

LAL Division

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Certificate of Analysis

*Relationship Between Control Standard Endotoxin (CSE) and
Reference Standard Endotoxin (RSE) – PYROSTARTMES-F Multi (Kit)*

RSE:	USP Endotoxin Reference Standard Lot # HOK354, 10,000 EU/vial
CSE:	Control Standard Endotoxin (FUJIFILM Wako Chemicals U.S.A. Corporation)
CSE Lot No.:	G-81USA
Concentration:	500 ng/vial, <i>E. coli</i> UKT-B
Tested Against:	<i>Limulus Amebocyte Lysate PYROSTARTMES-F MULTI TEST (5.2 mL) SENSITIVITY 0.015 EU/mL</i>
LAL Lot No.:	032004
Production Date:	19 MAR 2020
Sensitivity:	0.015 EU/mL
Expiration Date:	2023.02
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
EU per Vial:	3,700 EU/vial

Method

Reconstitute the CSE with 3.7 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: Jason Holliday Date: 05/22/2020

Quality Assurance Approval By: Seater Walden Date: 5/25/2020