

**Opticap® XLT 30 Capsule Filter**  
with Millipore Express® SHC Hydrophilic Membrane

0.5/0.2 µm Rated

Catalogue Number: KHGEA3T11

Lot Number: C9JN12844

**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 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* ASTM F638 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 (12/6 mbar) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

**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 FU/ml, as determined using the Limulus Amebocyte Lysate (LAL) test.

**Integrity**

Samples exhibited a water bubble point equal to or greater than 58.0 psig (4000 mbar) with air at 23° C.

Samples exhibited an air diffusional flow rate of less than or equal to 84.5 cc/min at 40 psig (2758 mbar) in water at 23° C.

**Flow Rate and Pressure Drop**

Samples meet a maximum pressure drop of 1.1 psid (7.6 mbar) at 2.0 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 6 L per autoclaved sample.

**Bacterial Retention**

Samples were qualitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of  $1 \times 10^7$  CFU/cm<sup>2</sup> using ASTM F638 methodology.

**Thermal and Hydraulic Stress**

Samples were steamed at 135° C for 30 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 µS/cm per USP <645> after autoclaving and a WFI water flush of 60 L at 25° C.

**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 128° C.

**Maximum Differential Pressure**

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

Peter Eichert  
Quality Manager



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