LAL Division
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237

Phone: (804) 271-7677
Fax: (804) 271-7791

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-63USA
Concentration:	500 ng/vial, *E. coli UKT-B*
Tested Against:	***Limulus Amebocyte Lysate*** ***PYROSTAR™ES-F MULTI TEST (5.2 mL)*** ***SENSITIVITY 0.125 EU/mL***
LAL Lot No.:	021701
Production Date:	06 FEB 2017
Sensitivity:	0.125 EU/mL
Expiration Date:	2020.01
Determination Method:	KTA

Approximate Biological Activity:

EU per Vial:	4,500 EU/vial

Method
Reconstitute the CSE with 4.5 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: Jason Holliday ***Date:*** 3/2/2017

Quality Assurance Approval By: Takeshi Kitagawa ***Date:*** 3/15/2017

FDA U.S. License Number 1762