

Corning Incorporated  
Life Sciences

Registered  
ISO 9001:2008

# Certificate of Compliance

**Catalog Number:** 431431

**Lot Number:** 21513003

**Product Description:** Corning® 250 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 <i>USP, Class VI</i> requirements for plastic containers and closures.   |
| Cap    | - Virgin Polypropylene, meets <i>USP, Class VI</i> requirements for plastic containers and closures. Heavy metal free (meets <i>CONEG</i> 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 Test	Pass
Visual Attributes	Pass
Packaging	Pass



Arthur D. Birdsall  
Quality Assurance Manager

Rev No: 4