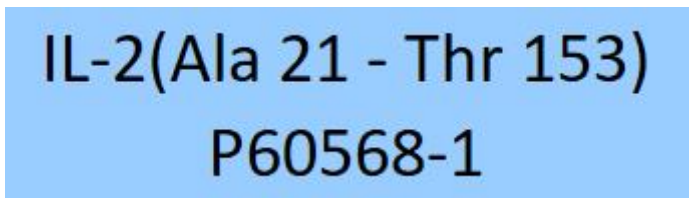
Features

- 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-2 Protein(GMP-L02H14) is expressed from E. coli cells. It contains AA Ala 21 - Thr 153 (Accession # P60568-1).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 15.4 kDa. The protein migrates as 16 kDa±2 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

chain1: Met-Ala-Pro-Thr-Ser-Ser-Ser-Thr-Lys-Lys-Thr-Gln-Leu-Gln-Leu
chain2: Ala-Pro-Thr-Ser-Ser-Ser-Thr-Lys-Lys-Thr-Gln-Leu-Gln-Leu-Glu
(Routinely tested)

Endotoxin

Less than 5.0 EU/Vial by the LAL method / rFC method.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.1 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 phosphate 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

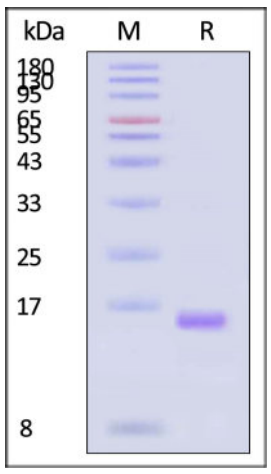
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

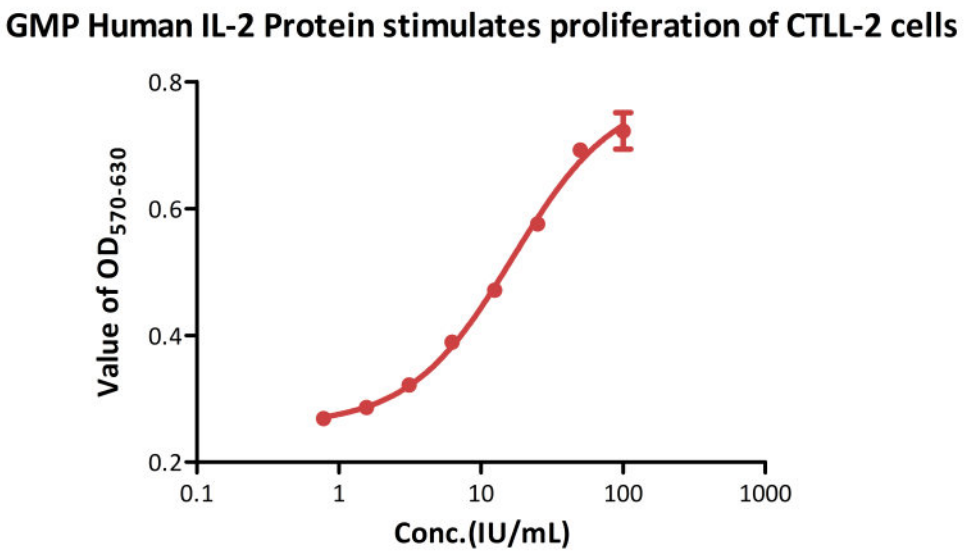
- -20°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE



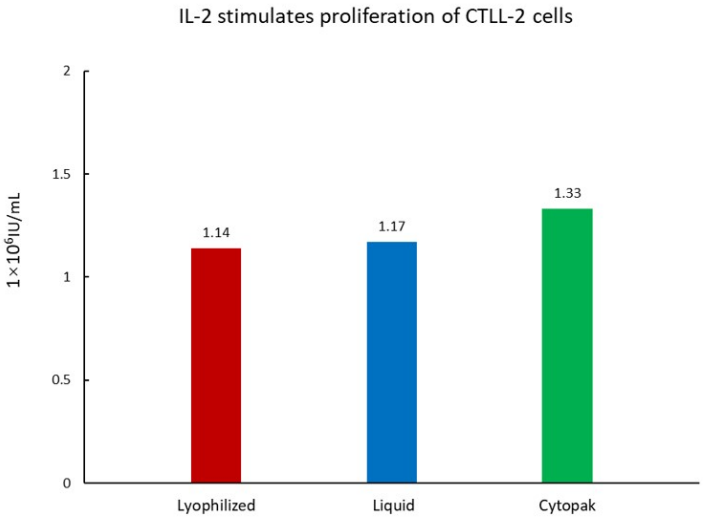
GMP Human IL-2 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE



