Quality Certificate



229584

2000mL Roller Bottle, Non-treated Suspension Culture, Printed Graduations, Non-Vented Cap, Sterile
12/CS, 1/Bag

Lot Number: SAMPLE
Expiration Date: 07/04/1776

This product is assembled in accordance with ISO 9001:2015 and ISO 13485:2016 quality management systems in a class 100,000 clean room.

Component Materials
Bottle: Virgin Polystyrene: meets USP, Class VI requirements.
Cap: HDPE: meets USP, Class VI requirements.

Sterilization Assurance Level
SAL 10–6 This lot has been gamma irradiated and dosimetrically released. Procedures for determining the dosage comply with ANSI/AAMI/ISO 11137.

Cytotoxicity
All material resins are qualified using USP and/or ISO 10993 standards for cytotoxicity and have been shown to be non toxic.

Non-pyrogenic
Products have been validated to have 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
CELLTREAT Scientific Products controls materials used in manufacturing processes such that no known animal derivative components are used in the manufacture of its products. Materials and processing meet EMEA/410/01-Rev3, Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

Quality Control Testing
Representative Samples have been selected and inspected according to ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection for Attributes. This lot has passed inspection.

Country of Origin
China

This manufacturing lot has met quality standards and has been accepted by quality assurance.

Heloisa Oliveira
Product Quality Department
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