

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	212230825		Pack Size		2.3 M NP Units	
Catalog Number	003-2000		Storage		-20±5°C	
Date of Manufacture	25 Aug 2023		Expiry Date		Aug 2027	
TEST		ACCEPTANCE CRITERIA		RESULT		
Appearance		White lyophilized cake		Conforms		
Endotoxin EU/mg protein¹ USP <85>		< 50.0 EU/mg		2.6 EU/mg		
Total Neutral Protease Activity ²		> 1,800,000 Units/bottle		2,579,120 Units/bottle		
Total Protein ³		Report Only		15.2 mg/bottle		

Signature:

Andrew Breite, Director of Quality Assurance

11 Sept 2023

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

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

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