mdi
Membrane Technologies

Certificate of Quality

The Hydrophilic PVDF Membrane filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using ***validated production processes***.

AseptiCap WS-γ Hydrophilic PVDF Membrane Filters

Catalog No.	: VWSX1001BBRX102
Type	: VWS
Pore Size	: 0.2 µm (0.45 µm + 0.2 µm)
Lot Number	: IV5884L
Manufacturing Date	: 2024 - 12
Expiry Date	: 2029 - 12

SPECIFICATION

Membrane	: Hydrophilic PVDF
Housing	: Polypropylene
Filter Diameter	: 50 mm
Effective Filtration Area (Nominal)	: 20 cm²
Burst pressure	: > 8 Kg/cm²
Sterilization	: Can be sterilized by Gamma Irradiation upto 50 kGy

LOT RELEASE CRITERIA

The above lot meets the following lot release criteria:

100% Integrity Tested : The 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)

Typical Water Flow Rate : 150 ml/min @ 0.70 kg/cm² @ 27 ºC

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* 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 ≥ 18 psi (1.24 Bar)

Bacterial Endotoxin : Filtrate meets the USP requirements for Sterile WFI of ≤ 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.

Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

Cytotoxicity : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.

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 µS/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/016-03

Head of Quality Assurance

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An ISO 9001 Company