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. | : CWH15436A0SS101 |
| Type | : CPWS |
| Pore Size | : 0.1 µm (0.2 µm + 0.1 µm) |
| Lot Number | : CV3354L Sl.No. 065 |
| Manufacturing Date | : 2024 - 12 |
| Expiry Date | : 2029 - 12 |

**SPECIFICATION**

| | |
|---|---|
| **Length** | 10” |
| **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 purified water.
Diffusion flows were: ≤ 30 ml/min @ 3.52 kg/cm² (3.45 Bar)
Bubble point was: ≥ 70 psi (4.83 Bar).

**Typical Water Flow Rate** : 13 lpm @ 0.70 Kg/cm² (0.69 Bar) @ 27 ºC

**Microbial Challenge Test** : Retains ≥ $10^7$ organisms/cm² of *Acholeplasma laidlawii (*ATCC 23206).

**VALIDATED FOR**

**Bubble point (50% IPA)** : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 28 psi (1.93 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

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