

## Millidisk® Hydrophilic Filter Unit

0.22 µm Rated  
Catalogue Number: MCGL10S03  
Lot Number: C6EN57430

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which meets or exceeds FDA Device Good Manufacturing Practice standards.

### ISO 9000 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 9000 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* HIMA 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 HIMA methodology.

### USP Bacterial Endotoxins

A cartridge 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 12.5 psid (860 mbard) at 1.0 gpm (3.8 L/min) per cartridge with clean water at 25 °C.

### USP Oxidizable Substances

Effluent was negative after a water flush of 200 mL per autoclaved cartridge.

## 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 cartridge after 24 hours in ASIM® Type 1 reagent-grade water at controlled room temperature.

### Multiple Sterilization Cycles

Integrity was maintained after 5 steam-in-place cycles of 60 minutes at 135 °C.

  
Peter Eichart  
BioPharmaceutical Quality Manager

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