

## Pellicon® XL Filter

Catalogue Number: PXB100C50

Lot Number: C9HN11896

Membrane Type: PBHK

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: Polyethersulfone

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 membrane 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 3 cc/min at 30 psig (2.1 bar) inlet pressure.

#### Feed Channel Air Flow

Each unit exhibited a maximum air flow of 2.5 - 4.0 L/min at 30 psi (2.1 bar) pressure drop.

The feed channel air flow translates to a typical water cross flow of 50 - 80 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