Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 3319

Product Description: Corning ® CellSTACK® - 5 Chamber

Component Materials:

Top Plate	-	Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
Middle Plate	-	Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
Bottom Plate	-	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. Heavy metal free (meets *CONEG* req.) color concentrate.
Filter	-	.2µm/polyester non-woven membrane, meets *USP, Class VI* requirements for plastic containers and closures.
Adhesive	-	Proprietary Acrylate, meets ISO-10993, Biocompatibility requirements and does not contain any animal products.

Product Dimensions:

Overall Length	-	13.2 in. (335mm)	Overall Width	-	8.1 in. (206mm)
Overall Height with cap	-	4.9 in. (124mm)	Tolerances	-	+/- 0.1 in. (2.5mm)
Neck ID	-	1.0 in. (26mm)	Neck O.D. incl. Threads	-	1.3 in. (32mm)
Distance between plates	-	0.67 in. (17mm)			

Total Cell Growth Area:
3180 cm^2

Recommended Working Volume:
650 - 1000 ml

Sterilization:
This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*
Sterility Assurance Level: SAL 10^{-6}

Pyrogens:
The CellStack 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 negatively charged. The negatively charged, carboxyl 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.

Integrity Testing:	Forward pressurization of the product to 1.5 psi.
Cell Culture Treatment:	Wettability test using water to insure the presence of a hydrophilic surface.
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.

POINGUE DUTSCHER SAS

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Serial Number Designation:
12 Digit Serial Number: First 8 digits - Lot number (see lot number designation above); Next 3 digits CellSTACK serial number; Last digit - Stack designation.

Rev No: 13

DOMINIQUE DUTSCHER SAS