Pellicon® XL Filter

Catalogue Number: PXHVMPC50
Lot Number: C9DN94362
Membrane Type: HVMP
Membrane Area: 50 cm2

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 membrane of the filter.

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 1.6 - 4.3 L/min at 10 psi (0.69 bar) pressure drop.

The feed channel air flow translates to a typical water cross flow of 130 - 170 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

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