

Opicap® XL 4 Capsule Filter with Aervent® Membrane

0.2 µm Rated
Catalogue Number: KTGRA04TT3
Lot Number: C9DN96287

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.

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 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 9.0 cc/min at 1.4 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 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 1.1 psid (76.0 mbar) at an air flow rate of 10 SCFM (0.283 m³/min) and 0 psig (0 mbar) outlet air pressure at 23° C per 4-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 15 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

