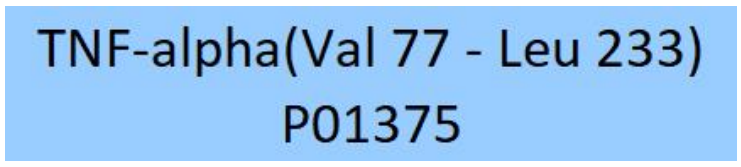
Features

- 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 TNF-alpha Protein(GMP-TNAH23) is expressed from human 293 cells (HEK293). It contains AA Val 77 - Leu 233 (Accession # P01375).
Predicted N-terminus: Val 77

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 17.4 kDa. The protein migrates as 17 kDa±3 kDa 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.

>95% as determined by SEC-HPLC.

Formulation

Lyophilized from 0.22 μm filtered solution in PBS, pH7.4 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

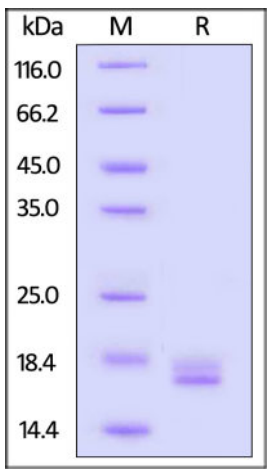
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

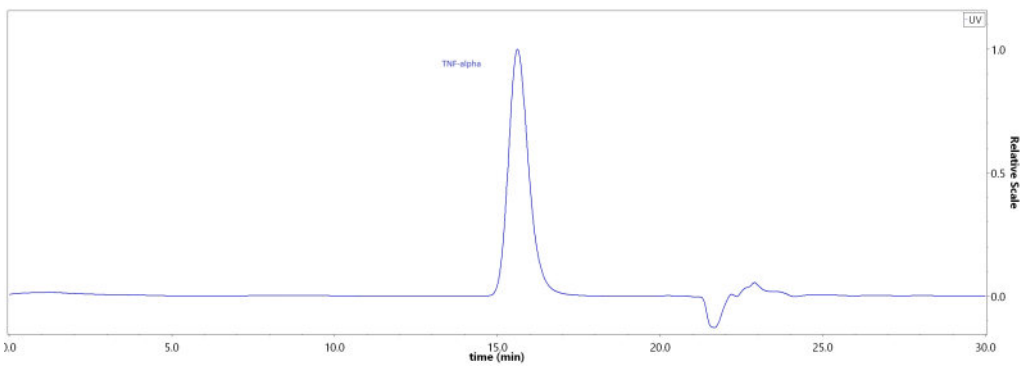
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE



