

## Prep/Scale® TFF Cartridge

Catalogue Number: CDUF002LM

Lot Number: xxxxxxxxxx

Membrane Type: PLMK

Membrane Area: 2.5 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 438 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 6 psig (0.41 bar) at 1.0 - 1.4 gpm (3.9-5.5 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<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 Eichert

BioPharmaceutical Quality Manager