GMP Human IL-3 Protein

Catalog # GMP-L03H18

Product Details

IL-3 (Interleukin-3) functions as a multilineage hematopoietic growth factor, promoting the expansion and survival of early hematopoietic progenitors and myeloid lineage cells. In HSC expansion systems, IL-3 supports the proliferation of multipotent and committed progenitors, especially in combination with SCF and FLT3L. In iPSC-to-HSC differentiation, IL-3 enhances the generation and output of hematopoietic progenitors from hemogenic endothelial-like cells, contributing to increased myeloid and erythroid potential.

Product Features and Advantages

- **Specific HSC Expansion Driver**: Efficiently supports hematopoietic stem cell expansion and hPSC-derived hematopoietic stem and progenitor cell differentiation, validated in multiple clinical trials and cell manufacturing processes.
- **Reliable Large-Scale Supply**: Ensures batch production capacity, supporting robust and consistent manufacturing scale-up.
- **High Lot-to-Lot Consistency**: Ensures reliable and reproducible performance in every batch, supporting scalable applications.

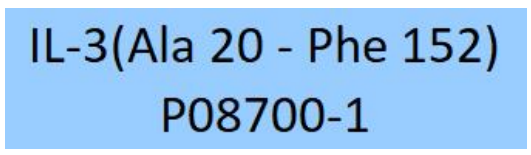
GMP Platform Advantages

- **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-3 Protein (GMP-L03H18) is expressed from *E. coli* cells. It contains AA Ala 20 - Phe 152 (Accession # P08700-1).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 15.2 kDa. The protein migrates as 14 kDa±3 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

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

Endotoxin

Less than 10 EU/mg, 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

<0.02 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

Lyophilized from 0.22 μm filtered solution in PBS, pH7.4 with protectants.

Contact us for customized product form or formulation.

Vial Specification

2R (13 mm neck finish)

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.

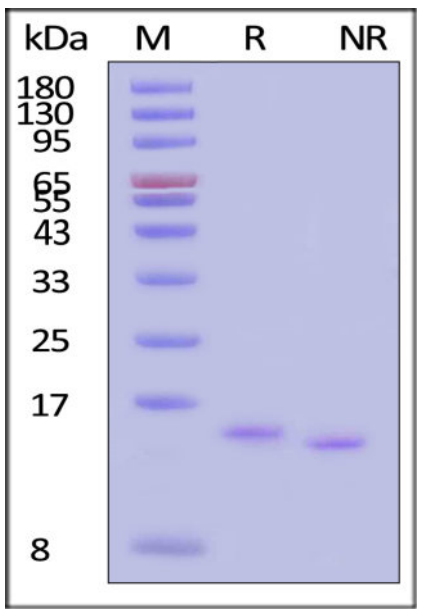
This product is stable after storage at:

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

ACRO Quality Management System

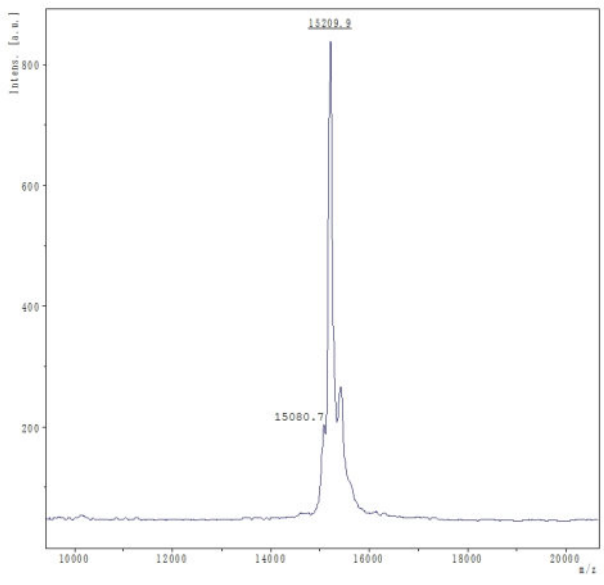
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



