

Opticap™ XL Capsule Filter with Milligard® Media

0.5/0.2 µm Nominal Rated
Catalogue Number: KWSSA10HH1
Lot Number: C8AN47640

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.

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:

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 from Milligard cartridges used in this lot were found to be integral as measured by an aerosol challenge test.

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 30.2 psid (2.08 bar) at 10.0 gpm (37.8 L/min) per capsule with clean water at 23 °C.

USP Oxidizable Substances

Effluent was negative after a water flush of 5 L per autoclaved capsule.

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 55 mg per capsule after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature.

Quality Performance Criteria

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

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.

Non-Fiber Releasing

This product was manufactured with a Millipore media combination which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).

Multiple Sterilization Cycles

Capsule integrity was maintained after 3 autoclave cycles of 30 minutes at 121 °C.

Indirect Food Additive

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.


Peter Eichert
BioPharmaceutical Quality Manager

MILLIPORE