

**Features**

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests

Source

GMP Human IL-12 Protein(GMP-L12H23) is expressed from human 293 cells (HEK293). It contains AA Ile 23 - Ser 328 & Arg 23 - Ser 219 (Accession # [P29460-1](#) & [P29459-1](#)).

Predicted N-terminus: Ile 23

Molecular Characterization

This protein carries no "tag".

The protein has a calculated MW of 58.9 kDa. The protein migrates as 76 kDa±3 kDa when calibrated against [Star Ribbon Pre-stained Protein Marker](#) under reducing (R) condition (SDS-PAGE) due to glycosylation.

Endotoxin

Less than 10 EU/mg by the LAL method.

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

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 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.

Shipping

This product is supplied and shipped with blue ice, please inquire the shipping cost.

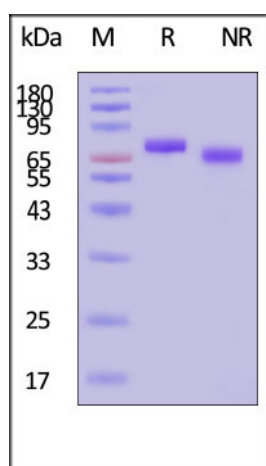
Storage

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-12 Protein 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](#)).

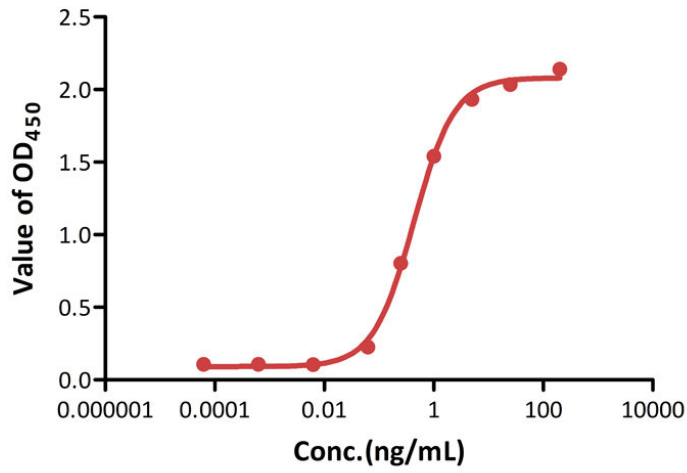
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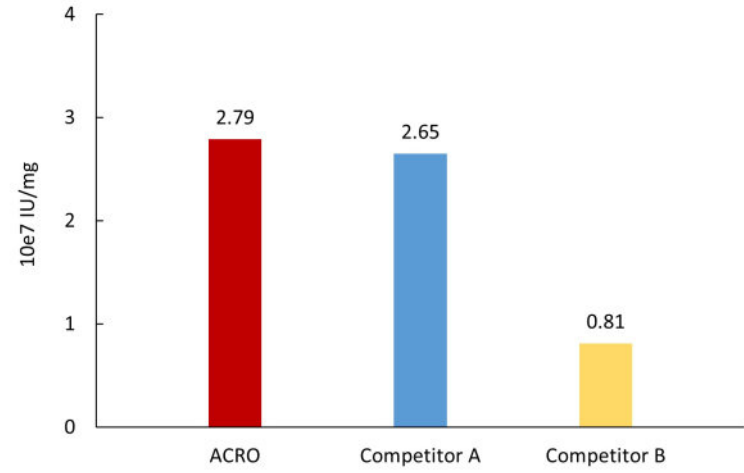


