

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

Source

GMP Human IL-7 Protein(GMP-L07H24) is expressed from human 293 cells (HEK293). It contains AA Asp 26 - His 177 (Accession # [P13232-1](#)).
Predicted N-terminus: Asp 26

Molecular Characterization

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

This protein carries no "tag".

The protein has a calculated MW of 17.4 kDa. The protein migrates as 23 kDa and 28 kDa (±3 kDa) under reducing (R) condition (SDS-PAGE) due to glycosylation.

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 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

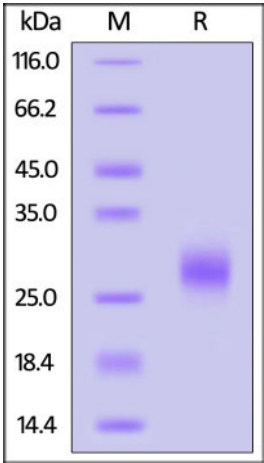
Upon receipt, store it immediately at -20°C or lower for long term storage.

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-7 Protein

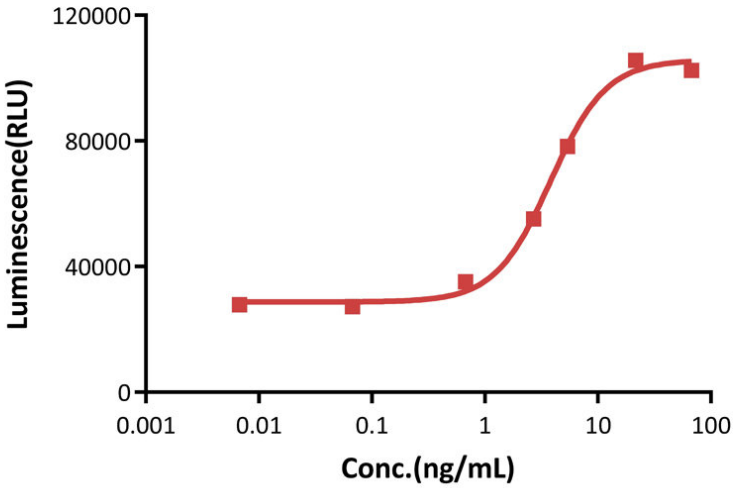
Catalog # GMP-L07H24



GMP Human IL-7 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

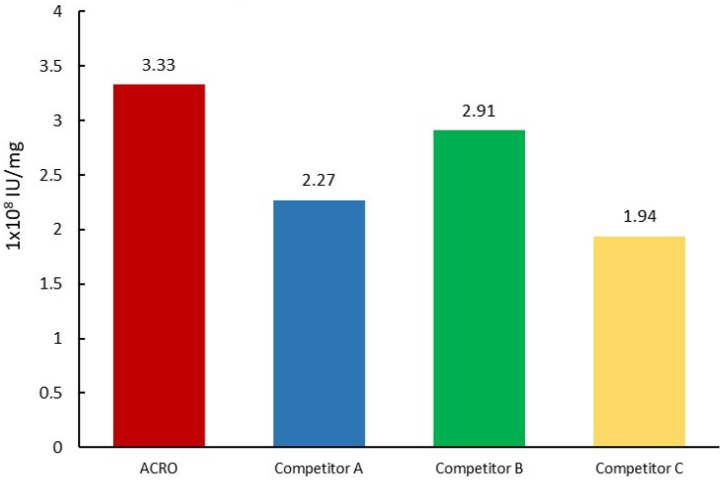
Bioactivity-CELL BASE

GMP Human IL-7 Protein stimulates proliferation of PBMC cells



GMP Human IL-7 Protein (Cat. No. GMP-L07H24) stimulates proliferation of PHA-P-activated human peripheral blood mononuclear cell (PBMC). The specific activity of GMP Human IL-7 is $> 1.00 \times 10^8$ IU/mg, which is calibrated against human IL-7 WHO International Standard (NIBSC code: 90/530) (QC tested).

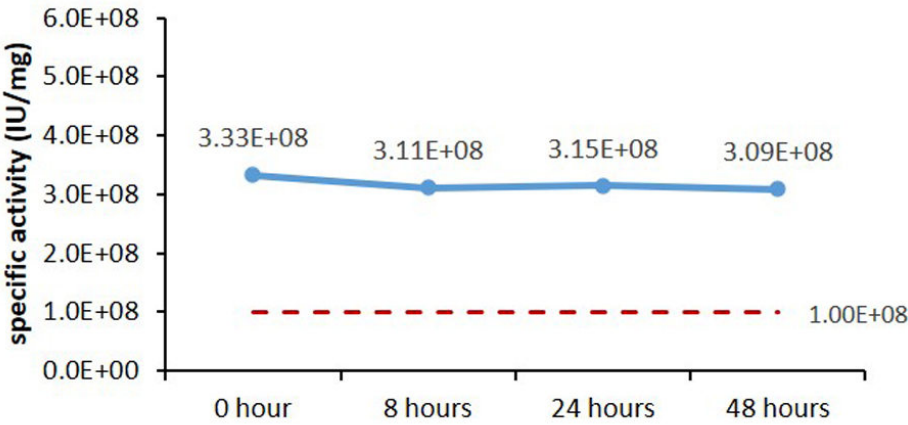
GMP Human IL-7 Protein stimulates proliferation of PBMC cells



The activity of GMP Human IL-7 Protein (Cat. No. GMP-L07H24) was higher than other competing products.

