

CERTIFICATE OF ANALYSIS

Material	Animal Origin Free Recombinant Collagenase HI GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed mixture of purified Class 1 and Class 2 Collagenase expressed in <i>E. coli</i>		
Lot Number	131250115	Pack Size	1,600 Wünsch Units
Catalog Number	001-4010	Storage	-20±5°C
Date of Manufacture (DD MMM YYYY)	15 Jan 2025	Expiry Date (MMM YYYY)	Jan 2027

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Identity¹	rC1 ± 1 min standard RT rC2 ± 1 min standard RT	+0.06 min +0.18 min
Purity²	> 90% AUC rC1 + rC2	96.5%
Total Wünsch Activity³	> 1,400 Units/bottle	1,515 Units/bottle
Endotoxin⁴ USP <85>	< 25.0 EU/mg	1.74 EU/mg
Total Collagen Degrading Activity⁵	Report Only (Units/bottle)	13,188,313 Units/bottle
Total Protein⁶	Report Only (mg/bottle)	377.8 mg/bottle

Printed Name & Title	Signature	Date (DD MMM YYYY)
Andrew Breite, Dir of Quality Assurance		31 Mar 2025

- ¹ Based on the Purity procedure described in USP <89.1> and <89.2> for peak retention time (RT)
- ² Integrated Area Under Curve for rC1 and rC2 based on the Purity procedure described in USP <89.1> and <89.2>
- ³ Reported as units of 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> using an internal conversion value from measurements made using the method of Jackson, R.J., Dao, M.L. and Lim, D.V. *Journal of Microbiological Methods* (1995) 21;209-215
- ⁴ Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system
- ⁵ 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
- ⁶ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$