

Catalog Number: 4615

Product Description: Corning® 100 x 20mm style Ultra Low Attachment, cell culture dish, with lid

Component Materials:

- Plate/Lid - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
Surface - Proprietary hydrogel.

Product Dimensions:

Outer Diameter of Dish	-	3.50 in.	Growth Surface Area	-	55 cm ²
Outer Diameter of Lid	-	3.65 in.	Growth Surface Diameter	-	3.30 in.
Height of dish with lid	-	0.82 in.	Tolerances of Dimensions	-	+/- 0.05 in.

Sterilization:

The product is 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 10⁻³

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing.* Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Surface Characterization:

Surface is characterized to be hydrophilic and neutrally charged, composed of a covalently bound hydrogel layer that is biologically inert and non-degradable. The surface composition has been optimized for cell attachment inhibition.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment inhibition utilizing an attachment- dependent mammalian cell line in a serum supplemented media. Cell attachment inhibition must be ≥ 98% as compared to a standard tissue culture treated surface.

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.

Performance Testing:

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

Visual Attributes: Visual 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:

06-18-20

Rev No: 1