mdi
Membrane Technologies

Certificate of Quality

The Nylon-66 Membrane Capsule filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using ***validated production processes***.

AseptiCap NSZ Nylon-66 Membrane Capsule Filters

Catalog No. : DNZX5301BBXX101
Type : DNSZ
Pore Size : 0.2 µm
Lot Number : DN8227G Sl.No. 008

SPECIFICATION

Length	5"
Filter Media	Positively charged Nylon-66 Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm² at 30 °C
Housing	Polypropylene
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 value with DI water 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

Sterilization : Maintains integrity after one autoclaving cycle at 125 °C of 30 minutes each.

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