Corning Incorporated Life Sciences

> Registered ISO 13485

Product Description

Catalog Number:	430492	
Product Description:	Corning ${ m I\!R}$ 5 mL cryogenic vial, internally th	readed, round bottom
Component Materials: Vial -	Virgin Delymony dense maste UCD Clease VI requirements for plastic containers and	
Cap -	Virgin Polypropylene, meets <i>USP</i> , <i>Class VI</i> requirements for plastic containers and closures. Heavy metal free (meets <i>CONEG</i> req.) color concentrate.	
Washer -	Cilianna manta LICD Class VI manusimamanta	for plastic containers and closures.
Product Dimensions: Length of vial w/cap Diameter of vial	- 3.50 in. Diameter of ca - 0.50 in. Tolerances	ap - 0.47 in. - +/- 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

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

BSE/TSE:

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 condition 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 - Batch identification.

Rev No: 8