mdi
Membrane Technologies

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***.

BioPro KSO-γ PES Membrane Capsule Filters

Catalog No.	: DBKO5701DDXX301	
Type	: DBKSO-S	
Pore Size	: 0.2 µm	
Lot Number	: DK9931B	Sl.No. 007
Ster. No.	: R111	
Date of Sterilization	: 2021 - 02	
Expiry Date	: 2023 - 02	

SPECIFICATION

Length	8”
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyethylene
Differential Pressure	< 4Kg/cm² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2Kg/cm²
Sterilization	Pre sterilized by Gamma Irradiation dose between 25 kGy to 40 kGy

LOT RELEASE CRITERIA

100% Integrity Tested : The capsule filter has been tested for integrity by Bubble point test using DI water. Bubble point was: ≥ 30 psi (2.07 Bar).

Typical Water Flow Rate : 13 lpm @ 0.70 Kg/cm² @ 27 °C

VALIDATED FOR

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

Microbial Challenge Test : Retains ≥ 10^5 organisms/cm² of *B. diminuta* ATCC 19146 challenge.

Bacterial Endotoxin : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.

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>.

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