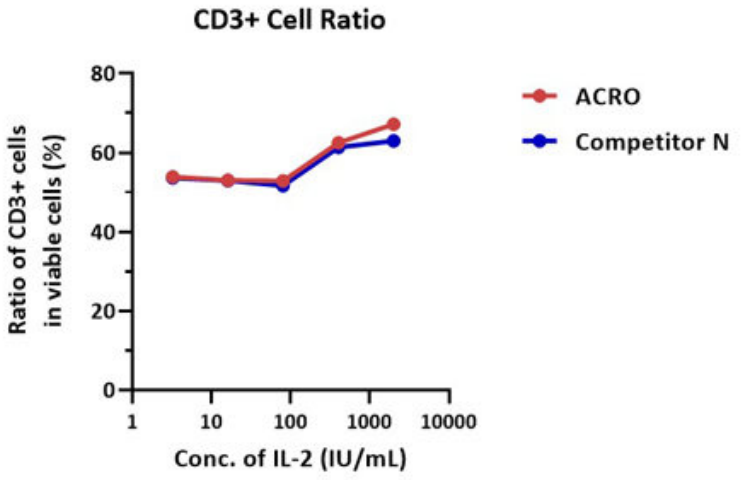
GMP Human IL-2 Protein (Cat. No. GMP-L02H14) stimulates proliferation of CTLL-2 cells. The specific activity of GMP Human IL-2 Protein is ≥ 1.20×10^7 IU/mg, which is calibrated against human Interleukin-2 China National Standard (NIFDC code: 270008) (QC tested). China National Institutes for Food and Drug Control (NIFDC) Standard was prepared and calibrated against human IL-2 WHO International Standard (NIBSC code: 86/500) by NIFDC.

