

## Certificate of Analysis

### Relationship Between Control Standard Endotoxin (CSE) and Reference Standard Endotoxin (RSE) – PYROSTAR<sup>TM</sup>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-74USA
Concentration:	500 ng/vial, <i>E. coli</i> UKT-B
Tested Against:	<b><i>Limulus Amebocyte Lysate</i></b> <b>PYROSTAR<sup>TM</sup>ES-F MULTI TEST (2.0 mL)</b> <b>SENSITIVITY 0.25 EU/mL</b>
LAL Lot No.:	031914
Production Date:	15 MAR 2019
Sensitivity:	0.25 EU/mL
Expiration Date:	2022.02
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
EU per Vial:	4,200 EU/vial
<b>Method</b> Reconstitute the CSE with 4.2 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.	
<b>Reference</b> 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:



Date:

5/3/19

Quality Assurance  
Approval By:

Date:

5/3/2019