



## CERTIFICATE OF ANALYSIS

<b>Catalog Number:</b>	CSE10V	<b>Lot Number:</b>	24045124
<b>Product:</b>	Control Standard Endotoxin (CSE)	<b>Manufacture Date:</b>	15-Apr-2024
<b>Bacterial strain</b>	<i>E.coli</i> O111: B4	<b>Expiration Date:</b>	14-Apr-2027
<b>Test Items</b>	<b>Description</b>	<b>Results</b>	
Appearance	White lyophilized powder	Pass	
Potency (EU/vial)	80	Pass	
<b>Storage</b>	2-8°C		

Reconstitute CSE with 1.6ml 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 80 EU/vial when assay parallel with USP/China Pharmacopoeia Reference Standard Endotoxin

Lot No.: H0K354/150800-201601.

### Reference:

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 *2024.04.21*

QA Administrator *Jame Lin* Date *2024.04.21*