Ultradyne®

TM0.4 Capsule

Description

The Ultradyne® TM grade 0.4 µm hydrophobic PTFE filter capsule is manufactured using high quality components that are nontoxic and biologically inert.

Materials of Construction

All components of the Ultradyne® filter capsule are either animal free or in compliance with EMEA/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:	Polytetrafluoroethylene	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
Capsule shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.4 µm

Minimum Bubble Point 7 psi (0,5 bar), 60% IPA / 40% water

Bacterial Retention >10^7 per cm^2 removal of *Serratia marcescens* per modified ASTM F838

Operating Characteristics

Operating temperature range: 32 ºF to 100 ºF (0 °C to 38 °C)
Maximum temperature rating: 160 ºF @ 35 psig (72 °C @ 2,4 bar)
Maximum operating pressure (liquid service): 75 psig @ 100 ºF (5,2 bar @ 38 ºC)
Maximum operating pressure (gas service): 50 psig @ 100 ºF (3,4 bar @ 38 ºC)

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles.
Capsules must not be steamed in place (SIP).
Gamma irradiation is not recommended.

Biological Safety

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

Quality Assurance

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.

MEISSNER FILTRATION PRODUCTS

Ordering Guide

Capsule Options	
Standard capsule	C

Vent / Drain Ports	
0	No vent / drain port
1	One luer port with cap, outlet side
2	Standard; two luer ports with caps
4	Two sanitary valve with hose barbs
5	One sanitary valve with hose barb, outlet side

Effective Filtration Area (nominal)	
2.5 ft^2 (0,23 m^2)	L
1.2 ft^2 (0,11 m^2)	S

Housing Material Designator	
Standard polypropylene	(blank)
Polypropylene, animal component free (ACF)	2

Inlet / Outlet Connections			
00	1" sanitary (TC) flange	44	1/4" MNPT
02	1" sanitary flange in; 3/8" hose barb out	55	3/8" FNPT
0C	1" sanitary flange in; 1/2" hose barb out	66	3/8" MNPT
CC	1/2" hose barb (rigid tubing)	77	3/4" sanitary flange
22	3/8" hose barb	88	3/4" hose barb
2B	3/8" hose barb w/filling-bell	99	1/2" hose barb (flexible tubing)

Product	Filter Media Grade	Retention Rating
Ultradyne® hydrophobic PTFE membrane	TM	0.4

Additional information about Ultradyne® filter products is available in the Green Docs document which is viewable at https://www.meissner.com/downloads/ultradyne-gd006.pdf

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