LAL Division
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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 0.06 EU/mL***
LAL Lot No.:	111507
Production Date:	12 NOV 2015
Sensitivity:	0.06 EU/mL
Expiration Date:	2018.10
Determination Method:	KTA

Approximate Biological Activity:

EU per Vial:	4,300 EU/vial

Method
Reconstitute the CSE with 4.3 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: Sarah Hu ***Date:*** 1/4/16

Quality Assurance Approval By: Jason Holliday ***Date:*** 1/4/2016