Prep/Scale® TFF Cartridge

Catalogue Number: CDUF006LT
Lot Number: C9CN76173
Membrane Type: PLTK
Membrane Area: 6 ft^2

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: Regenerated Cellulose
Screens: Polyethylene, Polypropylene
Central tube and housing: Polysulfone
Adhesive: Urethane
Toxicity: All parts in the fluid path were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

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.

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Quality Assurance Lot Release Criteria

Every unit was tested by Manufacturing and released by Quality Assurance to the following specifications:

Integrity

Each unit exhibited air flow through fully-wetted membranes less than or equal to 144 cc/min at 10 psig (0.7 bar) inlet pressure.

Housing Integrity

Each unit met a housing leakage less than 10 cc/min following pressurization to 80 psig (5.5 bar).

Pressure Drop

Each module exhibited a maximum pressure drop of 8 psig (0.55 bar) at 1.1 - 1.6 gpm (4.4-6.2 L/min) average cross flow of clean water at an inlet feed pressure of 40 psi (2.8 bar).

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 1500 mg per m^2 after an RO water flush.

Hydraulic Stress

Samples were tested and found to have a burst pressure of greater than 3X the maximum operating pressure of 80 psig (5.5 bar).

Peter Eichert
BioPharmaceutical Quality Manager

MILLIPORE