

Millistak+® Mini

Grade B1 of
Series HC Depth Filter
Catalogue Number: MB1HC23HH3
Lot Number: C9NN51379

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 Biological Test for Plastics.

Indirect Food Additives

All component materials meet the FDA Indirect Food Additive Requirements cited in 21CFR 177-186.

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

Media samples met a pressure drop versus flow rate specification that correlates to a capsule flow rate of 21.9-36.3 L/min/m² at 10 psid (690 mbar) with clean water at 23 °C.

Thickness

Samples measured met the required thickness
Media Layer 50DE: 0.125-0.145 in.
Media Layer 75DE: 0.125-0.145 in.

Basis Weight

The basis weight of samples tested were within
Media Layer 50DE: 851-1289 g/m².
Media Layer 75DE: 1000-1439 g/m².

Ash Content

Ash content was determined to be
Media Layer 50DE 49-59%.
Media Layer 75DE 46-56%.

Wet Tensile Strength

Wet tensile strength of the samples tested was
Media Layer 50DE: ≥ 10 lb/in.
Media Layer 75DE: ≥ 10 lb/in.

Quality Performance Criteria

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

Oxidizable Substances

Effluent was negative after a water flush of 5 L per square foot of media.

Multiple Sterilization Cycles

Integrity was maintained after 1 autoclave cycle of 60 minutes at 123 °C.



Peter Eichert
BioPharmaceutical Quality Manager