

Millipak® Gamma Gold Filter Units

0.22 µm Rated

Catalogue Number: MPGL04GF2

Lot Number: C9KN37686

Manufacturing Date: 08/09

Expiration Date: 08/11

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 Durapore® 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 Class VI Biological Test for Plastics.

Alcohol Reference Test

Sterilizing-grade (0.22 µm) hydrophilic Durapore membrane is certified to a bubble point equal to or greater than 18.5 psig (1280 mbarg) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test correlated to the *Brevundimonas diminuta* ASTM® F838 bacterial challenge test.

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 1×10^7 CFU/cm² using ASTM F838 methodology.

Sterility

Meets current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.

USP Bacterial Endotoxins

A filter aqueous extraction contains less than 0.5 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Integrity

Samples exhibited a water bubble point equal to or greater than 50.0 psig (3450 mbarg) with air at 23° C.

Hydraulic Stress

Samples maintained integrity after a forward stress to 60 psid (4.1 bard) and 45 pulses at 60 psid (4.1 bard).

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 10.0 psid (690 mbard) at 0.26 gpm (1.0 L/min) per filter unit with clean water at 25° C.

USP Oxidizable Substances

Affluent was negative after a water flush of 200 mL per autoclaved filter unit.

Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

Toxicity

This product is non-toxic per the current USP General (Mouse) Safety Test.

Gravimetric Extractables

The extractables level was equal to or less than 1.5 mg per filter unit after a 200 mL flush and 24 hours in ASTM Type 1 reagent-grade water at controlled room temperature.

Multiple Sterilization Cycles

Integrity was maintained after 3 autoclave cycles of 90 minutes at 123° C.

Peter Eichert

Quality Manager



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