GMP Human IL-2 Protein (Liquid)

Catalog # GMP-L02H14F002

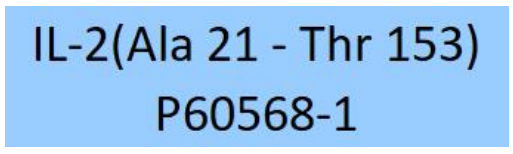
GMP Platform Advantages

- **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-2 Protein (Liquid) (GMP-L02H14F002) 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 25 EU/ Vial, tested by the LAL method in compliance with USP <85> and Ph. Eur. 2.6.14.

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

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

Supplied as 0.2 μm filtered solution in phosphate with protectants.

Contact us for customized product form or formulation.

Vial Specification

6R (20 mm neck finish)

Shipping

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

Storage

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

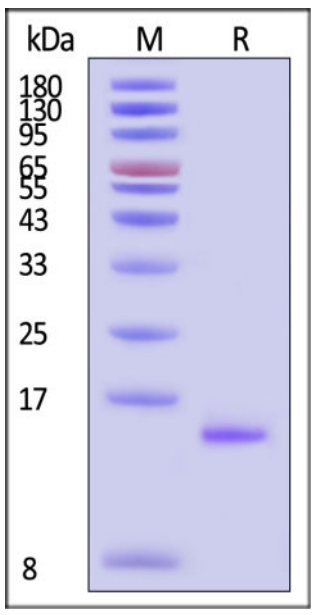
- The product MUST be stored at -70°C or lower upon receipt;

- -70°C for 5 years under sterile conditions.

ACRO Quality Management System

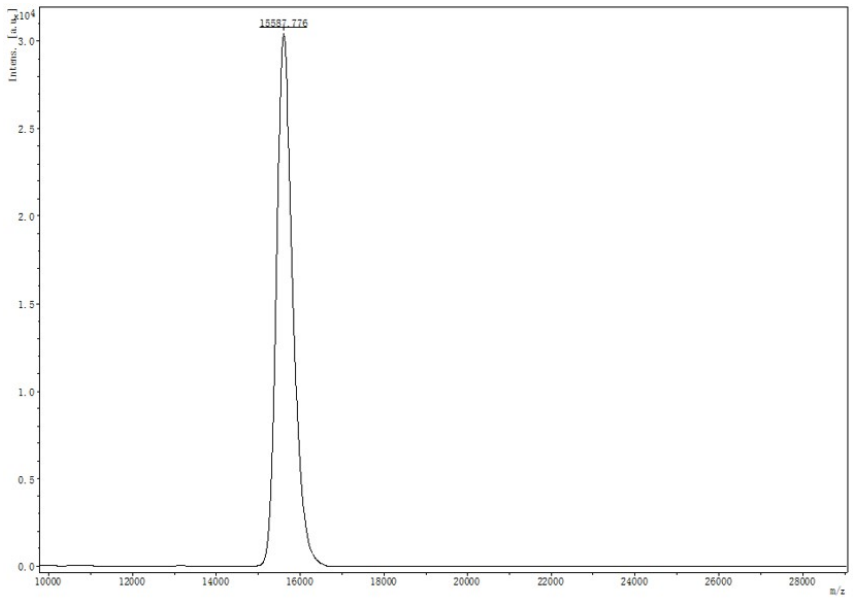
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



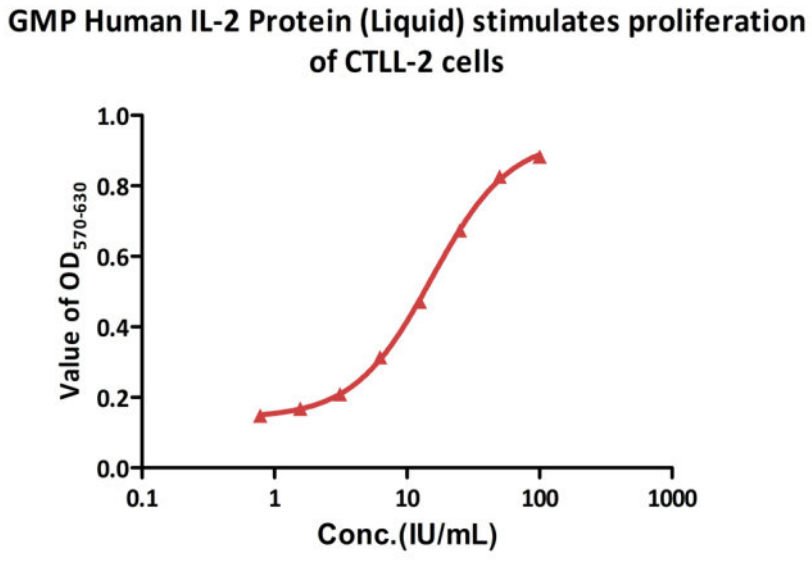
GMP Human IL-2 Protein (Liquid) on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Mass Spectrometry



