

Certificate of Quality

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

AseptiSure KSPES Membrane Cartridge Filters

Catalog No. : CPK15036E0SS101
 Type : CPPKS
 Pore Size : 0.1 µm (0.2 µm + 0.1 µm)
 Lot Number : CK5994L SI.No. 052
 Manufacturing Date : 2024 - 12
 Expiry Date : 2029 - 12

SPECIFICATION

Length	2.5"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm ² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm ²
Reverse Pressure	< 0.7 Kg/cm ² at 25°C
Sterilization	25 Autoclave/ Steam sterilization cycles at 121°C for 30 minutes each

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The cartridge filter has been tested for integrity by Bubble Point Test using purified water. Bubble point with was: ≥ 65 psi (4.48 Bar).
- Typical Water Flow Rate** : 4.0 lpm @ 0.70 Kg/cm² @ 27 °C
- Microbial Challenge Test** : Retains ≥ 10⁷ 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 ≥ 26 psi (1.79 Bar)
- Heat Stability** : Maintains integrity after 25 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>.
- Extractable** : Within limits as specified in USP.
- 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/004-04



Head of Quality Assurance

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An ISO 9001 Company