Milligard® Cartridge Filter

0.2 µm Nominal Rated
Catalogue Number: CWSS02S03
Lot Number: C9EN05548

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 Millipore media combination 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.

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.

Structural Integrity

Samples were found to be integral as measured by an aerosol challenge test.

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 10.0 psid (690 mbar) at 20 gpm (76 L/min) per 20-inch cartridge with clean water at 23 °C.

USP Oxidizable Substances

Effluent was negative after a water flush of 10 L per autoclaved 20-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 50 mg per 10-inch cartridge after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature.

Multiple Sterilization Cycles

Integrity was maintained after 10 steam-in-place cycles of 30 minutes at 121 °C.

Peter Eichert
BioPharmaceutical Quality Manager

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