mdi
Membrane Technologies

Certificate of Quality

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

AseptiPrime KS PES Membrane Capsule Filters

Catalog No.	: DKX75136AAXB101
Type	: DK
Pore Size	: 0.1 µm (0.5 µm + 0.1 µm)
Lot Number	: DK9694H Sl.No. 056
Manufacturing Date	: 2024 - 08
Expiry Date	: 2029 - 08

SPECIFICATION

Length	1”
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Housing	Polypropylene
Differential Pressure	< 4Kg/cm² at 30 °C
Maximum Operating Temperature	80 °C @ < 2 Kg/cm²
Sterilization	3 autoclaving cycles at 125 °C of 30 minutes each

LOT RELEASE CRITERIA

100% Integrity Tested : The Capsule filter has been tested for integrity by Air Diffusion Flow Test and Bubble Point Test using purified water.
Diffusion flows were: ≤ 1.8 ml/min @ 3.52 kg/cm²
Bubble point was: ≥ 65 psi (4.48 Bar).

Typical Water Flow Rate : 300 ml/min @ 0.14 Kg/cm² @ 27 °C

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 ≥ 26 psi (1.79 Bar)

Bacterial Endotoxin : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.

Heat Stability : Maintains integrity after 3 autoclaving cycles at 125 °C of 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).

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/CAP/001-04

Head of Quality Assurance

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An ISO 9001 Company