

Product Description

Catalog Number: 431419

Product Description: Corning® 2 mL cryogenic vial, internally threaded, round bottom, self-standing, Green Cap

Component Materials:

- Vial - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Cap - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Washer - Silicone, meets *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

Length of vial w/cap	-	1.91 in.	Diameter of cap	-	0.47 in.
Diameter of vial	-	0.50 in.	Tolerances	-	+/- 0.05 in.

Sterilization:

This lot has been irradiated and dosimetrically released based on current version of ANSI/AAMI/ISO 11137 *Sterilization of healthcare products- Requirements for validation and routine control-Radiation sterilization*.
Sterility Assurance Level: SAL 10⁻⁵

BSE/TSE:

Product complies with the latest revision of EMA/410/01 “Note for Guidance on minimising 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.

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

Non-Pyrogenic:

The product has been tested and has met the criteria established in current version of ANSI/AAMI ST 72 *Bacterial endotoxins - Test methodologies, routine testing, and alternative to batch testing*. Results: less than 0.1 EU/mL

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

- Visual Attributes: Visual examination of the product.
- Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits – Batch Identification.