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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 # H0K354, 10,000 EU/vial
CSE:	Control Standard Endotoxin (FUJIFILM Wako Chemicals U.S.A. Corporation)
CSE Lot No.:	G-85USA
Concentration:	500 ng/vial, <i>E. coli</i> UKT-B
Tested Against:	<i>Limulus Amebocyte Lysate</i> PYROSTAR™ ES-F MULTI TEST (5.2 mL) SENSITIVITY 0.03 EU/mL
LAL Lot No.:	122006
Production Date:	17 DEC 2020
Sensitivity:	0.03 EU/mL
Expiration Date:	2023.11
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
EU per Vial:	4,400 EU/vial
Method Reconstitute the CSE with 4.4 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), 2020, General Chapter <85>, Bacterial Endotoxins Test (BET) European Pharmacopeia (EP), Chapter 2.6.14, Bacterial Endotoxins	
This is to certify that this product lot was manufactured according to current FDA's cGMP Standards which meets FUJIFILM Wako Chemicals U.S.A. Corporation – LAL Division's product specifications and complies with all applicable requirements for product release.	

Created By: Date: 02/02/2021

Quality Assurance Approval By: Date: 02/02/2021