

# Millistak +<sup>®</sup> Mini

Grade: 45 of  
Series: DE Depth Filter  
Catalogue Number: M45DE23HH3  
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 21CFR 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 307–564 L/min/m<sup>2</sup> when tested at a differential pressure of 10 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 851–1289 g/m<sup>2</sup>.

### Ash Content

Ash content was determined to be 49-59%.

### Wet Tensile Strength

Wet tensile strength of the samples tested was ≥ 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