

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 11656

Product Description: Corning® 250mL Storage Bottle, with accessories and diptude, MPC

Component Materials:

- Cap - High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Bottle - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.

Accessories:

- Tubing - Thermoplastic Elastomer, meets *USP, Class VI* requirements for plastic containers and closures.
- Diptube - High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Filter - 50mm/0.2µm Polytetrafluoroethylene (PTFE), meets *USP, Class VI* requirements for Biological Plastics.
- MPC Connector/Plug - Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

- Length of bottle - 4.62 in.
- Inner Diameter (neck) - 1.52 in.
- Tolerances - +/- 0.05 in.
- Width of bottle - 2.90 in.
- Outer Diameter (neck) - 1.64 in.

Sterilization:

The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*.
Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

The Storage Bottle only has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: *Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing*.
Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest version of EMEA 410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:

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

Integrity Testing: Pull Force test of the accessory to 10lbs.

Visual Attributes: Visual examination of the product.

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

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year.

Rev No: 1