

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

Source

GMP Human IL-10 Protein(GMP-L10H25) is expressed from human 293 cells (HEK293). It contains AA Ser 19 - Asn 178 (Accession # P22301).

Predicted N-terminus: Ser 19

Molecular Characterization

IL-10(Ser 19 - Asn 178) P22301

This protein carries no "tag".

The protein has a calculated MW of 18.6 kDa. The protein migrates as 17 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

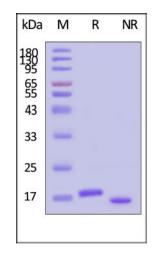
Upon receipt, store it immediately at -20°C or lower for long term storage.

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



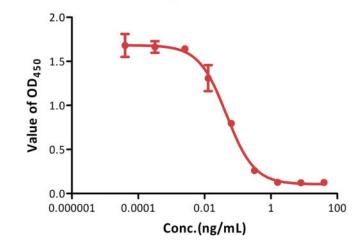




GMP Human IL-10 Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With <u>Star Ribbon Pre-stained Protein Marker</u>).

Bioactivity-Bioactivity CELL BASE

GMP Human IL-10 Protein inhibits the secretion of IL-6 by RAW264.7 cells

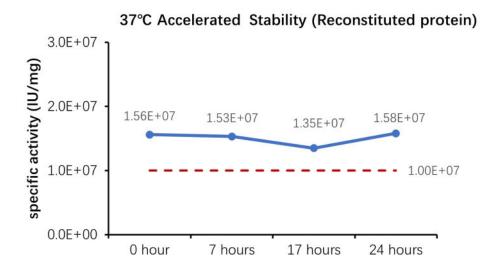


GMP Human IL-10 Protein (Cat. No. GMP-L10H25) inhibits the secretion IL-6 by RAW264.7 cells. The specific activity of GMP Human IL-10 Protein is > 1.00 x 10^7 IU/mg, which is calibrated against WHO Reference Reagent Interleukin-10 (Human, rDNA derived) (NIBSC code: 93/722) (QC tested).

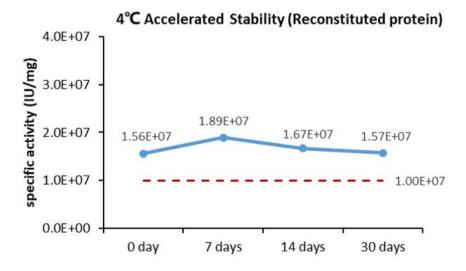
Human IL-10 Inhibits the secrection of IL-6 by RAW264.7 2 1.6 1.56 1.16 0.96 0.4 0.4 ACRO Competitor A Competitor B

The activity of GMP Human IL-10 (Cat. No. GMP-L10H25) was higher than other competing products.

Bioactivity-Stability



The Cell based assay shows that GMP Human IL-10 (Cat. No. GMP-L10H25) is stable at 37 °C for 24 hours.

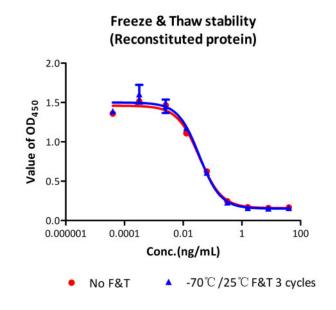


The Cell based assay shows that GMP Human IL-10 Protein (Cat. No. GMP-L10H25) is stable at 4°C for 30 days.

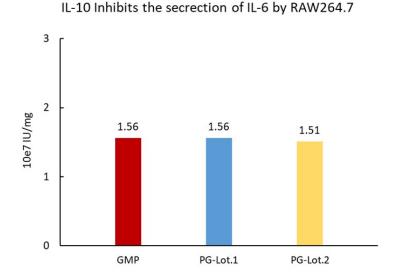
GMP Human IL-10 Protein

Catalog # GMP-L10H25





The Cell based assay shows that GMP Human IL-10 (Cat. No. GMP-L10H25) is stable after freezing and thawing 3 times.



The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG IL-10.

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-10 Protein

Catalog # GMP-L10H25



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

The protein encoded by this gene is a cytokine produced primarily by monocytes and to a lesser extent by lymphocytes. This cytokine has pleiotropic effects in immunoregulation and inflammation. It down-regulates the expression of Th1 cytokines, MHC class II Ags, and costimulatory molecules on macrophages. It also enhances B cell survival, proliferation, and antibody production. This cytokine can block NF-kappa B activity, and is involved in the regulation of the JAK-STAT signaling pathway. Knockout studies in mice suggested the function of this cytokine as an essential immunoregulator in the intestinal tract. Mutations in this gene are associated with an increased susceptibility to HIV-1 infection and rheumatoid arthritis. [provided by RefSeq, May 2020]

Clinical and Translational Updates

