

Catalog Number: 431283

Product Description: Corning® 3 Liter disposable Erlenmeyer flask, PETG, baffled bottom, 4/case

Component Materials:

- Flask - Virgin PETG, 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 has been deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

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

Rev No: 3