

Ultradyne®

TT0.2 UltraCap® H.D.

Description

The Ultradyne® TT0.2 hydrophobic, liquid rated, sterilizing grade PTFE filter capsule provides the added benefit of certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

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 0.2 µm

Maximum WIT Rate 0.6 mL/min water at 36 psi (2,48 bar) per 10" (25 cm)

Minimum Bubble Point 16 psi (1,1 bar), 70% IPA

Maximum Diffusion Rate 15.5 mL/min @ 10 psig (0,69 bar), 70% IPA, per 10" (25 cm) in Nitrogen
19.5 mL/min @ 10 psig (0,69 bar), 70% IPA, per 10" (25 cm) in Air

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 @ 55 psig (60 °C @ 3,8 bar) liquid, @ 35 psig (2,4 bar) gas

Maximum operating pressure (liquid service): 90 psig @ 100 °F (6,2 bar @ 38 °C)

Maximum operating pressure (gas service): 60 psig @ 100 °F (4,1 bar @ 38 °C)

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).

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

Each Ultradyne® TT0.2 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, lot number and serial number.

Ordering Guide

CR 2 TT 0.2 - 1 T 00 4

| Sterile Filter Option | |
|-----------------------|----|
| Standard; non-sterile | CR |

| Housing Material Designator | |
|--|---|
| Polypropylene, animal component free (ACF) | 2 |

| Vent/Drain Ports | |
|-----------------------|---|
| Inline Configuration | |
| 0 | No vents/ drains |
| 2 | Vent/drain at inlet and outlet |
| 4 | Vent/drain at outlet |
| T-style Configuration | |
| 0 | No vent; no drain |
| 1 | No vent; standard 1/4" drain plug |
| 2 | Std. vent valve; std. drain plug |
| 3 | Std. vent & drain plug; 3/4" TC gage port |
| 4 | Std. vent; no drain |
| 5 | Std. vent; no drain; gage port |
| 6 | No vent; no drain; gage port |
| A | No vent; sanitary drain valve |
| B | Std. vent; sanitary drain valve |
| C | Std. vent; san. drain valve; gage port |

| Inlet / Outlet Connections | | | |
|----------------------------|--------------------------------|----|----------------------|
| 00 | 1" sanitary (TC) flange | 77 | 3/4" sanitary flange |
| 02 | 1" TC in & 3/8" hose barb out | 88 | 3/4" hose barb |
| 08 | 1" TC in & 3/4" hose barb out | 99 | 9/16" hose barb |
| 09 | 1" TC in & 9/16" hose barb out | AA | 1/2" male Flaretek® |
| 0C | 1" TC in & 1/2" hose barb out | BB | 3/4" male Flaretek® |
| 0D | 1" TC in & 1" hose barb out | CC | 1/2" hose barb |
| 22 | 3/8" hose barb | DD | 1" hose barb |

| Body Style | | | |
|------------|----------------------|---|-----------------------|
| N | Inline configuration | T | T-style configuration |

| Cartridge Length | | | | | | | | | |
|------------------|-----|---|-----|---|-----|---|-----|---|-----|
| 1 | 10" | 2 | 20" | 3 | 30" | 4 | 40" | 5 | 50" |

| Product | Filter Grade | Retention Rating |
|--------------------------------------|--------------|------------------|
| Ultradyne® hydrophobic PTFE membrane | TT | 0.2 |

Additional information about Ultradyne® filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/ultradyne-gd006-2.2.pdf>

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