Millipak® Filter Unit

5.0 µm Rated
Catalogue Number: MPSL06CB1
Lot Number: C8SN10809

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
Effluent 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.

B. Weber

Brigette Weber
Molsheim Quality Manager

Peter Eichert
Jaffrey Quality Manager

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