 10"

Minimum Bubble Point 16 psi (1.1 bar), 60% IPA/40% water, air 16 psi (1.1 bar), 70% IPA/30% water, air

Maximum Diffusion Rate 10 mL/min @ 10 psig (0.69 bar), 60% IPA, per 10" (25 cm) in air

19.5 mL/min @ 10 psig (0.69 bar), 70% IPA, per 10" (25 cm) in air

Water Intrusion Rate 0.6 mL/min water at 36 psi (2.48 bar) per 10" (25 cm)

Specification can vary by instrumentation; consult Meissner.

Typical Air Flow Rate 33.0 scfm @ 1 psid per 10" (40.7 Nm³/hr @ Δp 50 mbar)

Typical Water Flow Rate 1.91 gpm @ 1 psid (1.05 L min⁻¹ @ Δp 10 mbar)

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 @ 45 psig (60 °C @ 3.1 bar), liquid Maximum temperature rating: 140 °F @ 30 psig (60 °C @ 2.1 bar), gas Maximum operating pressure: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid Maximum reverse pressure: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas 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 minutes, \geq 3 cycles. Capsules must not be in-line steam sterilized. Irradiation is not recommended.

Biological Safety

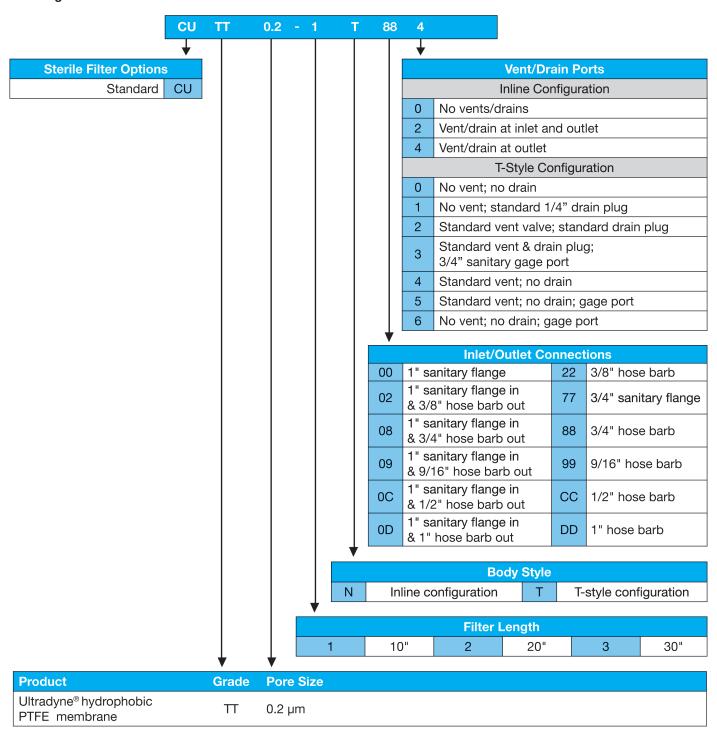
Ultradyne® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and pyrogenicity tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No. 10/2011.



Quality Assurance

Ultradyne® TT0.2 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. Ultradyne® 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 Ultradyne® 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 Ultradyne® Green Docs document at https://www.meissner.com/green-docs.



