

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 PES Membrane Capsule Filters

Catalog No. : LBKO5401EEXT101
 Type : LBKSO
 Pore Size : 0.2 µm
 Lot Number : LK8771B SI.No. 005

SPECIFICATION

Length	10"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polypropylene
Housing	Polypropylene
Differential Pressure	< 4Kg/cm ² at 30 °C
Maximum Operating Temperature	80 °C @ < 2 Kg/cm ²

LOT RELEASE CRITERIA

100% Integrity Tested : The Capsule filters have been tested for integrity by Air Diffusion test and Bubble point test using DI water.
 Diffusion flows were: ≤ 35 ml/min @ 1.54 kg/cm²
 Bubble point was: ≥ 30 psi (2.07 Bar)

Typical Water Flow Rate : 55 lpm @ 0.70 Kg/cm² @ 27 °C

VALIDATED FOR

Microbial Challenge Test : Retains ≥ 10⁵ 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>.

Sterilization : Maintains integrity after 25 autoclaving cycles at 125 °C of 30 minutes each.

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