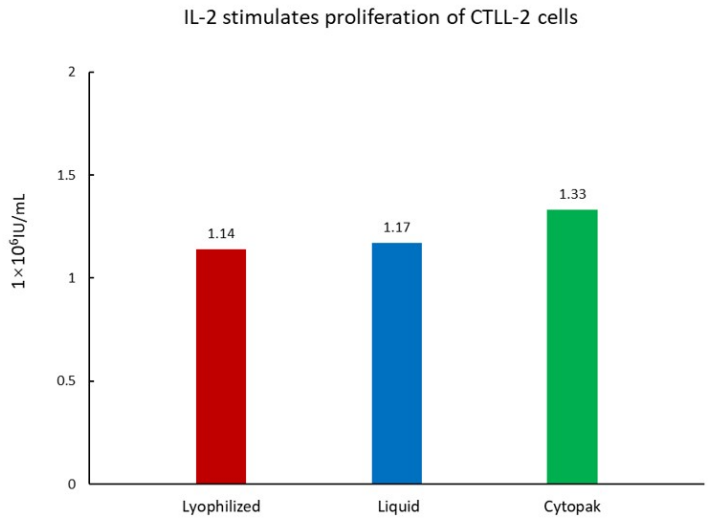
MALDI-TOF analysis of GMP Human IL-2 Protein (Liquid) (Cat. No. GMP-L02H14F002). The labeled peak at 15587.776 Da corresponds to the calculated molecular mass with the N-terminal Met (15549 Da) (Routinely tested).

Bioactivity-CELL BASE



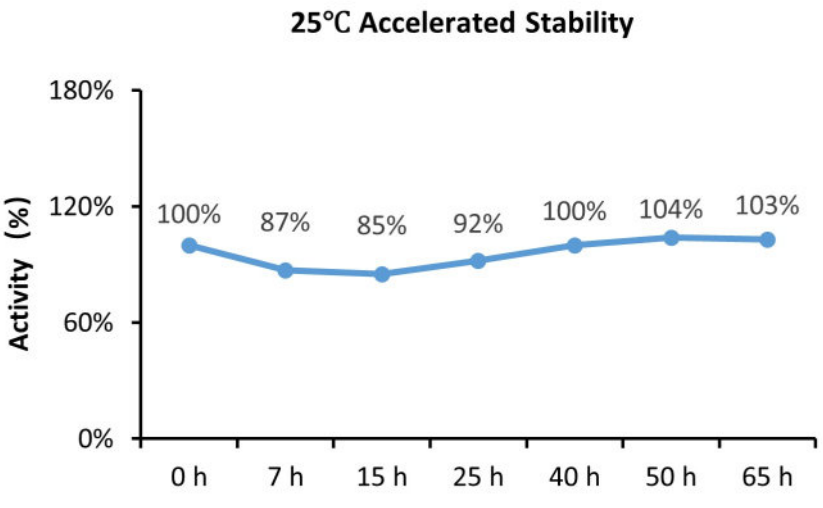
GMP Human IL-2 Protein (Liquid) (Cat. No. GMP-L02H14F002) stimulates proliferation of CTLL-2 cells. The specific activity of GMP Human IL-2 Protein (Liquid) is ≥ 1.20 × 10^7 IU/mg, which is calibrated against human Interleukin-2 China National Standard (NIFDC code: 270008) (QC tested). China National 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

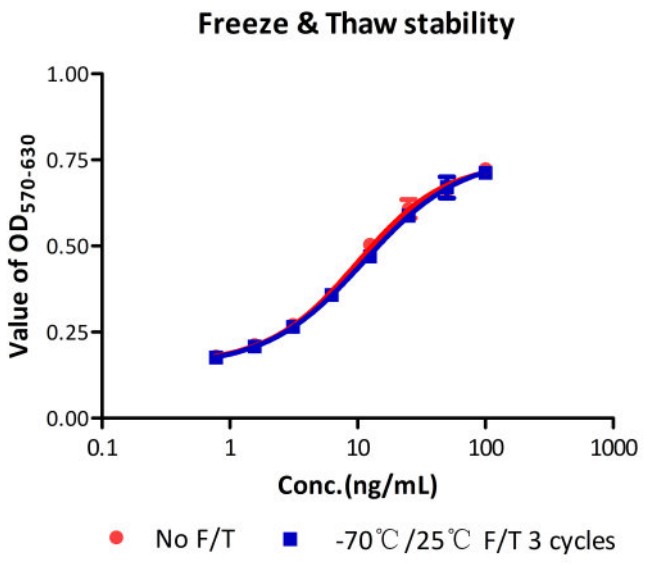


Consistent specific activity (IU/mg) is maintained across lyophilized IL-2 (Cat. No. GMP-L02H14), liquid IL-2 (Cat. No. GMP-L02H14F002), and Cytopak IL-2 (Cat. No. GMP-L02H14GB01).

Bioactivity-Stability



Cell-based assay demonstrates that GMP Human IL-2 Protein (Liquid) (Cat. No. GMP-L02H14F002) is stable at 25°C for 65 hours.



Cell-based assay demonstrates that GMP Human IL-2 Protein (Liquid) (Cat. No. GMP-L02H14F002) is stable after 3 freeze-thaw cycles.

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.

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
- Batch-to-batch consistency

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