

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-18 Protein(GMP-L18H16) is expressed from E. coli cells. It contains AA Tyr 37 - Asp 193 (Accession # [Q14116](#)).

Molecular Characterization

IL-18(Tyr 37 - Asp 193)  
Q14116

This protein carries no "tag".  
  
The protein has a calculated MW of 18.2 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

Tyr-Phe-Gly-Lys-Leu-Glu-Ser-Lys-Leu-Ser-Val-Ile-Arg-Asn-Leu  
(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 qPCR.

Sterility

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

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.

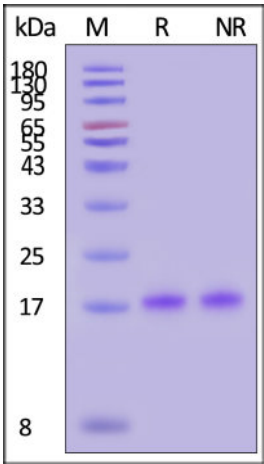
*Please avoid repeated freeze-thaw cycles.*

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

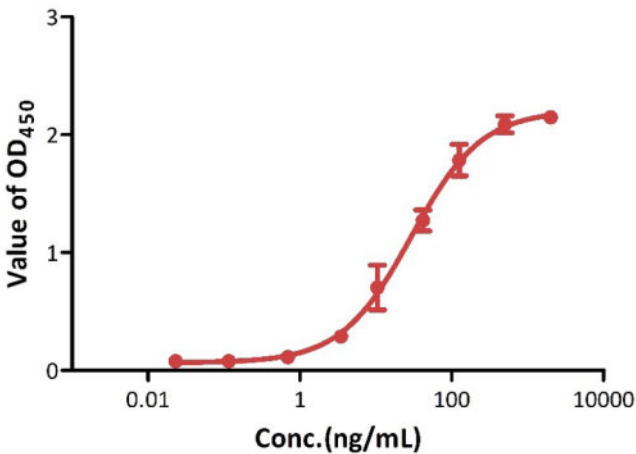




GMP Human IL-18 Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With [Star Ribbon Pre-stained Protein Marker](#)).

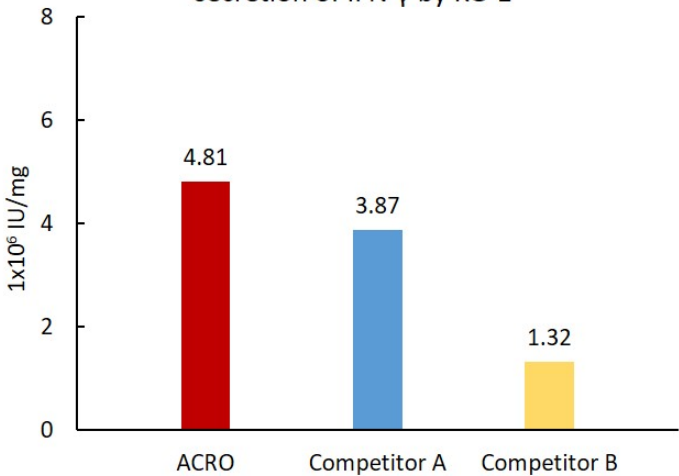
Bioactivity-CELL BASE

GMP Human IL-18 Protein stimulates secretion of IFN- $\gamma$  by KG-1 cells.



