

GMP Human IL-7 Protein (E. coli)

Catalog # GMP-L07H15



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-7 Protein (*E. coli*) (GMP-L07H15) is expressed from *E. coli* cells. It contains AA Asp 26 - His 177 (Accession # [P13232-1](#)).

Molecular Characterization

IL-7(Asp 26 - His 177)
P13232-1

This protein carries no "tag".

The protein has a calculated MW of 17.5 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-Asp-Cys-Asp-Ile-Glu-Gly-Lys-Asp-Gly-Lys-Gln-Tyr-Glu-Ser
(Routinely tested)

Endotoxin

Less than 10 EU/mg, tested by the rFC method in compliance with USP <86> and Ph. Eur. 2.6.32.

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.

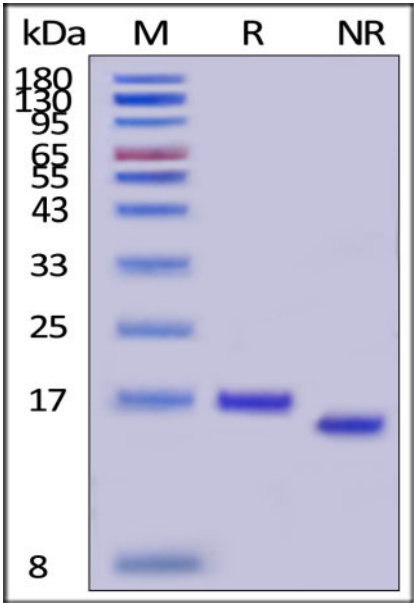
This product is stable after storage at:

- -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

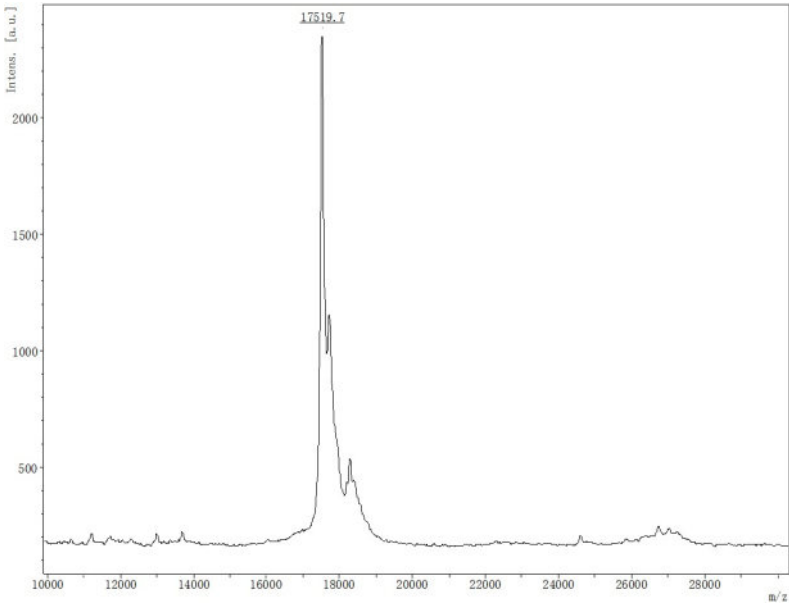
- [QMS\(ISO, GMP\)](#).
- [Quality Advantages](#)
- [Quality Control Process](#)

SDS-PAGE



GMP Human IL-7 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](#)).

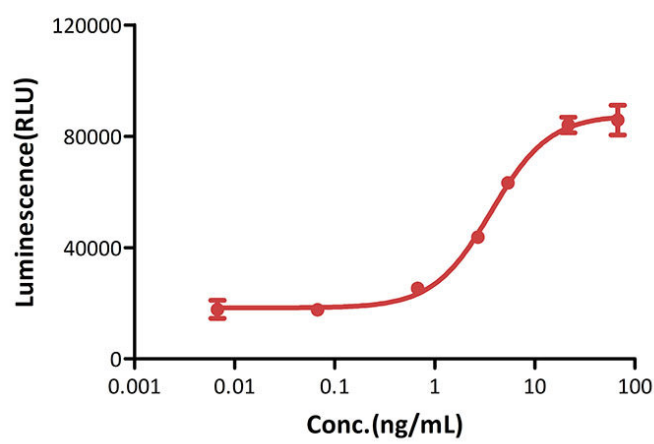
Mass Spectrometry



MALDI-TOF analysis of GMP Human IL-7 Protein (*E. coli*) (Cat. No. GMP-L07H15), the labeled peak at 17519.7 Da corresponds to the calculated molecular mass 17518.38 Da. The two minor peaks following the major peak are matrix-associated artifacts of the MALDI-TOF (Routinely tested).

