GMP Human IL-10 Protein

Catalog # GMP-L10H25

Product Features and Advantages

- **Wide-ranging functions**: Plays a key regulatory role in suppressing excessive pro-inflammatory responses and cytokine release syndrome (CRS) in immune cell culture, while promoting immune tolerance and regulating anti-inflammatory phenotypes in TIL, CAR-T and regulatory T cell (Treg) cultures.
- **High Performance**: Exhibits superior biological activity, making it the preferred choice for numerous pharmaceutical enterprises in preclinical and clinical-stage cell therapy and immunomodulatory drug development.
- **Comprehensive Safety Assurance**: ECACC-compliant HEK293 host cell origin and comprehensive testing (28 items), animal origin-free (AOF) production process, with stringent final product quality control and release specifications to support clinical-grade applications.
- **Lot-to-Lot Consistency**: Achieved through a stable cell line and robust process, ensuring reliable performance from research to clinical manufacturing.

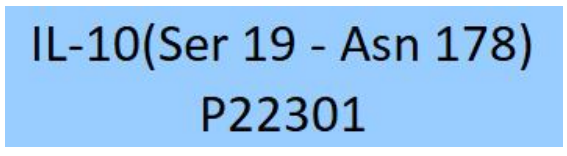
GMP Platform Advantages

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

Molecular Characterization



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 Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

Ser-Pro-Gly-Gln-Gly-Thr-Gln-Ser-Glu-Asn-Ser-Cys-Thr-His-Phe-Pro
(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.

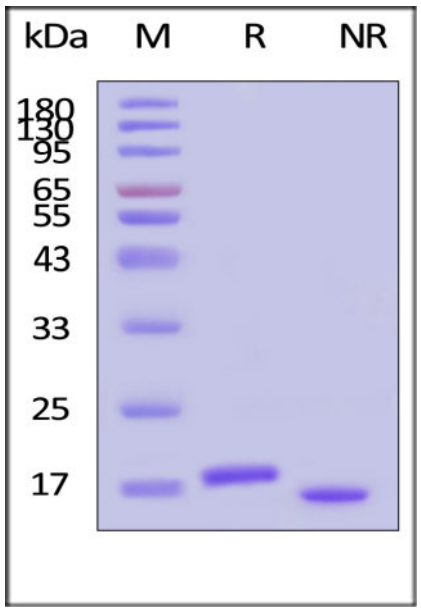
This product is stable after storage at:

- -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

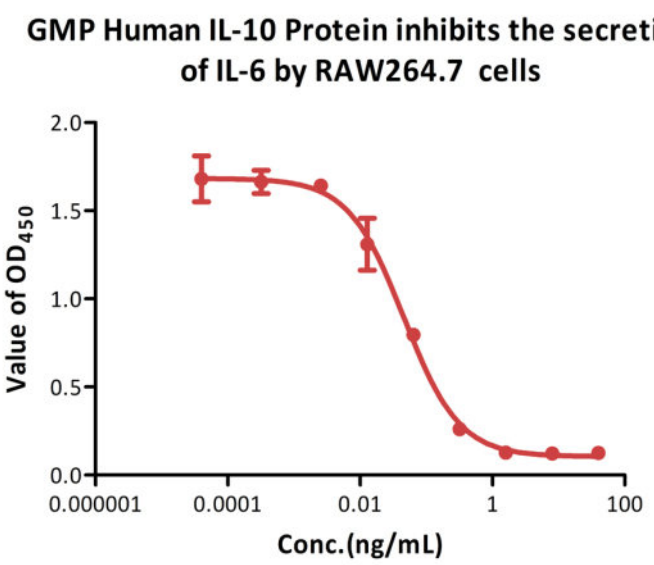
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE

