

Product Description

Catalog Number: 431433

Product Description: Corning® 1000 mL Square Polycarbonate Storage Bottle, with cap

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.

Product Dimensions:

- | | | | | | |
|--------------------------|---|--------------|--------------------------|---|----------|
| Height of bottle w/cap | - | 8.68 in. | O.D.(neck) incl. Threads | - | 1.73 in. |
| Height of bottle w/o cap | - | 8.50 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 10⁻⁶

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: 6