GMP Human IL-15 Protein

Catalog # GMP-L15H13

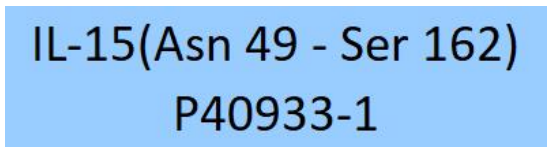
GMP Platform Advantages

- **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-15 Protein (GMP-L15H13) is expressed from *E. coli* cells. It contains AA Asn 49 - Ser 162 (Accession # P40933-1).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 12.9 kDa. The protein migrates as 13 kDa±3 kDa under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

Met-Asn-Trp-Val-Asn-Val-Ile-Ser-Asp-Leu-Lys-Lys-Ile-Glu-Asp
(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 DNA Fluorescent Staining method.

Sterility

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

Mycoplasma

Negative

In vitro virus assay

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 μm filtered solution in 25 mM His, pH6.2 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.

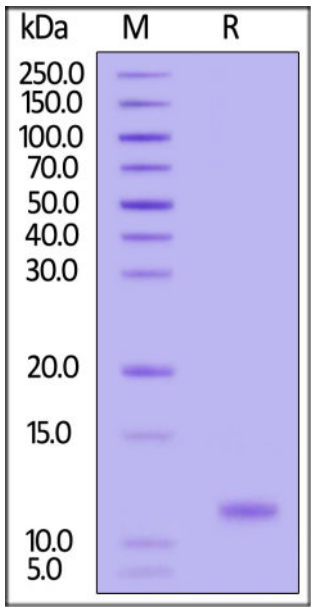
This product is stable after storage at:

- -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

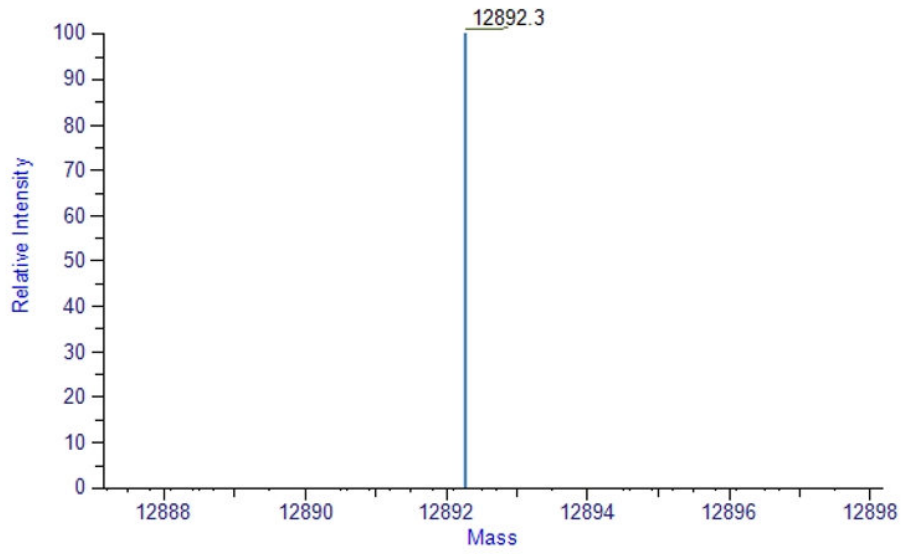
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



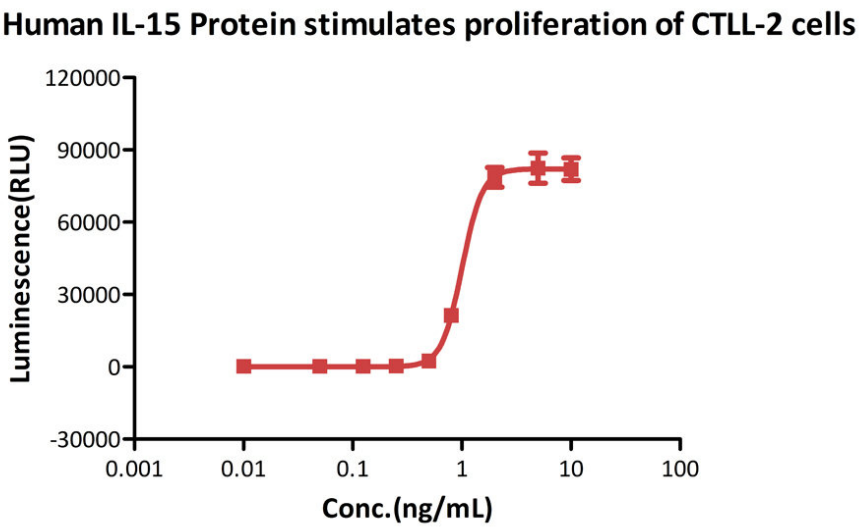
GMP Human IL-15 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

