mdi
Membrane Technologies

Certificate of Quality

The Nylon-66 Membrane Cartridge Filter has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using ***validated production processes***.

AseptiSure NS Nylon-66 Membrane Cartridge Filter

Catalog No. : CPNX5301A0SE101
Type : CPNS
Pore Size : 0.2 µm (0.45 µm + 0.2 µm)
Lot Number : CN8067G Sl.No. 002

SPECIFICATION

Length	5”
Filter Media	Nylon-66 Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm²
Reverse Pressure	< 0.7 Kg/cm² at 25°C

LOT RELEASE CRITERIA

100% Integrity Tested : The Cartridge filter has been tested for integrity by Air Diffusion test and Bubble point test using DI water.
Diffusion flow was: ≤ 15 ml/min @ 2.60 kg/cm²
Bubble point was: ≥ 50 psi (3.44 Bar)
The capsule filter is also certified for integrity by Bubble point test using 50% IPA/Water solution.
Bubble point with 50% IPA/Water solution is ≥ 17 psi (1.17 Bar)

Water Flow Rate : ≥ 10 lpm @ 0.70 Kg/cm² @ 27 °C

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

Extractable : Within limits as specified in 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