mdi
Membrane Technologies

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 KS PES Membrane Cartridge Filters

Catalog No. : CPKX5401A0SS101

Type : CPPKS

Pore Size : 0.2 µm (0.45 µm + 0.2 µm)

Lot Number : CK5537G Sl.No. 014

SPECIFICATION

Length	10”
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
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	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 Air Diffusion Flow test and Bubble Point test using DI water.
Diffusion flows with DI water were: ≤ 30 ml/min @ 2.60 kg/cm²
Bubble point value with DI water was: ≥ 50 psi (3.44 Bars)
The cartridge filter is also certified for integrity by Bubble point test using 50% IPA/Water solution.
Bubble point with 50% IPA/Water solution is ≥ 16 psi (1.10 Bars)

Water Flow Rate : ≥ 7.5 lpm @ 0.70 Kg/cm² @ 27 ºC

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

Heat Stability : Maintains integrity after 25 autoclave/ Steam sterilization cycles at 121°C for 30 minutes each.

Extractable : Within limits as specified in USP.

Oxidizable matter : Passes test as per USP.

Bacterial Endotoxins : 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).

CUSTOMER SUPPORT

mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

Head of Quality Assurance

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An ISO 9001 Company