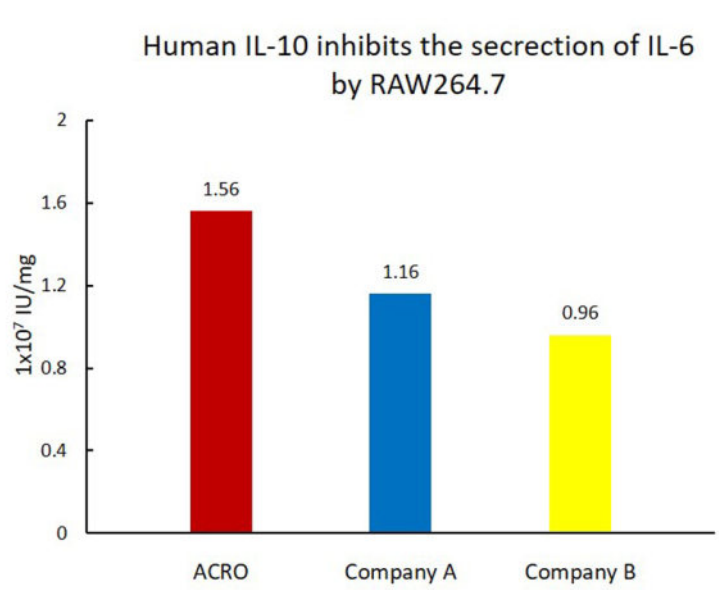


GMP Human IL-10 Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE

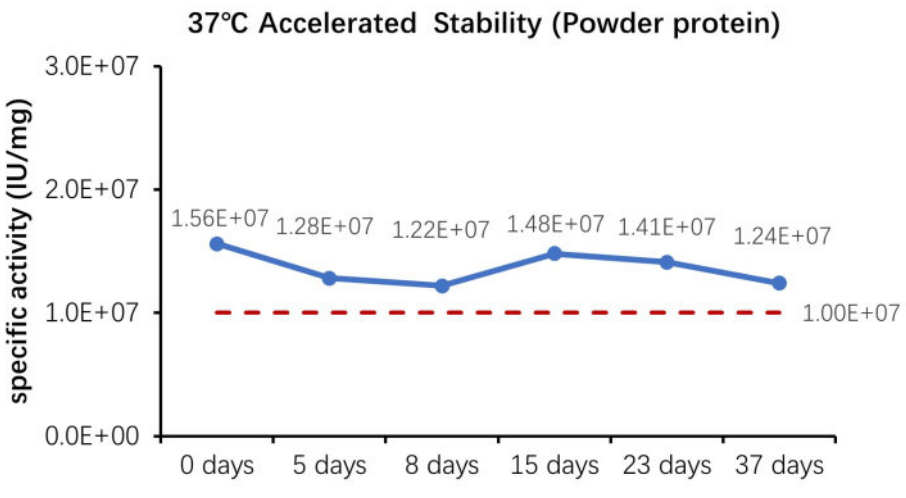


GMP Human IL-10 Protein (Cat. No. GMP-L10H25) inhibits the secretion IL-6 by RAW264.7 cells. The specific activity of GMP Human IL-10 Protein is > 1.00 x 10^7 IU/mg, which is calibrated against WHO Reference Reagent Interleukin-10 (Human, rDNA derived) (NIBSC code: 93/722) (QC tested).

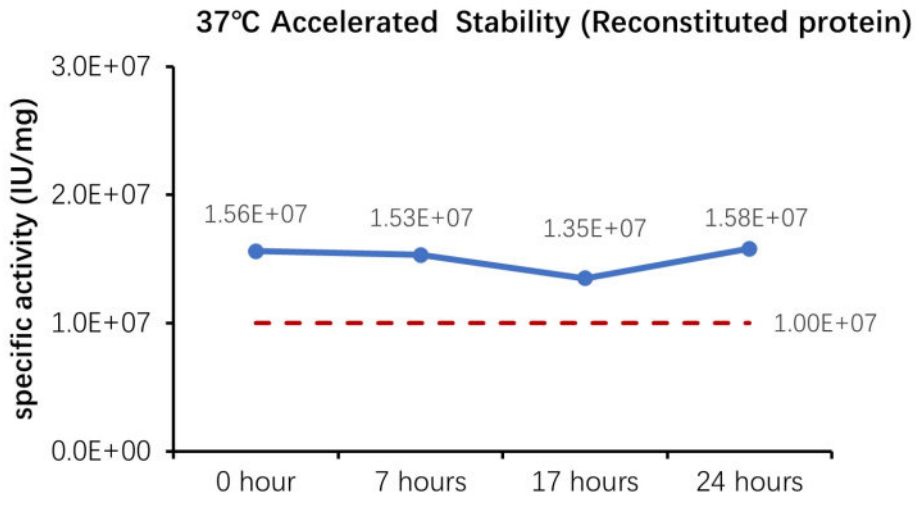


GMP Human IL-10 (Cat. No. GMP-L10H25) exhibits superior activity compared to commercially available products.

