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Date of certificate : 2025 - 03 - 04

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Product description

Octagonal bottle, 1000 mL graduated H214 Ø31 & tamper-evident screw cap na, 12/filmed pack, STERILE R

Catalogue number

431734

Manufacturing date

2025/01/01

Lot number

915725

Quality Management System

Complies with the current version of the ISO9001 standard.

Sterility Assurance Level

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.

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is No More Than 0.10 EU/ml or No More Than 4 EU/device.

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."

BSE/TSE : Product complies with the latest revision of EMA/410/10 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Quality Control Testing : Representative production samples are collected and inspected in accordance with current applicable product specifications. Key inspections and inline tests are listed below:

Visual Inspection - Pass
Packaging Inspection - Pass
Leak Test - Pass

Expiration date

2028/01/01

Expiration statement

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

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



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