

**Gamma Opticap® XL300 Capsule Filler
with Millipore Express® SHF Hydrophilic Membrane**

0.2 µm Rated
Catalogue Number: KGERG003FF3
Lot Number: C9JN16871

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 USP <88> Biological Reactivity Tests for Class VI Plastics.

100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test conformed 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 (0.2 µm) hydrophilic Millipore Express SHF membrane is certified to a bubble point equal to or greater than 18.5 psig (127.6 mbar) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

Gamma Radiation Compatibility

This product is compatible with gamma radiation. Validation confirmed that capsule integrity and performance characteristics are maintained after a gamma radiation dose of 45kGy.

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 practice to ensure safe use. In compliance with Article 383 of this Pressure Equipment Directive, this product does not bear the CE mark.

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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 0.7% 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 (551.6 mbar) continuous
100 psi (689.5 mbar) intermittent

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 2.8 cc/min at 4.0 psig (27.58 mbar) in water at 23° C.

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 5.0 psid (34.5 mbar) at 0.5 gpm (1.9 l/min) with clean water at 23° C.

Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1 x 10⁷ CFU/cm² using ASTM F838 methodology

TOC/Conductivity

Samples exhibited less than 500 ppb IOC per USP <643> and less than 1.3 µS/cm per USP <645> after gamma irradiation and a WI water flush of 2.5 l at 25° C.

Hydraulic Stress

Samples maintained integrity after a forward stress to 100 psid (689.5 mbar) and a reverse stress to 30 psid (2069 bar).

Peter Eichert
Quality Manager

