

CORNING B.V. - Life Sciences
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Product Name	: STORAGE BOTTLE, 250 mL, 31.7mm HDPE SCREW CAP, PET, S, BK, 24/TRA		
Catalog Number	: 431732	Manufacture Date	: 2021-04-01
Lot ID	: 781183		
Expiration Date	: 2024-04-01		

Quality Management System - Complies with the current version of the ISO 9001 Standard.

Animal Content - Product does not contain materials of animal origin.

Non-Pyrogenic - Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.1 EU/ml.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

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

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

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



ANDREW J (ANDY) FRANKS
CMO Quality Manager