

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 431386

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

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 the *Sterilization of healthcare products- Requirements for validation and routine control-Radiation sterilization*.
Sterility Assurance Level: SAL 10⁻⁵

RNase/DNase Testing:

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

Pyrogens:

The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: *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 - Run number for that year.

Rev No: 2