

Certificate of Compliance

CORNING B.V. - Life Sciences **FOGOSTRAAT 12** 1060 LJ AMSTERDAM The Netherlands www.corning.com/lifesciences Refer to website for regional contact information

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STORAGE BOTTLE, 125 mL, 31.7mm HDPE SCREW CAP, PET, S, BK, 24/TRA Product Name

Catalog Number 431731 Manufacture Date : 2023-02-01

Lot ID 846033

Expiration Date 2026-02-01

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

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