

Optiseal™ Cartridge Filter with Hydrophilic Durapore® Membrane

0.45 µm Rated
Catalogue Number: LAHL04PP6
Lot Number: xxxxxxxxxx

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 Durapore 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.

Indirect Food Additive

The Durapore membrane used in this product meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.182.

100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test.

Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the cartridge fabrication process. In-process controls are used to assure stability of the process.

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P34776 Rev C 03/09

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 water bubble point equal to or greater than 28 psig (1931 mbar) with air at 23 °C.

Samples exhibited an air diffusional flow rate of less than or equal to 4.0 cc/min at 22 psig (1517 mbar) in water at 23 °C per cartridge.

Thermal and Hydraulic Stress

Samples were steamed in place at 135 °C and maintained integrity after a forward stress to 80 psid (5.5 bar) and a reverse stress to 50 psid (3.4 bar).

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 4.0 psid (276 mbar) at 2 gpm (7.6 L/min) per cartridge with clean water at 25 °C.

USP Oxidizable Substances

Effluent was negative after a water flush of 500 mL per autoclaved 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 10 mg per cartridge after 24 hours in ASTM Type 1 reagent-grade water at controlled room temperature.

Multiple Sterilization Cycles

Integrity was maintained after 30 steam-in-place cycles of 30 minutes at 135 °C.


Peter Eicherl
BioPharmaceutical Quality Manager

