

**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 IL-4 Protein(GMP-L04H26) is expressed from human 293 cells (HEK293). It contains AA His 25 - Ser 153 (Accession # [P05112-1](#)).
Predicted N-terminus: His 25

Molecular Characterization

IL-4(His 25 - Ser 153)
P05112-1

This protein carries no "tag".

The protein has a calculated MW of 15.0 kDa. The protein migrates as 19 kDa \pm 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/ μ g of protein tested by ELISA.

Host Cell DNA

<0.02 ng/ μ g 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 μ m 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.

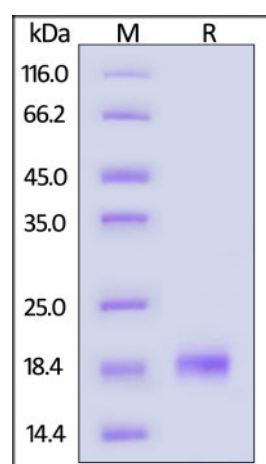
Storage

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 IL-4 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than

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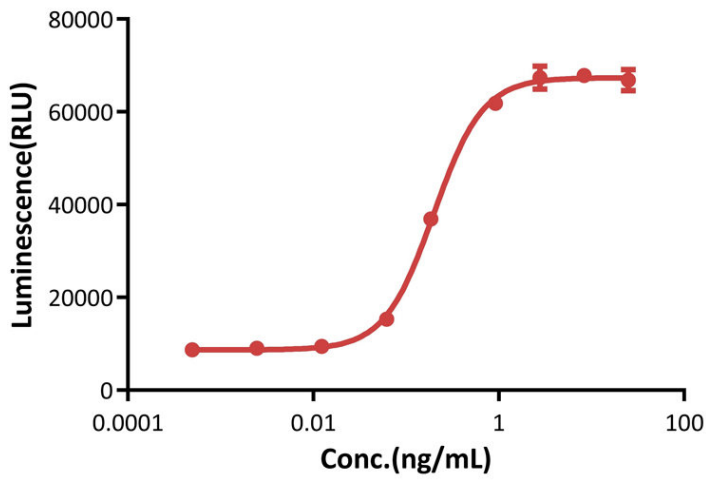




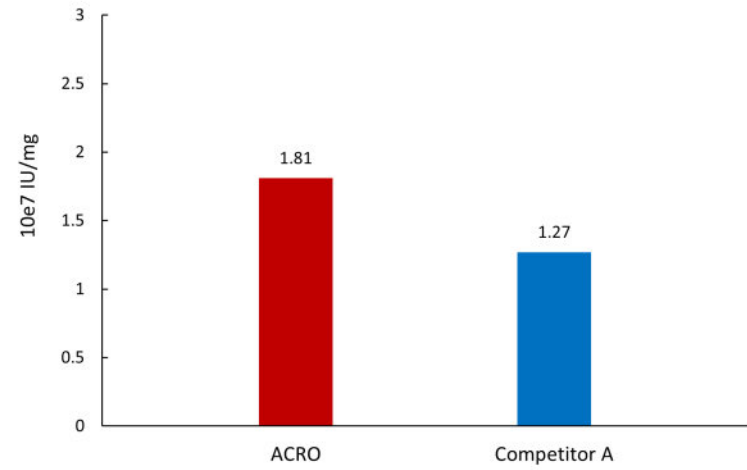
95%.

Bioactivity-Bioactivity CELL BASE

GMP Human IL-4 Protein stimulates proliferation of TF-1 cells



GMP Human IL-4 Protein stimulates proliferation of TF-1 cells

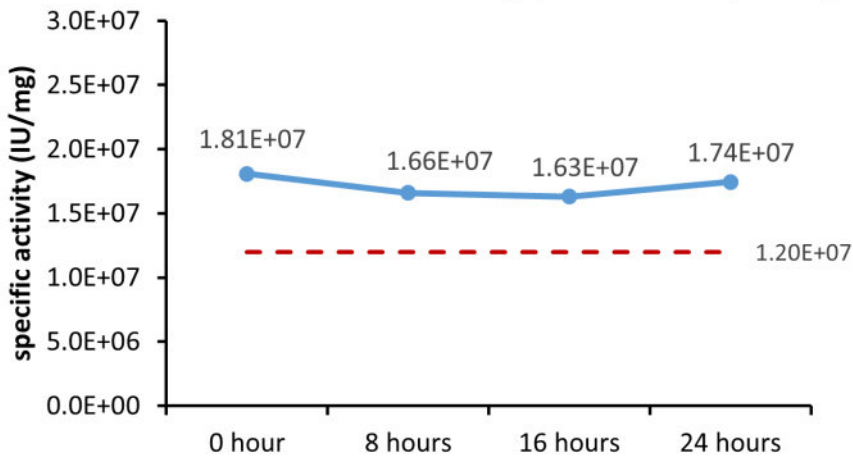


GMP Human IL-4 Protein (Cat. No. GMP-L04H26) stimulates proliferation of TF-1 human erythroleukemic cell line. The specific activity of GMP Human IL-4 Protein is $> 1.20 \times 10^7$ IU/mg, which is calibrated against human IL-4 WHO International Standard (NIBSC code: 88/656) (QC tested).

