

Catalog Number: HZ-1248-GMP

Data Sheet



GMP HumanKine® TPO (Thrombopoietin) (Recombinant Human)

Animal Component-Free

Human cell expressed

Tag-Free

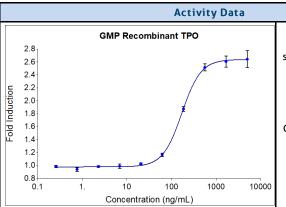
Endotoxin Free

Product Description

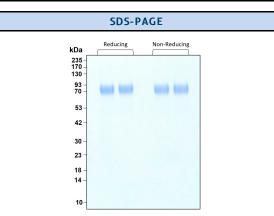
Animal-free Recombinant Human TPO (Thrombopoietin) is expressed from human 293 cells as a monomeric glycoprotein with an apparent molecular mass of 70 to 93 kDa. This cytokine is produced in a serum-free, chemically defined media. Production in human 293 cells offers authentic glycosylation, contributing to stability in cell growth media and other applications. C- terminal domain glycosylation is thought to be important for the secretion of Thrombopoietin from cells and for survival of Thrombopoietin in the circulation.

Alternative Names	MGDF, MKCSF, ML, MPLLG, THPO, Thrombopoietin			
Accession Number	P40225			
Source	Source Human Embryonic Kidney cells (HEK293). HEK293-derived TPO (Thrombopoietin) protein			
Adventitious Virus	Adventitious Virus Master Cell Bank tested Negative for Adventitious Viruses			

Specifications					
Test	Method	Specification			
Activity	Dose-dependent stimulation of the proliferation of M07e cells in Defined media (human megakaryoblastic leukemia cell line)	100-500 ng/mL EC50 in MO7e cells in defined media			
Molecular Mass	SDS-PAGE	70 to 93 kDa reduced and non-reduced, monomer, glycosylated.			
Purity	SDS-PAGE	>95%			
Endotoxin	LAL	<0.1 EU/ µ g			
Mycoplasma	PCR	Not Detected			



GMP Recombinant human TPO (HZ-1248-GMP) stimulates dose-dependent proliferation of the MO7e (human megakaryoblastic leukemia) cell line. Cell number was quantitatively assessed by PrestoBlue® Cell Viability Reagent. MO7e cells under defined media conditions were treated with increasing concentrations of GMP recombinant TPO for 72 hours. The EC50 was



Purity of GMP-grade recombinant human TPO 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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Document #: FR-QA118-101 Rev 0 Data Sheet Version #: Proteintech Group, Inc.

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Preparation				
Shipping Temperature	ambient temperature			
Formulation	ation 1x PBS, See Certificate of Analysis for details			
Reconstitution Briefly centrifuge the vial before opening. It is recommended to reconstitute the protein in sterile 1xPBS containing endotoxin-free recombinant human serum albumin (HSA).				

	Product Form	Temperature Conditions	Storage Time (From Date of Receipt)
	Lyophilized	-20°C to -80°C	Until Expiry Date
Stability and Storage	Lyophilized	Room Temperature	2 weeks
	Reconstituted as per CofA	-20°C to -80°C	6 months
	Reconstituted as per CofA	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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