Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description



Catalog Number: 430770

Product Description: Corning® 500 mL filter system, cellulose acetate membrane, 0.45 µm pore size

Component Materials:

Funnel, Funnel Lid & Receiver/Storage Bottle

Virgin Polystyrene, meets USP Class VI requirements for plastic containers and

closures.

Funnel Adapter, Hose -Connector & Plug

Virgin High Density Polyethylene, meets USP, Class VI requirements for plastic containers and closures. Heavy metal free (meets CONEG reg.) color concentrate.

Seal Cap Membrane

Cellulose Acetate, 0.45 µm pore size Polyethylene Foam liner

Gasket Adapter 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 current version of ANSI/AAMI ST 72: Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing. Results: less than

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. Forward pressurization of the membrane seal to the funnel. Membrane Integrity Test:

Visual Attributes: Visual examination of the product.

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

product configuration.

Revision Date:

03-01-14

Rev No: 4