Aervent™ Cartridge Filter

0.2 µm Rated
Catalogue Number: CTGR71TP1
Lot Number: C6AN37234

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 correlated to the *Brevundimonas diminuta* HIMA bacterial challenge test.

Quality Assurance Lot Release Criteria

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

Bacterial-Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 CFU/cm^2 using HIMA methodology.

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 16 psig (1103 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 24 cc/min at 14 psig (966 mbar) in a 70/30% IPA/water mixture at 23 °C per 10-inch cartridge.

Samples exhibited a HydroCorr test value less than or equal to 0.75 mL/min per 10-inch cartridge at 38 psig (2620 mbar).

Thermal and Hydraulic Stress

Samples were steamed in place at 145 °C and maintained integrity after a forward stress to 80 psid (5.5 bar) and a reverse stress to 60 psid (4.1 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 nm^3/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 100 forward and 50 reverse steam-in-place cycles of 30 minutes at 145 °C.

Peter Eichert
BioPharmaceutical Quality Manager

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