Bioactivity-Bioactivity CELL BASE

GMP Human IL-12 Protein stimulates secretion of IFN- γ by NK92



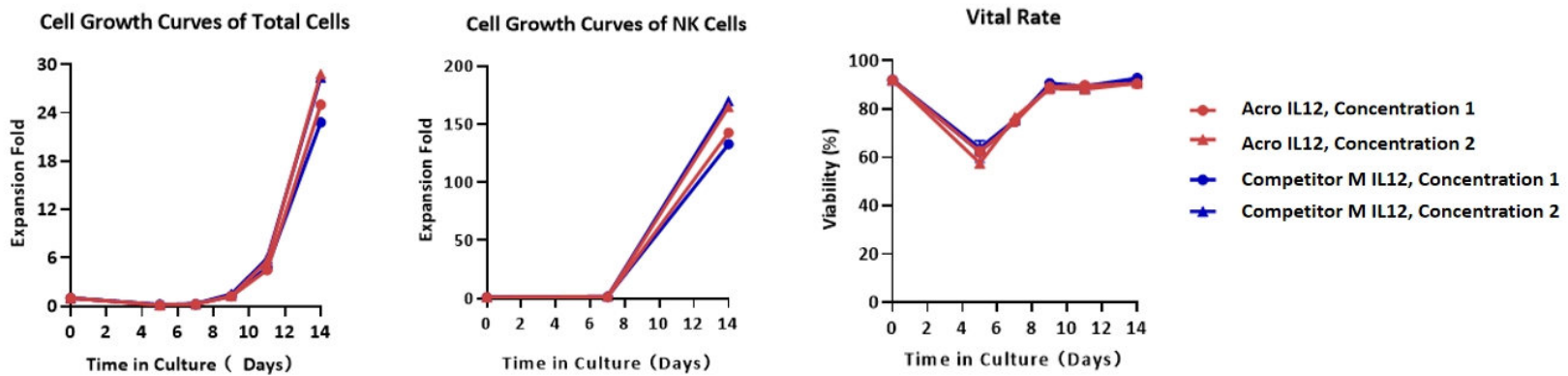
GMP Human IL-12 Protein stimulates the secretion of IFN-gamma by NK92 cells



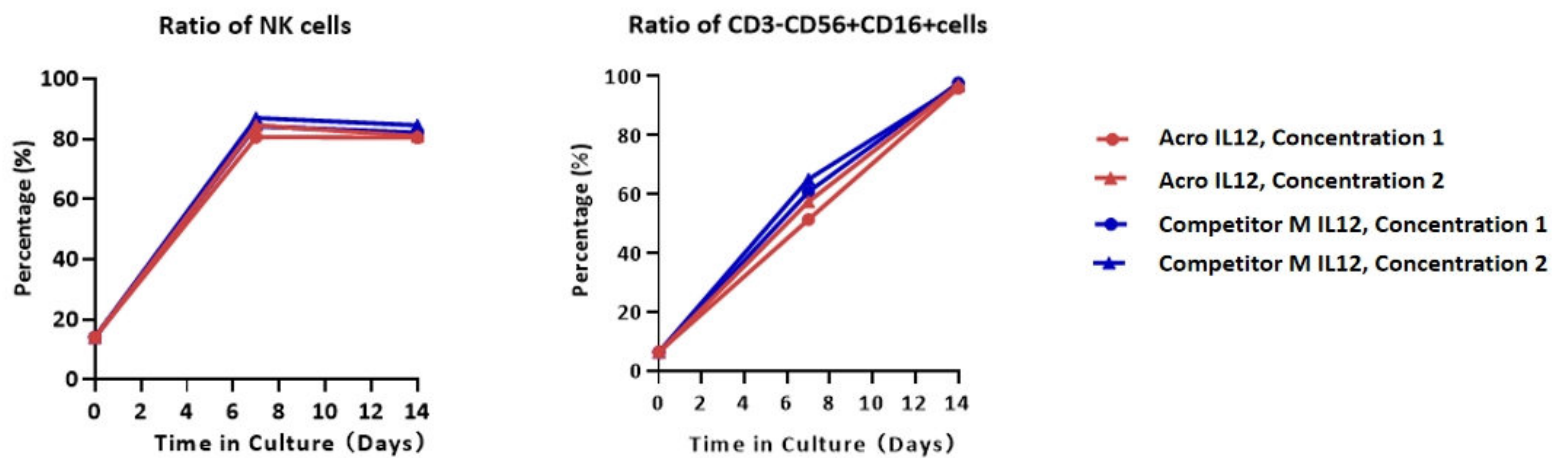
GMP Human IL-12 Protein (Cat. No. GMP-L12H23) stimulates secretion of IFN- γ by NK-92. The specific activity of GMP Human IL-12 Protein is > 1.00x10⁷ IU/mg, which is calibrated against human IL-12 WHO International Standard (NIBSC code: 95/544) (QC tested).