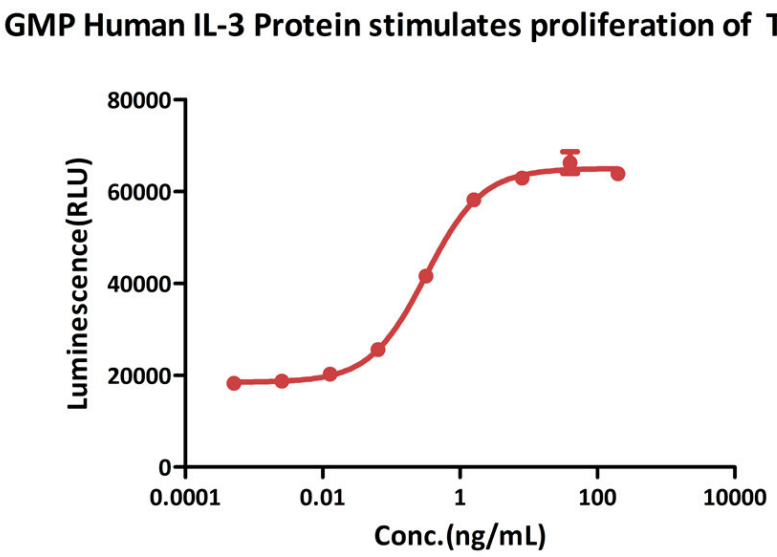
GMP Human IL-3 Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

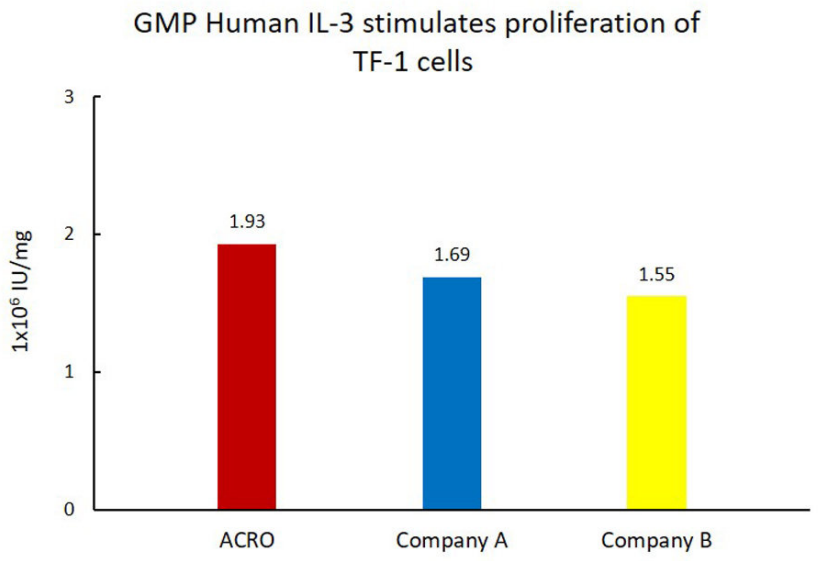
Mass Spectrometry



MALDI-TOF analysis of GMP Human IL-3 Protein (Cat. No. GMP-L03H18). The labeled peaks at 15209.9 Da and 15080.7 Da correspond to the calculated molecular mass with the N-terminal Met (15213 Da), and without the N-terminal Met (15081 Da), respectively. The minor peak following the major peak is a matrix-associated artifact of the MALDI-TOF (Routinely tested).

Bioactivity-CELL BASE

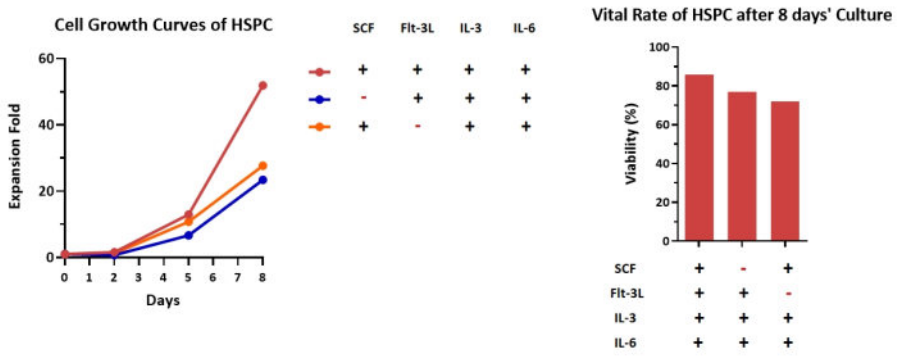




GMP Human IL-3 Protein (Cat. No. GMP-L03H18) stimulates proliferation of TF-1 cells. The specific activity of GMP Human IL-3 Protein is > 1.00x10^6 IU/mg, which is calibrated against human IL-3 WHO International Standard (NIBSC code: 91/510) (QC tested).