Bioactivity-CELL BASE

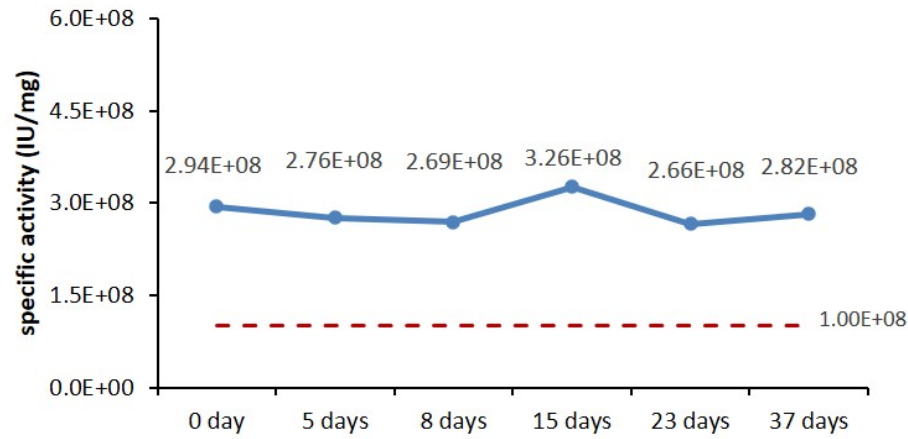
GMP Human IL-7 Protein (E. coli) stimulates proliferation of PBMC cells



GMP Human IL-7 Protein (*E. coli*) (Cat. No. GMP-L07H15) stimulates proliferation of PHA-P-activated human peripheral blood mononuclear cell (PBMC). The specific activity of GMP Human IL-7 Protein (*E. coli*) > 1.00 x10^8 IU/mg, which is calibrated against human IL-7 WHO International Standard (NIBSC code: 90/530) (QC tested).

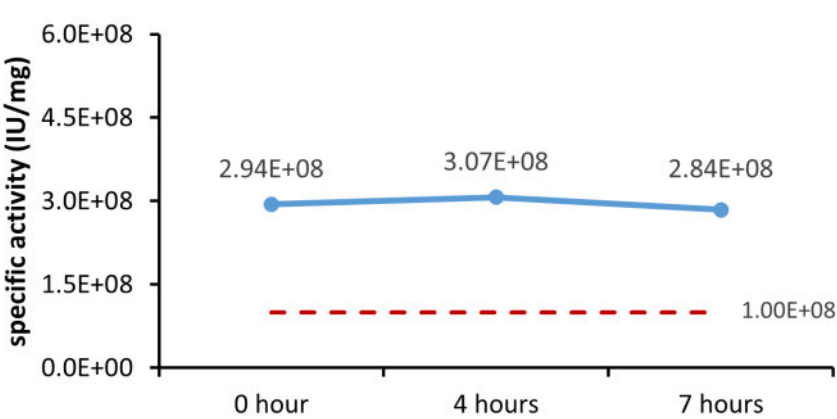
Bioactivity-Stability

37°C Accelerated Stability (Powder protein)



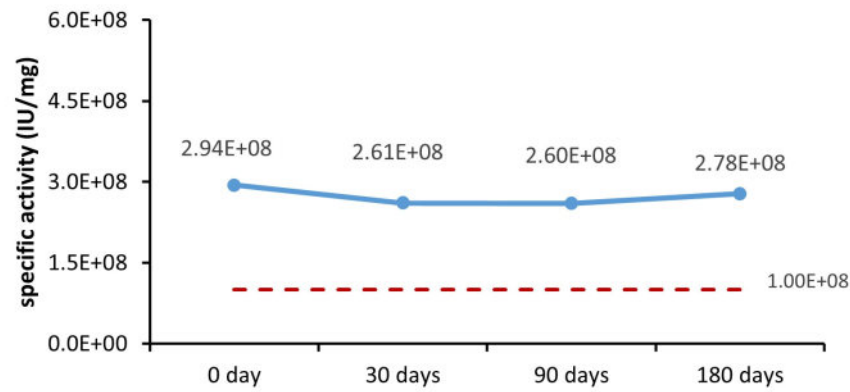
Cell-based assay demonstrates that the lyophilized GMP Human IL-7 Protein (*E. coli*) (Cat. No. GMP-L07H15) is stable at 37°C for 37 days.

