

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 rColG (Class 1 Collagenase) and rColH (Class 2 Collagenase) expressed in <i>E. coli</i>		
Lot Number	131231214	Pack Size	1,600 Wünsch Units
Catalog Number	001-4010	Storage	-20±5°C
Date of Manufacture	14 Dec 2023	Expiry Date	Dec 2025
TEST		ACCEPTANCE CRITERIA	RESULTS
Appearance		White lyophilized cake	Conforms
Identity¹		rC1 ± 1 min standard RT rC2 ± 1 min standard RT	+0.04 min -0.02 min
Purity²		> 90% AUC rC1 + rC2	97.7%
Total Wünsch Activity³		> 1,400 Units/bottle	1,563 Units/bottle
Total Collagen Degrading Activity⁴		Report Only	19,186,982 Units/bottle
Endotoxin EU/mg protein USP <85>⁵		< 25.0 EU/mg	2.42 EU/mg
Total Protein⁶		Report Only	434.1 mg/bottle

Signature:



Andrew Breite, Director of Quality Assurance

9 Jan 2024

- 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 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>
- ⁴ 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
- ⁵ Charles River Endosafe® nexgen-PTS™ Endotoxin Assay
- ⁶ Based on absorbance at 280 nm with an extinction coefficient of $\epsilon^{0.1\%} = 1.41$