



PRODUCT SPECIFICATIONS

Version Apr 2024

Material	Collagenase HA GMP Grade (For ex vivo 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	2,000 Wünsch Units
Catalog Number	001-1000	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 Wünsch Activity¹	> 2.8 Units/mg	<i>Lot Specific</i>
Total Wünsch Activity¹	> 1,900 Units/bottle	<i>Lot Specific</i>
Endotoxin² USP <85>	< 10.0 EU/mg	<i>Lot Specific</i>
Total Collagen Degrading Activity³	Report Only (Units/bottle)	<i>Lot Specific</i>
Total Protein⁴	Report Only (mg)	<i>Lot Specific</i>
Trypsin Like Activity (BAEE Unactivated)⁵	Report Only (U/mg)	<i>Lot Specific</i>
Clostripain (BAEE Activated)⁵	Report Only (U/mg)	<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 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 Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$

⁵ Mitchell WM, Harrington WF. Clostripain. *Methods in Enzymology* (1970) 19;635-642