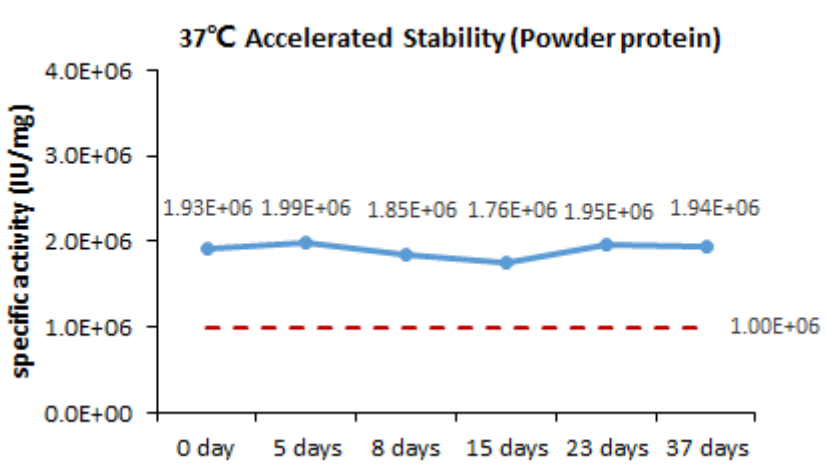
GMP Human IL-3 (Cat. No. GMP-L03H18) exhibits superior activity compared to commercially available products.

Application Data

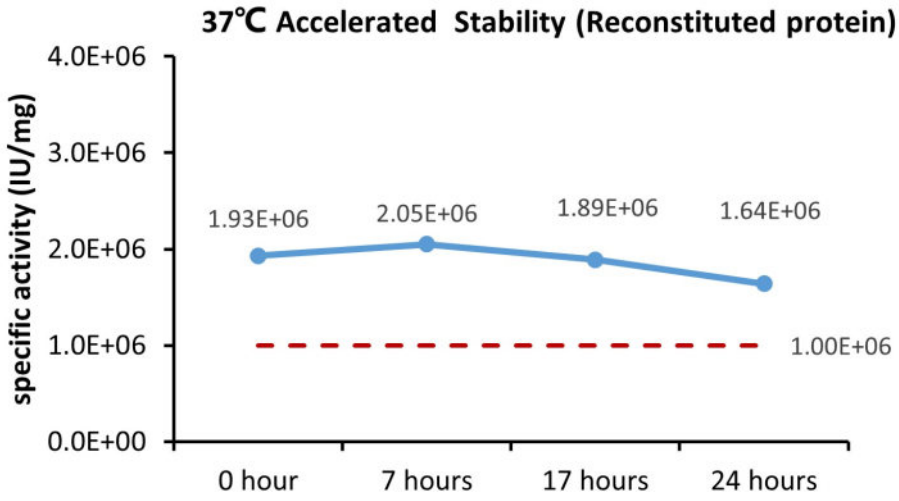


GMP Human SCF Protein (Cat. No. GMP-SCFH25), Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human IL-3 Protein (Cat. No. GMP-L03H18) and GMP Human IL-6 Protein (Cat. No. GMP-L06H27) could support the rapid cell expansion and good cell viability of CD34+ hematopoietic stem cells.

