

CERTIFICATE OF ANALYSIS

Material	Clostripain GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed purified neutral protease from <i>B. polymyxa</i>		
Lot Number	241230922	Pack Size	25 mg
Catalog Number	004-2000	Storage	-20±5°C
Date of Manufacture	22 Sept 2023	Expiry Date	Sept 2025
TEST	ACCEPTANCE CRITERIA	RESULT	
Appearance	White lyophilized cake	Conforms	
Endotoxin EU/mg protein¹ USP <85>	≤ 50.0 EU/mg	1.6 EU/mg	
Specific BAEE Activity (Unactivated)²	≥ 5 Units/mg	10.3 Units/mg	
Specific BAEE Activity (Activated)²	≥ 50 Units/mg	85.4 Units/mg	
Total TLA Activity (BAEE Unactivated)²	> 125 Units/bottle	259.3 Units/bottle	
Total Clostripain Activity (BAEE Activated)²	Report Only	2,154 Units/bottle	
Total Protein³	Report Only	25.2 mg/bottle	

Signature:



Andrew Breite, Director of Quality Assurance

16 Oct 2023

¹ Test performed on the Charles River nexgenEndosafe[®] PTS Endotoxin Assay system

² Mitchell WM and Harrington WF. Methods in Enzymology (1970) 19:635-42

³ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$

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