

**Catalog Number:** 11665

**Product Description:** Corning® 500mL Storage Bottle, with accessories and dip tube, Non-pyrogenic

**Component Materials:**

- Bottle - Virgin Polystyrene, 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 requirements) color concentrate.
- Accessories:**
  - Tubing - Chemically resistant, heat sealable, Thermoplastic Elastomer, meets USP, Class VI requirements for containers and closures.
  - Connector - Polypropylene, meets USP Class VI requirements for plastic containers and closures.
  - Filter - 25mm/ 0.2µm Acrylic Proprietary formulation, meets USP Class VI requirements for Biological Plastics.
  - dip tube - High Density Polyethylene, meets USP, Class VI requirements for plastic containers and closures.
  - Reducer - Polypropylene, meets USP, Class VI requirements for plastic containers and closures.
  - Luer Locks - Polypropylene, meets USP, Class VI requirements for plastic containers and closures.

**Product Dimensions:**

Length of Bottle	-	5.44 in.	Width of Bottle	-	3.70 in.
Inner Diameter (neck)	-	1.52 in.	Outer Diameter (neck)	-	1.64 in.
Tolerances	-	+/-0.05 in.			

**Animal Content** – Product does not contain materials of animal origin.

**Non-Pyrogenic** – Tested and met the criteria established in the current version of ANSI/AAMI ST 72, “Bacterial Endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing” and USP <85> “Bacterial Endotoxin Test”. The acceptance level for product is  $\leq 0.5$  EU/mL or  $\leq 20$  EU/device.

**Sterilization** – Product has been sterilized and dosimetrically released per the requirements ANSI/AAMI/ISO 11137 “Sterilization of health care products- Radiation”. Products meet a minimum Sterility Assurance Level (SAL) of  $10^{-6}$ .

**Sterility** – Products labeled Sterile Fluid Path have been designed to ensure sterility of the portion of the product intended for contact with fluids.

**Quality Control Testing** – Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

**Lot Number Designation -**

8 Digit Lot Number: First 3 digits – Julian date, start of manufacturing; Next 2 digits – Year of manufacture; Last 3 digits – Batch identification.