

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	131230309	Pack Size	1,600 Wunsch Units
Catalog Number	001-4010	Storage	-20±5°C
Date of Manufacture	9 Mar 2023	Expiry Date	Mar 2025
TEST	ACCEPTANCE CRITERIA		RESULTS
Appearance	White lyophilized cake		Conforms
Identity¹	rC1 ± 1 min standard RT rC2 ± 1 min standard RT		+0.03 min +0.03 min
Purity²	> 90% AUC rC1 + rC2		98.0%
Total Wunsch Activity³	> 1,400 Units/bottle		1,659 Units/bottle
Total Collagen Degrading Activity⁴	Report Only		20,963,947 Units/bottle
Endotoxin EU/mg protein USP <85>⁵	< 25.0 EU/mg		1.53 EU/mg
Total Protein⁶	Report Only		411.3 mg/bottle

Signature:



Andrew Breite, Director of Quality Assurance

27 Mar 2023

- 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 Wunsch 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 $\epsilon^{0.1\%} = 1.41$