

Opticap™ XL Capsule Filter with Aervent® Membrane

0.2 µm Rated

Catalogue Number: KTGRA04TT3

Lot Number: C8CN64604

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 in the following specifications:

Bacterial Retention

Samples were qualitatively rechecked at a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 CFU/cm² using HIMA methodology.

USP Bacterial Endotoxins

A capsule aqueous extraction containing 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 (1.10 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 (9.66 mbar) in 70/30% IPA/water mixture at 23 °C.

Samples exhibited a HydroCoil Test value less than or equal to 0.25 ml/min per capsule at 38 psig (2.620 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 1.5 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 Fichell

Biopharmaceutical Quality Manager