BIOENDO



CERTIFICATE OF ANALYSIS

22015103 Lot Number: CSE10V Catalog Number: 18-Jan-2022 Manufacture Date: Control Standard Endotoxin (CSE) 17-Jan-2025 **Expiration Date:** Product: E.coli O111: B4 Bacterial strain Results Description **Test Items** Pass White lyophilized powder Appearance Pass 100 Potency (EU/vial) 2-8°C Storage

Reconstitute CSE with 2.0ml Water for BET, mix vigorously for 5 minutes on a vortex mixer, obtaining 50 EU/ml standard stock solution. Reconstituted endotoxin solution of potency less than 20 EU/ml is stable for up to one day at 2-8°C, for endotoxin solution potency is equal or higher than 20 EU/ml, it is stable for at least one week at 2-8°C. The endotoxin level is 100 EU/vial when assay parallel with USP/China Pharmacopoeia Reference Standard Endotoxin

Lot No.: H0K354/150601-202089.

United States Pharmacopoeia (USP), General Chapter <85>, Bacterial Endotoxins Test (BET) and China Pharmacopoeia <2020 version>, volume 4, general rules 1143.

Operator Sandy Xiao

Date 2022.01.25

QA Administrator Jane un

Date 2021. 01. 75