



## PRODUCT SPECIFICATIONS

Version Apr 2024

<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>	<i>Lot Specific</i>	<b>Pack Size</b>	1.1 M NP Units
<b>Catalog Number</b>	003-1000	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b>	<i>Lot Specific</i>	<b>Expiry Date</b>	4 years from date of manufacture

TEST	ACCEPTANCE CRITERIA	RESULT
<b>Appearance</b>	White lyophilized cake	<i>Lot Specific</i>
<b>Total Neutral Protease Activity<sup>1</sup></b>	> 800,000 Units/bottle	<i>Lot Specific</i>
<b>Endotoxin<sup>2</sup> USP &lt;85&gt;</b>	< 50.0 EU/mg	<i>Lot Specific</i>
<b>Total Protein<sup>3</sup></b>	Report Only	<i>Lot Specific</i>

Electronically signed in Qualio® eQMS

<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® PTS Endotoxin Assay system

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