



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 (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±3 kDa under reducing (R) condition (SDS-PAGE) due to glycosylation.

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.

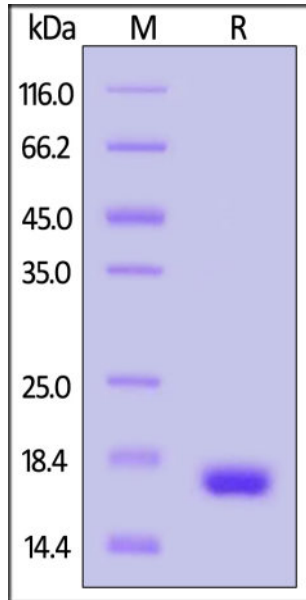
This product is stable after storage at:

- -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](#)

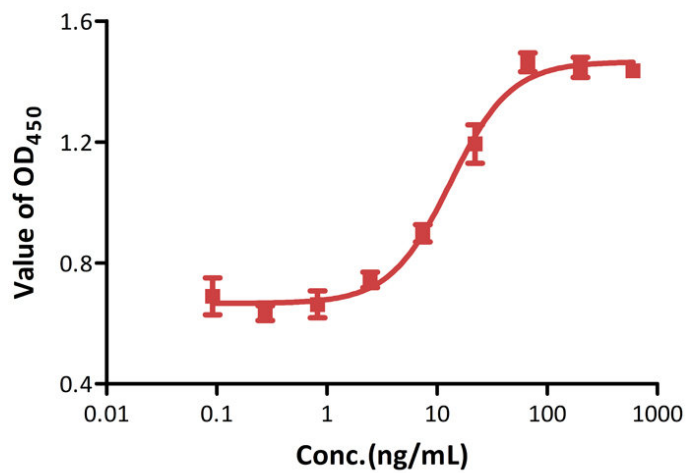
SDS-PAGE



GMP Human IL-21 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

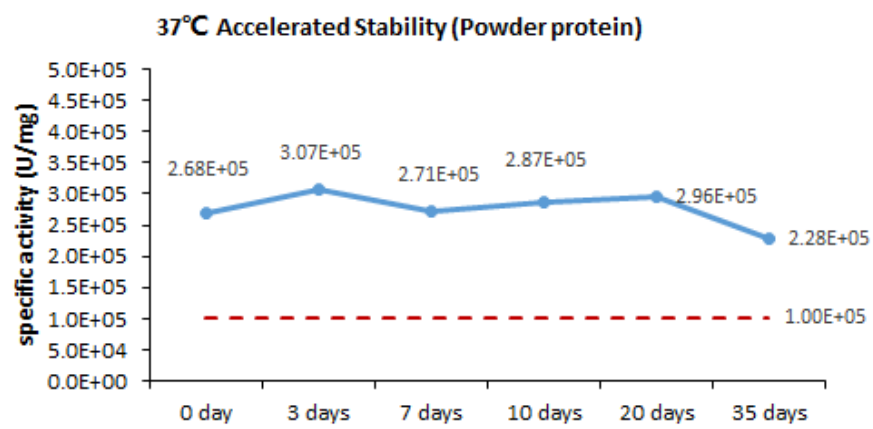
Bioactivity-CELL BASE

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

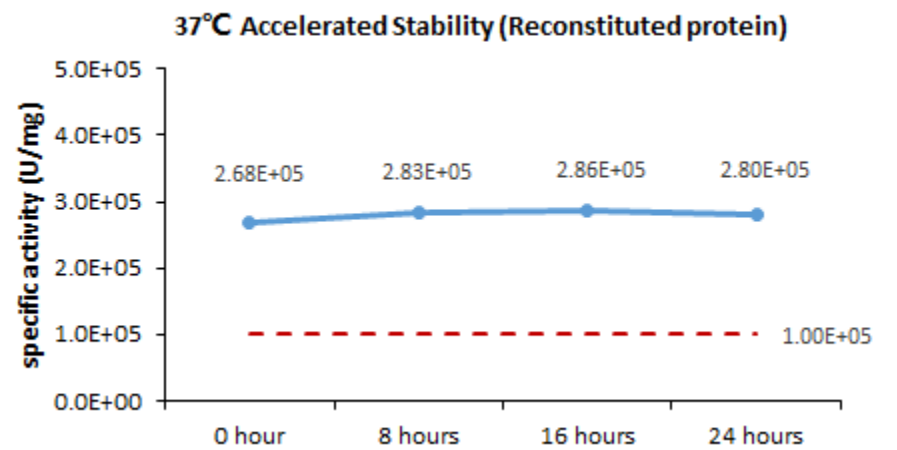


GMP Human IL-21 Protein (Cat. No. GMP-L21H25) stimulates secretion of IFN- γ by NK-92 human natural killer lymphoma cells stimulated with 10 ng/mL GMP Human IL-15 Protein (Cat. No. GMP-L15H13). The specific activity of GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is $> 1.00 \times 10^5$ U/mg (QC tested).

