

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Product Description

Catalog Number: 3200

Product Description: Corning® CellCube® Culture Module, 10 Layer, TCT

Fluid Path Components Materials:

- Middle Plates - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- End Plates - Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.
- Encapsulate - Polycarbonate and white concentrate blend, both meet *USP, Class VI* requirements for plastic containers and closures.
- Hose Barb Adapter - Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.
- Conical End Plug - Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.
- Tubing - Silicone, meets *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

- | | | | | | |
|-------------------------|---|----------------------------|---------------|---|-------------------------|
| Overall Length | - | 4 cm. (1.6 in.) | Overall Width | - | 24cm. (9.4 in.) |
| Overall Height | - | 24 cm. (9.4 in.) | Tolerances | - | +/- 1 cm. (+/- 0.4 in.) |
| Distance between plates | - | 1 mm (reference dimension) | | | |

Total CellCube Module:

8,500 cm²

Average Module Working Volume:

0.7 liters +/- 0.1

Operating Pressures:

Not to exceed 5.0 psi

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization*
Sterility Assurance Level: SAL 10⁻⁶

Surface Characteristics:

The 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 serum supplemented media.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest version of EMEA 410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary 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.

Cell Culture Treatment: Wettability test using water to insure the presence of a hydrophilic surface.

Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Performance Testing (Additional):

Each manufacturing item is inspected in accordance with Standard Operating Procedures.

Integrity Test: Pressurization of the product to 6.0 psi.

Visual Attributes: Visual examination of the product.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

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Product Description

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Product Description: Corning ® CellCube ® Culture Module, 10 Layer,TCT

Serial Number Designation:

12 Digit Serial Number: First 8 digits - Lot number (see Lot Number Designation above); Next 4 digits - CellCube subassembly serial number.

Rev No: 15