Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 4515

Product Description: Corning ® Spheroid Microplate, 96-well, black clear round bottom, ultra low attachment, with Lid

Component Materials:

Plate walls	-	Medium Impact Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures. Black concentrate.
Plate bottom	-	Polystyrene, meets *USP, Class VI* requirments for plastic containers and closures.
Lid	-	Virgin Polystyrene, meets *USP, Class VI* requirments for plastic containers and closures.
Surface	-	Proprietary hydrogel.

Product Dimensions:

Length of Plate	-	5.034 in.	Diameter @ top of well	-	0.270 in
Width of Plate	-	3.365 in.	Well bottom radius	-	0.100 in.
Depth of Well	-	.492 in.	Well bottom elevation	-	0.073 in.
Tolerances of Dimensions	-	+/-. 010 in.	Height with Lid	-	0.650 in.
Working Volume per well	-	0.075 to 0.30 mL			

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^{-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)*

Optical Characteristics:
The product is made of opaque black polystyrene walls to minimize well-to-well crosstalk and background fluorescence. The bottom is made of clear thin polystyrene to permit direct microscopic viewing.

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. This surface composition has been optimized for cell attachment inhibition.

Cell Spheroid Growth Characteristics:
This product has been tested for the attribute of cell spheroid growth using a tumor cell line in serum supplemented media. Cell spheroid formation must be observed in ≥ 95% of the wells in a plate

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product is manufactured with animal free materials.

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

Cell Spheroid Formation:	Verification of cell spheroid formation.
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.

Rev No: 1