

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Certificate of Compliance

Catalog Number: 431402

Lot Number: 34706001

Product Description: Corning® 1 Liter disposable Baffled Erlenmeyer flask, plug seal cap

Component Materials:

- Flask - Virgin Polycarbonate, meets *USP, Class VI* requirements for plastic containers and closures.
- Cap - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.

Sterilization:

This lot 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

Pyrogens:

The product has been tested and has met the criteria established in the *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987)*.

Results: less than 0.1 EU/mL

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure:	Results:
Leak Test	Pass
Visual Attributes	Pass
Packaging	Pass



Wendy Loitsch
Quality Manager

Rev No: 2