

CORNING GOSSELIN SAS
123 Rue de Caëstre - CS40019
59529 HAZEBROUCK CEDEX
BORRE - FRANCE
www.corning.com/lifesciences
Refer to website for regional contact information

Date of certificate : 2023 - 08 - 21

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Product description

Octagonal bottle, 500 ml PET na graduated H180 Ø31 & tamper-evident screw cap na, 12/filmed pack, STERILE R

Catalogue number

431733

Manufacturing date

2022/10/01

Lot number

835017

Quality Management System

Complies with the current version of the ISO9001 standard.

Raw material statement

The Substances Bisphenol A, BSE / TSE, latex, and phthalates are not used or intentionally incorporated in the manufacture of the raw materials or final product.

Sterility Assurance Level

This product is sterilized using an irradiation method compliant with the requirements of ANSI/AAMI/ISO 11137 to achieve a Sterility Assurance Level (SAL) of 10⁻⁶

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 less than 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."

Expiration date

2025/10/01

Expiration statement

This product is designed to have an expiration date of 3 years from the date of manufacture regarding sterility.

Performance testing (AQL)

Inspection based on a statistically significant number of samples towards to internal or agreed specifications that determine Assurance Quality Level.

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



Sandra Bianchi
Plant Quality Manager, Borre
BianchiS@corning.com