## Corning Incorporated Life Sciences

Registered ISO 9001:2008

## Certificate of Compliance

 Catalog Number:
 430512

 Lot Number:
 22705002

Product Description: Corning® 500 mL bottle top filter, 33 mm neck size, cellulose acetate membrane,

0.45 μM pore size

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

closures.

Funnel Adapter & Hose Connector Membrane 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

Gasket - Polyethylene Foam liner

Filter Plug - Cellulose Acetate

## Sterilization:

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<sup>-5</sup>

## 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:Results:Leak TestPassVisual AttributesPassPackagingPass

Wendy Lintsch

Wendy Loitsch Quality Manager

Rev No: 6