

**Features**

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

Source

GMP Human IL-21 Protein(GMP-L21H25) is expressed from human 293 cells (HEK293). It contains AA Gln 30 - Ser 162 (Accession # [Q9HBE4-1](#)).

Predicted N-terminus: Gln 30

Molecular Characterization

IL-21(Gln 30 - Ser 162)
Q9HBE4-1

This protein carries no "tag".

The protein has a calculated MW of 15.5 kDa. The protein migrates as 16 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.

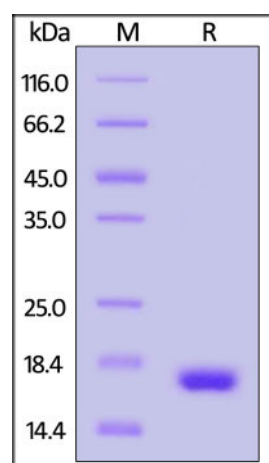
Storage

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-21 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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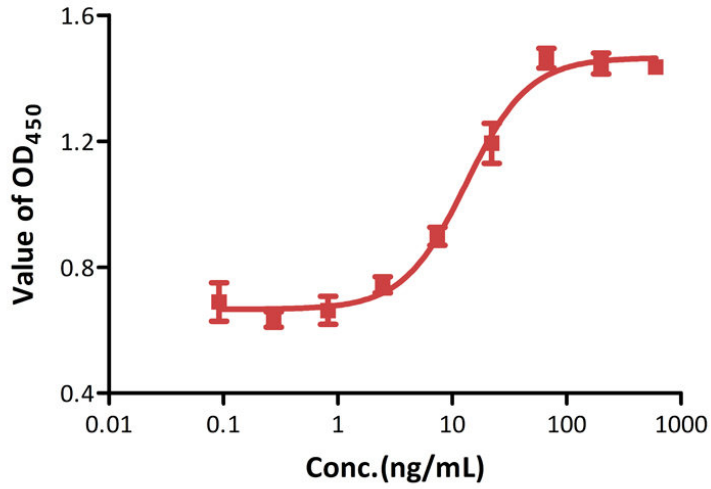




95%.

Bioactivity-Bioactivity CELL BASE

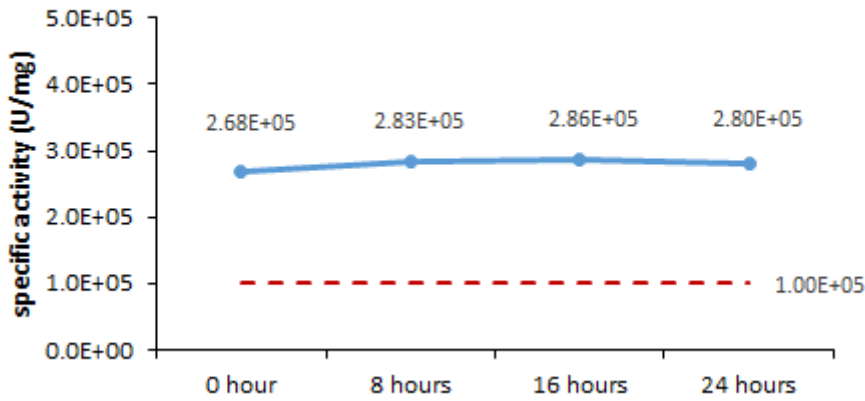
GMP Human IL-21 Protein stimulates secretion of IFN-γ by NK92



GMP Human IL-21 Protein (Cat. No. GMP-L21H25) stimulates secretion of IFN-γ by NK-92 human natural killer lymphoma cells stimulated with 10 ng/mL GMP Human IL-15 Protein (Cat. No. GMP-L15H13). The specific activity of GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is > 1.00×10⁵ U/mg (QC tested).

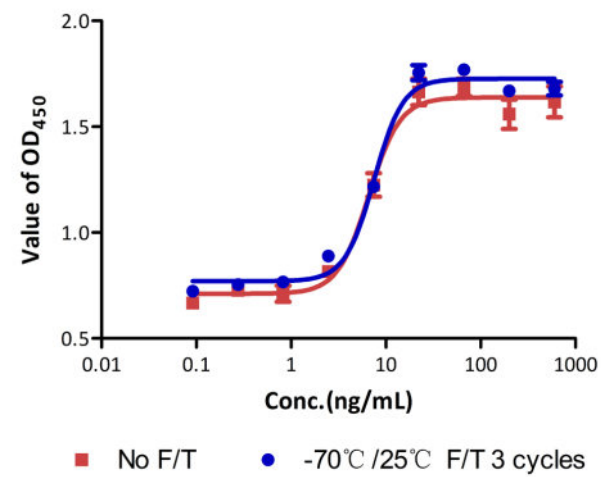
Bioactivity-Stability

37°C Accelerated Stability (Reconstituted protein)



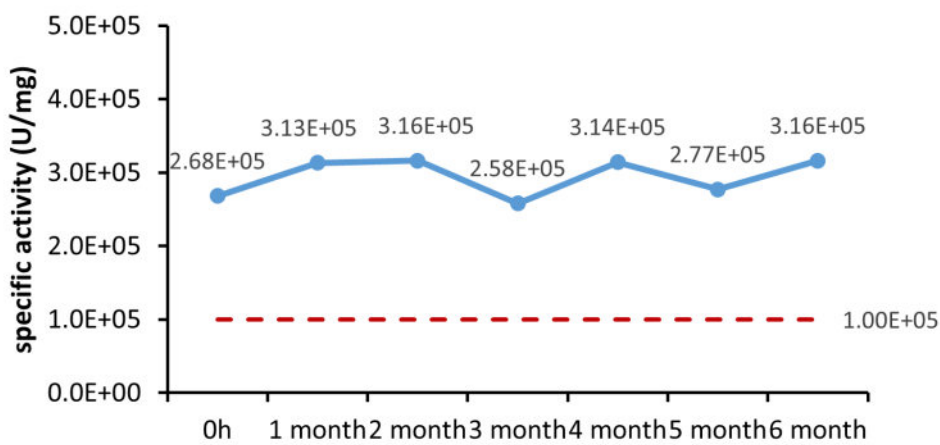
The Cell based assay shows that GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is stable at 37°C for 24 hours.

Freeze & Thaw stability (Reconstituted protein)



The Cell based assay shows that GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is stable after freezing and thawing 3 times.

4°C Accelerated Stability (Reconstituted protein)



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The Cell based assay shows that GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is stable at 4°C for 6 months.

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-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 (γ c) 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.

Clinical and Translational Updates

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