

Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 431432

Product Description: Corning® 500 mL Square Polycarbonate Storage Bottle, with cap

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. |

Product Dimensions:

- | | | | | | |
|--------------------------|---|--------------|--------------------------|---|----------|
| Height of bottle w/cap | - | 6.99 in. | O.D.(neck) incl. Threads | - | 1.73 in. |
| Height of bottle w/o cap | - | 6.89 in. | I.D. (neck) | - | 1.49 in. |
| Tolerances | - | +/- 0.05 in. | | | |

Sterilization:

This product 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)*.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Integrity Testing: Forward pressurization of the product to 39 inches of water column.

Visual Attributes: Visual examination of the product.

Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

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.

Rev No: 5