

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Product Description

Catalog Number: 430829

Product Description: Corning® 50 mL centrifuge tube, polypropylene, centristar cap, bulk

Component Materials:

- 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.

Product Dimensions:

- Length of Tube - 4.501 in. I.D. (neck) - 1.146 in.
- Tolerances - +/- 0.05 in.
- Outer Diameter of cap - 1.364 in.

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (TIR 33) *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 ANSI/AAMI ST 72:2002/(R) 2010: *Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing.* Results: less than 0.1 EU/mL

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

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: Forward pressurization of the product to 60 inches of water column at the molding stage. Inverted leak test with an alcohol based solution during final assembly.
- Centrifugation: Centrifugation of the product, fully supported to an RCF of 17,000 x g.
- 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 - Run number for that year.

Rev No: 9