GMP Human IL-21 Protein (E. coli)

Catalog # GMP-L21H15

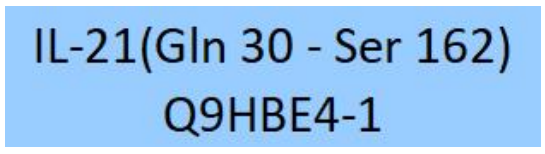
GMP Platform Advantages

- **Quality Assurance**: Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance**: Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents**: Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory Support**: Includes RSF and DMF to meet global requirements.
- **Resilient Supply Chain**: Intelligent modular facilities ensure a stable global supply.
- **Professional Support**: Extensive manufacturing and application expertise to accelerate development.

Source

GMP Human IL-21 Protein (*E. coli*) (GMP-L21H15) is expressed from *E. coli* cells. It contains AA Gln 30 - Ser 162 (Accession # Q9HBE4-1).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 15.5 kDa. The protein migrates as 17 kDa±3 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

Met-Gln-Gly-Gln-Asp-Arg-His-Met-Ile-Arg-Met-Arg-Gln-Leu-Ile
(Routinely tested)

Endotoxin

Less than 10 EU/mg, tested by the LAL method in compliance with USP <85> and Ph. Eur. 2.6.14.

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

Sterility testing was performed using the membrane filtration method in compliance with USP <71> and Ph. Eur. 2.6.1.

Mycoplasma

Negative

Purity

>95% as determined by SDS-PAGE.

Formulation

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

Contact us for customized product form or formulation.

Vial Specification

2R (13 mm neck finish)

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.

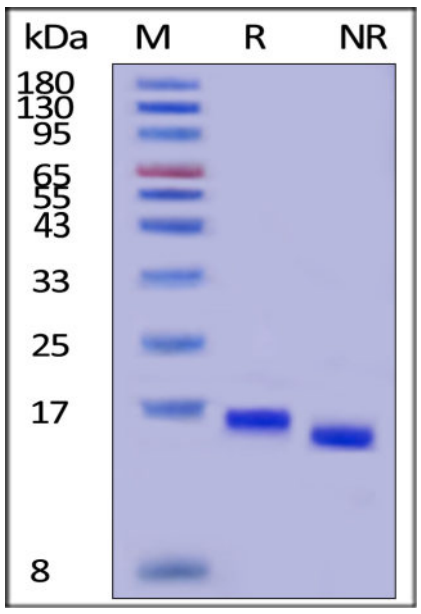
This product is stable after storage at:

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

ACRO Quality Management System

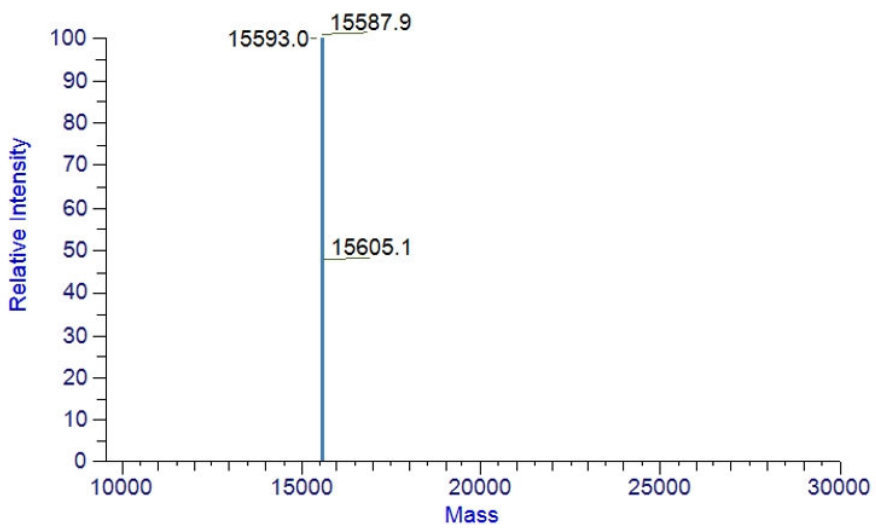
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



