

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	211230608		Pack Size		1.1 M NP Units
Catalog Number	003-1000		Storage		-20±5°C
Date of Manufacture	8 Jun 2023		Expiry Date		Jun 2027
TEST		ACCEPTANCE CRITERIA		RESULT	
Appearance		White lyophilized cake		Conforms	
Endotoxin EU/mg protein¹ USP <85>		< 50.0 EU/mg		3.2 EU/mg	
Total Neutral Protease Activity ²		> 800,000 Units/bottle		1,506,216 Units/bottle	
Total Protein ³		Report Only		8.5 mg/bottle	

Signature:

Andrew Breite, Director of Quality Assurance

10 Jul 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