

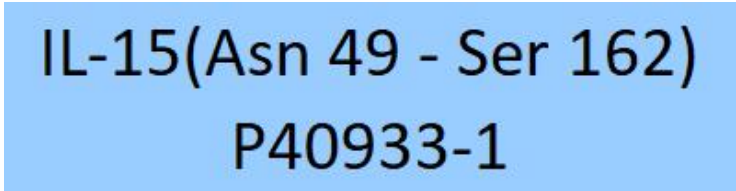
Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- FDA DMF filed
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests
- No animal derived peptone and lactose used in production process

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 12.8 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 by the LAL method / rFC method.

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

The sterility testing was performed by membrane filtration method described in 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.

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:

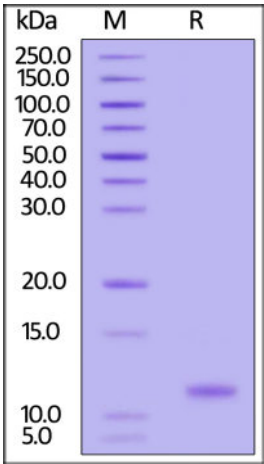
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE



GMP Human IL-15 Protein

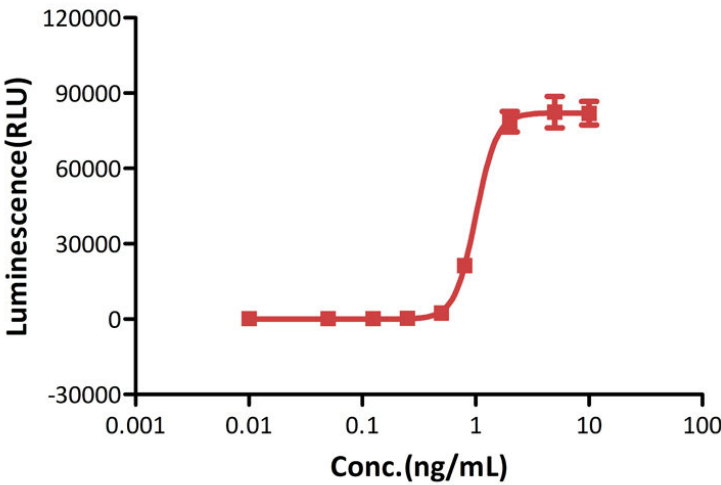
Catalog # GMP-L15H13



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%.

Bioactivity-CELL BASE

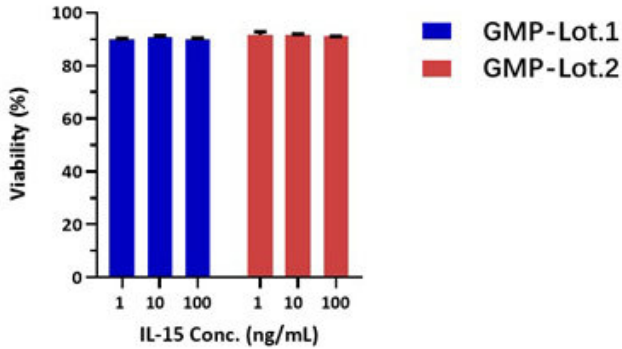
GMP Human IL-15 Protein stimulates proliferation of CTLL-2 cells



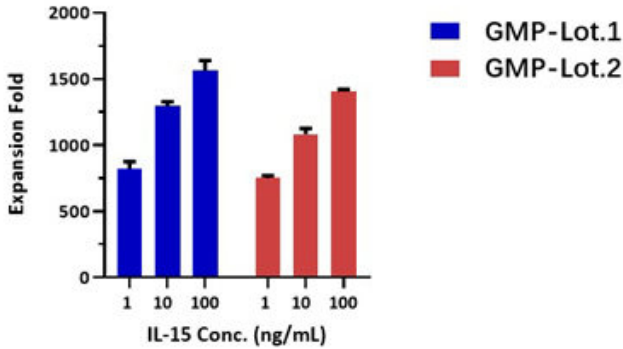
GMP Human IL-15 Protein (Cat. No. GMP-L15H13) stimulates proliferation of CTLL-2 cells. The specific activity of GMP Human IL-15 is > 8.00x10^6 IU/mg, which is calibrated against human IL-15 WHO International Standard (NIBSC code: 95/554) (QC tested).