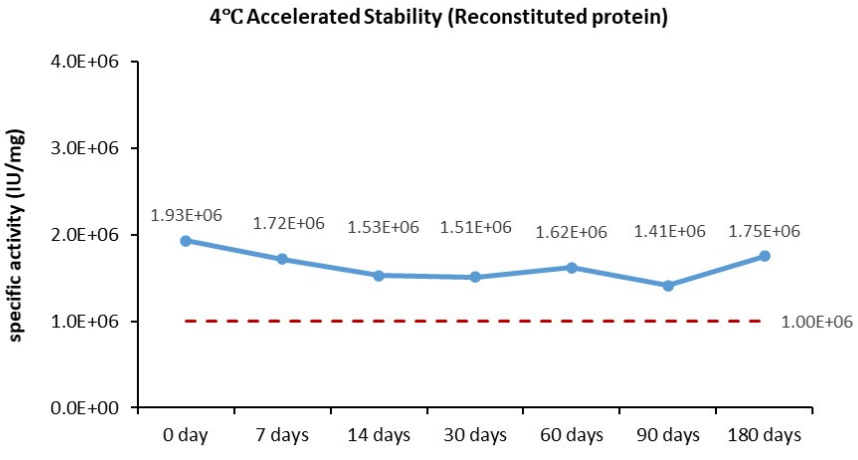
Bioactivity-Stability



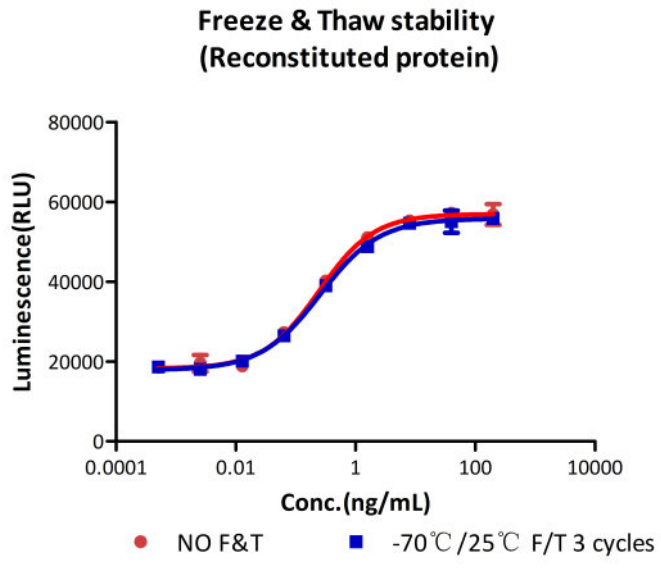
Cell-based assay demonstrates that the lyophilized GMP Human IL-3 Protein (Cat. No. GMP-L03H18) is stable at 37°C for 37 days.



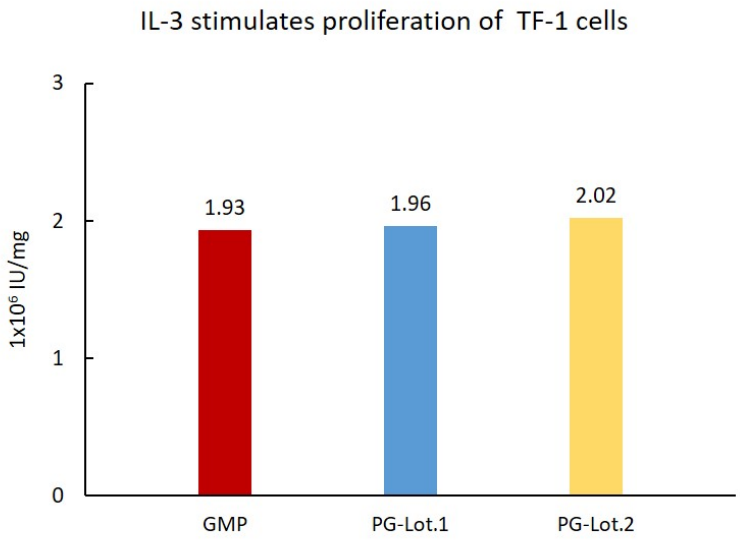
Cell-based assay demonstrates that the reconstituted GMP Human IL-3 Protein (Cat. No. GMP-L03H18) is stable at 37°C for 24 hours.



Cell-based assay demonstrates that the reconstituted GMP Human IL-3 Protein (Cat. No. GMP-L03H18) is stable at 4°C for 180 days.



Cell-based assay demonstrates that the reconstituted GMP Human IL-3 Protein (Cat. No. GMP-L03H18) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG IL-3.

Background

Interleukin-3 (IL-3) is an interleukin, a type of biological signal (cytokine) which is encoded by the IL-3 gene located on chromosome 5 and produced primarily by activated T cells beside human thymic epithelial cells, activated murine mast cells, murine keratinocytes and neurons/astrocytes. The protein acts in hematopoiesis by controlling the production, differentiation, and function of 2 related white cell populations of the blood, the granulocytes and the monocytes-macrophages. The human IL-3 reported to be a monomer, as it is known, contains 133 amino acids residues which is a single non-glycosylated polypeptide. Specifically, human and murine IL-3 share low homology and it does not show activity on murine cells.

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
- Residual moisture
- Batch-to-batch consistency

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