

Catalog Number	0644318	Mfg. Date	07/21/2025
Lot Number	20325016	Sample Id	N/A
Product Description	Fisher 50 mL polypropylene centrifuge tube, flat top cap, racked		

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.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure	Result
Leak Test	Pass
Centrifugation Test (9400 x g)	Pass
Visual Attributes	Pass
Packaging	Pass

Sterilization:

This lot has been irradiated and dosimetrically released based on the Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization. Sterility Assurance Level: SAL 10⁻⁵

Pyrogens:

Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

DNase/RNase:

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10⁻⁷ Kunitz units/uL for DNase and 10⁻⁹ Kunitz units/uL for RNase.

BSE/TSE:

The product mentioned above complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01. The product mentioned above complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01. The product mentioned above complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

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

Expiration Statement:

This product has an expiration date of 3 years from the date of manufacture for the attributes contained within this certificate.

**Quality Assurance Department
Fisher Scientific Company L.L.C.**

This document has been produced electronically and is valid without a signature.

This certificate has been compiled with data that has been provided by the manufacturer of the product.

Fisher Scientific Channel has not independently verified such data.

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