**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 431339

Product Description: Corning® 48 mm Erlenmeyer Vent Cap, Pouched

Component Materials:

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 and Thermoplastic elastomer liner meet *USP, Class VI* requirements for plastic containers and closures.

Product Dimensions:

Height of cap - 1.00 in. Tolerances - +/- 0.05 in.
Outer Diameter of cap - 2.13 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.

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.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.
Dimensional Testing: Conforms to product drawing.
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:

03-01-14

Rev No: 4