

# Millipak® Gamma Gold Filter Units

0.1 µm Rated

Catalogue Number: MPV11GCF3

Lot Number: C9JN26317

Manufacturing Date: 07/09

Expiration Date: 07/11

## 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.

## 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  $1 \times 10^7$  CFU/cm<sup>2</sup> 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 70.0 psig (4800 mbar) with air at 23° C.

### Hydraulic Stress

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

### Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 12.5 psid (862 mbar) at 0.34 gpm (1.3 L/min) per filter unit with clean water at 25° C.

### USP Oxidizable Substances

Effluent 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 2.5 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

