

**Prep/Scale® TFF Cartridge**

Catalogue Number: CDUF006LM

Lot Number: C6EN71284P

Membrane Type: PLMK

Membrane Area: 6 ft<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: 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 1050 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 - 1.5 gpm (4.1-5.8 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 Extractions**

The extractables level was equal to or less than 1500 mg per m<sup>2</sup> 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 Eicher

BioPharmaceutical Quality Manager



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