

Certificate of Quality

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

AseptiPrime KS-γ PES Membrane Filters

Catalog No. : IKX70601HHRX104
Type : IK
Pore Size : 0.2 μm (0.5 μm + 0.2 μm)
Lot Number : IK5934L
Manufacturing Date : 2024 - 12
Expiry Date : 2029 - 12

SPECIFICATION

Membrane : Polyethersulfone
Housing : Polypropylene
Filter Diameter : 25 mm
Effective Filtration Area (Nominal) : 5 cm²
Burst pressure : > 14 Kg/cm²
Sterilization : Can be sterilized by Gamma Irradiation upto 50 kGy

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)
Typical Water Flow Rate : 40 ml/min @ 0.70 kg/cm² @ 27 °C
Microbial Challenge Test : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

VALIDATED FOR

Bubble point (50% IPA) : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 18 psi (1.24 Bar)
Bacterial Endotoxin : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
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).
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.

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.

T. No.: COQ/ILF/007-03

Head of Quality Assurance

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An ISO 9001 Company