

Certificate of Quality

The Polyethersulfone Membrane Vacuum Filter Device has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

AseptiVac KS-γ PES Membrane Vacuum Filter Device

Catalog No. : AKX73101ZXXG301
Type : AVKS-S
Pore Size : 0.2 μm (0.5 μm + 0.2 μm)
Lot Number : AK0068C
Ster. No. : R088
Date of Sterilization : 2018 - 08
Expiry Date : 2020 - 08

SPECIFICATIONS

Materials of Construction

- Filter Membrane : Polyethersulfone
- Filter Housing : Polypropylene
- Funnel : Polystyrene

Filtration Area (Nominal) : 100 cm²

Maximum Operating Temperature : 45 °C

Sterilization : Pre sterilized by Gamma Irradiations at ≥ 25 kGy

LOT RELEASE CRITERIA

100% Integrity Tested

: The filter has been tested for integrity by Bubble Point Test using 50% IPA/Water solution. Bubble point was: ≥ 16 psi (1.10 Bar)

Water Flow Rate

: ≥ 0.8 lpm @ Vacuum of 500 mm of Hg @ 27 °C

Microbial Challenge Test

: Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

Sterility

: The sterilization process has been validated to assure Sterility Assurance Level (SAL) of 10⁻⁶ in accordance with ISO 11137.

Bacterial Endotoxin Levels

: Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) test.

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>.

Extractable

: Within limits as specified in USP.

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

Issue Date: 05-Sep-18

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