

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Certificate of Compliance

Catalog Number: 431417
Lot Number: 21214001
Product Description: Corning® 2 mL cryogenic vial, internally threaded, round bottom, self-standing, Yellow 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.

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

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

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:	Results:
Visual Attributes	Pass
Packaging	Pass

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.

Expiration Statement:
This product has an expiration date of 3 years from the date of manufacture for the attributes contained within this certificate.



Viviana Niño
Quality Supervisor

Rev No: 2