Opticap® XL Capsule Filter with Milligard® Media

0.5/0.2 µm Nominal Rated
Catalogue Number: KWSSA10TT1
Lot Number: C9NN45642

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 Millipore media combination 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.

Indirect Food Additive

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

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 sample aqueous extraction contains less than 0.5 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Structural 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 10.2 psid (702 mbar) at 10.0 gpm (37.8 L/min) with clean water at 23° C.

USP Oxidizable Substances

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

Quality Performance Criteria

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

Toxicity

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

Gravimetric Extractables

The extractables level was equal to or less than 55 mg per sample after 24 hours in ASTM® Type I reagent-grade water at controlled room temperature.

Multiple Sterilization Cycles

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

Peter Eichert
Quality Manager

Millipore, Milligard and Opticap are registered trademarks of Millipore Corporation.
ISO is a registered trademark of the International Organization for Standardization.
ASTM is a registered trademark of the American Society for Testing and Materials.
P72039 Rev D 03/09

MILLIPORE