Gamma Opticap® XL 3 Capsule Filler with Millipore Express® SHF Hydrophilic Membrane

0.2 µm Rated
Catalogue Number: KGEPG03HH3
Lot Number: C9NN60559

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 SHF 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® 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 SHF 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.

Gamma-Radiation Sterilizability
This product is compatible with gamma radiation. Validation confirmed that sample integrity and performance characteristics are maintained after a gamma radiation dose of 45 kGy.

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.

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ISO is a registered trademark of The International Organization for Standardization.
ASTM is a registered trademark of the American Society for Testing and Materials.
P33550 Rev K 10/09

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 9.5 cc/min at 40 psig (2758 mbar) in water at 23° C.

Flow Rate and Pressure Drop
Samples met a maximum pressure drop of 6.5 psid (448 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 1 L per autoclaved sample.

Bacterial Retention
Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 CFU/cm^2 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 µS/cm per USP <645> after autoclaving and a WFI water flush of 3.5 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 123° C.

Maximum Differential Pressure
80 psi (5516 mbar) continuous
100 psi (6895 mbar) intermittent

Lauren LeClair
Quality Manager

MILLIPORE