

Opticap® XT 30 Capsule Filter
with Millipore Express® SHC Hydrophobic Membrane

0.5/0.2 µm Rated
Catalogue Number: K11GEASTT1
Lot Number: C9KN12847

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 <68> Biological Reactivity Tests for Class VI Plastics.

100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test correlated to the *Brevundimonas diaziuta* ASTM® 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) hydrophobic 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.

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 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 (2756 mbar) in water at 23° C.

Flow Rate and Pressure Drop

Samples met 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 quantitatively retentive of a minimum *Brevundimonas diaziuta* challenge concentration of 1×10^7 CFU/cm² using ASTM F838 methodology.

Thermal and Hydraulic Stress

Samples were steamed at 155° 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 <68> 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 126° C.

Maximum Differential Pressure

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



Peter Eichert
Quality Manager

