



PRODUCT SPECIFICATIONS

Version Apr 2024

Material	Collagenase MA GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from <i>C. histolyticum</i>		
Lot Number	<i>Lot Specific</i>	Pack Size	2.5 M CDA Units
Catalog Number	001-2030	Storage	-20±5°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 Collagen Degrading Activity¹	15,000 – 30,000 Units/mg	<i>Lot Specific</i>
Total Collagen Degrading Activity¹	2.25 – 2.75 M Units/bottle	<i>Lot Specific</i>
Endotoxin² USP <85>	< 10.0 EU/mg	<i>Lot Specific</i>
Total Protein³	Report Only	<i>Lot Specific</i>

Electronically signed in Qualio® eQMS

¹ 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

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

³ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$