

# Optiseal®-M Cartridge Filter with Aervent® Membrane

0.2 µm Rated

Catalogue Number: LAGRM1S02

Lot Number: C9DN87741

## 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 1838 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  $1 \times 10^7$  CFU/cm<sup>2</sup> using ASTM F838 methodology.

### USP Bacterial Endotoxins

A cartridge aqueous extraction contains less than 0.5 LU/ml as determined using the Limulus Amebocyte Lysate (LAL) test.

### Integrity

Samples exhibited a bubble point equal to or greater than 16 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 m<sup>3</sup>/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 µg 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