37°C Accelerated Stability(Reconstituted protein)



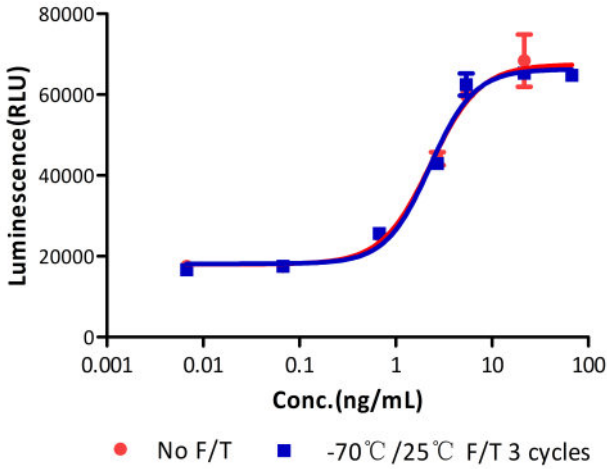
Cell-based assay demonstrates that the reconstituted GMP Human IL-7 Protein (*E. coli*) (Cat. No. GMP-L07H15) is stable at 37°C for 7 hours.

4°C Accelerated Stability (Reconstituted protein)

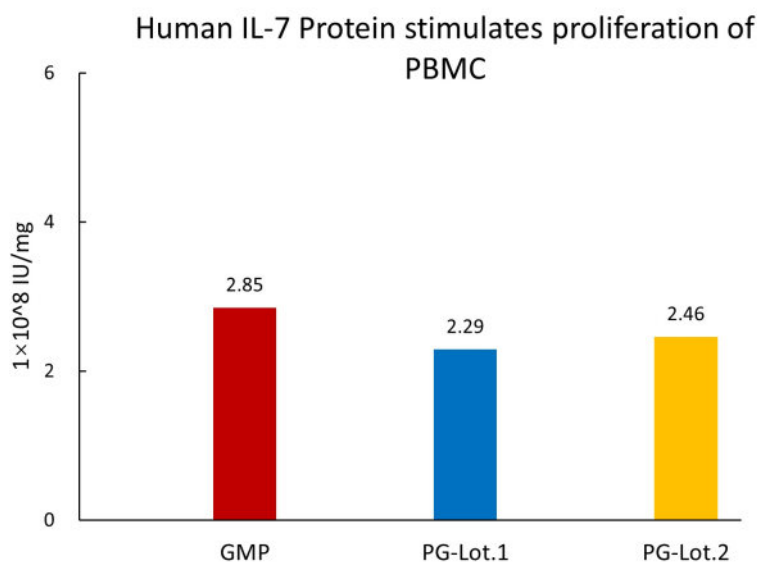


Cell-based assay demonstrates that the reconstituted GMP Human IL-7 Protein (*E. coli*) (Cat. No. GMP-L07H15) is stable at 4°C for 180 days.

Freeze & Thaw stability (Reconstituted protein)



Cell-based assay demonstrates that the reconstituted GMP Human IL-7 Protein (*E. coli*) (Cat. No. GMP-L07H15) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG IL-7.

Background

Interleukin 7 is also known as IL7, IL-7, and is a hematopoietic growth factor secreted by stromal cells in the red marrow and thymus. It is also produced by keratinocytes, dendritic cells, hepatocytes, neurons, and epithelial cells, but is not produced by lymphocytes. IL-7 stimulates the differentiation of multipotent (pluripotent) hematopoietic stem cells into lymphoid progenitor cells, It also stimulates proliferation of all cells in the lymphoid lineage (B cells, T cells and NK cells). It is important for proliferation during certain stages of B-cell maturation, T and NK cell survival, development and homeostasis. IL-7 is a cytokine important for B and T cell development. This cytokine and the hepatocyte growth factor (HGF) form a heterodimer that functions as a pre-pro-B cell growth-stimulating factor. IL-7 binds to the IL-7 receptor, a heterodimer consisting of Interleukin-7 receptor alpha and common gamma chain receptor. Il-7 promotes hematological malignancies (acute lymphoblastic leukemia, T cell lymphoma). Elevated levels of IL-7 have also been detected in the plasma of HIV-infected patients. IL-7 as an immunotherapy agent has been examined in many pre-clinical animal studies and more recently in human clinical trials for various malignancies and during HIV infection. IL-7 could also be beneficial in improving immune recovery after allogenic stem cell transplant.

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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