Pellicon® 2 Filter

Catalogue Number: P2B300C05
Lot Number: C8PN43190GL
Membrane Type: PBMK
Membrane Area: 0.5 m^2

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 60 cc/min at 10 psig (0.7 bar) inlet pressure.

Pressure Drop

Samples met a maximum pressure drop of 4-12 psi (0.3-0.8 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/m^2 after an RO water flush

Peter Eichert
Quality Manager

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