

# Aerex™ 2 Cartridge Filters

0.2 µm Rated

Catalogue Number: CTGX73TP3

Lot Number: C9HN11705

## 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.

## Non-Fiber Releasing

This product was manufactured with a PTFE membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).

## Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

## 100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test.

## Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

### USP Bacterial Endotoxins

A cartridge aqueous extraction contains less than 0.5 EU/ml as determined using the Limulus Amebocyte lysate (LAL) test.

### Integrity

Samples exhibited a bubble point equal to or greater than 14.0 psig (965 mbar) in a 70/30% IPA/water mixture using nitrogen as the test gas at 23°C.

Samples exhibited a nitrogen diffusional flow rate of less than or equal to 60.0 cc/min per 10-inch element at 6.0 psig (410 mbar) in a 70/30% IPA/water mixture at 23 °C.

Samples exhibited a HydroCoil<sup>SM</sup> test value less than or equal to 0.40 mL/min per 10-inch element at 10 psig (690 mbar).

### Thermal and Hydraulic Stress

Samples were steamed in place at 145°C and maintained integrity after a forward stress to 60 psid (4.1 bar) and a reverse stress to 20 psid (1.4 bar).

## Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

### Toxicity

This product is non-toxic per the current USP General (Mouse) Safety Test.

### Multiple Sterilization Cycles

Integrity was maintained after 200 forward steam-in-place cycles of 30 minutes at 145°C.

### Virus Aerosol Retention

This product has been qualified to retain a ΦX-174 virus aerosol challenge of 10<sup>7</sup> to 10<sup>10</sup> PFU at an air flow rate of 50 SCFM per 10-inch cartridge after 200 steam-in-place cycles of 30 minutes at 145°C.

### Bacterial Grow-Through

The membrane has been qualified to retain bacteria when challenged for 21 days with a minimum *Brevundimonas diminuta* concentration of 1 x 10<sup>7</sup> CFU/cm<sup>2</sup>.



Peter Eichert  
BioPharmaceutical Quality Manager