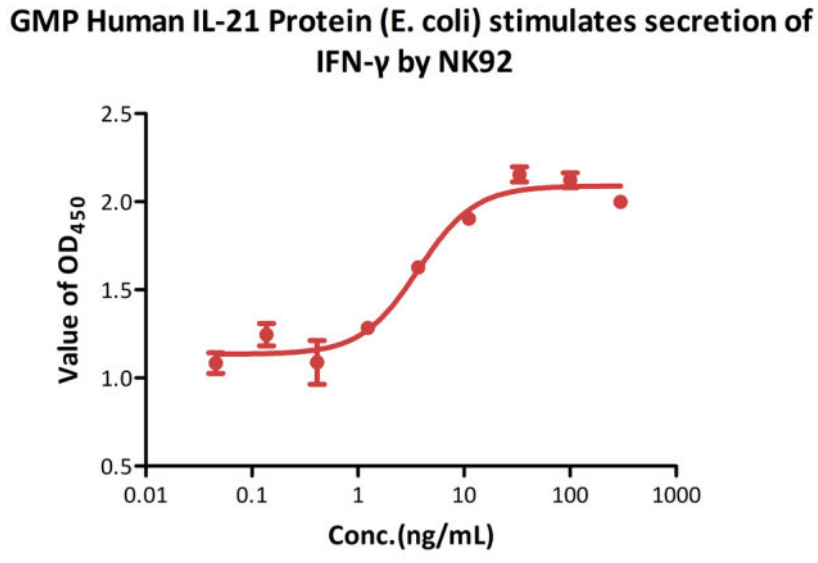
GMP Human IL-21 Protein (*E. coli*) on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Mass Spectrometry



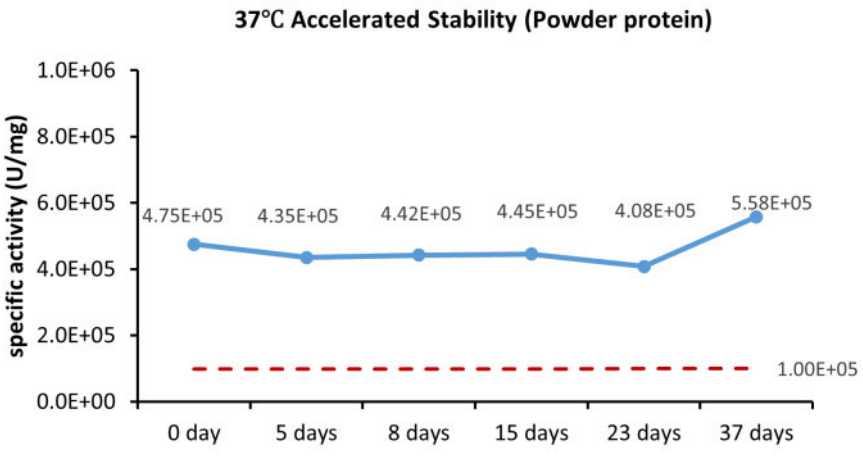
ESI-MS analysis of GMP Human IL-21 Protein (*E. coli*) (Cat. No. GMP-L21H15), showing a major peak at 15587.9 Da. The minor peak following the major peak is a matrix-associated artifact of the ESI-MS (Routinely tested).

