Corning Incorporated Life Sciences

<u>Registered</u> ISO 9001:2008

Product Description

431402 Catalog Number:

Product Description: Corning® 1 Liter disposable Baffled Erlenmever flask, flat cap

Component Materials:

Virgin Polycarbonate, meets USP, Class VI requirements for plastic containers and Flask

Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and Cap

closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Product Dimensions:

Height of flask with cap 8.18 in. Height of flask w/o cap 8.08 in. Diameter of flask @ 5.03 in. Tolerances +/- 0.05 in.

widest point

Diameter of cap 1.91 in.

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 10⁻⁶

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: Forward pressurization of the product to 39 inches of water column.

Visual examination of the product. Visual Attributes:

Inspection for seal and barrier integrity, accurate labeling, and correct Packaging:

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: 10