

Millidisk® 40 Cartridge Durapore® Membrane

Hydrophilic 0.45 µm Rated
CAT. NO. MCHL40S03
LOT NO. C0AB19751
Manufacture Date: Jan 2020

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 either animal free or in compliance with EMA/410/01.

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).

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 10 mg per sterilized device after 24 hours in water at controlled room temperature.

Multiple Sterilization Cycles

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

Quality Lot Release Criteria

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.

Integrity

Samples exhibited a water bubble point equal to or greater than 26.0 psi (1790 mbar) using air as a test gas at 23 °C.

Hydraulic Stress

Samples maintained integrity after sterilization and 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 5.0 psi (340 mbar) at 4.0 gpm (15 L/min) per device with water at 25 °C.

USP Oxidizable Substances

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



Fuad Ashour
Quality Manager
Manufacturing Site: Jaffrey, NH