



CERTIFICATE OF ANALYSIS

Catalog Number:	CSE10V	Lot Number:	24115185
Product:	Control Standard Endotoxin (CSE)	Manufacture Date:	07-Nov-2024
Bacterial strain	<i>E.coli</i> O111: B4	Expiration Date:	06-Nov-2027
Test Items	Description	Results	
Appearance	White lyophilized powder	Pass	
Potency (EU/vial)	90	Pass	
Storage	2-8°C		

Reconstitute CSE with 1.8ml 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 90 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 *2024.11.14*QA Administrator *Jane Lin*Date *2024.11.14*