

## Product Description

**Catalog Number:** 431433

**Product Description:** Corning® 1000 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	-	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<sup>-6</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)*.

**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.
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Visual Attributes:	Visual examination of the product.
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Packaging:	Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.
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**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