

836 North Street - Life Sciences

Tewksbury MA 01876 USA

www.corning.com/lifesciences

Refer to website for regional contact information.

Product Name	: BOTTLE, 1000mL, PET, 45mm ORANGE CAP, S, IND WRAPPED, 12/24
Catalog Number	: 431533
Lot ID	: 16621011
Expiration Date	: 2024-06-15
Manufacture Date	: 2021-06-15

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 - Validated per FDA guidelines on Pyrogen and Endotoxins testing. The acceptance level for product is ≤ 0.1 EU/ml.

Cytotoxicity - All fluid path materials are 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" or related ISO 10993 standards.

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
Dimensional testing-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