Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Certificate of Compliance

Catalog Number: 431432

Lot Number: 18712001

Product Description: Corning® 500 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^{-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

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

Art Birdsall

Arthur D. Birdsall
Quality Assurance Manager

Rev No: 4