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.	: LKS55502EEXT301
Type	: LKS-S
Pore Size	: 0.45 µm (0.8 µm + 0.45 µm)
Lot Number	: LK9504K Sl.No. 056
Ster. No.	: R2565
Date of Sterilization	: 2024 - 11
Expiry Date	: 2026 - 11

SPECIFICATION

Length	20"
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 dose between 25 kGy to 40 kGy

LOT RELEASE CRITERIA

100% Integrity Tested : The capsule filter has been tested for integrity by Air Diffusion Flow test and Bubble Point test using DI water.
Diffusion flows with DI water were: ≤ 70 ml/min @ 1.54 kg/cm²
Bubble point value with DI water was: ≥ 30 psi (2.07 Bar)

Typical Water Flow Rate : 80 lpm @ 0.70 Kg/cm² @ 27 °C

VALIDATED FOR

Bubble point (50% IPA) : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 10 psi (0.69 Bar)

Sterility : The sterilization process has been validated to assure Sterility Assurance Level SAL) of 10^{-6} in accordance with ISO 11137.

Microbial Retention : Retains microbial challenge of *S. marcescens* (ATCC 14756).

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

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/004-05

Head of Quality Assurance

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An ISO 9001 Company