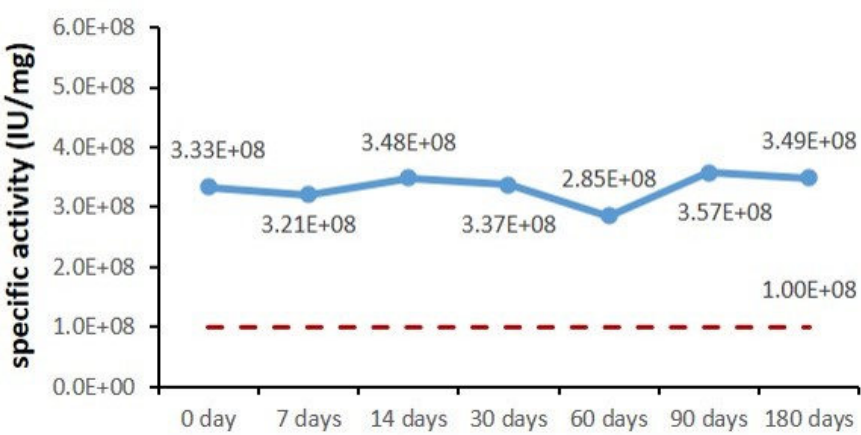
Bioactivity-Stability

37°C Accelerated Stability (Reconstituted protein)



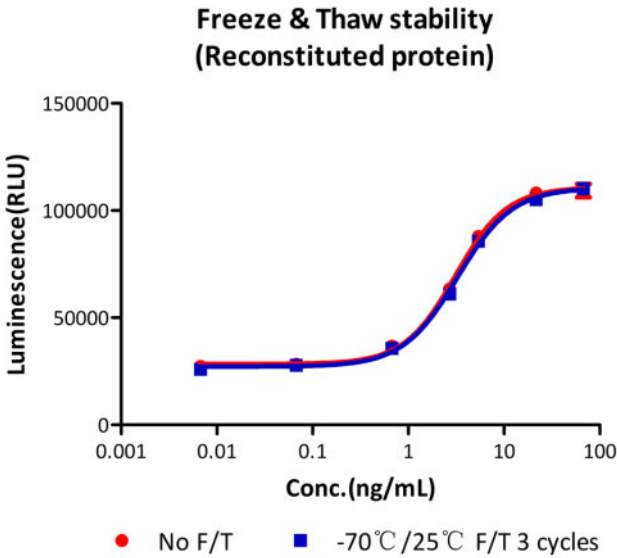
The Cell based assay shows that GMP Human IL-7 Protein (Cat. No. GMP-L07H24) is stable at 37°C for 48 hours.

4°C Real time Stability (Reconstituted protein)

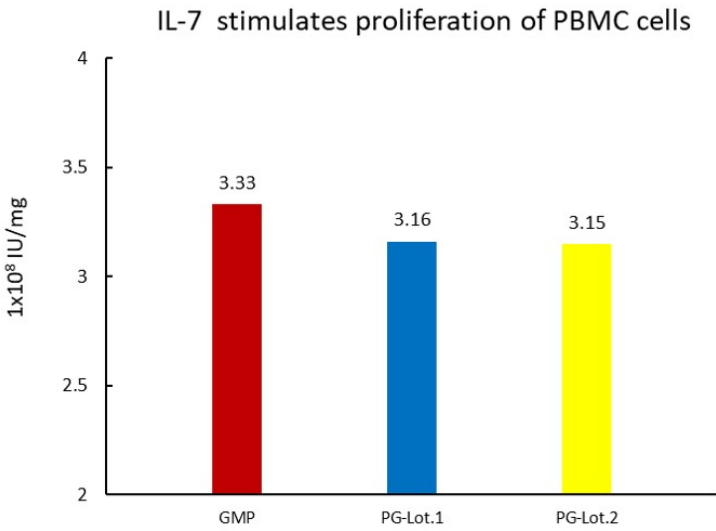


The Cell based assay shows that GMP Human IL-7 Protein (Cat. No. GMP-L07H24) is stable at 4°C for 6 months in 4°C real time stability experiment.





The Cell based assay shows that GMP Human IL-7 Protein (Cat. No. GMP-L07H24) is stable after freezing and thawing 3 times.



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

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 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 malignacies (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.

