


CERTIFICATE OF ANALYSIS

Material	Collagenase HA 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	111240418	Pack Size	2,000 Wunsch Units
Catalog Number	001-1000	Storage	-20±5°C
Date of Manufacture	18 Apr 2024	Expiry Date	Apr 2028

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Specific Wunsch Activity¹	> 2.8 Units/mg	4.43 Units/mg
Total Wunsch Activity¹	> 1,900 Units/bottle	2,153 Units/bottle
Endotoxin² USP <85>	< 10.0 EU/mg	2.67 EU/mg
Total Collagen Degrading Activity³	Report Only (Units/bottle)	26,813,860 Units/bottle
Total Protein⁴	Report Only (mg)	486.1 mg/bottle
Trypsin Like Activity (BAEE Unactivated)⁵	Report Only (U/mg)	0.002 U/mg
Clostripain (BAEE Activated)⁵	Report Only (U/mg)	0.044 U/mg

Signature:



10 May 2024

Aaron B. Craig, Director Quality Assurance

Date

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 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