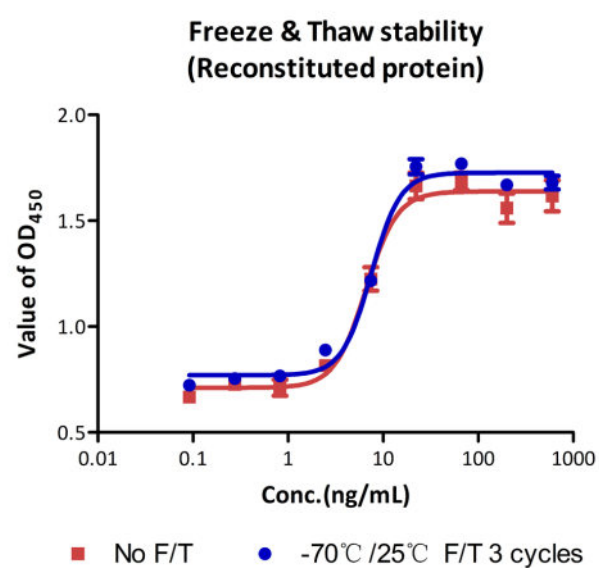
Bioactivity-Stability



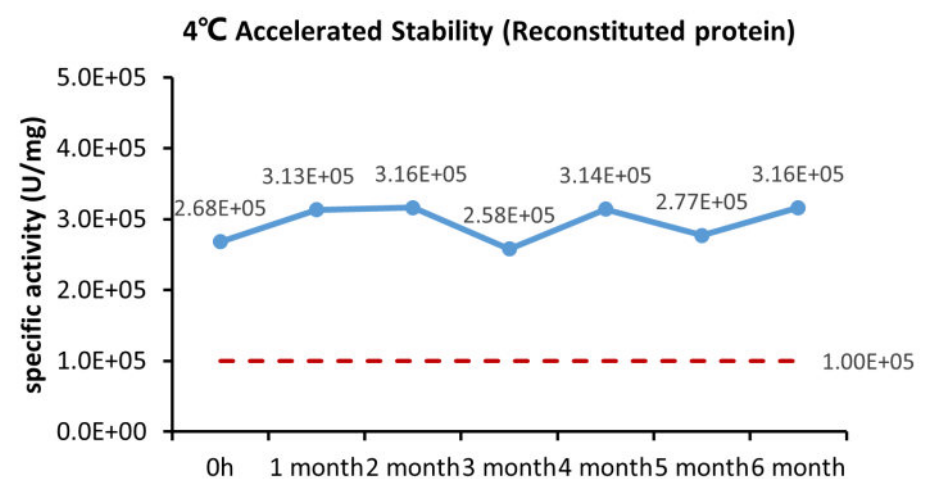
Cell-based assay demonstrates that the lyophilized GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is stable at 37°C for 35 days.



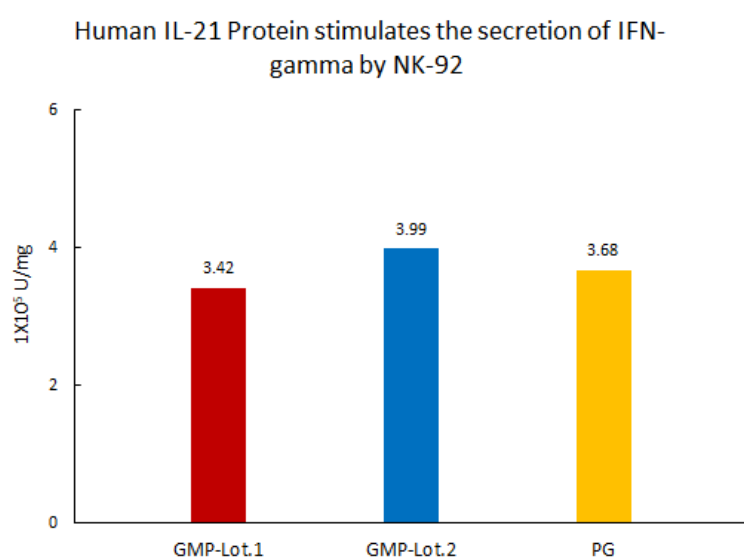
Cell-based assay demonstrates that the reconstituted GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is stable at 37°C for 24 hours.



