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***.

***AseptiPrime KS* PES Membrane Cartridge Filters**

Catalog No. : CKH75501A0SS101

Type : CK

Pore Size : 0.2 µm (0.5 µm + 0.2 µm)

Lot Number : CK4667I Sl.No. 003

SPECIFICATION

Length	20"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Housing	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 Air Diffusion Flow test using DI water. Diffusion flow with DI water was: ≤ 60 ml/min @ 2.60 kg/cm²

Water Flow Rate : ≥ 60 lpm @ 0.70 Kg/cm² @ 27 °C

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 135°C for 30 minutes each.

Extractable : Within limits as specified in USP.

Oxidizable matter : Passes test as per 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).

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

Issue Date: 11-Sep-17

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An ISO 9001 Company