

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

Durapore 0.45/0.22 µm Rated  
Catalogue Number: SHGLA47HH3  
Lot Number: C9EN05190

**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 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  
BioPharmaceutical Quality Manager

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P60210 Rev B 12/04