

Millistak +[®] Mini

Grade 65 of
Series DE Depth Filter
Catalogue Number: M65DE23HH3
Lot Number: xxxxxxxx

Good Manufacturing Practices

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

ISO 9000 Quality Standard

This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI – 70 °C Biological Test for Plastics.

Indirect Food Additives

All component materials meet the applicable sections of the FDA Indirect Food Additive Requirements cited in 21 CFR 176-186.

Quality Assurance Lot Release Criteria

The filter material used in this manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

USP Bacterial Endotoxins

An aqueous extraction contained less than 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Flow Rate and Pressure Drop

Samples met the required flow rate of 67.7 – 122 L/min/m² when tested at a differential pressure of 110 psi (690 mbar) with clean water at 23 °C.

Thickness

Samples measured met the required thickness of 0.125–0.145 inches.

Basis Weight

The basis weight of samples tested were within 882-1320 g/m².

Ash Content

Ash content was determined to be 48-58%.

Wet Tensile Strength

Wet tensile strength of the samples tested was \geq 10 lb./in.

Quality Performance Criteria

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

USP Oxidizable Substances

The effluent meets the requirements of the USP Sterile Water For Injection Oxidizable Substances Test after a water flush of 5 L per square foot of media.

Autoclavability

Integrity was maintained after one autoclave cycle of 60 minutes at 123 °C.



Peter Eichert
BioPharmaceutical Quality Manager