OptiScale™ Capsule Filter with Hydrophilic Durapore® Membrane

Durapore 0.22 µm Rated
Catalogue Number: SVGLA47HH3
Lot Number: C9CN89095

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.

Millipore and Durapore are registered trademarks of Millipore Corporation.
OptiScale is a trademark of Millipore Corporation.
P60210 Rev B 12/04

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

MILLIPORE