



Membrane Technologies

Certificate of Quality

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

AseptiCap KS-γ PES Membrane Filters

Catalog No. : IKSX0601HHXX304
Type : IKS-S
Pore Size : 0.2 μm (0.45μm + 0.2μm)
Lot Number : IK57571
Ster. No. : R123
Expiry Date : 2019 - 09

SPECIFICATION

Membrane : Polyethersulfone
Housing : Polypropylene
Filter Diameter : 25 mm
Effective Filtration Area (Nominal) : 5 cm²
Burst pressure : > 14 Kg/cm²
Sterilization : Pre sterilized by Gamma Irradiation

LOT RELEASE CRITERIA

The above lot meets the following lot release criteria:

- 100% Integrity Tested** : The filter has been tested for integrity by Bubble Point Test using purified water. Bubble point was: ≥ 50 psi (3.44 bar)
The 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** : ≥ 30 ml/min @ 0.70 kg/cm²
- Microbial Challenge Test** : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.
- Sterility** : Samples passed the sterility test in accordance with U.S Pharmacopoeia.
- VALIDATED FOR**
- Bacterial Endotoxin Levels** : Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test.
- Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).
- 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).

PRECAUTIONS

1. During handling, avoid contamination of outlet.
2. If pressure required to maintain the required flow becomes too high, the filter unit should be changed.

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