GMP Human TNF-alpha Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater

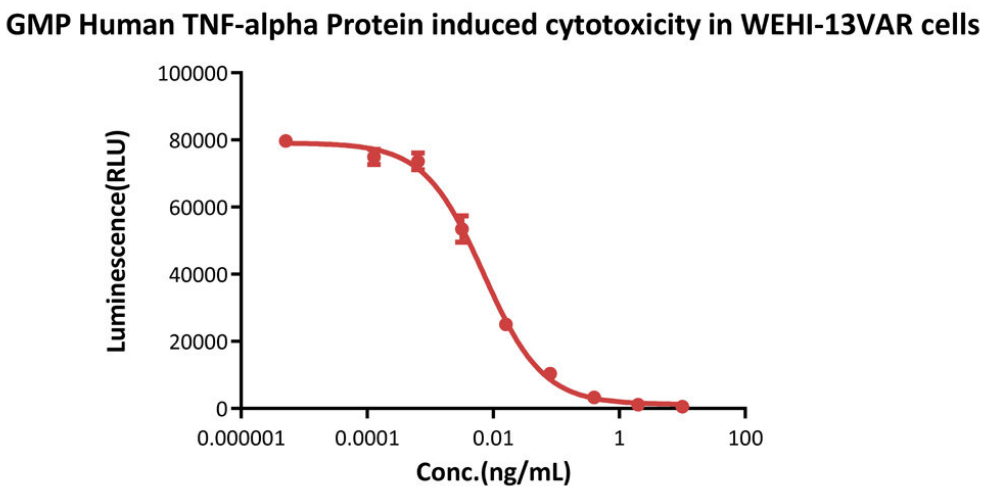
SEC-HPLC



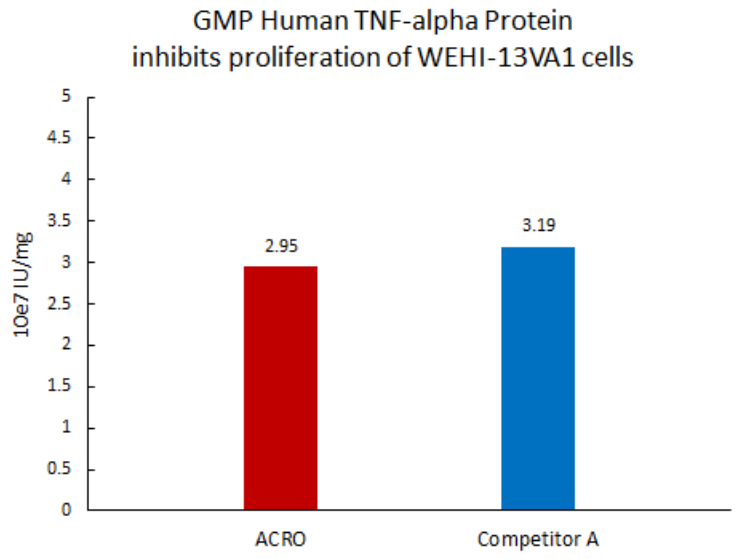
The purity of GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) was greater than 95% as determined by SEC-HPLC.

than 95%.

Bioactivity-Bioactivity CELL BASE

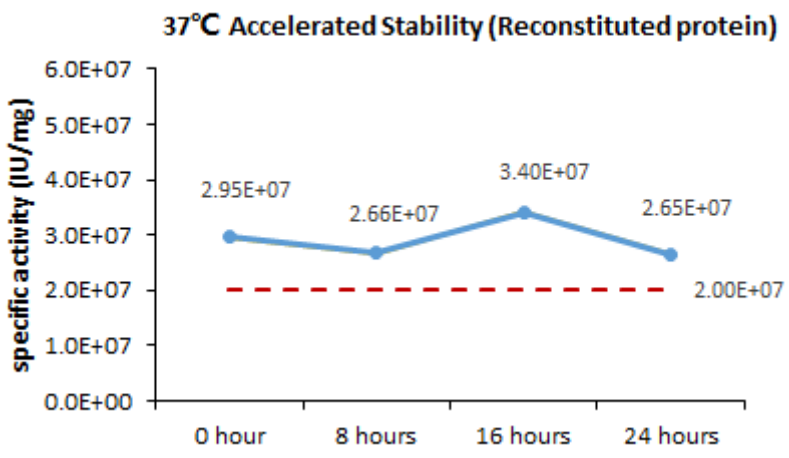


GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) induces cytotoxicity effect on the WEHI-13VAR cells in the presence of the metabolic inhibitor actinomycin D. The specific activity GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) is ≥ 2.00×10^7 IU/mg, which is calibrated against human TNF-alpha WHO International Standard (NIBSC code: 12/154) (QC tested).

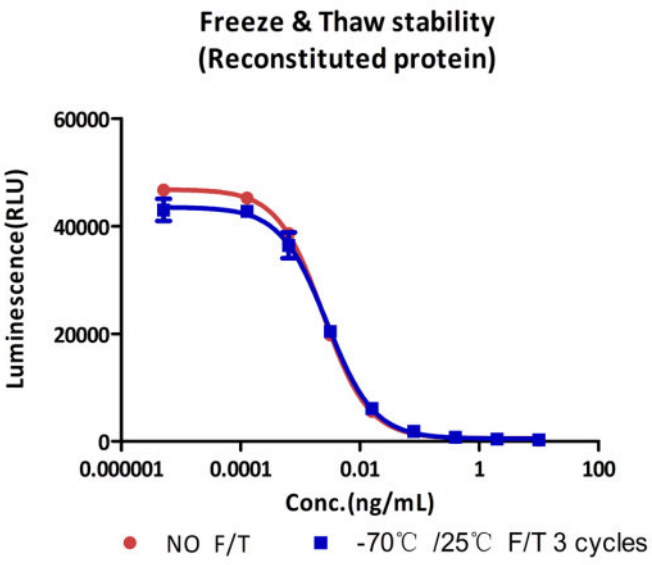


The activity of GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) was consistent with competing products.

