

CERTIFICATE OF ANALYSIS

Material	BP Protease GMP Grade (For ex vivo Use Only)					
Description	Aseptically dispensed purified neutral protease from <i>B. polymyxa</i>					
Lot Number	211220929		Pack Size		1.1 M NP Units	
Catalog Number	003-1000		Storage		-20±5°C	
Date of Manufacture	29 Sept 2022		Expiry Date		Sept 2026	
TEST		ACCEPTANCE CRITERIA		RESULT		
Appearance		White lyophilized cake		Conforms		
Endotoxin EU/mg protein ¹ USP <85>		< 50.0 EU/mg		2.5 EU/mg		
Total Neutral Protease Activity ²		> 800,000 Units/bottle		1,312,422 Units/bottle		
Total Protein ³		Report Only		8.1 mg/bottle		

Signature:

Andrew Breite, Director of Quality Assurance

14 Oct 2022

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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