

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Certificate of Compliance

Catalog Number: 430512
Lot Number: 19007002
Product Description: Corning® 500 mL bottle top filter, 33 mm neck size, cellulose acetate membrane, 0.45 µM pore size

Expiration Date:

An expiration date exists for this product. Please refer to the case label and the filter funnel for the expiration date for this product.

Component Materials:

- Funnel & Funnel Lid - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Funnel Adapter & Hose Connector - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Membrane - Cellulose Acetate, 0.45 µM pore size
- Gasket - Polyethylene Foam liner
- Filter Plug - Cellulose Acetate

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 10⁻⁵

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: 6