Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

10024 Catalog Number:

Product Description: Corning ® HYPERFlask ® Cell Culture Vessel, solid cap, CellBIND ® surface

Component Materials:

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and Flask

closures.

Virgin high density polyethylene, meets USP, Class VI requirements for plastic Cap

containers and closures. Heavy metal free (meets CONEG requirements) color

Polyethylene, meets *USP*, *Class VI* requirements for plastic containers and closures. Liner Film

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

Product Dimensions:

Length 8.009 in. I.D. (neck) 1.02 in. Width 4.809 in. O.D. (cap) 1.40 in. 1720 cm² Height (depth) 2.091 in. Growth surface

Tolerances +/- .005 in.

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization Sterility Assurance Level: SAL 10⁻⁶

This product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins - Test methodologies,routine testing, and alternative to batch testing. Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Surface Characterization:

Surface is characterized to be hydrophilic and negatively charged, composed of > 20% oxygen atoms. This surface composition has been optimized for cell attachment and growth.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth utilizing an attachment- dependent mammalian cell line in a serum supplemented media.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product is manufactured and packaged with animal free materials.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Forward pressurization of the product to 0.5 psi. Integrity Testing:

Cell Culture Treatment: Wettability test using water to insure the presence of a hydrophilic

surface.

Visual examination of the product. Visual Attributes:

Inspection for seal and barrier integrity, accurate labeling, and correct Packaging:

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: 7