Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 11665

Product Description: Corning® 500mL Storage Bottle, with accessories and diptube

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* req.) color concentrate.

Accessories:

Tubing	-	C-Flex, Thermoplastic Elastomer, meets *USP, Class VI* requirements for plastic containers and closures.
Connector	-	Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.
Filter	-	25mm/ 0.2µm Acrylic/ Versapor filter with female luer lock inlet and male luer lock outlet, meets *USP, Class VI* requirements for Biological Plastics.
Diptube	-	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.

Product Dimensions:

Length of bottle	-	5.44 in	Inner Diameter (neck)	-	1.52 in
Outer Diameter (neck)	-	1.64 in	Width of bottle	-	3.70 in
Tolerances	-	+/- 0.05 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 product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies,routine monitoring, and alternative to batch testing.* Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
The product is manufactured and packaged with animal free materials..

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 - Batch Identification.

Rev No: 3