The activity of GMP Human IL-12 Protein (Cat. No. GMP-L12H23) was higher than other competing products.

Application Data



Human PBMCs were cultured with GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14), GMP Human IL-12 Protein (ACROBiosystems, Cat. No. GMP-L12H23) and GMP Human 4-1BB Ligand Protein (ACROBiosystems, Cat. No. GMP-41LH26), in CelThrea™ GMP T Cell Expansion Medium (ACROBiosystems, Cat. No. GMP-CM3101 & GMP-CM3101-1) for two weeks. The result shows that GMP Human IL-12 Protein (ACROBiosystems) can promote the expansion of these cells with a reasonable cell viability, and can be comparable with the Competitor M IL-12 protein.



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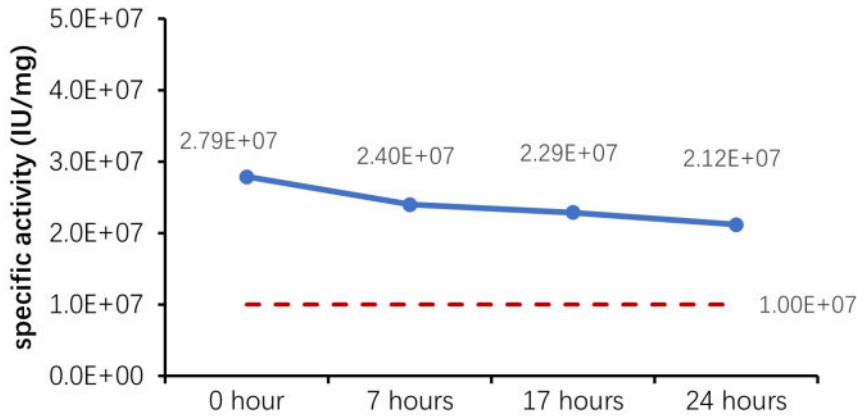
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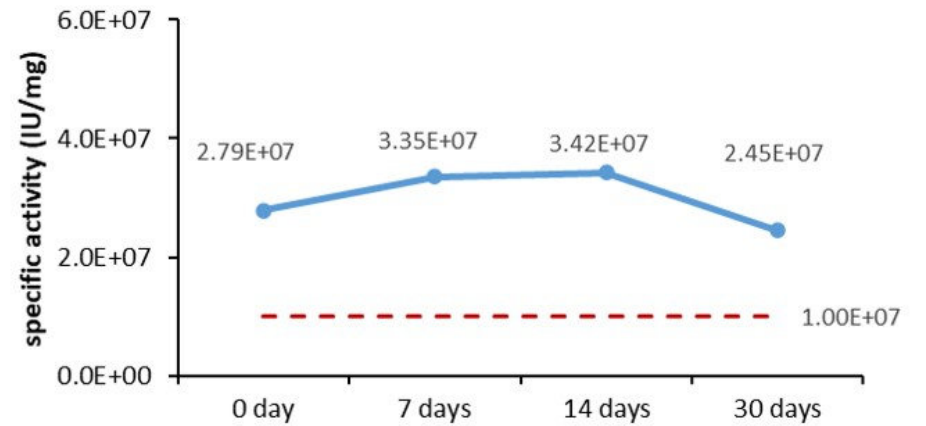
Bioactivity-Stability

37°C Accelerated Stability (Reconstituted protein)



