

The Polyethersulfone membrane filter has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

AseptiCap Nano PES Membrane Filters

Catalog No. : VKNX10S7BBXX101
Type : VKN
Pore Size : Sterilizing Grade
Lot Number : IK5594L
Manufacturing Date : 2024 - 12
Expiry Date : 2029 - 12

SPECIFICATION

Membrane : Polyethersulfone
Housing : Polypropylene
Filter Diameter : 50 mm
Effective Filtration Area (Nominal) : 20 cm²
Burst pressure : > 8 Kg/cm²

LOT RELEASE CRITERIA

100% Integrity Tested : The filter has been tested for integrity by Air Diffusion Flow test using DI water. Diffusion flow with DI water was: ≤ 0.05 ml/min @ 1.41 kg/cm² (20 psi)
Typical Water Flow Rate : 120 ml/min @ 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 μ S/cm at 25 °C for water conductivity after flushing specified volume of water for injection.

PRECAUTIONS

1. During handling, avoid contamination of outlet.
2. If pressure required to maintain the required flow becomes too high, the filter unit should be changed.

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/ILF/006-03



Head of Quality Assurance

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