Bioactivity-CELL BASE

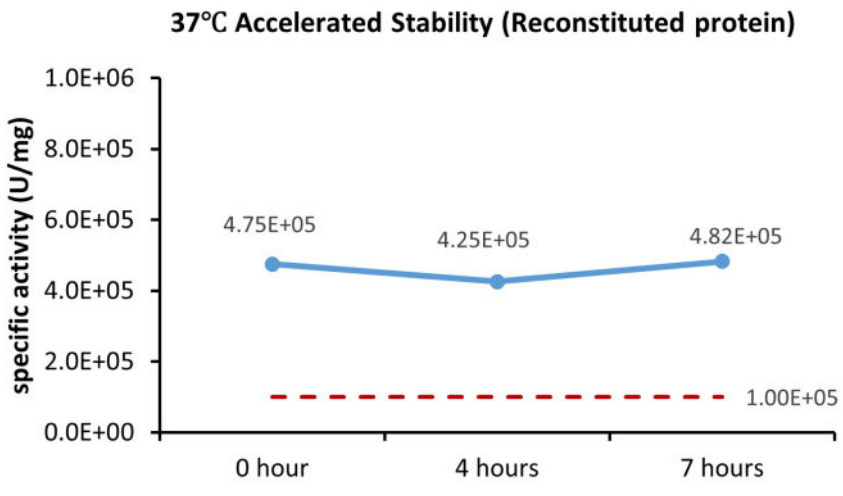


GMP Human IL-21 Protein (*E. coli*) (Cat. No. GMP-L21H15) stimulates secretion of IFN-γ by NK-92 human natural killer lymphoma cells stimulated with GMP Human IL-15 Protein (Cat. No. GMP-L15H13). The specific activity of GMP Human IL-21 Protein (*E. coli*) is > 1.00 x 10^5 U/mg (QC tested).

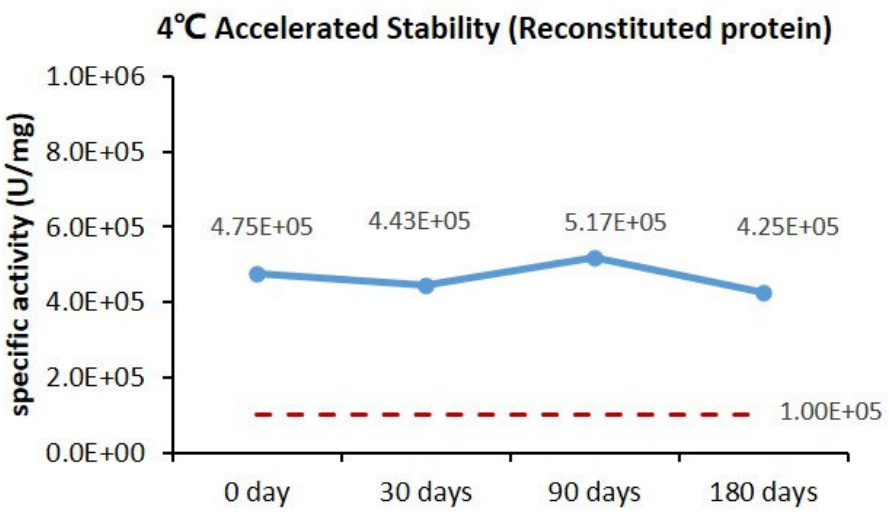
Bioactivity-Stability



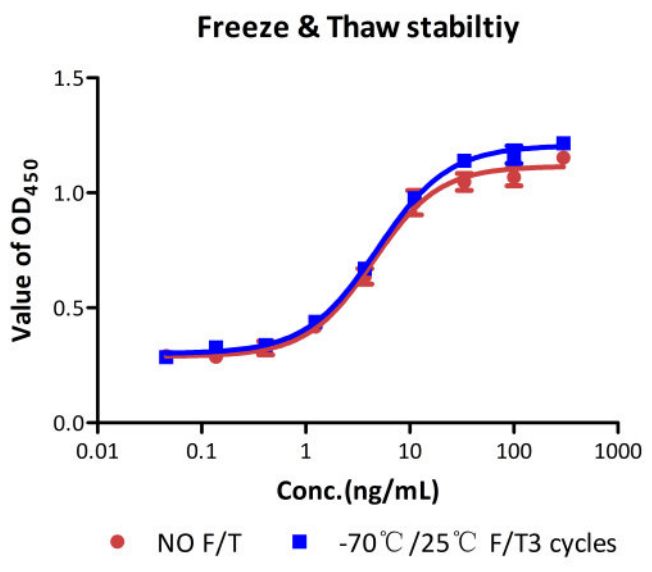
Cell-based assay demonstrates that the lyophilized GMP Human IL-21 Protein (*E. coli*) (Cat. No. GMP-L21H15) is stable at 37°C for 37 days.



