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Refer to website for regional contact information

Date of certificate : 2022 - 12 - 28

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### Product description

Octagonal bottle, 125 mL PET na graduated H115 Ø31 & tamper-evident screw cap na, 24/filmed pack, STERILE R

### Catalogue number

431731

### Manufacturing date

2022/10/01

### Lot number

831001

**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<sup>-6</sup>

### 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



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