#### Corning Incorporated Life Sciences

#### Registered ISO 9001:2008

# Certificate of Compliance

Catalog Number: 431430

Lot Number: 06113001

Product Description: Corning® 150 mL Square Polycarbonate Storage Bottle, with cap

#### Lot Number Designation:

This production lot has been uniquely identified with an 8 digit lot number as follows: First 3 digits - Julian date; Next 2 digits - last 2 digits of year of manufacture; Last 3 digits - Batch identification.

### **Component Materials:**

Bottle - Virgin Polycarbonate, meets USP, Class VI requirements for plastic containers and

closures.

Cap - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and

closures. Heavy metal free (meets *CONEG* req.) color concentrate.

#### 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

# **Performance Testing:**

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

Bulsall

Arthur D. Birdsall

**Quality Assurance Manager** 

Rev No: 4