

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
- No animal derived peptone and lactose used in production process

Source

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

Predicted N-terminus: Met

Molecular Characterization

IL-3(Ala 20 - Phe 152) P08700-1

This protein carries no "tag".

The protein has a calculated MW of 15.1 kDa. The protein migrates as 14 kDa±3 kDa when calibrated against <u>Star Ribbon Pre-stained Protein Marker</u> under reducing (R) condition (SDS-PAGE).

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

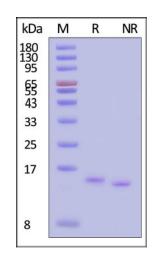
Upon receipt, store it immediately at -20°C or lower for long term storage.

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



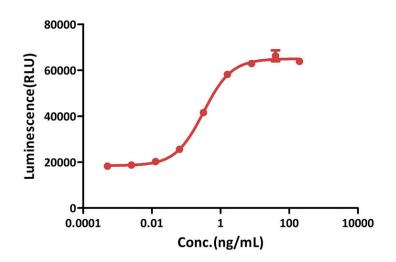




GMP Human IL-3 Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With <u>Star Ribbon Pre-stained Protein Marker</u>).

Bioactivity-Bioactivity CELL BASE

GMP Human IL-3 Protein stimulates proliferation of TF-1 cells

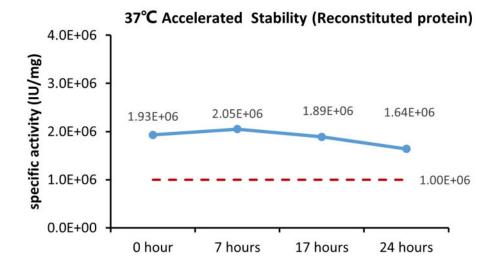


GMP Human IL-3 Protein (Cat. No. GMP-L03H18) stimulates proliferation of TF-1 cells. The specific activity of GMP Human IL-3 Protein is > 1.00x10⁶ IU/mg, which is calibrated against human IL-3 WHO International Standard (NIBSC code: 91/510) (QC tested).

GMP Human IL-3 stimulates proliferation of TF-1 cells 3 1.93 1.69 1.55 ACRO Competitor A Competitor B

The activity of GMP Human IL-3 (Cat. No. GMP-L03H18) was higher than other competing products.

Bioactivity-Stability

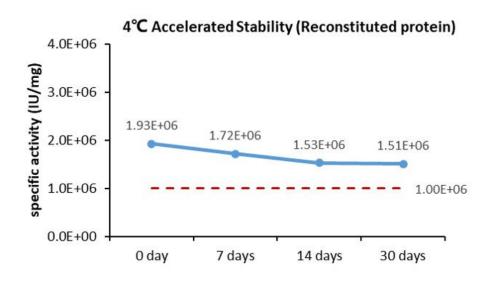


The Cell based assay shows that GMP Human IL-3 Protein (Cat. No. GMP-L03H18) is stable at 37°C for 24 hours.

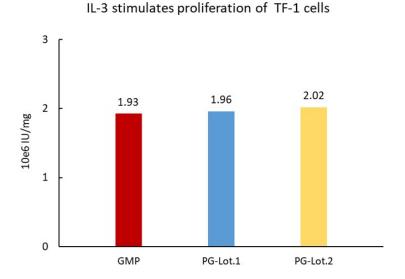
Freeze & Thaw stabiltiy

The Cell based assay shows that GMP Human IL-3 Protein (Cat. No. GMP-L03H18) is stable after freezing and thawing 3 times.





The Cell based assay shows that GMP Human IL-3 Protein(Cat. No. GMP-L03H18) is stable at 4°C for 30 days.



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

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



GMP Human IL-3 Protein

Catalog # GMP-L03H18



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-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.

Clinical and Translational Updates