Mass Spectrometry



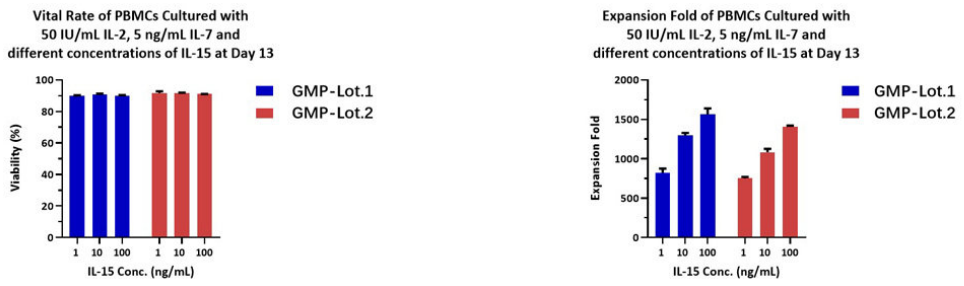
ESI-MS analysis of GMP Human IL-15 Protein (Cat. No. GMP-L15H13), the labeled peak at 12892.3 Da corresponds to the calculated molecular mass 12904.69 Da (Routinely tested).

Bioactivity-CELL BASE

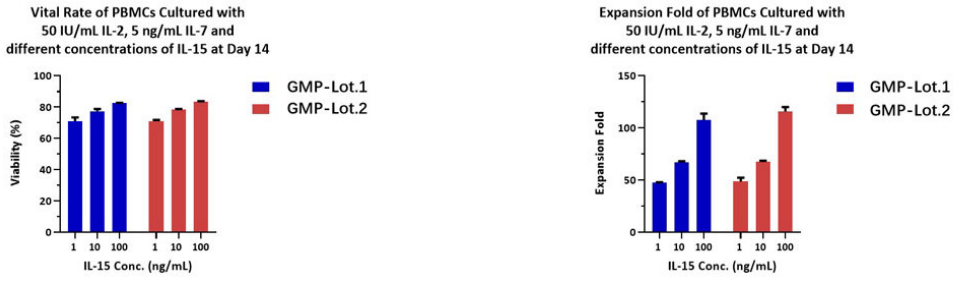


GMP Human IL-15 Protein (Cat. No. GMP-L15H13) stimulates proliferation of CTLL-2 cells. The specific activity of GMP Human IL-15 is > 8.00x10^6 IU/mg, which is calibrated against human IL-15 WHO International Standard (NIBSC code: 95/554) (QC tested).

