GMP Human Thrombopoietin Protein

Catalog # GMP-THNH25

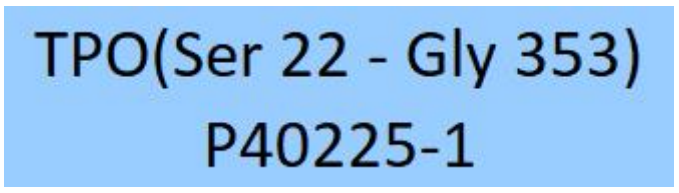
Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests

Source

GMP Human Thrombopoietin Protein(GMP-THNH25) is expressed from human 293 cells (HEK293). It contains AA Ser 22 - Gly 353 (Accession # P40225-1).
Predicted N-terminus: Ser 22

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 35.5 kDa. The protein migrates as 75 kDa±5 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE) due to glycosylation.

Endotoxin

Less than 10 EU/mg by the LAL method.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Sterility

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.

Mycoplasma

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 μm filtered solution in 20 mM NaAc-HAc, pH5.0 with protectants.

Contact us for customized product form or formulation.

Shipping

This product is supplied and shipped with blue ice, please inquire the shipping cost.

Storage

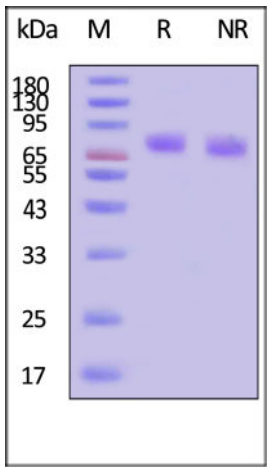
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

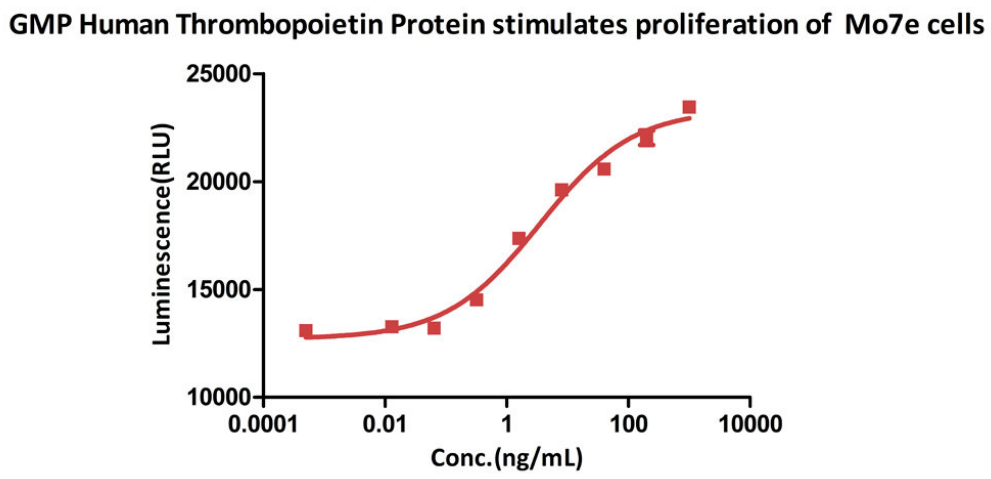
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE

