

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

0.5/0.2 µm Rated

Catalogue Number: KHGEA3THH1

Lot Number: C7MNO0694

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

### 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.

### Alcohol Reference Test

Sterilizing-grade (0.2µm) hydrophilic Millipore Express SHC 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.

## 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  $1 \times 10^7$  CFU/cm<sup>2</sup> using HIMA methodology.

### USP Bacterial Endotoxins

A capsule aqueous extraction contains less than 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

### Integrity

Samples tested on an automated integrity tester 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.

### Thermal and Hydraulic Stress

Cartridge samples were steamed at 135 °C for 30 minutes and maintained integrity after a forward stress to 100 psig (6895 mbar) and a reverse stress to 30 psig (2069 mbar).

### Flow Rate and Pressure Drop

Capsule samples met a maximum pressure drop of 1.4 psid (97 mbar) at 2.0 gpm (7.6 L/min) per capsule 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 liters per autoclaved capsule.

### 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 liters at 25 °C.

## Quality Performance Criteria\*

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

### Multiple Sterilization Cycles

Capsule integrity was maintained after 3 autoclave cycles of 60 minutes at 126 °C.

### Maximum Differential Pressure

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

### Toxicity

Component materials were tested and meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

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

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

### Indirect Food Additive

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.182.

### Non-Fiber Releasing

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



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# MILLIPORE