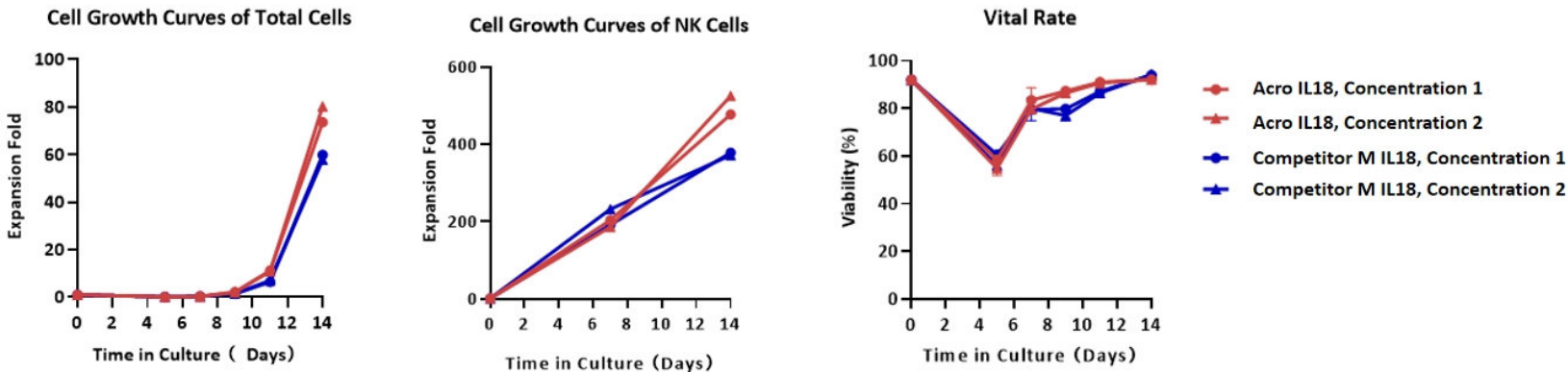
GMP Human IL-18 Protein (Cat. No. GMP-L18H16) stimulates secretion of IFN- $\gamma$  by KG-1 cells. The specific activity of GMP Human IL-18 Protein is > 3.00x10<sup>6</sup> IU/mg, which is calibrated against WHO Reference Reagent Interleukin-18 (Human rDNA derived) (NIBSC code: 03/200) (QC tested).

GMP Human IL-18 Protein stimulates the secretion of IFN- $\gamma$  by KG-1



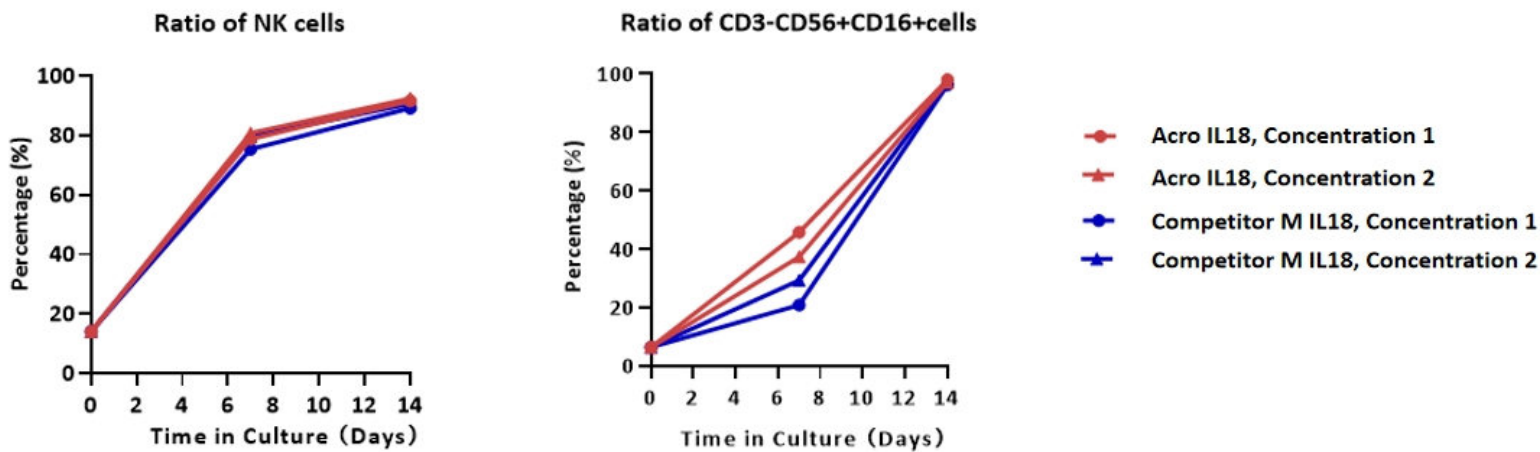
The activity of GMP Human IL-18 Protein (Cat. No. GMP-L18H16) was higher than other competing products.

