

**OptiScale® Capsule Filter with
Hydrophilic Millipore
Express® SHR Membrane**

Millipore Express SHR 0.5/0.1 µm Rated
Catalogue Number: SHVEA47HH3
Lot Number: C9AN58048

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.

Millipore, Millipore Express and OptiScale are registered trademarks of Millipore Corporation.
ISO is a registered trademark of the International Standards Organization.
P88060 Rev B 08/05

MILLIPORE

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
outcloved 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