

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Product Description

Catalog Number: 10034

Product Description: Corning® HYPERFlask® M Cell Culture Vessel, solid cap, CellBIND® surface

Component Materials:

- Flask - 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 requirements) color concentrate.
- Liner - Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Film - Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

- | | | | | | |
|----------------|---|--------------|----------------|---|----------------------|
| Length | - | 8.009 in. | I.D. (neck) | - | 1.02 in. |
| Width | - | 4.809 in. | O.D. (cap) | - | 1.40 in. |
| Height (depth) | - | 2.091 in. | Growth surface | - | 1720 cm ² |
| Tolerances | - | +/- .005 in. | | | |

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

Pyrogens:

This 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 negatively charged, composed of ≥ 20% 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.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This 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 0.5 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.

Serial Number Designation:

11 Digit Serial Number: First 8 digits - Lot Number (see lot number designation above); Last 3 digits - HYPERFlask M Vessel Serial Number.

Rev No: 7