mdi
Membrane Technologies

Certificate of Quality

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

AseptiSure WS PVDF Membrane Cartridge Filter

Catalog No.	: CWHX5301E0SS101
Type	: CPWS
Pore Size	: 0.2 µm (0.45 µm + 0.2 µm)
Lot Number	: CV6684L Sl.No. 052
Manufacturing Date	: 2024 - 12
Expiry Date	: 2029 - 12

SPECIFICATION

Length	5”
Filter Media	Hydrophilic PVDF Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm² (3.43 Bar) at 25 °C
Maximum operating Temperature	80 °C at < 2 Kg/cm² (1.96 Bar)
Reverse Pressure	< 0.7 Kg/cm² (0.69 Bar) 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 Air Diffusion Flow test and Bubble Point test using DI water.
Diffusion flows with DI water were: ≤ 15 ml/min @ 2.60 kg/cm² (2.55 Bar)
Bubble point value with DI water was: ≥ 50 psi (3.45 Bar)

Typical Water Flow Rate : 12 lpm @ 0.70 Kg/cm² (0.69 Bar) @ 27 ºC

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

VALIDATED FOR

Bubble point (50% IPA) : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 18 psi (1.24 Bar)

Heat Stability : Maintains integrity after 3 Steam sterilization cycles at 135 °C for 30 minutes each.

Extractable : Within limits as specified in USP.

Oxidizable matter : Passes test as per USP.

Bacterial Endotoxin : Filtrate meets the USP requirements for Sterile WFI of ≤ 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.

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).

Total Organic Carbon : Meets USP <643> limit of 500 ppb for total organic carbon after flushing specified volume of water for injection.

Conductivity : Meets USP <645> limit of 1.3 µS/cm at 25 °C for water conductivity after flushing specified volume of water for injection.

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/010-04

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