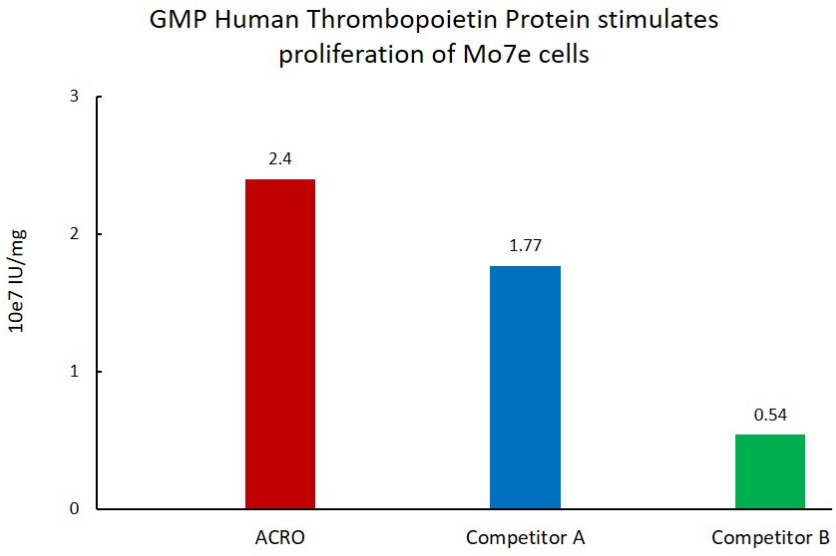


GMP Human Thrombopoietin Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-Bioactivity CELL BASE

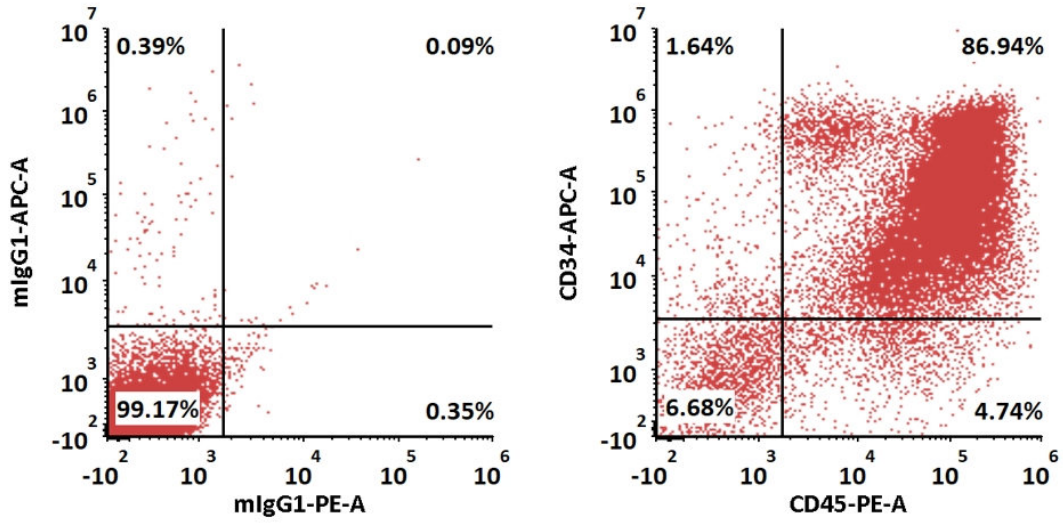


GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25) stimulates proliferation of Mo7e cells. The specific activity of GMP Human Thrombopoietin Protein is >1.00x10^7 IU/mg, which is calibrated against human TPO Standard (NIBSC code: 03/124) (QC tested).

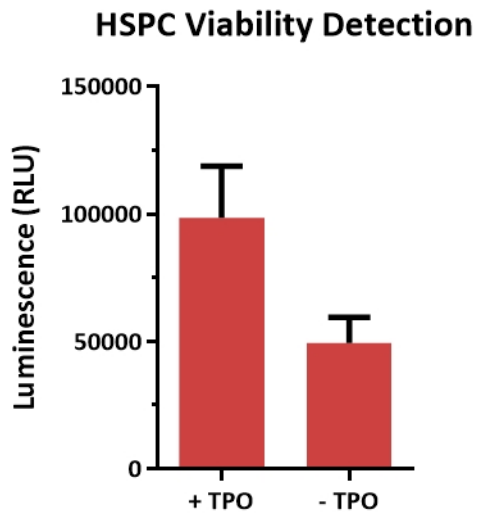


The activity of GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25) was higher than other competing products.

