

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	131230712	Pack Size	1,600 Wünsch Units
Catalog Number	001-4010	Storage	-20±5°C
Date of Manufacture	12 Jul 2023	Expiry Date	Jul 2025
TEST	ACCEPTANCE CRITERIA		RESULTS
Appearance	White lyophilized cake		Conforms
Identity¹	rC1 ± 1 min standard RT rC2 ± 1 min standard RT		-0.06 min +0.06 min
Purity²	> 90% AUC rC1 + rC2		95.4%
Total Wünsch Activity³	> 1,400 Units/bottle		1,413 Units/bottle
Total Collagen Degrading Activity⁴	Report Only		16,541,278 Units/bottle
Endotoxin EU/mg protein USP <85>⁵	< 25.0 EU/mg		1.36 EU/mg
Total Protein⁶	Report Only		396.5 mg/bottle

Signature:



Andrew Breite, Director of Quality Assurance

31 Jul 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 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 $\epsilon^{0.1\%} = 1.41$