

Opticap™ XL Capsule Filter with Aervent® Membrane

0.2 µm Rated
Catalogue Number: KTGRA04TT3
Lot Number: C6BN49578

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.

Millipore and Aervent are registered trademarks of Millipore Corporation.
Opticap is a trademark of Millipore Corporation.
P75410 Rev D 12/04

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 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 14 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
BioPharmaceutical Quality Manager

MILLIPORE