

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. : DKSX5201EEXX301
 Type : DKS-S
 Pore Size : 0.2 μm (0.45 μm + 0.2 μm)
 Lot Number : DK7757G Sl.No. 002
 Ster. No. : R123
 Expiry Date : 2019 - 07

SPECIFICATION

Length	2"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm ² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2Kg/cm ²
Sterilization	Pre sterilized by Gamma Irradiation

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The capsule filter has been tested for integrity by Bubble point test using DI water. Bubble point value with DI water was: ≥ 50 psi (3.44 Bar)
 The capsule 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** : ≥ 3.5 lpm @ 0.70 Kg/cm² @ 27 °C
- 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**
- Extractable** : Within limits as specified in USP.
- Oxidizable matter** : Passes test as per USP.
- Bacterial Endotoxins** : Filtrate meets the USP requirements for Sterile WFI of ≤ 0.25 EU/ml as determined 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>.
- 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).

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