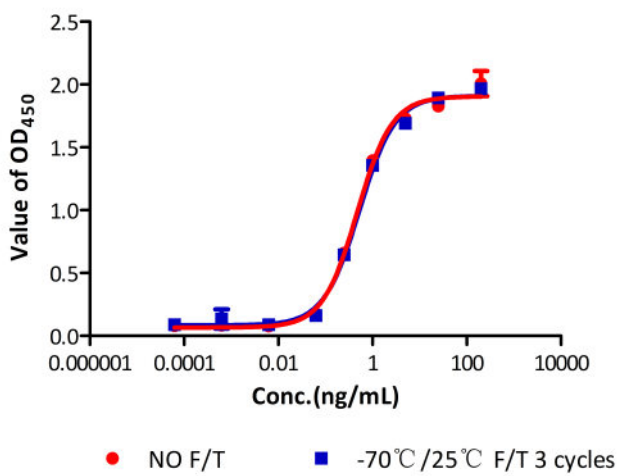
The Cell based assay shows that GMP Human IL-12 Protein (Cat. No. GMP-L12H23) is stable at 37°C for 24 hours.

4°C Accelerated Stability (Reconstituted protein)



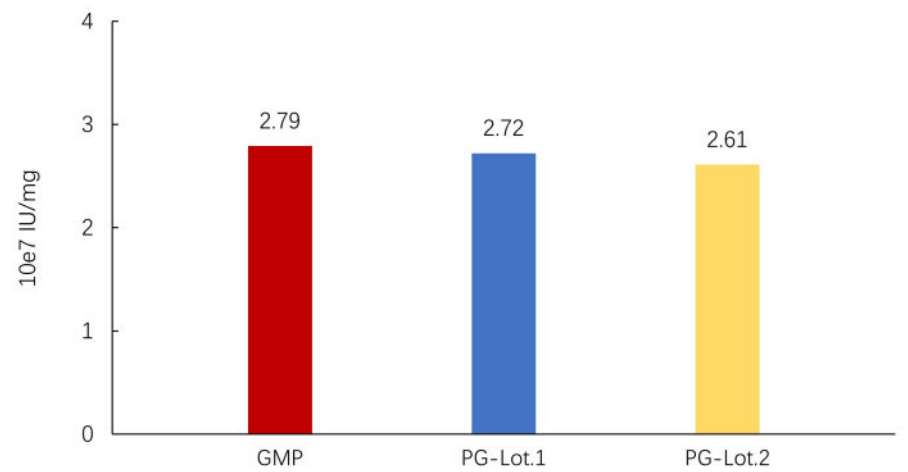
The Cell based assay shows that GMP Human IL-12 Protein (Cat. No. GMP-L12H23) is stable at 4°C for 30 days.

Freeze & Thaw stability (Reconstituted protein)



The Cell based assay shows that GMP Human IL-12 Protein (Cat. No. GMP-L12H23) is stable after freezing and thawing 3 times.

Human IL-12 stimulates secretion of IFN-γ by NK92



The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG IL-12.

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

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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

IL-12 is produced by macrophages and B lymphocytes and has been shown to have multiple effects on T cells and natural killer (NK) cells. These effects include inducing production of IFN-gamma and TNF by resting and activated T and NK cells, synergizing with other IFN-gamma inducers at both the transcriptional and post-transcriptional levels. This interaction induces IFN-gamma gene expression, enhancing the cytotoxic activity of resting NK and T cells, inducing and synergizing with IL-2 in the generation of lymphokine-activated killer (LAK) cells, acting as a co-mitogen to stimulate proliferation of resting T cells, and inducing proliferation of activated T and NK cells. Current evidence indicates that IL-12, produced by macrophages in response to infectious agents, is a central mediator of the cell-mediated immune response by its actions on the development, proliferation, and activities of TH1 cells. In its role as the initiator of cell-mediated immunity, it has been suggested that IL-12 has therapeutic potential as a stimulator of cell-mediated immune responses to microbial pathogens, metastatic cancers, and viral infections such as AIDS.

Clinical and Translational Updates

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