Application Data

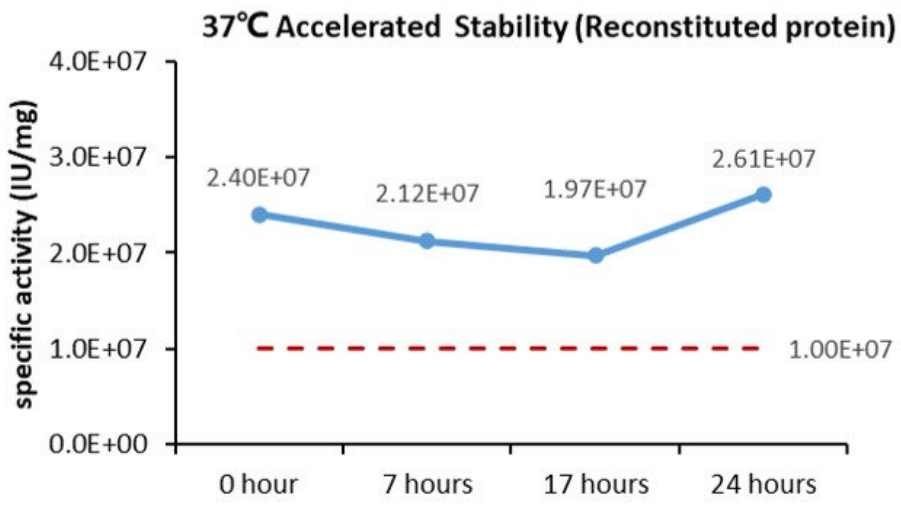


GMP Human SCF Protein (Cat. No. GMP-SCFH25), GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25), GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) and GMP Human VEGF165 Protein (Cat. No. GMP-VE5H23) could significantly promote the iPSC differentiation to HSPCSs after 14 days, highly expressed hematopoietic stem cell markers CD34 and CD45.

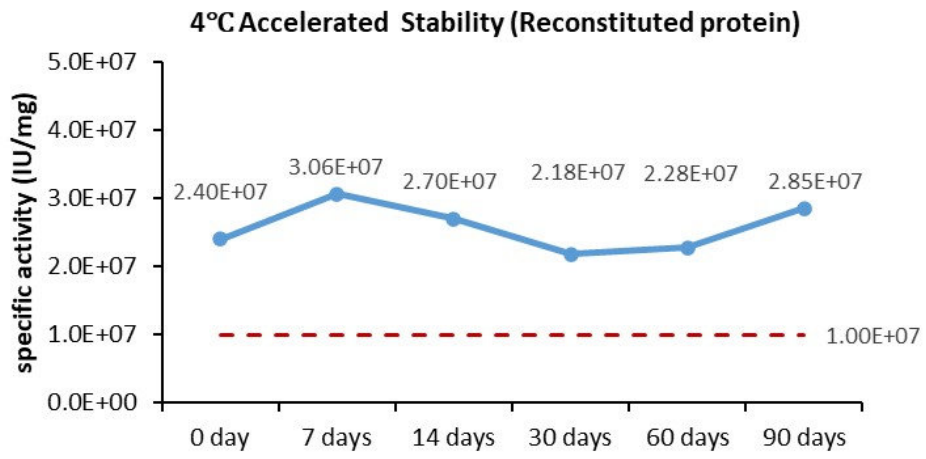


GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25) is crucial for the expansion of human CD34+ hematopoietic cells cultured with medium containing GMP Human SCF Protein (Cat. No. GMP-SCFH25) and GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28). Cell viability was checked using a luminescent cell viability detection reagent.

