

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 KS-γ PES Membrane Capsule Filters

Catalog No. : LBKS5401EEXT301
 Type : LBKS-S
 Pore Size : 0.2 μm
 Lot Number : LK5994L SI.No. 045
 Ster. No. : R2234
 Date of Sterilization : 2024 - 12
 Expiry Date : 2026 - 12

SPECIFICATION

Length	10"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Housing	Polypropylene
Differential Pressure	< 4Kg/cm ² at 30 °C
Maximum Operating Temperature	80 °C @ < 2Kg/cm ²
Sterilization	Pre sterilized by Gamma Irradiation dose between 25 kGy to 40 kGy

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

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 ≥ 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>.

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).

Total Organic Carbon

: Meets USP <643> limit of 500 ppb for total organic carbon after flushing specified volume of water for injection.

Conductivity

: Meets USP <645> limit of 1.3 μS/cm at 25 °C for water conductivity after flushing specified volume of water for injection.

CUSTOMER SUPPORT

mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

T. No.: COQ/CAP/004-05



Head of Quality Assurance

Issue Date: 16-Dec-24

Advanced Microdevices Pvt. Ltd.

Jawahargarh Road,

Village-Tepla, Ambala, INDIA.

Tel: +91-171-2699290/2699274

Website: www.mdimembrane.com

Email: info@mdimembrane.com

An ISO 9001 Company