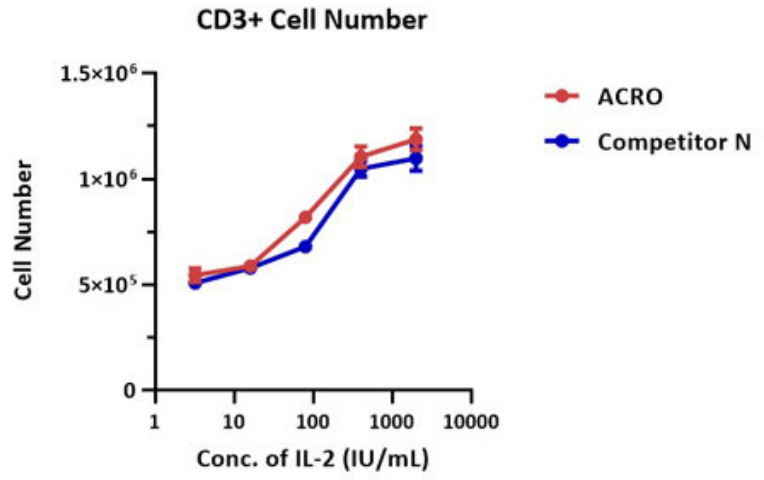
Consistent Specific Activity



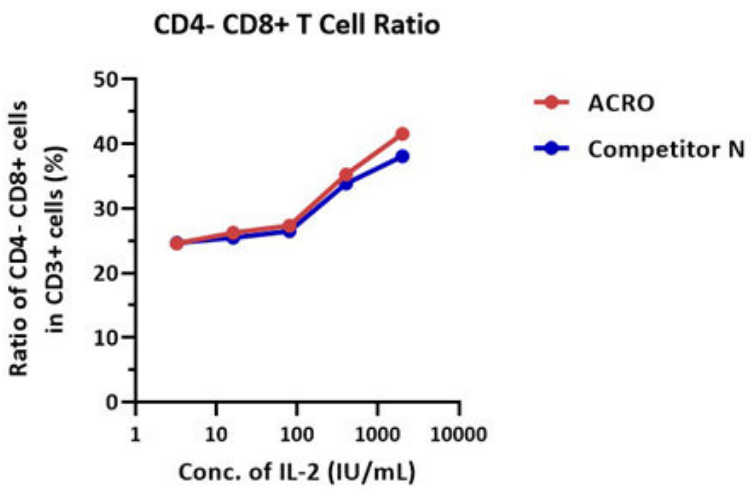
Consistent specific activity (IU/mg) is maintained across lyophilized IL-2 (Cat. No. GMP-L02H14), liquid IL-2 (Cat. No. GMP-L02H14F002), and Cytopak IL-2 (Cat. No. GMP-L02H14GB01).

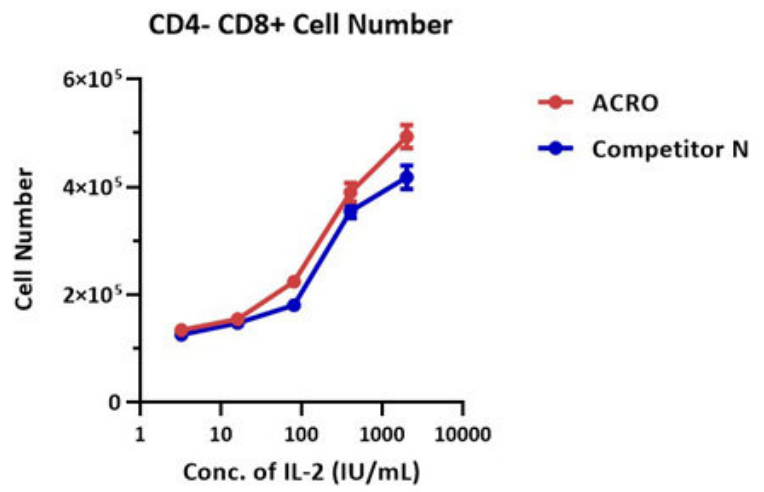
Application Data



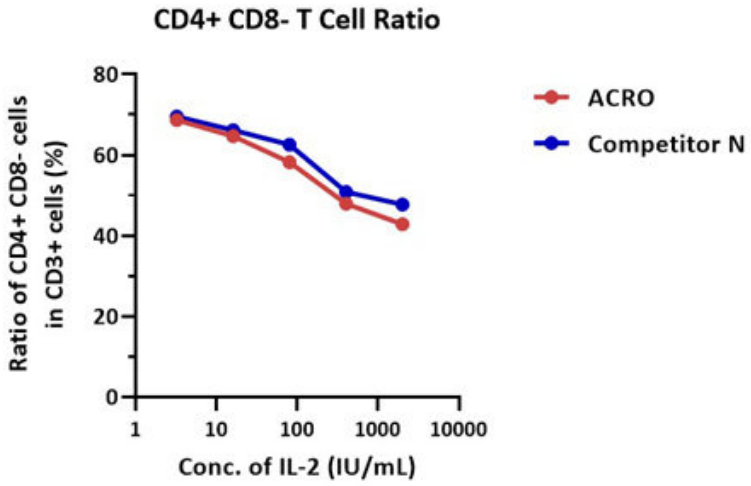


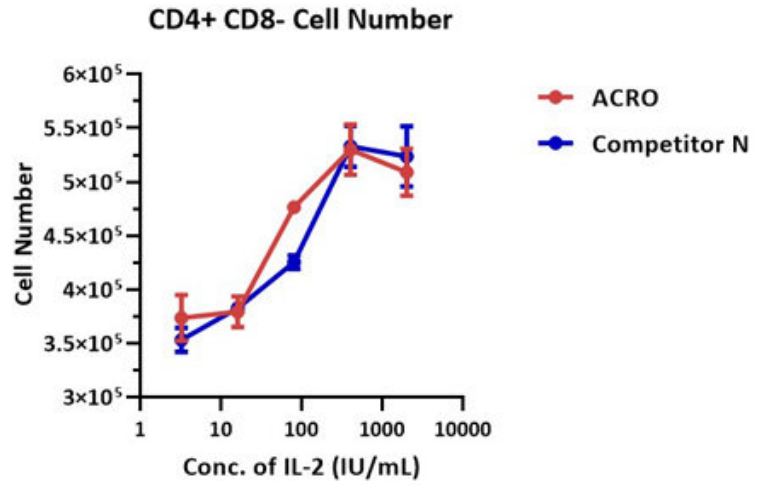
3 × 10^6 Human PBMCs were cultured with various concentrations of GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14) or IL-2 Protein (Competitor N) for a week. For the negative control group (w/o IL-2), the CD3+ ratio was 47.6%, and the CD3+ cell number was 4.8 × 10^5. The result shows that GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14) has a similar activity to IL-2 Protein (Competitor N).