Application Data

Vital Rate of PBMCs Cultured with 50 IU/mL IL-2, 5 ng/mL IL-7 and different concentrations of IL-15 at Day 13

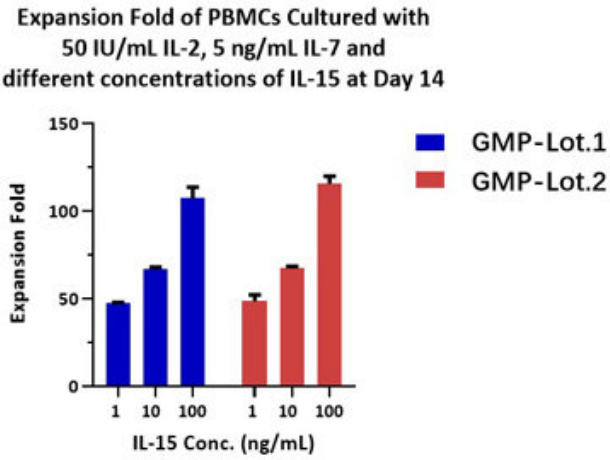
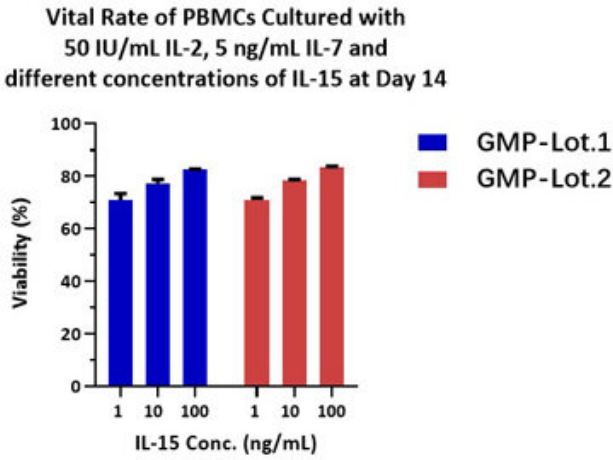


Expansion Fold of PBMCs Cultured with 50 IU/mL IL-2, 5 ng/mL IL-7 and different concentrations of IL-15 at Day 13



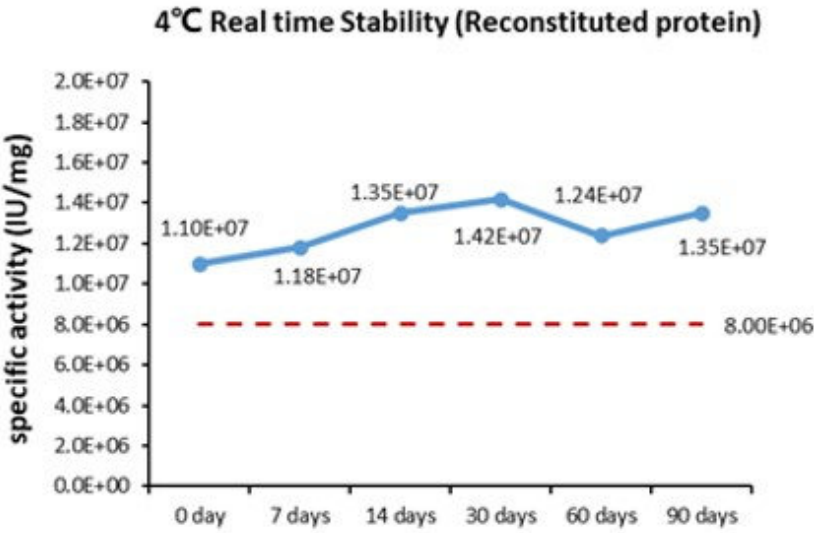
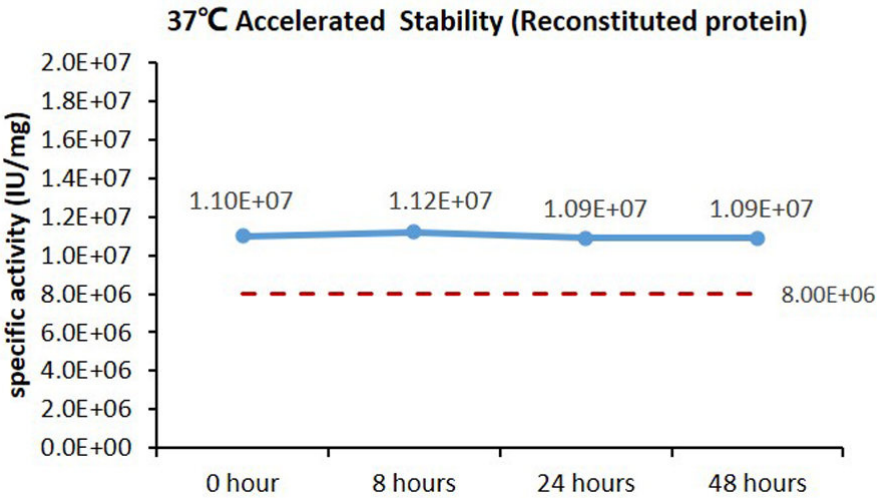
Human PBMCs were cultured in CelThera™ GMP T Cell Expansion Medium (ACROBiosystems, Cat. No. GMP-CM3101) with 50 IU/mL GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14), 5 ng/mL GMP Human IL-7 Protein (ACROBiosystems, Cat. No. GMP-L07H24) and 1, 10 or 100 ng/mL GMP Human IL-15 Protein (ACROBiosystems, Cat. No. GMP-L15H13) for 13 days. The result shows that Acro's GMP Human IL-15 Protein activity is consistent across batches.





