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 KS PES Membrane Capsule Filters

Catalog No. : DBKS5101AAXX101
Type : DBKS
Pore Size : 0.2 µm
Lot Number : DK9981B Sl.No. 005

SPECIFICATION

Length	1”
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Housing	Polypropylene
Differential Pressure	< 4Kg/cm² at 30 °C
Maximum Operating Temperature	80 °C @ < 2 Kg/cm²

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 : 900 ml/min @ 0.14 Kg/cm² @ 27 °C

VALIDATED FOR

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>.

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