

Millipak® Filter Unit

5.0 µm Rated

Catalogue Number: MPSL06CL1

Lot Number: C9MN41128

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.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

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 2.0 psig (140 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 10.0 psid (690 mbard) at 1.2 gpm (4.5 L/min) per filter unit with clean water at 25° C.

USP Oxidizable Substances

Affluent 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.



Peter Eichert

Jaffrey Quality Manager

