Corning Incorporated Life Sciences

Registered ISO 9001:2008

Certificate of Compliance

Catalog Number: 431206

Lot Number: 15504002

Product Description: Corning® 1 Liter filter system, cellulose acetate membrane, 0.45 μM pore size,

500 mL funnel

Expiration Date:

An expiration date exists for this product. Please refer to the case label and the filter funnel for the expiration date for this product.

Component Materials:

Funnel, Funnel Lid & - Receiver/Storage

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and

closures.

Bottle

Funnel Adapter, Hose -

Connector & Plug

Seal Cap

Virgin High Density Polyethylene, meets *USP*, *Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Cellulose Acetate, 0.45 μM pore size

Filter Plug - Cellulose Acetate

Sterilization:

Membrane

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*Sterility Assurance Level: SAL 10⁻⁵

Pyrogens:

The product has been tested and has met the criteria established in the *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987).*

Results: less than 0.1 EU/mL

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:

Leak Test
Visual Attributes
Pass
Packaging

Results:
Pass
Pass
Pass
Pass

Wendy Lintsch

Wendy Loitsch Quality Manager

Rev No: 4