

OptiScale™ Capsule Filter with Prefiltration and Clarification

Media

Polysep II 1.0/0.2 µm Nominal Rated

Catalogue Number: SGW3A47HH3

Lot Number: C9HN05485

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

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 121 °C.



Peter Eichert
BioPharmaceutical Quality Manager

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