

## Opticap® XL 5 Capsule Filter with Aervent® Membrane

0.2 µm Rated  
Catalogue Number: KTRAO5FF1  
Lot Number: C9EN04035

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

### 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.

### 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.

### 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.

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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 sample aqueous extraction sample 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 12.0 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 0.38 ml/min 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).

### Air Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 0.52 psid (36.0 mbar) at an air flow rate of 10 SCFM (0.283 m<sup>3</sup>/min) and 0 psig (0 mbar) outlet air pressure at 23° C per 5-inch capsule.

## Quality Performance Criteria

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

### Gravimetric Extractables

The extractables level was equal to or less than 28 mg per sample after 24 hours in a 70/30% IPA/water mixture at controlled room temperature.

### Toxicity

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

### Multiple Sterilization Cycles

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

Peter Eichert  
Quality Manager