# Corning Incorporated Life Sciences

Registered ISO 9001:2008

# **Product Description**

Catalog Number: 430897

Product Description: Corning ® 50 mL centrifuge tube, polypropylene, self-standing, plug seal cap, bulk

**Component Materials:** 

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

closures.

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

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

**Product Dimensions:** 

Length of Tube - 4.52 in. Outer Diameter of tube - 1.15 in.

Length of tube w/cap - 4.55 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<sup>-5</sup>

### 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, unsupported to 3000 x g (RCF).

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: 5