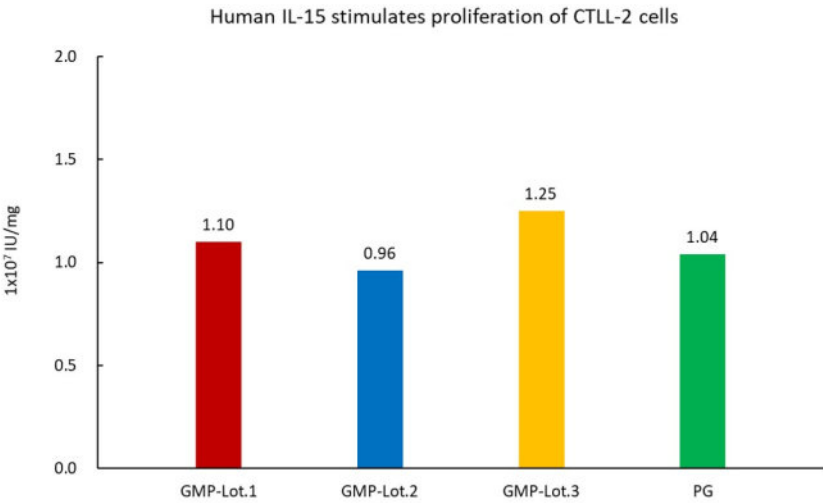
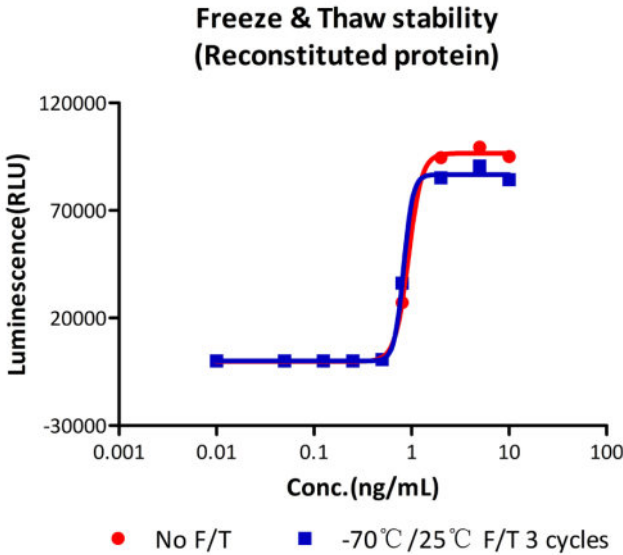
Human PBMCs were cultured in X-VIVO-15 with 50 IU/mL GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14), 5 ng/mL GMP Human IL-7 Protein (ACROBiosystems, Cat. No. GMP-L07H24) and 1, 10 or 100 ng/mL GMP Human IL-15 Protein (ACROBiosystems, Cat. No. GMP-L15H13) for 14 days. The result shows that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

Bioactivity-Stability



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

The Cell based assay shows that GMP Human IL-15 Protein (Cat. No. GMP-L15H13) is stable at 4°C for 3 months in 4°C real time stability experiment.



The Cell based assay shows that GMP Human IL-15 Protein (Cat. No. GMP-L15H13) is stable after freezing and thawing 3 times.

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

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

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



GMP Human IL-15 Protein

Catalog # GMP-L15H13



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.

