

## **OptiScale® Capsule Filter with Hydrophilic Durapore® Membrane**

Durapore 0.45/0.22 µm Rated

Catalogue Number: SHGLA47HH3

Lot Number: C9KN30501

### **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.

### **Indirect Food Additive**

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.182.

### **Quality Assurance Lot Release Criteria**

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

#### **Integrity**

Samples exhibited a water bubble point equal to or greater than 50.0 psig (3450 mbar) with air at 23 °C.

### **Quality Performance Criteria**

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

#### **Oxidizable Substances**

Effluent meets the requirements for USP Sterile Water for Injection after a water flush of 100 mL per autoclaved capsule.

#### **Toxicity**

Component materials were tested and meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

This product is non-toxic per the USP <88> Safety Test with 0.9% Sodium Chloride extraction procedure.

#### **Multiple Sterilization Cycles**

Capsule integrity was maintained after 3 autoclave cycles of 60 minutes at 126 °C.



Peter Eichert  
Quality Manager

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