

Certificate of Quality

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

Nylon-66 Membrane Disc Filters

Catalog No. : NNXX1901XXXX103
Type : NN
Pore Size : 0.2 μ m
Diameter : 293 mm
Lot Number : NA888787G

LOT RELEASE CRITERIA

The above lot meets the following lot release criteria:

- Integrity** : The membrane filter lot has been tested for integrity by Bubble point Test using DI water. Bubble point was: ≥ 50 psi (3.4 Bars)
- Water Flow Rate** : ≥ 14 ml/min/cm² @ 0.70 Kg/cm² @ 27 °C
- Microbial Challenge Test** : Retains $\geq 10^7$ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

- Heat Stability** : Maintains integrity after 5 autoclaving/steam sterilization cycles at 121 °C of 30 minute each.
- Fiber/Particle release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Extractables** : Within limits as specified in USP.

- EXPIRY** : 3 years when stored in a cool and dry place.



Head of Quality Assurance
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An ISO 9001 Company