Corning Incorporated Life Sciences

Registered ISO 9001:2008

Product Description

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Catalog Number: 11750

Product Description: Coming® 500 mL centrifuge tube, polypropylene, with accessories and diptube

Component Materials:

Centrifuge Tube - Virgin Polypropylene, meets USP, Class VI requirements for plastic containers and

closures.

Cap - Virgin High Density Polyethylene, meets USP, Class VI requirements for plastic

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

Accessories:

Filter

Tubing - C-Flex, Thermoplastic Elastomer, meets USP, Class VI requirements for plastic

containers and closures.

Connector - Polypropylene, meets *USP*, *Class VI* requirements for plastic containers and closures.

- 25mm/. 2µm Acrylic/Versapor, meets USP, Class VI requirements for Biological Test for

Plastics.

Reducer - Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.

Diptube - High Density Polyethylene, meets *USP*, *Class VI* requirements for plastic containers

and closures.

Product Dimensions:

Length of Tube - 5.73 in. O.D. (neck) incl. Threads - 1.85 in. Length of tube w/cap - 6.73in. I.D. (neck) - 1.65 in. Outer Diameter of tube - 3.76in. Tolerances: - +/- 0.05 in.

Sterilization:

The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.* Sterility Assurance Level: SAL 10 ⁻⁶

Pyrogens:

The Čentrifuge Tube has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 Bacterial Endotoxins - Test methodologies,routine monitoring, and alternative to batch testing.

Results: ≤ 0.1 EU/mL (≤ 4EU/device)

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.

Integrity Test: Pull Force Test of the accessory to 10lbs.

Visual Attributes: Visual examination of the product,

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

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 - Batch identification.

Rev No: 6