

The Hydrophobic PTFE Membrane Cartridge Filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

AseptiSure TH Hydrophobic PTFE Membrane Cartridge Filters

Catalog No. : CPTH5301E0SS101
 Type : CPTH
 Pore Size : 0.2 µm
 Lot Number : CT6604L SI.No. 056
 Manufacturing Date : 2024 - 12
 Expiry Date : 2029 - 12

SPECIFICATION

Length	5"
Filter Media	Hydrophobic PTFE Membrane
Drainage Layers	Polypropylene
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm ² at 25°C
Maximum operating Temperature	95 °C at < 2 Kg/cm ²
Reverse Pressure	< 0.7 Kg/cm ² at 25°C
Sterilization	By Autoclaving or Steam-in-place (SIP)

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The cartridge filters have been tested for integrity by Air Diffusion flow test and Bubble point test using 70% IPA/Water solution.
 Diffusion flow was: ≤ 22 ml/min at 1.12 Kg/cm²
 Bubble point was: ≥ 22 psi (1.52 Bar)
- Water Intrusion Rate** : ≤ 6.0 ml /10 min at 2.0 kg/cm²
- Typical Air Flow Rate** : 100 Nm³/Hr @ 0.10 Kg/cm²
- Microbial Challenge Test** : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.
- VALIDATED FOR**
- Heat Stability** : Maintains integrity after 80 Steam sterilization cycles at 135 °C for 30 minutes each.
- Bacterial Endotoxin** : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
- Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
- Cytotoxicity** : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.
- Indirect Food Additives** : Passes as per FDA 21CFR 177.1520(a)1(i).
- Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).

CUSTOMER SUPPORT

mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

T. No.: COQ/CAR/008-00



Head of Quality Assurance

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An ISO 9001 Company