# **GMP Human IL-6 Protein**

Catalog # GMP-L06H27



#### Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Batch-to-batch consistency
- Stringent quality control tests

#### Source

GMP Human IL-6 Protein(GMP-L06H27) is expressed from human 293 cells (HEK293). It contains AA Val 30 - Met 212 (Accession # <u>P05231</u>).Predicted N-terminus: Val 30

## **Molecular Characterization**

# IL-6(Val 30 - Met 212) P05231

This protein carries no "tag".

The protein has a calculated MW of 20.8 kDa. The protein migrates as 23-29 kDa when calibrated against <u>Star Ribbon Pre-stained Protein Marker</u> under reducing (R) condition (SDS-PAGE) due to glycosylation.

## Endotoxin

Less than 10 EU/mg by the LAL method.

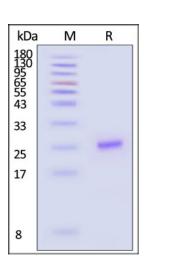
# **Host Cell Protein**

<0.5 ng/µg of protein tested by ELISA.

## **Host Cell DNA**

<0.02 ng/µg of protein tested by qPCR.

# **SDS-PAGE**



#### 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  $\mu$ m 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.

GMP Human IL-6 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than

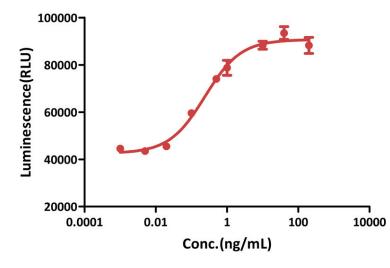


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95% (With Star Ribbon Pre-stained Protein Marker).

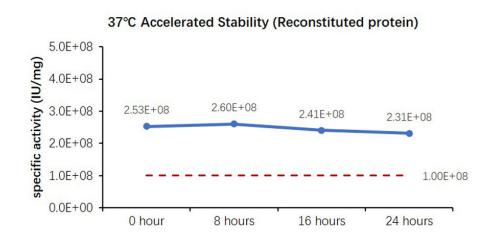
#### **Bioactivity-Bioactivity CELL BASE**



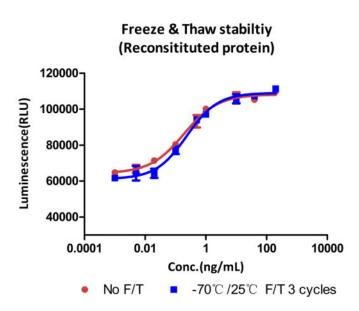
GMP Human IL-6 Protein stimulates proliferation TF-1 cells

GMP Human IL-6 Protein (Cat. No. GMP-L06H27) stimulates proliferation of TF-1 human erythroleukemic cell line. The specific activity of GMP Human IL-6 Protein is  $> 1.00 \times 10^{8}$  IU/mg, which is calibrated against human IL-6 WHO International Standard (NIBSC code: 21/308) (QC tested).

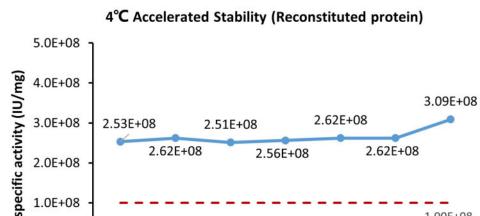
## **Bioactivity-Stability**



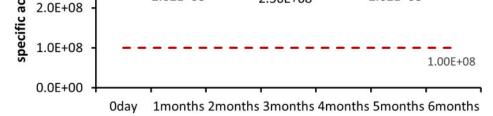
The Cell based assay shows that GMP Human IL-6 Protein (Cat. No. GMP-L06H27) is stable at 37 °C for 24 hours.



The Cell based assay shows that GMP Human IL-6 Protein (Cat. No. GMP-L06H27) is stable after freezing and thawing 3 times.









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The Cell based assay shows that GMP Human IL-6 Protein (Cat. No. GMP-L06H27) is stable at 4°C for 6 months.

# 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 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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## Background

Interleukin 6 (IL-6) is also known as HGF, BSF2,HSF, IFNB2 and IL-6, originally identified as a B cell differentiation factor, is a multifunctional cytokine that regulates immune responses, hematopoiesis, acute phase responses, and inflammatory reactions. It is secreted by T cells, macrophages, monocytes, fibroblasts, endothelial cells, et.al. to stimulate immune response to trauma, especially burns or other tissue damage leading to inflammation. Interleukin 6 has been shown to interact with interleukin-6 receptor and glycoprotein. IL-6 is relevant to many disease processes such as diabetes, atherosclerosis, depression, Alzheimer's Disease, systemic, lupus erythematosus, prostate cancer and rheumatoid arthritis. Advanced/metastatic cancer patients have higher levels of IL-6 in their blood. Hence there is an interest in developing anti-IL-6 agents as therapy against many of these diseases.

## **Clinical and Translational Updates**



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