Recombinant Human Thrombopoietin/Tpo GMP

Catalog Number: BT-TPO-GMP

DESCRIPTION

Source	*E. coli*-derived human Thrombopoietin/Tpo protein Ser22 - Leu195 with an N-terminal Alanine Accession # NP_000451.1 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ala-Ser22-Pro-Ala-Pro-Pro-Ala-(Cys)-Asp-Leu
Predicted Molecular Mass	18.7 kDa

SPECIFICATIONS

SDS-PAGE	18-19 kDa, under reducing conditions.
Activity	Measured in a cell proliferation assay using MO7e human megakaryocytic leukemic cells. Avanzi, G. *et al.* (1988) Br. J. Haematol. **69**:359. The ED_{50} for this effect is 0.0500-0.500 ng/mL. The specific activity of Recombinant Human Thrombopoietin is >1.00 x 10^7 units/mg, which is calibrated against the Human Thrombopoietin reference standard (NIBSC code: 03/124).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>95%, by SDS-PAGE with quantitative densitometry by Coomassie® Blue Staining.
Mass Spectrometry	18732 Da ± 50 Da
Host Cell Protein	<5.00 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative for Mycoplasma
Host Cell DNA	<0.00150 ng per µg of protein when tested by PCR.
Formulation	Lyophilized from a 0.2 µm filtered solution in Acetonitrile and TFA with Trehalose. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 500 µg/mL in sterile water.
Shipping	The product is shipped with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	**Use a manual defrost freezer and avoid repeated freeze-thaw cycles.** • A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date. • 1 month, 2 to 8 °C under sterile conditions after reconstitution. • 3 months, ≤ -20 °C under sterile conditions after reconstitution.

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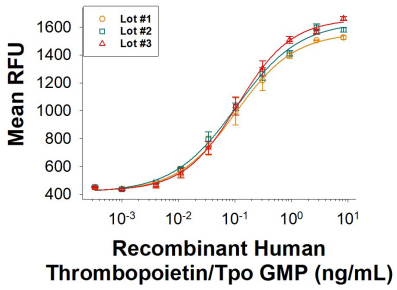
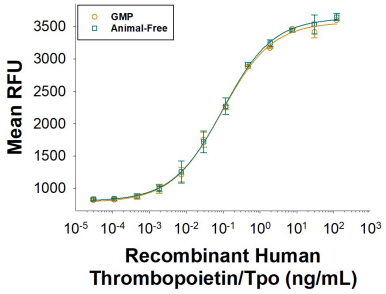
DATA

Bioactivity



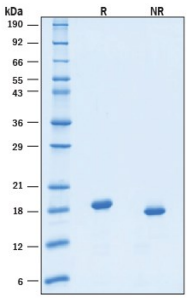
Recombinant Human Thrombopoietin/Tpo GMP Protein Bioactivity. The bioactivity of Recombinant Human Thrombopoietin/Tpo GMP Protein (Catalog # BT-TPO-GMP) was measured in a cell proliferation assay using MO7e human megakaryocytic leukemic cells. The ED_{50} for this effect is 0.0500-0.500 ng/mL. Three independent lots were tested for bioactivity and plotted on the same graph to show lot-to-lot consistency of GMP Thrombopoietin/Tpo protein.

Bioactivity



Equivalent Bioactivity of GMP and Animal-Free grades of Recombinant Human Thrombopoietin/Tpo. Equivalent bioactivity of GMP (Catalog # BT-TPO-GMP) and Animal-Free (Catalog # BT-TPO-AFL) grades of Recombinant Human Thrombopoietin/Tpo as measured in a cell proliferation assay using MO7e human megakaryocytic leukemic cells (orange and green, respectively).

SDS-PAGE



Recombinant Human Thrombopoietin/Tpo GMP Protein SDS-PAGE. 2 µg/lane of Recombinant Human Thrombopoietin/Tpo GMP Protein (Catalog # BT-TPO-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing bands at 18-19 kDa under reducing conditions.

BACKGROUND

Thrombopoietin (TPO) is a crucial regulator of hematopoietic stem cell (HSC) differentiation, maturation, and proliferation, as well as megakaryocytopoiesis and thrombopoiesis. TPO is often used in conjunction with Stem Cell Factor (SCF) and Flt-3 ligand in cell culture protocols to expand HSCs for bone marrow transplantation and cellular therapies. When combined with SCF and Flt-3 ligand, it promotes the differentiation of HSCs into megakaryocytes, leading to the production of platelets. It has shown promise in emerging cellular therapies for treating sickle cell disease, beta thalassemia, and other blood-related disorders. Moreover, TPO in combination with other cytokines is utilized in the generation of iNK cells, which have the potential to be incorporated into cellular immunotherapies.

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MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and Eu. Ph. 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, mass spectrometry, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial testing according to USP <71>
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells GMP grade products for preclinical or clinical *ex vivo* use. They are not for *in vivo* use. Please read the following End User Terms prior to using this product.

Animal-Free Manufacturing Conditions

Our dedicated controlled-access animal-free laboratories ensure that at no point in production are the products exposed to potential contamination by animal components or byproducts. Every stage of manufacturing is conducted in compliance with R&D Systems' stringent Standard Operating Procedures (SOPs). Production and purification procedures use equipment and media that are confirmed animal-free.

Production

- All molecular biology procedures use animal-free media and dedicated labware.
- Dedicated fermentors are utilized in committed animal-free areas.

Purification

- Protein purification columns are animal-free.
- Bulk proteins are filtered using animal-free filters.
- Purified proteins are stored in animal-free containers in a dedicated cold storage room.

Quality Assurance

- Low Endotoxin Level.
- No impairment of biological activity.
- High quality product obtained under stringent conditions.

Please read our complete Animal-Free Statement

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