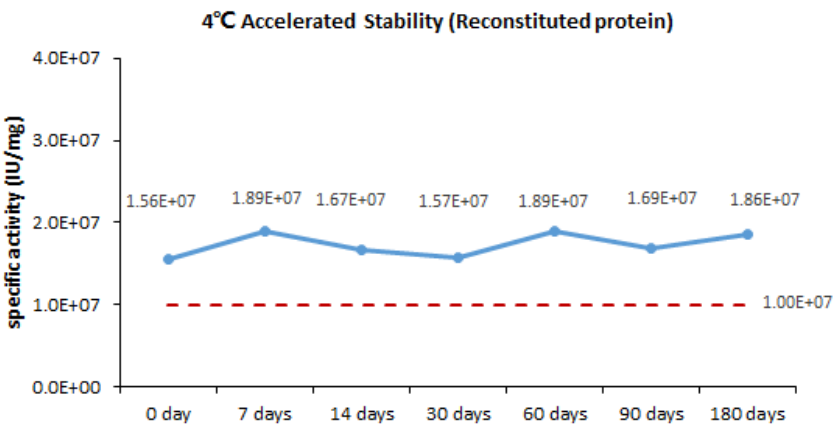
Bioactivity-Stability



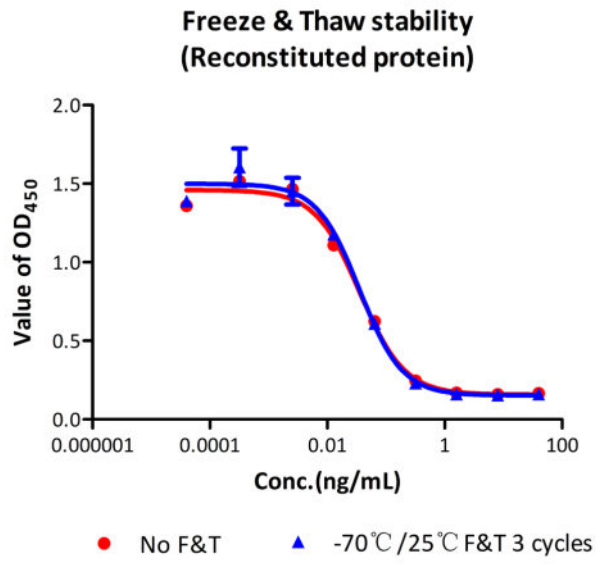
Cell-based assay demonstrates that the lyophilized GMP Human IL-10 Protein (Cat. No. GMP-L10H25) is stable at 37°C for 37 days.



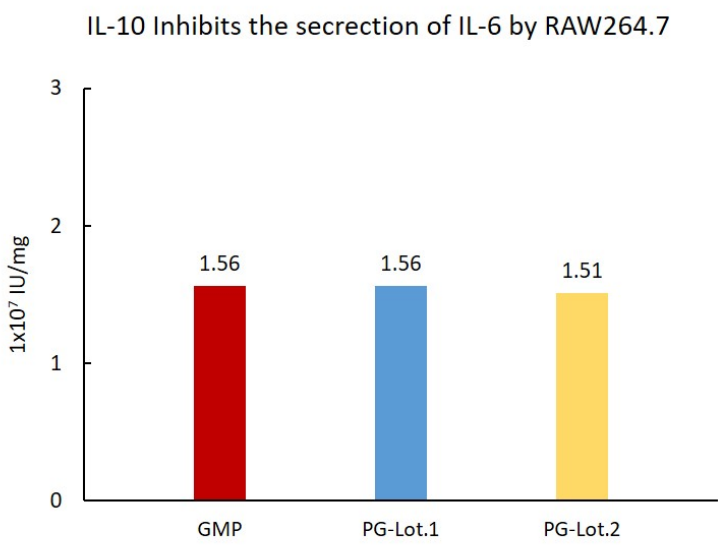
Cell-based assay demonstrates that the reconstituted GMP Human IL-10 (Cat. No. GMP-L10H25) is stable at 37 °C for 24 hours.



Cell-based assay demonstrates that the reconstituted GMP Human IL-10 Protein (Cat. No. GMP-L10H25) is stable at 4℃ for 180 days.



Cell-based assay demonstrates that the reconstituted GMP Human IL-10 (Cat. No. GMP-L10H25) is stable after 3 freeze-thaw cycles.



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

Background

Interleukin-10 (IL-10) is also known as human cytokine synthesis inhibitory factor (CSIF), is an anti-inflammatory cytokine. IL-10 is an immunosuppressive cytokine produced by a variety of mammalian cell types including macrophages, monocytes, T cells, B cells and keratinocytes. Mature human IL-10 shares 72% - 86% amino acid sequence identity with bovine, canine, equine, feline, mouse, ovine, porcine, and rat IL-10. Whereas human IL-10 is active on mouse cells, mouse IL-10 does not act on human cells. IL-10 is capable of inhibiting synthesis of pro-inflammatory cytokines such as IFN-γ, IL-2, IL-3, TNFα and GM-CSF made by cells such as

macrophages and regulatory T-cells. It also displays a potent ability to suppress the antigen-presentation capacity of antigen presenting cells. However, it is also stimulatory towards certain T cells and mast cells and stimulates B cell maturation and antibody production. Knockout studies suggested the function of Interleukin-10 / IL-10 as an essential immunoregulator in the intestinal tract. Patients with Crohn's disease react favorably towards treatment with bacteria producing recombinant interleukin-10, showing the importance of interleukin-10 for counteracting excessive immunity in the human body.

