

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**.

AseptiCap Nano PES Membrane Capsule Filters

Catalog No. : LKNX54S7EEXX101
 Type : LKN
 Pore Size : Sterilizing Grade
 Lot Number : LK2294L SI.No. 085
 Manufacturing Date : 2024 - 12
 Expiry Date : 2029 - 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 @ < 2 Kg/cm ² |
| Sterilization | 3 autoclaving cycles at 125 °C of 30 minutes each |

LOT RELEASE CRITERIA

100% Integrity Tested

: The capsule filter has been tested for integrity by Air Diffusion Flow test using DI water. Diffusion flow with DI water was: ≤ 8.4 ml/min @ 1.41 kg/cm² (20 psi)

Typical Water Flow Rate

: 22 lpm @ 0.70 Kg/cm² @ 27 °C

Microbial Challenge Test

: LRV > 7 for *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

Bacterial Endotoxin

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

Heat Stability

: Maintains integrity after 3 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).

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/001-04



Head of Quality Assurance

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