

Optiseal[®]-M Cartridge Filter with Aervent[®] Membrane

0.2 µm Rated

Catalogue Number: LAGRM1S02

Lot Number: C8KN09518

Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to FDA Device Good Manufacturing Practice standards.

ISO[®] 9001 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 9001 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.

Indirect Food Additive

All component materials 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 correlated to the *Brevundimonas diminuta* ASTM F838 bacterial challenge 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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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/cm² using ASTM F838 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 1.6 psig (1100 mbar) in a 70/30% IPA/water mixture using nitrogen as the test gas at 23 °C.

Thermal and Hydraulic Stress

Samples were steamed in place at 135 °C and maintained integrity after a forward stress to 80 psig (5.5 bar) and a reverse stress to 50 psig (3.5 bar).

Air Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 5 psid (340 mbar) at an air flow rate of 10 SCFM (17 nm³/hr), and 0 psig (0 bar) outlet air pressure at 23 °C per 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 a 70/30% IPA/water mixture at controlled room temperature.

Multiple Sterilization Cycles

Integrity was maintained after 80 steam-in-place cycles of 30 minutes at 135 °C.



Peter Eichert
BioPharmaceutical Quality Manager

MILLIPORE