

## Certificate of Analysis

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

|   |   |
|---|---|
| RSE:                                    | USP Endotoxin Reference Standard<br>Lot # HOK354, 10,000 EU/vial  |
| CSE:                                    | Control Standard Endotoxin (Wako Chemicals USA, Inc.)   |
| CSE Lot No.:                            | G-63USA   |
| Concentration:                          | 500 ng/vial, <i>E. coli</i> UKT-B   |
| Tested Against:                         | <b><i>Limulus Amebocyte Lysate</i></b><br><b>PYROSTAR™ ES-F MULTI TEST (2.0 mL)</b><br><b>SENSITIVITY 0.125 EU/mL</b> |
| LAL Lot No.:                            | 021812  |
| Production Date:                        | 16 FEB 2018   |
| Sensitivity:                            | 0.125 EU/mL   |
| Expiration Date:                        | 2021.01   |
| Determination Method:                   | KTA   |
| <u>Approximate Biological Activity:</u> |   |
| 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: Jason Holliday Date: 9 April 2018

Quality Assurance  
Approval By: [Signature] Date: 9 April 2018