

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.	: CPNX5401A0FV101
Type	: CPNS
Pore Size	: 0.2 μ m (0.45 μ m + 0.2 μ m)
Lot Number	: CN8224L SI.No. 054
Manufacturing Date	: 2024 - 12
Expiry Date	: 2029 - 12

SPECIFICATION

Length	10"
Filter Media	Nylon-66 Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm ² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm ²
Reverse Pressure	< 0.7 Kg/cm ² 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: \leq 30 ml/min @ 2.60 kg/cm ² Bubble point was: \geq 50 psi (3.44 Bar)
Typical Water Flow Rate	: 25 lpm @ 0.70 Kg/cm ² @ 27 °C
Microbial Challenge Test	: Retains \geq 10 ⁷ organisms/cm ² of <i>B. diminuta</i> ATCC 19146 challenge as per ASTM F838 methodology.
VALIDATED FOR	
Bubble point (50% IPA)	: The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point \geq 17 psi (1.17 Bar)
Sterilization	: In-line steam sterilizable/Autoclavable @ 121°C for 30 minutes @ differential pressure of < 3psi (< 0.2 Kg/cm ²).
Extractable	: Within limits as specified in USP.
Bacterial Endotoxin	: Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
Biosafety	: Passes Biological Reactivity Tests, <i>In Vivo</i> 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.

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/CAR/002-02



Head of Quality Assurance

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