

Catalog Number: 431191

Product Description: Corning® 1700 cm² expanded surface roller bottle, easy grip vent cap, 20/pk

Component Materials:

- Bottle - 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.
0.2 µM microporous PTFE membrane. Heavy metal free (meets *CONEG* req.) color concentrate.

Product Dimensions:

- Length of bottle w/cap - 10.76 in. Inner diameter of 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 bottle and of the cap at molding stage to 39 inches of water column. Forward pressurization of the membrane seal to 10 inches of water column using an aqueous dye solution.

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: 11