

PRODUCT SPECIFICATIONS

Version Apr 2024

Material	Collagenase Gold Plus GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed enriched Collagenase from <i>C. histolyticum</i>		
Lot Number	<i>Lot Specific</i>	Pack Size	1,500 Wunsch Units
Catalog Number	011-2000	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>
Specific FALGPA Activity¹	> 3.4 Units/mg	<i>Lot Specific</i>
Total FALGPA Activity¹	> 1,500 Units/bottle	<i>Lot Specific</i>
Endotoxin² USP <85>	< 25.0 EU/mg	<i>Lot Specific</i>
Specific Collagen Degrading Activity³	> 30,000 Units/mg	<i>Lot Specific</i>
Collagenase Purity⁴	> 90% AUC C2 + C1	<i>Lot Specific</i>
Total Protein⁵	Report Only (mg)	<i>Lot Specific</i>

Electronically signed in Qualio® eQMS

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

² Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system

³ 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

⁴ As measured by strong anion exchange analytical chromatography method based on USP <89.1> and <89.2>

⁵ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$