mdi
Membrane Technologies

Certificate of Quality

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

AseptiSure TK Hydrophilic/Hydrophobic Membrane Cartridge Filters

Catalog No.	: CPTK5301A0SS101	
Type	: CPTK	
Pore Size	: 0.2 µm	
Lot Number	: CK5994L	Sl.No. 056
Manufacturing Date	: 2024 - 12	
Expiry Date	: 2029 - 12	

SPECIFICATION

Length	5”
Filter Media	Hydrophilic Polyethersulfone and 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	By Autoclaving or Steam-in-place (SIP)

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: ≥ 16 psi (1.10 Bar)

Typical Water Flow Rate : 18.0 lpm @ 1.40 Kg/cm² @ 27 ºC

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 4 Autoclaving/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>.

Extractable : Within limits as specified in USP.

Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

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/012-00

Head of Quality Assurance

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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