

Millipak® 40 Gamma Gold Capsule Durapore® Membrane

Hydrophilic 0.22 µm Rated
REF MPGL04GK2
LOT NO. C9AA80699
Expiration Date: Jan 2021

Good Manufacturing Practices

This product was manufactured in a facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

Quality Design and Performance Criteria Animal Origin Statement

Based on the current information from our suppliers, all component materials used in the manufacture of this device are animal free.

Non-Fiber Releasing

This product was manufactured with a Durapore membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).

Alcohol Reference Test

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

Toxicity

Component materials meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. These products meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.

Gravimetric Extractables

The extractables level was equal to or less than 1.5 mg per sterilized device after a 200 mL flush and 24 hours in water at controlled room temperature.

Multiple Sterilization Cycles

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

Quality Lot Release Criteria Bacterial Retention

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

Sterile Statement

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

USP Bacterial Endotoxins

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

100% Integrity Testing in Manufacturing

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

Integrity

Samples exhibited a water bubble point equal to or greater than 50.0 psi (3450 mbar) using air as a test gas at 23 °C.

Hydraulic Stress

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

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 10.0 psi (689 mbar) at 0.26 gpm (1.0 L/min) per device with water at 25 °C.

USP Oxidizable Substances

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



Fuad Ashour
Quality Manager
Manufacturing Site: Jaffrey, NH