Cell-based assay demonstrates that the reconstituted GMP Human IL-21 Protein (Cat. No. GMP-L21H25) is stable after 3 freeze-thaw cycles.



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



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG IL-21.

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

ACROBIOSYSTEMS - LEGAL NOTICES FOR GMP GRADE PRODUCTS

1. PRODUCT USE RESTRICTIONS & PROHIBITIONS

- 1.1 ACROBiosystems ("ACRO") GMP grade products ("Products") are designed for research, manufacturing use or ex vivo use.
- 1.2 Products are NOT intended for diagnostic purposes or for direct or indirect administration into humans.
- 1.3 Purchaser shall not market, distribute, or resell Products obtained from ACRO without ACRO's prior written consent.

2. REVERSE ENGINEERING PROHIBITED & CONFIDENTIALITY

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- 2.2 All specifications, data, and know-how related to the Products provided by ACRO are ACRO's confidential information and shall be protected accordingly.

3. LIMITED WARRANTY & DISCLAIMERS

- 3.1 ACRO warrants solely that Products will conform to their published specifications when used under normal, specified laboratory/manufacturing conditions and within their labeled expiration date. **THIS IS THE ONLY WARRANTY PROVIDED.**
- 3.2 Purchaser assumes ALL risk and responsibility for:
 - (a) Determining the suitability of Products for Purchaser's intended application(s).
 - (b) Obtaining any necessary regulatory approvals or intellectual property licenses for Purchaser's use.
 - (c) Compliance with all applicable laws, regulations (including but not limited to cGMP/GLP where claimed), and industry standards.
 - (d) Conducting all necessary quality control, safety, efficacy, and validation testing of Products within Purchaser's process or final product.
 - (e) Proper storage, handling, and use of Products according to ACRO's instructions.

3.3 ACRO EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING BUT NOT LIMITED TO: (A) WARRANTIES OF MERCHANTABILITY; (B) WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE; (C) WARRANTIES OF NON-INFRINGEMENT; AND (D) WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

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(a) LOST PROFITS, LOST REVENUE, LOST SAVINGS, LOSS OF USE, LOSS OF DATA, BUSINESS INTERRUPTION, OR ANY OTHER INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES.

(b) ANY DIRECT DAMAGES, COSTS, OR EXPENSES EXCEEDING THE AMOUNT PAID BY PURCHASER FOR THE SPECIFIC PRODUCT(S) GIVING RISE TO THE CLAIM.

(c) DAMAGES ARISING FROM: (i) MISUSE, ABUSE, OR UNAUTHORIZED MODIFICATION OF PRODUCTS; (ii) USE BEYOND THE EXPIRATION DATE; (iii) IMPROPER STORAGE OR HANDLING; (iv) ACCIDENTAL DAMAGE; (v) FAILURE TO CONDUCT ADEQUATE VALIDATION OR TESTING BY PURCHASER; (vi) INFRINGEMENT CLAIMS RELATED TO PURCHASER'S USE; OR (vii) THE COST OF PROCURING SUBSTITUTE GOODS OR SERVICES.

(d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

5. END USER ACKNOWLEDGEMENT & COMPLIANCE

5.1 By accepting, opening, or using the Products, the End User (Purchaser or its downstream recipient) agrees to be irrevocably bound by all terms herein.

5.2 End User explicitly acknowledges the Products are NOT FOR HUMAN ADMINISTRATION and agrees not to use them in any in vivo human application, directly or indirectly.

5.3 End Users unwilling to accept these terms must immediately: (a) cease all use; (b) notify ACRO or their supplier; and (c) return the unopened, unused Products. 5.4 ACRO reserves the right to audit End User's compliance with these restrictions upon reasonable notice

ACRO has the right, at its sole discretion, to modify, add or remove any terms herein without notice to Purchaser and/or End User. Any changes to these terms are effective immediately following the updating of such changes on ACRO's website or published specifications or product-related documents



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