

CERTIFICATE OF ANALYSIS

Material	BP Protease GMP Grade (For <i>ex vivo</i> Use Only)				
Description	Aseptically dispensed purified neutral protease from <i>B. polymyxa</i>				
Lot Number	211240125		Pack Size		1.1 M NP Units
Catalog Number	003-1000		Storage		-20±5°C
Date of Manufacture	25 Jan 2024		Expiry Date		Jan 2028
TEST		ACCEPTANCE CRITERIA		RESULT	
Appearance		White lyophilized cake		Conforms	
Endotoxin EU/mg protein ¹ USP <85>		< 50.0 EU/mg		4.3 EU/mg	
Total Neutral Protease Activity ²		> 800,000 Units/bottle		1,455,406 Units/bottle	
Total Protein ³		Report Only		8.6 mg/bottle	

Signature:

23-Feb-2024

Date

Aaron B. Craig, Director of Quality Assurance

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

² Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54

³ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%}$ =1.0