Corning Incorporated Life Sciences

> <u>Registered</u> ISO 9001

# **Product Description**

Catalog Number:	431430			
Product Description:	Corning® 150 mL Square Polycarbonate Storage Bottle, with cap			
Component Materials: Bottle - Cap -	Virgin Polycarbonate, meets <i>USP, Class VI</i> requirements for plastic containers and closures. Virgin Polypropylene, meets <i>USP, Class VI</i> requirements for plastic containers and closures. Heavy metal free (meets <i>CONEG</i> req.) color concentrate.			
<b>Product Dimensions:</b> Height of bottle w/cap Height of bottle w/o cap Tolerances	- 3.92 in. - 3.75 in. - +/- 0.05 in.	O.D.(neck) incl. Threads I.D. (neck)	-	1.73 in. 1.49 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.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