

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. : CPTH5001E0SS101
 Type : CPTH
 Pore Size : 0.2 µm
 Lot Number : CT89911 SI.No. 006
 Manufacturing Date : 2021 - 09
 Expiry Date : 2026 - 09

SPECIFICATION

Length	2.5"
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
Sterilization	By Autoclaving or Steam-in-place (SIP)

LOT RELEASE CRITERIA

The above filter meets the following lot release criteria:

- 100% Integrity Tested** : The cartridge filter has been tested for integrity by Bubble point Test using 70% IPA/Water solution. Bubble point was: ≥ 22 psi (1.52 Bar)
- Water Intrusion Rate** : ≤ 3.0 ml /10 min at 2.0 kg/cm²
- Typical Air Flow Rate** : 8.0 Nm³/Hr at 0.07 kg/cm²
- Microbial Challenge Test** : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 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.



Head of Quality Assurance

Issue Date: 01-Sep-2021

Advanced Microdevices Pvt. Ltd.
 21, Industrial Area, Ambala Cantt, INDIA,
 Tel: +91-171-2699290/ 2699274
 Website: www.mdimembrane.com
 Email: info@mdimembrane.com

An ISO 9001 Company