Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 431303

Product Description: Corning® 850 cm^2 roller bottle, easy grip cap, 20/pk

Component Materials:

Bottle	-	Virgin Polystyrene, meets *USP, Class VI* requirements or 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.

Product Dimensions:

Length w/cap	-	10.73 in.	I.D. neck	-	1.64 in.
Outer diameter of bottle	-	4.60 in.	Tolerances	-	+/- 0.05 in.

Sterilization:
The product 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^{-6}

Pyrogens:
The 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: less than 0.1EU/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.

Surface Characterization:
Surface is characterized to be hydrophilic and negatively charged, composed of 9-17% 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.

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

Integrity Testing:	Forward pressurization of the product to 39 inches of water column.
Cell Culture Treatment:	Wettability test using deionized distilled water to insure the presence of a hydrophilic surface.
Visual Attributes:	Visual and microscopic 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.

Revision Date:
08-31-16

Rev No: 10

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