



PRODUCT SPECIFICATIONS

Version Apr 2024

Material	Clzyme AS GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed mixture of purified Class 1 and Class 2 Collagenase from <i>C. histolyticum</i> and purified Neutral Protease from <i>P. polymyxa</i>		
Lot Number	<i>Lot Specific</i>	Pack Size	35 Wünsch + 280k NP Units
Catalog Number	005-1090	Storage	2-8°C
Date of Manufacture	<i>Lot Specific</i>	Expiry Date	4 years from date of manufacture

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	<i>Lot Specific</i>
Total Wünsch Activity¹	30 – 40 Units/bottle	<i>Lot Specific</i>
Total Neutral Protease Activity²	220,000 – 350,000 Units/bottle	<i>Lot Specific</i>
Endotoxin³ USP <85>	< 25.0 EU/OD 280 nm	<i>Lot Specific</i>
Total Collagen Degrading Activity⁴	Report Only (Units/bottle)	<i>Lot Specific</i>

Electronically signed in Qualio® eQMS

¹ Based on the method Wünsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>

² Based on the method of Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54

³ Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system

⁴ Based on the method McCarthy RC, et. al. Development and Characterization of a Collagen Degradation Assay to Assess Purified Collagenase Used in Islet Isolation. *Transplantation Proceedings* 40 (2008); 339-342