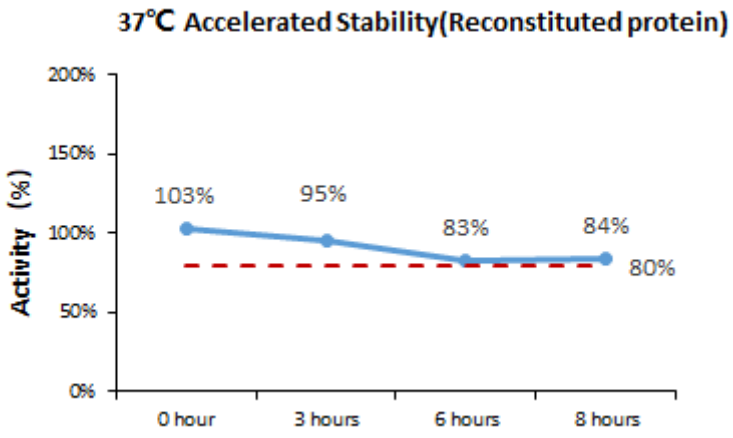
3 × 10^6 Human PBMCs were cultured with various concentrations of GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14) or IL-2 Protein (Competitor N) for a week. For negative control group (w/o IL-2), the CD3+ CD4- CD8+ ratio was 21.7%, and the CD3+ CD4- CD8+ cell number was 1.0 × 10^5. The result shows that GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14) has a similar activity to IL-2 Protein (Competitor N).



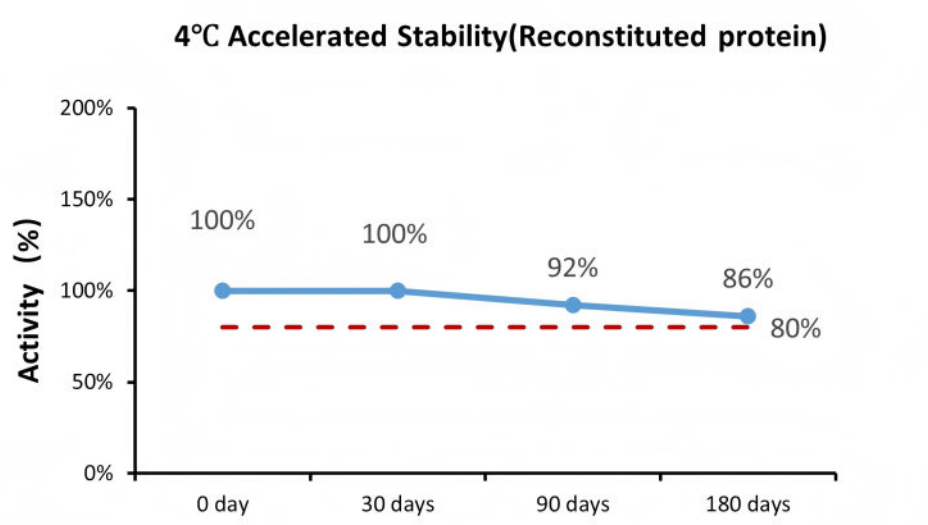


3 × 10^6 Human PBMCs were cultured with various concentrations of GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14) or IL-2 Protein (Competitor N) for a week. For negative control group (w/o IL-2), the CD3+ CD4+ CD8- ratio was 72.4%, and the CD3+ CD4+ CD8- cell number was 3.5 × 10^5. The result shows that GMP Human IL-2 Protein (ACROBiosystems, Cat. No. GMP-L02H14) has a similar activity to IL-2 Protein (Competitor N).

