## Corning Incorporated Life Sciences

Registered ISO 9001

# **Product Description**

size.

430625

Product Description:	Corning® 150 mL bottle top filter, 33 mm neck si
	cellulose acetate membrane, 0.45 µm pore size

#### **Component Materials:** Funnel & Funnel Lid

Virgin Polystyrene, meets	USP, Class	SVI requireme	nts for p	lastic cor	ntaine	ers a	and
closures.							

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

#### 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 10-5

#### 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. Membrane Integrity Test: Forward pressurization of the membrane seal to the funnel. Visual Attributes: Visual examination of the product. Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

### **Revision Date:**

05-04-20

Rev No: 7