Application Data

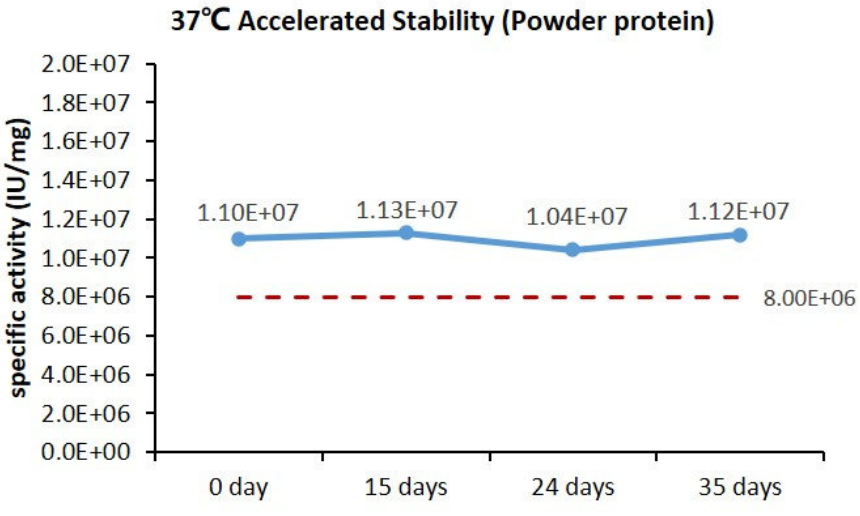


Human PBMCs were cultured in CelThera™ GMP T Cell Expansion Medium (ACROBiosystems, Cat. No. GMP-CM3103) with 50 IU/mL GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14), 5 ng/mL GMP Human IL-7 Protein (ACROBiosystems, Cat. No. GMP-L07H24) and 1, 10 or 100 ng/mL GMP Human IL-15 Protein (ACROBiosystems, Cat. No. GMP-L15H13) for 13 days. The result shows that Acro's GMP Human IL-15 Protein activity is consistent across batches.

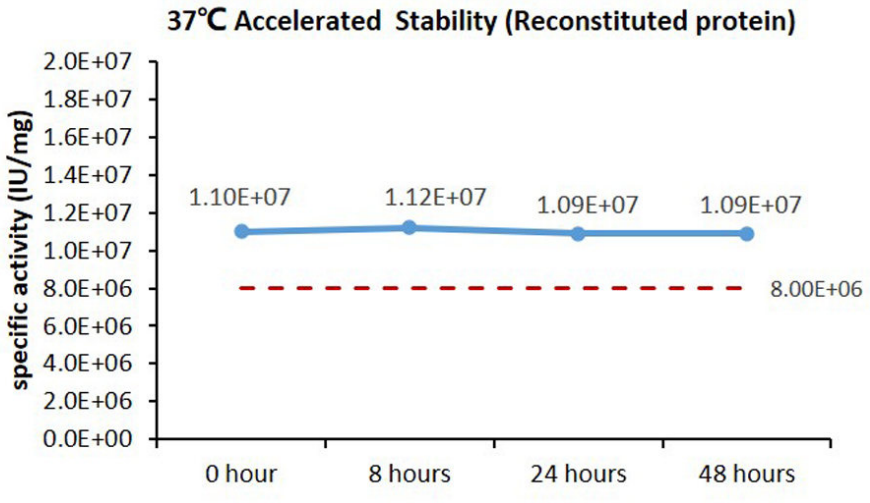


Human PBMCs were cultured in X-VIVO-15 with 50 IU/mL GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14), 5 ng/mL GMP Human IL-7 Protein (ACROBiosystems, Cat. No. GMP-L07H24) and 1, 10 or 100 ng/mL GMP Human IL-15 Protein (ACROBiosystems, Cat. No. GMP-L15H13) for 14 days. The result shows that Acro's GMP Human IL-15 Protein activity is consistent across batches.

