

CERTIFICATE OF ANALYSIS

Material	Clzyme AS 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> and purified Neutral Protease from <i>B. polymyxa</i>		
Lot Number	311240215	Pack Size	25 Wunsch + 280k NP Units
Catalog Number	005-1090	Storage	-20±5°C
Date of Manufacture	15 Feb 2024	Expiry Date	Feb 2028
TEST	ACCEPTANCE CRITERIA	RESULT	
Appearance	White lyophilized cake	Conforms	
Total Wunsch Activity¹	30.0 – 40.0 Units/bottle	37.8 Units/bottles	
Total Neutral Protease Activity²	220,000 – 350,000 Units/bottle	259,788 Units/bottle	
Total Collagen Degrading Activity³	Report Only Units/bottle	595,614 Units/bottle	
Endotoxin EU/mg protein⁴ USP <85>	< 25.0 EU/OD 280 nm	2.91 EU/OD	

Signature:



Aaron B. Craig,

Director of Quality Assurance

07-Mar-2024

Date

- ¹ Reported as units of 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> 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
- ² Based on the method Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54
- 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 Test performed on the Charles River nexgenEndosafe[®] PTS Endotoxin Assay system