

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	212230316	Pack Size	2.3 M NP Units
Catalog Number	003-2000	Storage	-20±5°C
Date of Manufacture	16 Mar 2023	Expiry Date	Mar 2027
TEST	ACCEPTANCE CRITERIA	RESULT	
Appearance	White lyophilized cake	Conforms	
Endotoxin EU/mg protein¹ USP <85>	< 50.0 EU/mg	2.8 EU/mg	
Total Neutral Protease Activity²	> 1,800,000 Units/bottle	2,365,957 Units/bottle	
Total Protein³	Report Only	14.3 mg/bottle	

Signature:



Andrew Breite, Director of Quality Assurance

5 Apr 2023

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 $\epsilon^{0.1\%} = 1.0$