proteintech®
Antibodies | ELISA kits | Proteins

Catalog Number: HZ-3010-GMP

Data Sheet

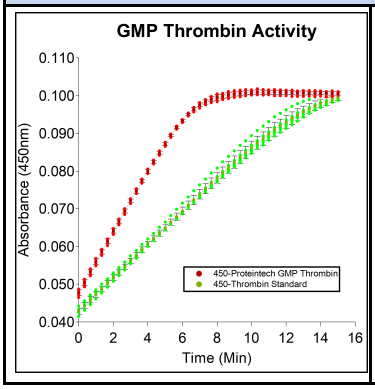
HumanKine® recombinant human Thrombin protein-GMP grade

Animal Component-Free	Human cell expressed	Tag-Free	Endotoxin Free

Product Description	
Animal-free Recombinant Human Thrombin is expressed in human 293 cells as a monomeric glycoprotein with an apparent molecular mass of 36 kDa. Production in human 293 cells ensures authentic glycosylation. Thrombin is a coagulation protein and a serine protease that catalyzes numerous coagulation correlated reactions. Thrombin also regulates the behavior of additional cells through protease activated receptors and endorses platelet activation. This recombinant protein is produced in a human cell expression system with serum-free, chemically defined media	
Alternative Names	Coagulation factor II, F2, Prothrombin, PT, Thrombin
Accession Number	P00734
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived Thrombin protein
Species Reactivity	human
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses

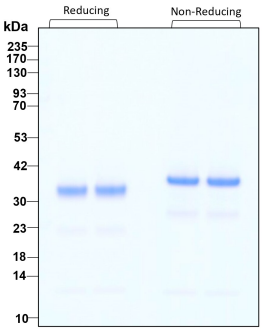
Specifications		
Test	**Method**	**Specification**
Activity	Rate of free chromophore formation from Chromozym TH thrombin substrate monitored by absorbance at 405 nm	1000-5000 units/mg
Molecular Mass	SDS-PAGE	34 kDa reduced, 36 kDa non-reduced, monomer, glycosylated
Purity	SDS-PAGE	> 95%
Endotoxin	LAL	<0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



The activity of GMP thrombin (HZ-3010-GMP) was measured by the rate of free chromophore formation from Chromozym TH thrombin substrate monitored by absorbance at 405 nm. The enzymatic reaction was carried out in 50mM Tris-HCl pH 8.3 buffer containing 0.1% BSA and 227 mM NaCl at 25°C. Activity was conducted in triplicate on a validated bioassay. Activity ranges from 1000-5000 units/mg.

SDS-PAGE



Purity of recombinant human GMP thrombin was determined by SDS- polyacrylamide gel electrophoresis. The protein was resolved in an SDS- polyacrylamide gel in reducing and non-reducing conditions and stained using Coomassie blue.

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Preparation	
Shipping Temperature	Dry Ice
Formulation	20 mM MES pH 6.0 + 500 mM Choline Chloride, See Certificate of Analysis for details
Reconstitution	Not Applicable. Product provided in liquid format.

	Product Form	Temperature Conditions	Storage Time (From Date of Receipt)
Stability and Storage	Liquid	-80°C	Until Expiry Date
	Liquid	-20°C	6 months
	Liquid	4°C	1 week
	Avoid repeated freeze-thaw cycles.		

Proteintech GMP Quality Policy
HumanKine® GMP Proteins

Invitro recombinant protein production can be prone to variability due to various reasons ranging from quality of raw materials to inconsistency in the process. Therefore, HumanKine®, a proteintech brand's GMP proteins are produced and tested under an ISO 13485 certified quality management system in a clean room facility. Proteintech manufactures the GMP HumanKine® products according to the applicable sections in the following documents: USP Chapter 1043 (Ancillary Materials for Cell, Gene, and Tissue-Engineered Products, USP Chapter 92 (Growth Factors and Cytokines Used in Cell Therapy Manufacturing), WHO TRS, No. 822, 1992 Annex 1 (Good Manufacturing Practices for Biological Products), Ph. Eur. General Chapter 5.2.12, and EudraLex – Volume 4 – Part IV (Guidelines on GMP specific to ATMPs). Proteintech strives to achieve the utmost quality GMP raw material ensuring all applicable guidelines are taken into consideration.

The QMS is built to provide our customers with consistent and pure product delivered by documented processes, qualified personnel, validated processes, qualified equipment, qualified vendors, and a stringent final product release process. Although the final product release process is important, Proteintech performs in-process QC steps after each major manufacturing stage. Production records and facilities may be available for an inspection by approved personnel.

Our GMP policy covers all the aspects of production; from raw materials, facility, equipment, and Instruments to training and personal hygiene of staff. It also guarantees that the process is explicit, validated and well documented for transparency and traceability.

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