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***.

AseptiCap KS-γ PES Membrane Capsule Filters

Catalog No.	: LKS15336QQXX301
Type	: LKS-S
Pore Size	: 0.1 µm (0.2 µm + 0.1 µm)
Lot Number	: LK9967G Sl.No. 008
Ster. No.	: R005
Expiry Date	: 2019 - 07

SPECIFICATION

Length	5”
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2 Kg/cm²
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: ≤ 15 ml/min @ 3.52 kg/cm²
Bubble point was: ≥ 31 psi (2.14 Bar).

Water Flow Rate : ≥ 5.0 lpm @ 0.70 Kg/cm² @ 27 ºC

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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Advanced Microdevices Pvt. Ltd.
21, Industrial Area, Ambala Cantt, INDIA,
Tel: +91-171-2699290/ 2699274
Website: www.mdimembrane.com
Email: info@mdimembrane.com

An ISO 9001 Company