

# Opticap® Capsule with Hydrophilic Durapore® Membrane

0.22 µm Rated

Catalogue Number: KYGLO4NP3

Lot Number: C9NIN47487

## 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.

## 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.

## 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 the stability of the process.

## 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.

### USP Bacterial Endotoxins

A capsule 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.

### Thermal and Hydraulic Stress

Samples were autoclaved at 126° C and maintained integrity after a forward stress to 80 psid (5.5 barg) and a reverse stress to 40 psid (2.8 barg).

### Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 11.4 psid (786 mbarg) at 2 gpm (7.6 L/min) per capsule with clean water at 25° C.

### USP Oxidizable Substances

Affluent was negative after a water flush of 500 mL per autoclaved capsule.

## Quality Performance Criteria

This product was designed and manufactured to meet the following specifications:

### 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 10.0 mg per capsule after 24 hours in ASTM Type 1 reagent-grade water at controlled room temperature.

### Multiple Sterilization Cycles

Integrity was maintained after 3 autoclave cycles of 60 minutes at 126° C.

Peter Eichert  
Quality Manager



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