

The Polyethersulfone Membrane Capsule filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiCap KSO-γ PES Membrane Capsule Filters**

Catalog No. : DKOX5201AAXX301  
 Type : DKSO-S  
 Pore Size : 0.2 μm (0.45 μm + 0.2 μm)  
 Lot Number : DK66571      SI.No. 005  
 Ster. No. : R123  
 Expiry Date : 2019 - 09

### SPECIFICATION

<b>Length</b>	2"
<b>Filter Media</b>	Polyethersulfone Membrane
<b>Drainage Layers</b>	Polypropylene
<b>Housing</b>	Polypropylene
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Maximum Operating Temperature</b>	80 °C @ < 2Kg/cm <sup>2</sup>
<b>Sterilization</b>	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/cm<sup>2</sup> @ 27 °C
- Microbial Challenge Test** : Retains ≥ 10<sup>7</sup> organisms/cm<sup>2</sup> 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>.
- 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

Issue Date: 11-Sep-17

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**An ISO 9001 Company**