

Pellicon® 3 - 0.11 m² Cassette

Catalogue Number: P3C010C01

Lot Number: C9AN54674GL

Membrane NMWCO: 10 kD

Membrane Area: 0.11 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 of 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 membrane, Polypropylene, Polyethylene, Thermoplastic elastomeric external seals, 3-4% Benzyl alcohol /20% glycerin/water

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:

- 9 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 600 mL /min average cross flow of clean water.

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

Exposure:

-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 parts in fluid paths were tested and meet the criteria of the USP <88> Biological Reactivity Tests for Class VI Plastics



Peter Eichert

Quality Manager

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P89837 Rev D 03/08

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