

Axygen Inc.

Registered
ISO 9001:2008
ISO EN 13485:2012

Certificate of Compliance

Catalog Number: TF-150-R-S
Lot Number: 110110-308
Product Description: 150ul Sterile Filtered Pipet Tips
Shelf Life :
3 years

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

Material:
Polypropylene

Sterilization:
This product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products- Radiation* recommended practices in effect at the time of validation. Product labeled sterile meets requirement of 10⁻⁶ Sterility Assurance Level (SAL).

PCR Certification:
PCR Inhibition and Human gDNA Contamination Detection Test. PCR reaction was conducted utilizing 16s primers of a human housekeeping gene. PCR inhibitor cocktail and Human gDNA served as positive controls. No PCR inhibition or Human gDNA were detected after 35 amplifications cycles.

Endotoxin (pyrogen) Testing:
This 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*. The acceptance level for product is less than 0.05 EU/ml.

RNase/DNase Testing:
This product has been tested according to our internal protocol and is free of any detectable RNase/DNase contamination and is confirmed by a gel assay.

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

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:	Results:
Visual Attributes	Pass
Functional	Pass
Dimensional	Pass
Accuracy	Pass



Kelly C. McMullin
Quality Manager

Rev No: 1