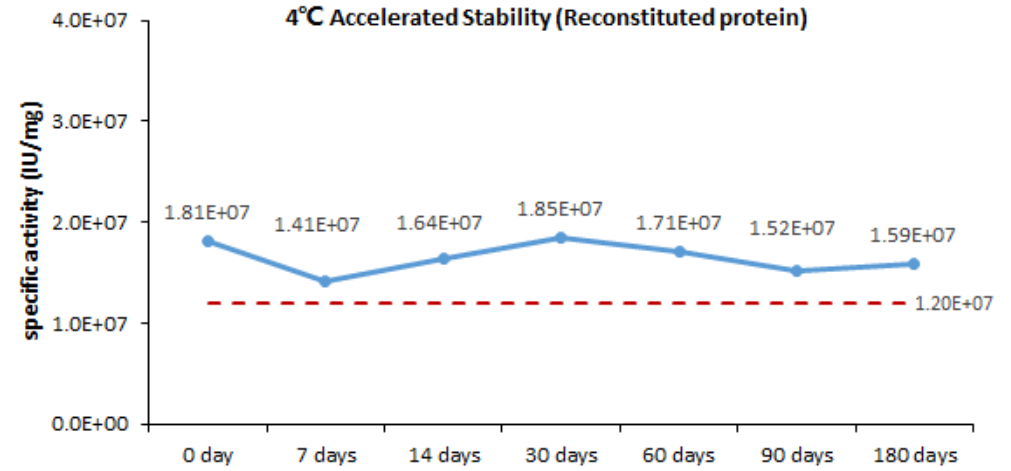
The activity of GMP Human IL-4 Protein (Cat. No. GMP-L04H26) was higher than other competing products.

Bioactivity-Stability

37°C Accelerated Stability (Reconstituted protein)



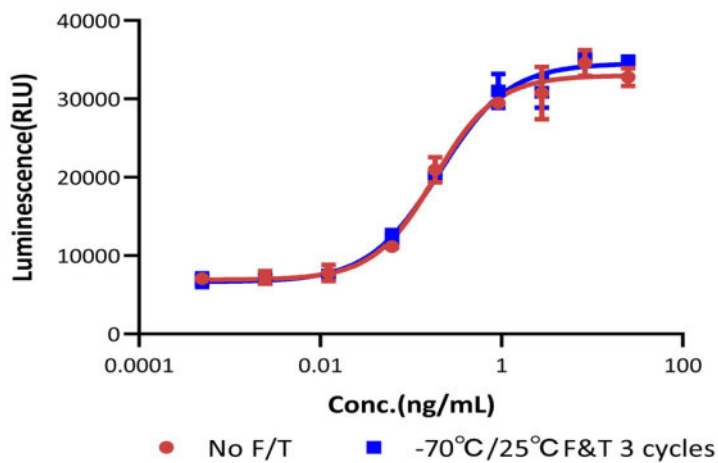
4°C Accelerated Stability (Reconstituted protein)



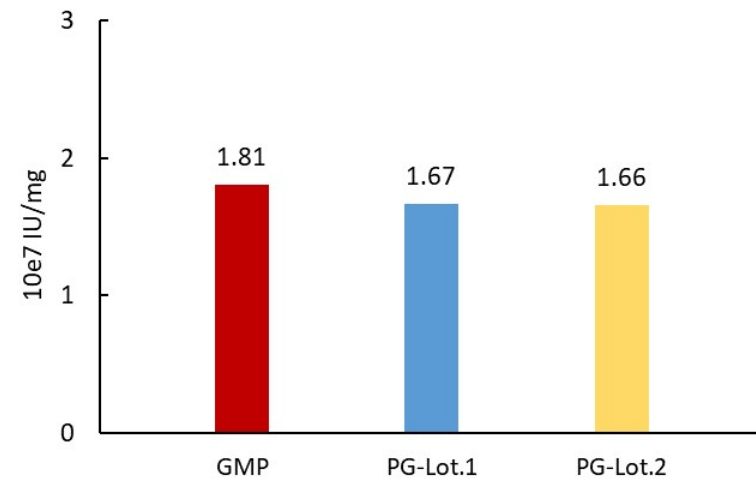
The Cell based assay shows that GMP Human IL-4 Protein (Cat. No. GMP-L04H26) is stable at 37°C for 24 hours.

The Cell based assay shows that GMP Human IL-4 Protein (Cat. No. GMP-L04H26) is stable at 4°C for 180 days.

Freeze & Thaw stability (Reconstituted protein)



IL-4 stimulates proliferation of TF-1 cells



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The Cell based assay shows that GMP Human IL-4 Protein (Cat. No. GMP-L04H26) is stable after freezing and thawing 3 times.

The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG IL-4.

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

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Background

Interleukin-4, is a cytokine that induces differentiation of naive helper T cells (Th0 cells to Th2 cells). In the presence of IL-4 and IL-13, cytokines that are produced in a Th-2 type response, particularly during allergy and parasitic infections, macrophages become differentially activated, And this cytokine is a ligand for interleukin 4 receptor. The interleukin 4 receptor also binds to IL13, which may contribute to many overlapping functions of this cytokine and IL13. STAT6, a signal transducer and activator of transcription, has been shown to play a central role in mediating the immune regulatory signal of this cytokine. Recently, researcher found that the cytokine IL-4 plays a key role in development of innate CD8+ T cells in the thymus of several gene-deficient mouse strains, including Itk, KLF2, CBP and Id3, without previous exposure to antigen.

Clinical and Translational Updates

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