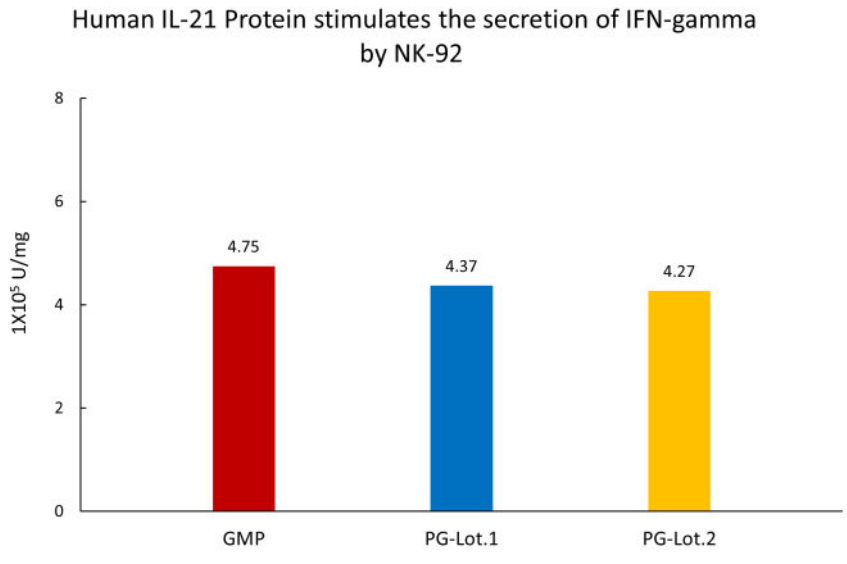
Cell-based assay demonstrates that the reconstituted GMP Human IL-21 Protein (*E. coli*) (Cat. No. GMP-L21H15) is stable at 37°C for 7 hours.



Cell-based assay demonstrates that the reconstituted GMP Human IL-21 Protein (*E. coli*) (Cat. No. GMP-L21H15) is stable at 4°C for 180 days.



Cell-based assay demonstrates that the reconstituted GMP Human IL-21 Protein (*E. coli*) (Cat. No. GMP-L21H15) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG IL-21 (*E. coli*).

Background

Interleukin-21 (IL-21) is a secreted protein which belongs to the IL-15 / IL-21 family. Interleukin-21 / IL-21 belongs to a family of cytokines that bind to a composite receptor consisting of a private receptor (IL21R) and the common cytokine receptor gamma chain (gamma(C)). Interleukin-21 / IL-21 impacts a number of cell types, including CD8+ memory T cells, NK cells and subsets of CD4 memory T cells. The IL-21R is widely distributed on lympho-haematopoietic cells. IL-21 is a pleiotropic cytokine produced by CD4+ T cells in response to antigenic stimulation. Its action generally enhances antigen-specific responses of immune cells. IL-21 promotes the anti-tumor activity of CD8+ T-cells and NK cells. IL-21 exerts its effect through binding to a specific type I cytokine receptor, IL-21R, which also contains the γ chain (γc) found in other cytokine receptors including IL-2, IL-4, IL-7, IL-9 and IL-15. The IL-21/IL-21R interaction triggers a cascade of events which includes activation of the tyrosine kinases JAK1 and JAK3, followed by activation of the transcription factors STAT1 and STAT3.

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：

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies
- Fully batch production and control records
- Equipment maintenance and calibration

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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