

## **OptiScale™ Capsule Filter with Prefiltration and Clarification Media**

### **Media**

Polysep II 1.0/0.5 µm Nominal Rated

Catalogue Number: SGW6A47FH3

Lot Number: C9AN61397

### **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 Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

### **Indirect Food Additive**

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

### **Quality Performance Criteria**

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

### **Oxidizable Substances**

Filtrate 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 121 °C.



Peter Eichert  
BioPharmaceutical Quality Manager

**MILLIPORE**