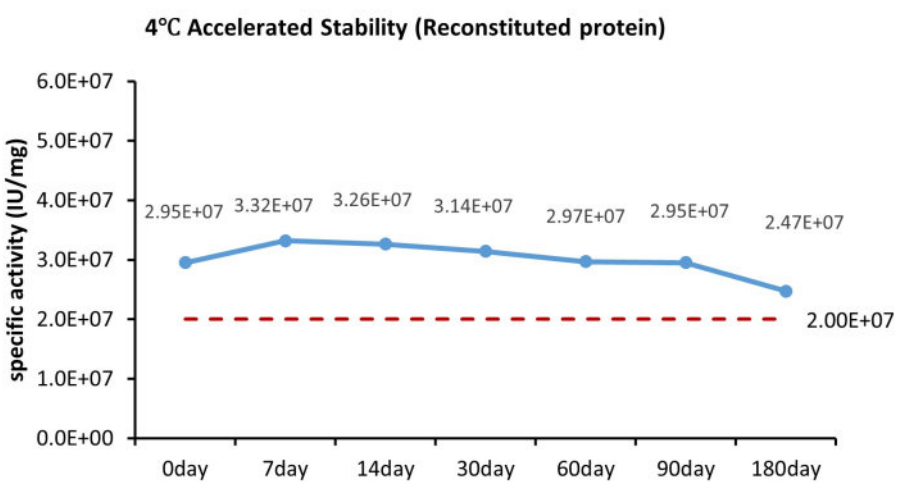
Bioactivity-Stability

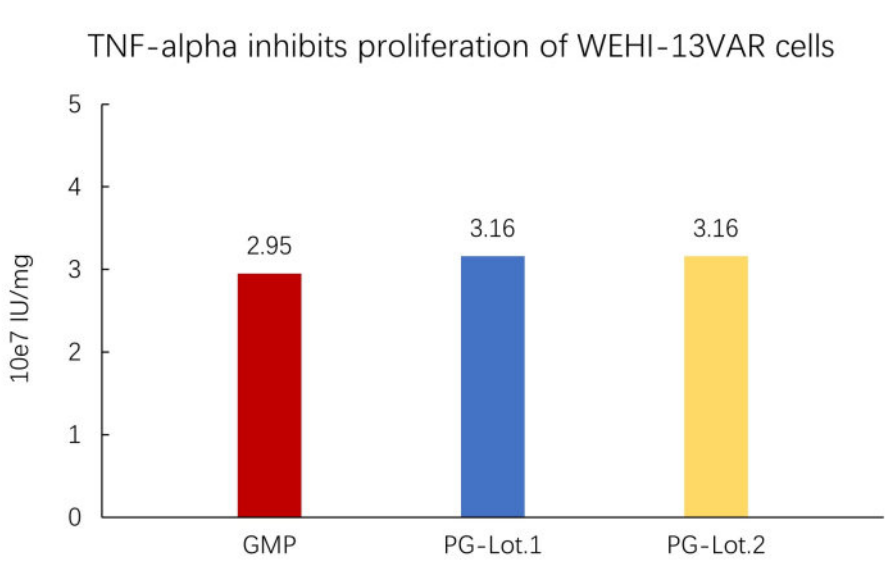


The Cell based assay shows that GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) is stable at 37 ℃ for 24 hours.



The Cell based assay shows that GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) is stable after freezing and thawing 3 times.





The Cell based assay shows that GMP Human TNF-alpha Protein (Cat. No. GMP-TNAH23) is stable at 4 ℃ for 180 days.

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

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

Tumor necrosis factor alpha (TNFα) is a cytokine produced primarily by monocytes and macrophages. It is found in synovial cells and macrophages in the tissues.The primary role of TNFα is in the regulation of immune cells. TNFα is able to induce apoptotic cell death, to induce inflammation, and to inhibit tumorigenesis and viral replication. Dysregulation of TNFα production has been implicated in a variety of human diseases, including major depression, Alzheimers disease and cancer. Recombinant TNFα is used as an immunostimulant under the INN tasonermin. TNFα can be produced ectopically in the setting of malignancy and parallels parathyroid hormone both in causing secondary hypercalcemia and in the cancers with which excessive production is associated.

Clinical and Translational Updates