

## Millipore® 3 - 0.11 m<sup>2</sup> Cassette

Logue Number: P3C010C01  
Number: C9AN68273  
Membrane NMWCO: 10 kD  
Membrane Area: 0.11 m<sup>2</sup>

### Good Manufacturing Practices

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

### ISO 9001 Quality Standard

This product was manufactured in a Millipore facility that adheres to a Quality Management System that is approved by an ISO 9001 registered certifying body to the appropriate ISO 9001 Quality Management Systems Standard.

### Integrity Tested in Manufacturing

Each unit must pass the Millipore Integrity Test based on the following 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

The filter consists of a Cellulose membrane, Polypropylene, Polyethylene, plastic elastomeric external seals, and 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/m<sup>2</sup> 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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