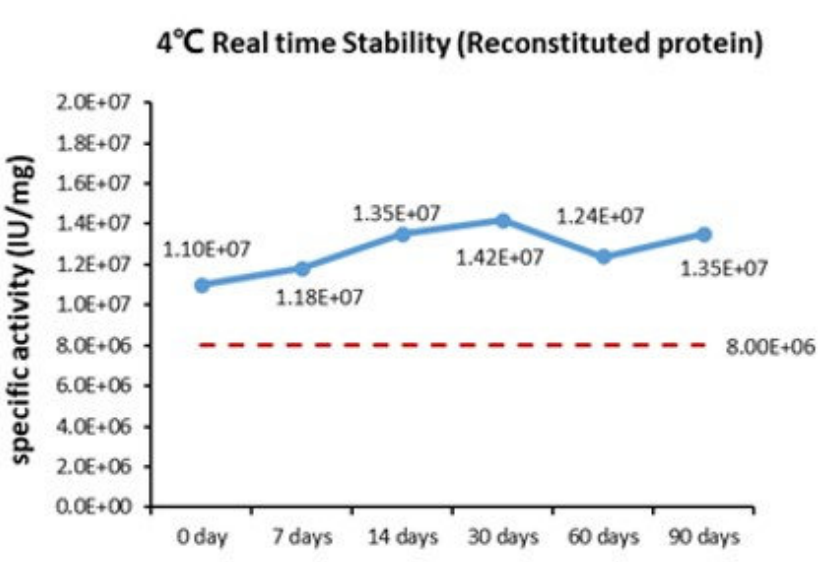
Bioactivity-Stability



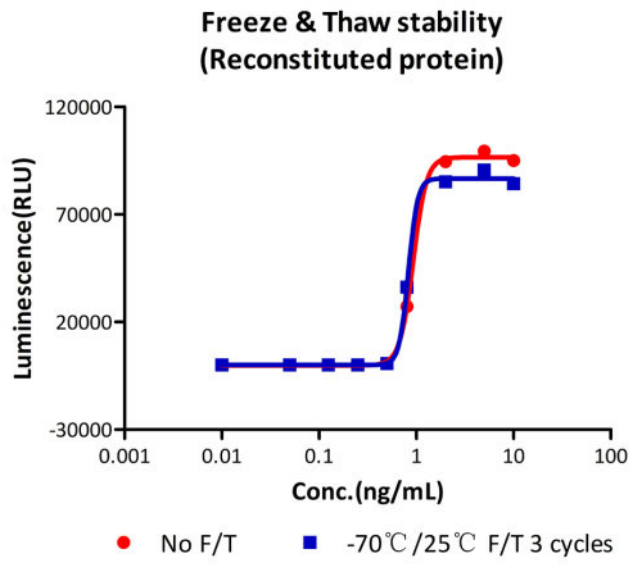
Cell-based assay demonstrates that the lyophilized GMP Human IL-15 Protein (Cat. No. GMP-L15H13) is stable at 37°C for 35 days.



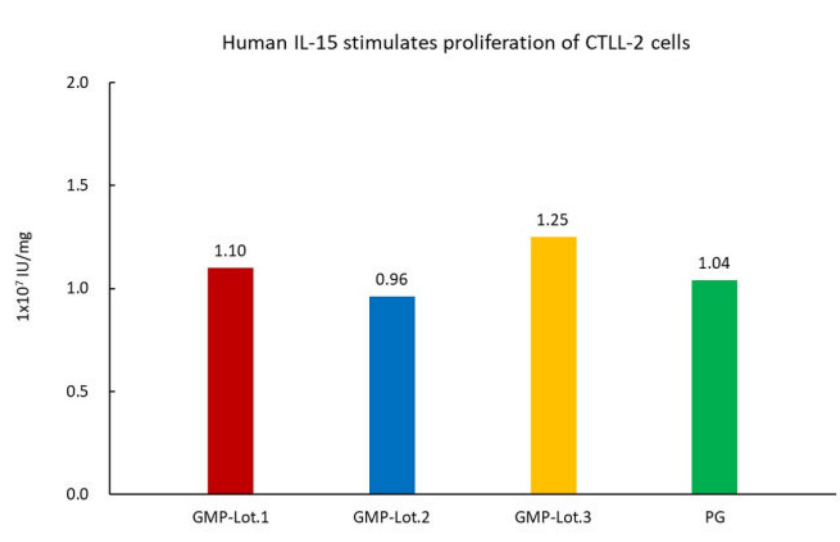
Cell-based assay demonstrates that the reconstituted GMP Human IL-15 Protein (Cat. No. GMP-L15H13) is stable at 37°C for 48 hours.



Cell-based assay demonstrates that the reconstituted GMP Human IL-15 Protein (Cat. No. GMP-L15H13) is stable at 4℃ for 3 months in 4℃ real time stability experiment.



Cell-based assay demonstrates that the reconstituted GMP Human IL-15 Protein (Cat. No. GMP-L15H13) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG IL-15.

Background

Interleukin 15 is also known as IL15, IL-15, and is a cytokine with structural similarity to IL-2. Like IL-2, IL-15 binds to and signals through the IL-2/IL-15 beta chain (CD122) and the common gamma chain (gamma-C, CD132). IL-15 is secreted by mononuclear phagocytes (and some other cells) following infection by virus(es). This cytokine induces cell proliferation of natural killer cells; cells of the innate immune system whose principal role is to kill virally infected cells. Interleukin 15 (IL-15) regulates T and natural killer (NK) cell activation and proliferation. Survival signals that maintain memory T cells in the absence of antigen are

provided by IL-15. This cytokine is also implicated in NK cell development. In rodent lymphocytes, IL-15 prevents apoptosis by inducing an apoptosis inhibitor, BCL2L1/BCL-x(L). IL-15 has been shown to enhance the anti-tumor immunity of CD8+ T cells in pre-clinical models. A phase I clinical trial to evaluate the safety, dosing, and anti-tumor efficacy of IL-15 in patients with metastatic melanoma and renal cell carcinoma (kidney cancer) has begun to enroll patients at the National Institutes of Health.

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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