

## Opticap™ XL Capsule Filter with Aervent® Membrane

0.2 µm Rated

Catalogue Number: KTGRA04TT3

Lot Number: C8BN53069

### 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.

### 100% Integrity Testing in Manufacturing

Each filter cartridge must pass the Millipore Integrity Test correlated to the *Brevundimonas diminuta* HIMA 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.

### European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

### 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 HIMA methodology.

#### USP Bacterial Endotoxins

A capsule 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 (1100 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 9.0 cc/min at 14 psig (966 mbar) in 70/30% IPA/water mixture at 23 °C.

Samples exhibited a HydroCorr test value less than or equal to 0.25 ml/min per capsule at 38 psig (2620 mbar).

#### Thermal and Hydraulic Stress

Samples were autoclaved at 135 °C and maintained integrity after a forward stress to 80 psid (5.5 bar) and a reverse stress to 60 psid (4.1 bar).

### Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

#### Gravimetric Extractables

The extractables level was equal to or less than 15 mg per capsule after 24 hours in a 70/30% IPA/water mixture at controlled room temperature.

#### Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

#### 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).

#### Toxicity

Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

This product is non-toxic per the current USP General (Mouse) Safety Test.

#### Multiple Sterilization Cycles

Capsule integrity was maintained after 30 autoclave cycles of 30 minutes at 135 °C.



Peter Eichert  
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