

Pellicon 2 Filter

Catalogue Number: P2B005A01
Lot Number: P5DN1531
Membrane Type: PBCC
Membrane Area: 0.1 m²

Good Manufacturing Practices

This product was manufactured in a Millipore facility which meets or exceeds FDA Device Good Manufacturing Practice standards.

ISO 9000 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

Materials

Membrane: Polyethersulfone
Screens: Polypropylene
Adhesives: Urethane
Toxicity: All parts in fluid paths were tested and meet the criteria of the USP Class VI Biological Tests for Plastics.

100% Integrity Tested in Manufacturing

Each unit must pass the Millipore Integrity Test based on air flow through the fully-wetted membranes of the filter.

Quality Assurance Lot Release Criteria

Every unit is tested by Manufacturing and released by Quality Assurance to the following specifications:

Integrity

Each unit exhibited air flow through fully-wetted membranes less than or equal to 4 cc/min at 10 psig (0.7 bar) inlet pressure.

Pressure Drop

Samples met a maximum pressure drop of 9-20 psi (0.6 - 1.4 bar) at 0.2 gpm (0.6 L/min) average cross flow of clean water.
(For 2.5m² Maxi's, note that test is done on 0.5m² elements.)

Quality Assurance Audit Criteria

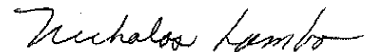
This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

USP Oxidizable Substances

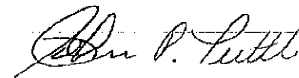
Effluent was negative after an RO water flush.

Gravimetric Extractables

The extractables level was equal to or less than 1500 mg/m² after an RO water flush.



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John P. Tuttle
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MILLIPORE

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