Corning Incorporated
Life Sciences
Registered
ISO 9001

Product Description

Catalog Number: **11650**

Product Description: **Corning® 150mL Storage Bottle, with accessories and dip tube, MLL, Non-pyrogenic**

Component Materials:

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

Accessories:

Tubing	-	Chemically resistant, heat sealable, Thermoplastic Elastomer, meets USP, Class VI requirements for containers and closures.
dip tube	-	High Density Polyethylene, 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 Proprietary formulation, meets USP Class VI requirements for Biological Plastics
Luer Connector	-	Polypropylene, meets USP Class VI requirements for plastic containers and closures.

Product Dimensions:

Length of Bottle	-	3.99 in.	Width of Bottle	-	2.50 in.
Inner Diameter (neck)	-	1.52 in.	Outer Diameter (neck)	-	1.64 in.
Tolerances	-	+/-0.05 in.			

BSE/TSE – Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

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.