

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 430662

Product Description: Corning® 4 mL cryogenic vial, externally 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 with cap | - | 3.00 in. | Diameter of cap | - | 0.54 in. |
| Diameter of vial | - | 0.50 in. | Tolerances | - | +/- 0.05 in. |

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (TIR 33) *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

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

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: 7