

Aerex™ FC Cartridge Filters.

0.2 µm Rated

Catalogue Number: CTGB01TP3

Lot Number: C9DN90153

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 LU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Integrity

Samples exhibited a bubble point equal to or greater than 13 psig (900 mbar) in a 60/40% 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 15 cc/min at 10 psig (690 mbar) in a 60/40% IPA/water mixture at 23 °C per 10-inch cartridge.

Samples exhibited a HydroCorr test value less than or equal to 0.40 mL/min per 10-inch cartridge at 20 psig (1380 mbar).

Thermal and Hydraulic Stress

Samples were steamed in place at 145 °C and maintained integrity after a forward stress to 100 psid (6.9 bar) and a reverse stress to 75 psid (5.2 bar).

Air Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 1.2 psid (83 mbar) at an air flow rate of 100 SCFM (170 nm³/hr), and 30 psig (2.1 bar) inlet air pressure at 23 °C per 10-inch cartridge.

Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

Toxicity

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

Gravimetric Extractables

The extractables level was equal to or less than 35 mg per 10-inch cartridge after 24 hours in a 70/30% IPA/water mixture at controlled room temperature.

Multiple Sterilization Cycles

Integrity was maintained after 150 forward and 50 reverse steam-in-place cycles of 30 minutes at 145 °C.

Integrity After Steaming

Integrity was maintained on cartridges steamed 165 hours at 145 °C.

Virus Aerosol Retention

This product has been qualified to retain a φX174 virus aerosol challenge of 10⁶ to 10¹⁰ PFU at an air flow rate of 50 SCFM per 10-inch cartridge after 50 steam-in-place cycles at 145 °C.

Bacterial Grow-Through

The membrane has been qualified to retain bacteria when challenged for 21 days with a minimum *Brevundimonas diminuta* aerosol concentration of 1 x 10⁷ CFU/cm².

Peter Lichert
BioPharmaceutical Quality Manager

