

## Pellicon<sup>®</sup> XL Filter

Catalogue Number: PXGVPPC50

Lot Number: C9KN34413

Membrane Type: GVPP

Membrane Area: 50 cm<sup>2</sup>

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which meets or exceeds FDA Device Good Manufacturing Practice standards.

### ISO 9000 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 9000 Quality Systems Standard.

### Materials

Membrane: PVDF

Screens: Polypropylene

Housing: Polypropylene

Toxicity: All materials 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 membranes of the filter.

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### 100% Housing Integrity Tested in Manufacturing

Each unit must pass the in-process Housing Integrity Test.

### 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 the membrane less than or equal to 2 cc/min at 10 psig (0.69 bar) inlet pressure.

#### Feed Channel Air Flow

Each unit exhibited a maximum air flow of 1.3 - 3.6 L/min at 10 psi (0.69 bar) pressure drop.

The feed channel air flow translates to a typical water cross flow of 100 - 140 ml/min at 20 psi (1.4 bar) pressure drop.

### 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 7.5 mg/device after an RO water flush.



Peter Eichert  
BioPharmaceutical Quality Manager