

Aerex™ 2 Cartridge Filters

0.2 µm Rated

Catalogue Number: CTGX71TP3

Lot Number: C9AN64340

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 HydroCorrSM 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 Φ X-174 virus aerosol challenge of 10^7 to 10^{10} 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 1×10^7 CFU/cm².



Peter Eichert
BioPharmaceutical Quality Manager

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