mdi
Membrane Technologies

Certificate of Quality

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

AseptiPrime KS-γ PES Membrane Capsule Filter

Catalog No.	: DKX75101AAXB301
Type	: DK-S
Pore Size	: 0.2 µm (0.5 µm + 0.2 µm)
Lot Number	: DK8337G Sl.No. 005
Ster. No.	: R015
Expiry Date	: 2019 - 07

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	Pre sterilized by Gamma Irradiation

LOT RELEASE CRITERIA

100% Integrity Tested : The capsule filter has been tested for integrity by Bubble point test using DI water. Bubble point value with DI water was: ≥ 50 psi (3.44 Bar)
The capsule 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 Bar)

Water Flow Rate : ≥ 250 ml/min @ 0.14 Kg/cm² @ 27 °C

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

Sterility : Samples passed the sterility test in accordance with USP <71>.

VALIDATED FOR

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: 24-Jul-17

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An ISO 9001 Company