

Pellicon® 3 - 0.57 m² Cassette

Catalogue Number: P3C010C05

Lot Number: C9EN05563

Membrane NMWCO: 10 kD

Membrane Area: 0.57 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, Stainless Steel, 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:

- 32 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 3.0 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 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

MILLIPORE