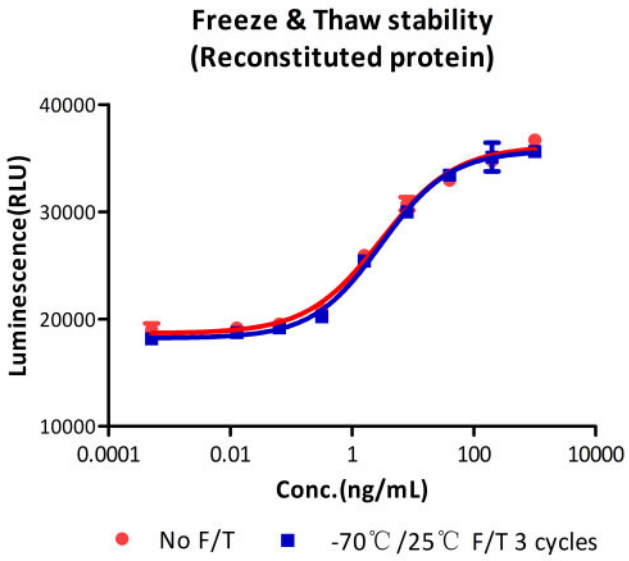
Bioactivity-Stability



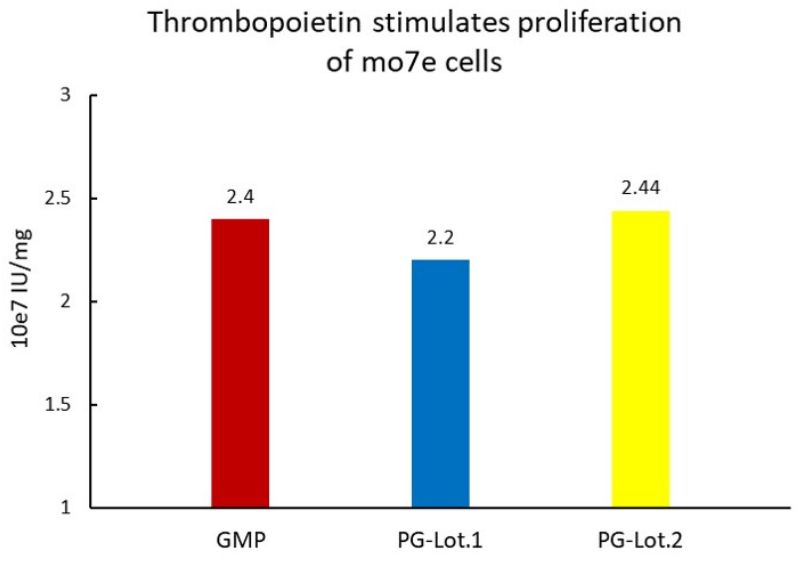
The Cell based assay shows that GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25) is stable at 37°C for 24 hours.



The Cell based assay shows that GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25) is stable at 4°C for 90 days.



The Cell based assay shows that GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25) is stable after freezing and thawing 3 times.



The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG Thrombopoietin.

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents：

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

Animal-Free materials

Materials purchased from the approved suppliers by QA

ISO 5 clean rooms and automatic filling equipment

Qualified personnel

Quality-related documents review and approve by QA

Fully batch production and control records

Equipment maintenance and calibration

Validation of analytical procedures

Stability studies conducted

Comprehensive regulatory support files

Request For Regulatory Support Files（RSF）

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

SDS-PAGE

Protein content

Endotoxin level

Residual Host Cell DNA content

Residual Host Cell Protein content

Biological activity analysis

Microbial testing

Mycoplasma testing

In vitro virus assay

Residual moisture

Batch-to-batch consistency

Background

Thrombopoietin (TPO) is a 332 amino acid glycoprotein made primarily in the liver and act as the major physiological regulator of platelet production. TPO binds the TPO receptor, activates JAK and STAT pathways, thus stimulating megakaryocyte growth and platelet production. Additionally, further investigation uncovered that thrombopoietin is a critical cytokine promoting hematopoietic rebound after myeloablation and its transcripts are expressed by multiple cellular sources.

Clinical and Translational Updates