

Pellicon® 2 Filter

Catalogue Number: P2B005A05
Lot Number: C9CN87828
Membrane Type: PBCC
Membrane Area: 0.5 m²

Good Manufacturing Practices
This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

ISO® 9001 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 9001 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 18 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 0.8 gpm (3.0 L/min) average cross flow of clean water.

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 1500mg/m² after an RO water flush.



Peter Eichert
Quality Manager

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00099620PU Rev F 06/08

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