mdi
Membrane Technologies

Certificate of Quality

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

AseptiSure TF Hydrophobic PTFE Membrane Cartridge Filters

Catalog No.	: CPTF5401A0FV101	
Type	: CPTF	
Pore Size	: 0.2 µm	
Lot Number	: CT5664L	Sl.No. 085
Manufacturing Date	: 2024 - 12	
Expiry Date	: 2029 - 12	

SPECIFICATION

Length	10”
Filter Media	Hydrophobic PTFE Membrane
Drainage Layers	Polypropylene
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm²
Reverse Pressure	< 0.7 Kg/cm² at 25°C
Sterilization	100 Autoclave/Steam sterilization cycles at 121°C for 30 minutes each

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 flows were: ≤ 45 ml/min at 1.12 Kg/cm²
Bubble point was: ≥ 22 psi (1.52 Bar)

Water Intrusion Rate : ≤ 13 ml /10 min at 2.0 kg/cm²

Typical Air Flow Rate : 200 Nm³/Hr @ 0.10 Kg/cm²

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

VALIDATED FOR

Heat Stability : Maintains integrity after 100 autoclave/steam sterilization cycles at 121°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

Issue Date: 17-Dec-24

Advanced Microdevices Pvt. Ltd.
Jawahargarh Road,
Village-Tepla, Ambala, INDIA.
Tel: +91-171-2699290/2699274
Website: www.mdimembrane.com
Email: info@mdimembrane.com

An ISO 9001 Company