Corning Incorporated Life Sciences

Registered
ISO 9001:2008

Certificate of Compliance

Catalog Number: 431465

Lot Number: 34313003

Product Description: Corning® 150 cm^2 canted neck flask, anti-tip skirt, vent cap
Non-treated

Component Materials:

Flask - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.

Cap - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate. 0.2 µm microporous PTFE membrane, meets *USP, Class VI* requirements for plastic containers and closures.

Sterilization:
This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*
Sterility Assurance Level: SAL 10^{-5}

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 Animal Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987).*
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:
Leak Test	Pass
Visual Attributes	Pass
Packaging	Pass

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

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.

Revision Date:
7-22-11

Wendy Loitsch

Wendy Loitsch
Quality Manager

Rev No: 3