

## Millistak+® Mini

Grade B1 of  
Series HC Depth Filter  
Catalogue Number: MB1HC23HH3  
Lot Number: C9HN05194

### 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/m<sup>2</sup> 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/m<sup>2</sup>.  
Media Layer 75DE: 1000–1439 g/m<sup>2</sup>.

#### 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

