CORNING

Certificate of Compliance

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

Product Name	:	Flask T225 TC Canted Plugseal		
Catalog Number	:	353139	**Manufacture Date**	: 2021-06-22
Lot ID	:	1152006		
Expiration Date	:	2026-05-25		

Quality Management System - Complies with the current version of the EN ISO 13485 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Non-Pyrogenic - Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85>,"Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.125 EU/ml or ≤ 5 EU/device.

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 90% confluency within 72 hours is required for acceptance.

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products - Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Cell Attachment & Growth Treatment Verification - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.

Emily D Roberts
Quality Manager