

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-γ PES Membrane Capsule Filters

Catalog No. : LKX95436QQXX301
 Type : LK-S
 Pore Size : 0.1 μm (0.3 μm + 0.1 μm)
 Lot Number : LK77571 Sl.No. 012
 Ster. No. : R111
 Expiry Date : 2019 - 09

SPECIFICATION

Length	10"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Housing	Polypropylene
Differential Pressure	< 4Kg/cm ² at 30 °C
Maximum Operating Temperature	80 °C @ < 2 Kg/cm ²
Sterilization	Pre sterilized by Gamma Irradiation

LOT RELEASE CRITERIA

100% Integrity Tested : The Capsule filters have been tested for integrity by Air Diffusion Flow Test using purified water and Bubble Point Test using 50% IPA/Water solution.
 Diffusion flows were: ≤ 29 ml/min @ 3.52 kg/cm²
 Bubble point was: ≥ 31 psi (2.14 Bar).

Water Flow Rate : ≥ 10 lpm @ 0.70 Kg/cm² @ 27 °C

Sterility : Samples passed the sterility test in accordance with U.S. pharmacopoeia.

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

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An ISO 9001 Company