

836 North Street - Life Sciences  
Tewksbury MA 01876 USA  
www.corning.com/lifesciences  
Refer to website for regional contact information.

Page: 1 / 1

<b>Product Name</b>	: BOTTLE, 250mL, PET, 45mm ORANGE CAP, S, IND WRAPPED, 12/24		
<b>Catalog Number</b>	: 431531	<b>Manufacture Date</b>	: 2022-03-03
<b>Lot ID</b>	: 06222001		
<b>Expiration Date</b>	: 2025-03-01		

**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** - Validated per FDA guidelines on Pyrogen and Endotoxins testing. The acceptance level for product is  $\leq 0.1$  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

- 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