

## CERTIFICATE OF ANALYSIS

<b>Material</b>	BP Protease GMP Grade (For <i>ex vivo</i> Use Only)		
<b>Description</b>	Aseptically dispensed purified neutral protease from <i>P. polymyxa</i>		
<b>Lot Number</b>	212241107	<b>Pack Size</b>	2.3 M NP Units
<b>Catalog Number</b>	003-2000	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b> (DD MMM YYYY)	7 Nov 2024	<b>Expiry Date</b> (MMM YYYY)	Nov 2028

TEST	ACCEPTANCE CRITERIA	RESULT
<b>Appearance</b>	White lyophilized cake	Conforms
<b>Total Neutral Protease Activity<sup>1</sup></b>	> 1,800,000 Units/bottle	2,510,433 Units/bottle
<b>Endotoxin<sup>2</sup> USP &lt;85&gt;</b>	< 50.0 EU/mg	3.7 EU/mg
<b>Total Protein<sup>3</sup></b>	Report Only (mg/bottle)	15.97 mg/bottle

Printed Name & Title	Signature	Date (DD MMM YYYY)
Andrew Breite Dir of Quality Assurance		22 Nov 2024

<sup>1</sup> Based on the method of Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. Transplantation Proceedings 42 (2010);2052-54

<sup>2</sup> Test performed on the Charles River nexgenEndosafe<sup>®</sup> PTS Endotoxin Assay system

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