Ultradyne®

0.2 µm TT-grade Filter Cartridge

Description

The Ultradyne® TT0.2 filter cartridge 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, lyophilizers, and autoclaves. 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 cartridge 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 CFR94.18 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
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/gaskets:	Typically Silicone	CFR Title 21, 177.2600
Sealing method:	Thermal bonding	

Pore Size 0.2 µm

Minimum Bubble Point

16 psi (1.10 bar), 60% IPA/40% water, with nitrogen or air
16 psi (1.10 bar), 70% IPA/30% water, with nitrogen or air

Maximum Diffusion Rate

8.7 mL/min at 10 psig (0.69 bar), 60% IPA, per 10" (25 cm) with nitrogen
10 mL/min at 10 psig (0.69 bar), 60% IPA, per 10" (25 cm) with air
15.5 mL/min @ 10 psig (0.69 bar), 70% IPA, per 10" (25 cm) with nitrogen
19.5 mL/min @ 10 psig (0.69 bar), 70% IPA, per 10" (25 cm) with air

Water Intrusion Rate

0.6 mL/min water at 36 psi per 10" (0.6 mL/min water at 2.48 bar per 25 cm)
Specification can vary by instrumentation; consult Meissner.

Typical Water Flow Rate 0.4 psid/gpm per 10" (1.37 L/min at Δp 10 mbar per 25 cm)

Typical Air Flow Rate 50 scfm/psid per 10" (61.6 Nm^3/hr at Δp 50 mbar per 25 cm)

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	180 °F @ 30 psid (82 °C @ 2.1 bar)
Maximum operating pressure:	80 psid @ 100 °F (5.5 bar @ 38 °C)
Maximum reverse pressure:	15 psid @ 100 °F (1.0 bar @ 38 °C)

Bacterial Retention >10^7 per cm^2 removal of *Brevundimonas diminuta* per ASTM F838

Sterilization

Autoclave: 121°C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
Steam-in-place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
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.

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Quality Assurance

Each Ultradyne® TT0.2 filter cartridge is 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 and lot number.

Ordering Guide

TT	0.2	-	1	C2		R	S

O-ring Seal Material	
B	Buna
E	EPR
S	Silicone
T	Teflon® over Silicone
V	Viton®
X	Teflon® over Viton®

Reinforcement Ring Option	
(blank)	Standard - no reinforcement ring
R	Reinforcement ring required for autoclave/ SIP applications

Cartridge Configuration	
C2	SOE; 222 O-rings, utton cap end
C6	SOE; 226 O-rings, button cap end
F2	SOE;-222 O-rings, fin end
F6	SOE; 226 O-rings, fin end

* See Green Docs for other configurations

Filter Length							
1	10"	2	20"	3	30"	4	40"

Product	Grade	Pore Size
Ultradyne® hydrophobic PTFE membrane	TT	0.2 µm

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

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