

**Sterile Opticap® XL 5 Capsule Filter**  
with Millipore Express® SHC Hydrophilic Membrane

0.5/0.2 µm Rated  
Catalogue Number: KHGES05TH1  
Lot Number: C9KN35706  
Manufacturing Date: 08/09  
Expiration Date: 08/11

**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 which 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 Express SHC 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 <88> Biological Reactivity Tests for Class VI Plastics.

**100% Integrity Testing in Manufacturing**

Each unit must pass the Millipore Integrity Test correlated to the *Brevundimonas diminuta* ASIM® 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.

**Indirect Food Additive**

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

**Alcohol Reference Test**

Sterilizing-grade (0.22 µm) hydrophilic Millipore Express SHC membrane is certified to a bubble point equal to or greater than 18.5 psig (1276 mbar) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

**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 383 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practices to ensure safe use. In compliance with Article 383 of this Pressure Equipment Directive, this product does not bear the CE mark.

Millipore, Millipore Express 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.

03/02

Rev J

P3559C

**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 0.25 EU/ml as determined using the Limulus Amebocyte Lysate (LAL) test.

**Integrity**

Samples exhibited a water bubble point equal to or greater than 18.0 psig (1267 mbar) with air at 23° C.

Samples exhibited an air diffusional flow rate of less than or equal to 14.0 cc/min at 40 psig (2758 mbar) in water at 23° C.

**Flow Rate and Pressure Drop**

Samples met a maximum pressure drop of 6.4 psid (441 mbar) at 7.0 gpm (7.6 L/min) with clean water at 23° C.

**USP Oxidizable Substances**

Effluent meets the requirements for USP Sterile Water for Injection after a water flush of 2 L per autoclaved sample.

**Bacterial Retention**

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of  $1 \times 10^7$  CFU/cm<sup>2</sup> using ASTM F838 methodology.

**Thermal and Hydraulic Stress**

Samples were autoclaved at 123° C for 60 minutes and maintained integrity after a forward stress to 100 psid (6895 mbar) and a reverse stress to 30 psid (2069 mbar).

**TOC/Conductivity**

Samples exhibited less than 500 ppb TOC per USP <643> and less than 1.3 US/cm per USP <645> after autoclaving and a WFI water flush of 9.5 L at 25° C.

**Sterility**

Meets current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.

**Quality Performance Criteria**

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

**Toxicity**

This product meets the requirements of the USP <88> Safety Test utilizing 0.9% Sodium Chloride extraction.

This product is non-cytotoxic per USP Cytotoxicity MEM Elution Test.

**Multiple Sterilization Cycles**

Sample integrity was maintained after 3 autoclave cycles of 60 minutes at 123° C.

**Maximum Differential Pressure**

80 psi (5516 mbar) continuous  
100 psi (6895 mbar) intermittent

Peter Eichert  
Quality Manager



TM