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

ACROBIOSYSTEMS - LEGAL NOTICES FOR GMP GRADE PRODUCTS

1. PRODUCT USE RESTRICTIONS & PROHIBITIONS

1.1 ACROBiosystems ("ACRO") GMP grade products ("Products") are designed for research, manufacturing use or ex vivo use.

1.2 Products are NOT intended for diagnostic purposes or for direct or indirect administration into humans.

1.3 Purchaser shall not market, distribute, or resell Products obtained from ACRO without ACRO's prior written consent.

2. REVERSE ENGINEERING PROHIBITED & CONFIDENTIALITY

2.1 Purchaser shall not reverse-engineer, decompile, disassemble, sequence, analyze via bioinformatics, or otherwise attempt to discover the structure, sequence, composition, construction, manufacturing process, or any trade secret embodied in the Products. Purchaser shall not permit any third party to undertake such activities.

2.2 All specifications, data, and know-how related to the Products provided by ACRO are ACRO's confidential information and shall be protected accordingly.

3. LIMITED WARRANTY & DISCLAIMERS

3.1 ACRO warrants solely that Products will conform to their published specifications when used under normal, specified laboratory/manufacturing conditions and within their labeled expiration date. THIS IS THE ONLY WARRANTY PROVIDED.

3.2 Purchaser assumes ALL risk and responsibility for:
(a) Determining the suitability of Products for Purchaser's intended application(s).
(b) Obtaining any necessary regulatory approvals or intellectual property licenses for Purchaser's use.
(c) Compliance with all applicable laws, regulations (including but not limited to cGMP/GLP where claimed), and industry standards.
(d) Conducting all necessary quality control, safety, efficacy, and validation testing of Products within Purchaser's process or final product.
(e) Proper storage, handling, and use of Products according to ACRO's instructions.

3.3 ACRO EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING BUT NOT LIMITED TO: (A) WARRANTIES OF MERCHANTABILITY; (B) WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE; (C) WARRANTIES OF NON-INFRINGEMENT; AND (D) WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

4. LIMITATION OF LIABILITY

IN NO EVENT SHALL ACRO, ITS AFFILIATES, OR SUPPLIERS BE LIABLE FOR ANY OF THE FOLLOWING, HOWSOEVER ARISING (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, STATUTE, OR OTHERWISE):
(a) LOST PROFITS, LOST REVENUE, LOST SAVINGS, LOSS OF USE, LOSS OF DATA, BUSINESS INTERRUPTION, OR ANY OTHER INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES.
(b) ANY DIRECT DAMAGES, COSTS, OR EXPENSES EXCEEDING THE AMOUNT PAID BY PURCHASER FOR THE SPECIFIC PRODUCT(S) GIVING RISE TO THE CLAIM.
(c) DAMAGES ARISING FROM: (i) MISUSE, ABUSE, OR UNAUTHORIZED MODIFICATION OF PRODUCTS; (ii) USE BEYOND THE EXPIRATION DATE; (iii) IMPROPER STORAGE OR HANDLING; (iv) ACCIDENTAL DAMAGE; (v) FAILURE TO CONDUCT ADEQUATE VALIDATION OR TESTING BY PURCHASER; (vi) INFRINGEMENT CLAIMS RELATED TO PURCHASER'S USE; OR (vii) THE COST OF PROCURING SUBSTITUTE GOODS OR SERVICES.
(d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

5. END USER ACKNOWLEDGEMENT & COMPLIANCE

5.1 By accepting, opening, or using the Products, the End User (Purchaser or its downstream recipient) agrees to be irrevocably bound by all terms herein.

5.2 End User explicitly acknowledges the Products are NOT FOR HUMAN ADMINISTRATION and agrees not to use them in any in vivo human application, directly or indirectly.

5.3 End Users unwilling to accept these terms must immediately: (a) cease all use; (b) notify ACRO or their supplier; and (c) return the unopened, unused Products.

5.4 ACRO reserves the right to audit End User's compliance with these restrictions upon reasonable notice.

ACRO has the right, at its sole discretion, to modify, add or remove any terms herein without notice to Purchaser and/or End User. Any changes to these terms are effective immediately following the updating of such changes on ACRO’s website or published specifications or product-related documents.