

Certificate of Analysis

Relationship Between Control Standard Endotoxin (CSE) and Reference Standard Endotoxin (RSE) - PYROSTARTMES-F/Plate (Kit) (2.0 mL)

RSE:	USP Endotoxin Reference Standard Lot # H0K354, 10,000 EU/vial
CSE:	Control Standard Endotoxin (FUJIFILM Wako Chemicals U.S.A. Corporation – LAL Division's Corporation)
CSE Lot No.:	G-81USA
Concentration:	500 ng/vial, <i>E. coli</i> UKT-B
Product Description:	<i>Limulus Amebocyte Lysate PYROSTARTMES-F/Plate (with CSE) (4 Vials of 2.0 mL LAL Reagent + 1 CSE vial)</i>
Lot No.:	062003
Production Date:	17 JUN 2020
Expiration Date:	2022.06
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
EU per Vial:	3,400 EU/vial

Method

Reconstitute the CSE with 3.4 mL LAL Reagent Water to get 1000 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 cGMP Standards, 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: 07 / 31 / 2020Quality Assurance
Approval By: John Walden Date: 07 / 31 / 2020