

Catalog Number: 431253

Product Description: Corning® 3 Liter disposable Fernbach culture flask, baffled bottom, easy grip vent cap with liner

Component Materials:

- Flask - Virgin Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.
- Vent Cap - Virgin Polypropylene, 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. Thermoplastic elastomer liner, meets *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

- | | | | | | |
|----------------------------------|---|----------|------------------|---|--------------|
| Height of flask with cap | - | 9.92 in. | Diameter of cap | - | 3.01 in. |
| Height of flask w/o cap | - | 9.86 in. | Diameter of neck | - | 2.64 in. |
| Diameter of flask @ widest point | - | 9.06 in. | Tolerances | - | +/- 0.05 in. |

Sterilization:

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

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.

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

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 medicinal 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.

Integrity Testing: Inverted leak test with an alcohol based solution.

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 - Run number for that year.

Revision Date:

04-14-20