

Certificate of Analysis

Relationship Between Control Standard Endotoxin (CSE) and Reference Standard Endotoxin (RSE) – PYROSTAR™ES-F Multi (Kit)

RSE: USP Endotoxin Reference Standard
Lot # HOK354, 10,000 EU/vial

CSE: Control Standard Endotoxin (Wako Chemicals USA, Inc.)
CSE Lot No.: G-60USA
Concentration: 500 ng/vial, *E. coli* UKT-B

Tested Against: ***Limulus Amebocyte Lysate***
PYROSTAR™ES-F MULTI TEST (2 mL)
SENSITIVITY 0.03 EU/mL

LAL Lot No.: 011703
Production Date: 20 JAN 2017
Sensitivity: 0.03 EU/mL
Expiration Date: 2019.12
Determination Method: KTA

Approximate Biological Activity:

EU per Vial: 5,000 EU/vial

Method

Reconstitute the CSE with 5.0 mL LAL Reagent Water to get 1,000 EU/mL and vortex for 2 minutes at room temperature. After reconstitution, store CSE at 2→10°C for up to 1 month. DO NOT FREEZE CSE. For subsequent usages, vigorously vortex the solution for 1 minute before use. Vortex each CSE dilution for at least 30 seconds during preparation of dilutions.

Reference

United States Pharmacopeia (USP), 2011, General Chapter <85>, Bacterial Endotoxins Test (BET)

This is to certify that this product lot was manufactured according to current cGMP Standards, meets Wako Chemicals USA – LAL Division's product specifications, and complies with all applicable requirements for product release.

Created By:

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Date:

2/23/2017

Quality Assurance

Approval By:

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Date:

2/23/2017