Application Data



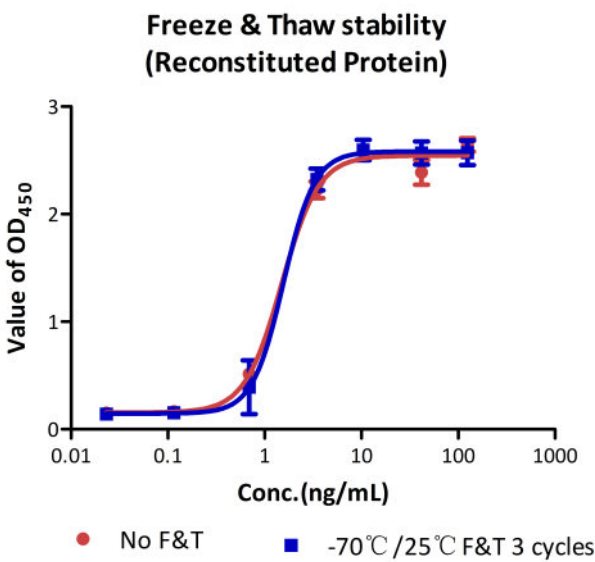
Human PBMCs were cultured with GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14), GMP Human IL-18 Protein (ACROBiosystems, Cat. No. GMP-L18H16) and GMP Human 4-1BB Ligand Protein (ACROBiosystems, Cat. No. GMP-41LH26), in CelThrea™ GMP T Cell Expansion Medium (ACROBiosystems, Cat. No. GMP-CM3101 & GMP-CM3101-1) for two weeks. The result shows that GMP Human IL-18 Protein can promote the expansion of these cells with a reasonable cell viability. Notably, the cells exhibit better expansion in GMP Human IL-18 Protein (ACROBiosystems).



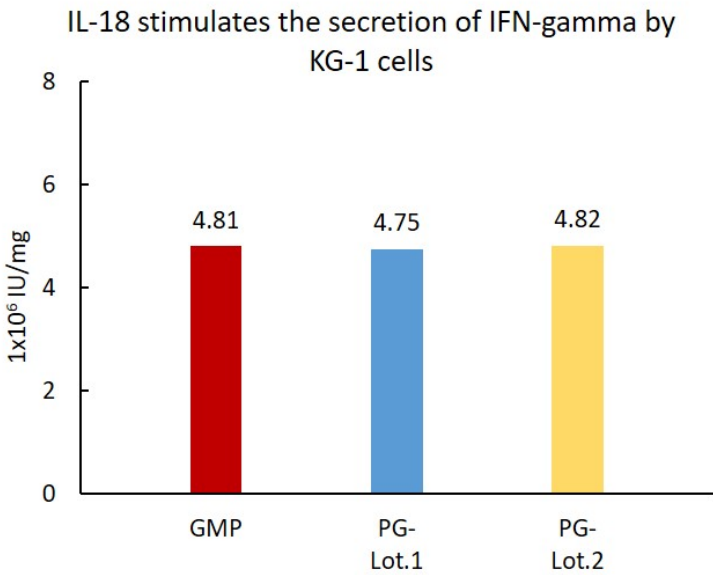


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Bioactivity-Stability



The Cell based assay shows that GMP Human IL-18 Protein (Cat. No. GMP-L18H16) is stable after freezing and thawing 3 times.



The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG IL-18.

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-18 (IL-18) is a potent proinflammatory cytokine that induces interferon-gamma (IFN-gamma) production from Th1 cells, NK cells and activated macrophages, particularly in the presence of IL-12. IL-18 also functions in developmental regulation of T-lymphocyte helper type I cells and in Fas-mediated cytotoxicity. Suppression of IL-18 activity is being investigated for treatment of chronic inflammatory diseases such as Crohn's disease and rheumatoid arthritis. It acts by inducing heterodimerization of the two subunits of its receptor, IL-18RA $\alpha$  and IL-18RB $\beta$  shows structural similarity to IL-1.

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