

Catalog Number: 4537

Product Description: Corning® Elplasia® 12K Flask with Vent Cap, Round Bottom 850/650, Ultra-Low Attachment Surface

Component Materials:

- Flask (Body & Lid) - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Microcavity Bottom - 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. 0.2 µM microporous PTFE membrane, meets *USP, Class VI* requirements for plastic containers and closures.
- Surface - Proprietary hydrogel

Product Dimensions:

| | | | | | |
|-------------------------|---|----------|---------------------------|---|--------------|
| Length w/o cap | - | 6.56 in. | O.D. (neck) incl. Threads | - | 1.23 in. |
| Width | - | 3.25 in. | I.D. (neck) | - | 1.02 in. |
| Height (depth of flask) | - | 1.59 in. | Tolerances | - | +/- 0.05 in. |

Microcavity Nominal Dimensions:

| | | |
|----------|---|--------|
| Diameter | - | 850 µm |
| Height | - | 650 µm |

Sterilization:

The product 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: *Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing.* Results: less than 0.1EU/mL.

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.

Tissue Culture:

The product has been tested for the ability to promote the growth and formulation of 3D cellular spheroids of mammalian suspension cells in culture.

Performance Testing:

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

| | |
|--------------------|--|
| Integrity Testing: | Forward pressurization of the product to 10 inches of water column. |
| 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.

Revision Date:

09-13-22