

Pellicon® 3 - 1.14 m² Cassette

Catalogue Number: P3C010C10

Lot Number: C9MN48966

Membrane NAWCO: 10 μ

Membrane Area: 1.14 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.

100% Integrity Tested in Manufacturing

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

Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the device fabrication process. In-process controls are used to assure stability of the process.

Materials

Regenerated Cellulose membranes, Polypropylene, Polyethylene, Stainless Steel, Thermoplastic elastomeric extended seals, 3-4% Benzyl alcohol / 20% glycerol/water

Millipore and Pellicon are registered trademarks of Millipore Corporation. ISO is a registered trademark of the International Standards Organization. ASTM is a registered trademark of the American Society for Testing and Materials.

Rev E 06/09

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 membranes fully-wetted with water, less than or equal to:

- 60 cc/min at 30 psig (2.1 bar) inlet pressure

Pressure Drop

Each unit met a maximum pressure drop of 6-18 psi (0.4-1.2 bar) at 6.0 L/min average cross flow of clean water.

Sealing

Each device is challenged at 100 psi air pressure.

Quality Performance Criteria

This product was designed and tested to meet the following performance specifications.

Maximum Operating Temperature and Pressure:

80 psi TMP at 40°C

40 psi TMP at 50°C

Maximum Reverse Pressure

-30 psi TMP at 25°C

Design Criteria

This product was designed and manufactured to meet the following specifications:

Gravimetric Extractables

The NVR extractables level was equal to or less than 1500 mg/m² after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature.

Class VI Toxicity Testing

All points in fluid paths were tested and met the criteria of the USP <88> Biological Reactivity Tests for Class VI Devices.



Peter Erichert
Quality Manager