

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 KSPES Membrane Capsule Filters

Catalog No. : LKS55502EEXX101
 Type : LKS
 Pore Size : 0.45 µm (0.8 µm + 0.45 µm)
 Lot Number : LK9394K SI.No. 085
 Manufacturing Date : 2024 - 11
 Expiry Date : 2029 - 11

SPECIFICATION

Length	20"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm ² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2 Kg/cm ²
Sterilization	25 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 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)
- 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>.
- Heat Stability** : Maintains integrity after 25 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