

REGISTERED
ISO 9001:2000
CORNING INCORPORATED
LIFE SCIENCES
MANUFACTURING

Corning Incorporated Certificate of Compliance

Catalog Number: 430663
Lot Number: 04607003
Product Description: Corning® 5 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.

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 the *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987)*. Results: less than 0.1 EU/mL

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.

Viviana Niño
Quality Supervisor

Rev No: 7