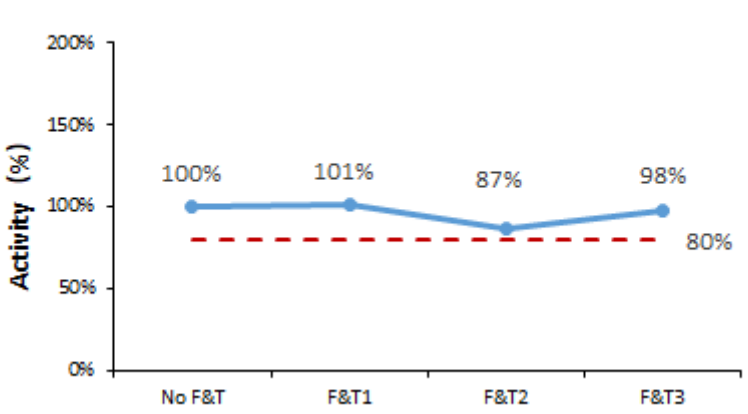
Bioactivity-Stability



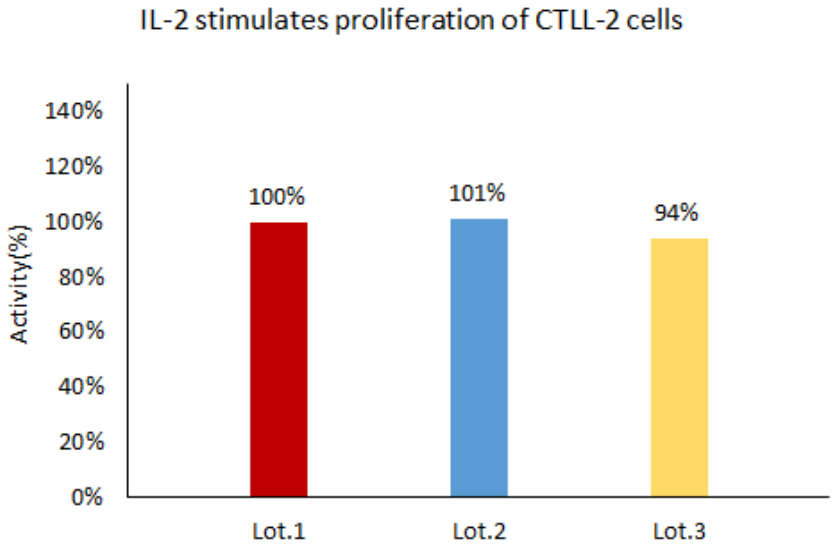
The Cell based assay shows that GMP Human IL-2 Protein (Cat. No. GMP-L02H14) is stable at 37°C for 8 hours.



The Cell based assay shows that GMP Human IL-2 Protein (Cat. No. GMP-L02H14) is stable at 4°C for 180 days.



The Cell based assay shows that GMP Human IL-2 (Cat. No. GMP-L02H14) is stable after freezing and thawing 3 times.



The Cell based assay shows that GMP Human IL-2 Protein (Cat. No. GMP-L02H14) is stable in the quality of different batches.

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-2 (IL-2) is an interleukin, a type of cytokine immune system signaling molecule, which is a leukocytotrophic hormone that is instrumental in the body's natural response to microbial infection and in discriminating between foreign (non-self) and self. IL-2 mediates its effects by binding to IL-2 receptors, which are expressed by lymphocytes, the cells that are responsible for immunity. Mature human IL-2 shares 56% and 66% aa sequence identity with mouse and rat IL-2, respectively. Human and mouse IL-2 exhibit crossspecies activity. The receptor for IL-2 consists of three subunits that are present on the cell surface in varying preformed complexes. IL-2 is also necessary during T cell development in the thymus for the maturation of a unique subset of T cells that are termed regulatory T cells (T-regs). After exiting from the thymus, T-Regs function to prevent other T cells from recognizing and reacting against "self antigens", which could result in "autoimmunity". T-Regs do so by preventing the responding cells from producing IL-2. Thus, IL-2 is required to discriminate between self and non-self, another one of the unique characteristics of the immune system.