# **GMP Human IFN-gamma Protein**

Catalog # GMP-IFGH24



### 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 IFN-gamma Protein(GMP-IFGH24) is expressed from human 293 cells (HEK293). It contains AA Gln 24 - Gln 166 (Accession # <u>P01579</u>). Predicted N-terminus: Gln 24

## **Molecular Characterization**

IFN-gamma(Gln 24 - Gln 166) P01579

This protein carries no "tag".

The protein has a calculated MW of 16.8 kDa. The protein migrates as 15 kDa, 19 kDa and 24 kDa±3 kDa under reducing (R) condition (SDS-PAGE) due to glycosylation.

## Endotoxin

Less than 10 EU/mg by the LAL method.

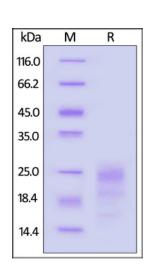
# **Host Cell Protein**

<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 IFN-gamma Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein



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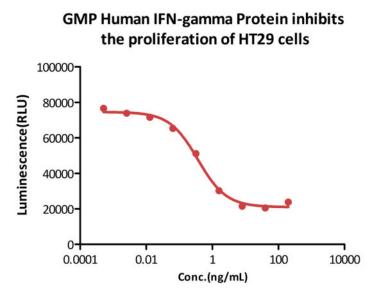
9/18/2024

## **GMP Human IFN-gamma Protein**

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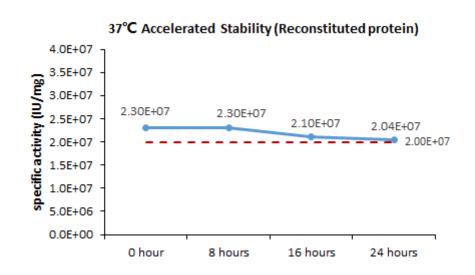
is greater than 95%.

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

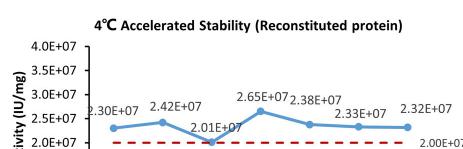


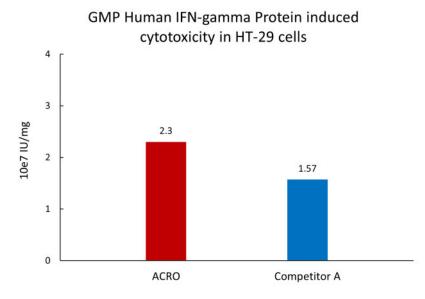
GMP Human IFN-gamma Protein (Cat. No. GMP-IFGH24) inhibits the proliferation of HT-29 cells. The specific activity of GMP Human IFN-gamma Protein is  $> 2.00 \times 10^{7}$  IU/mg, which is calibrated against human interferon gamma Standard (NIBSC code: 87/586) (QC tested).

#### **Bioactivity-Stability**

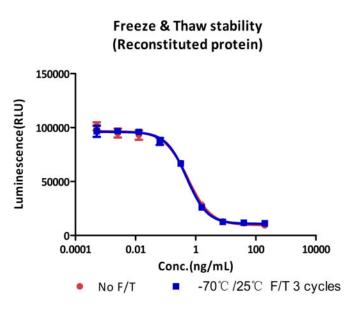


The Cell based assay shows that GMP Human IFN-gamma Protein (Cat. No. GMP-IFGH24) is stable at 37°C for 24 hours.

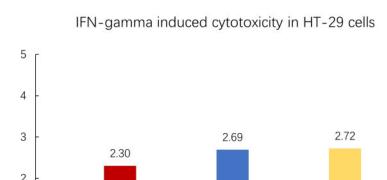




The activity of GMP Human IFN-gamma Protein (Cat. No. GMP-IFGH24) was higher than other competing products.



The Cell based assay shows that GMP Human IFN-gamma Protein (Cat. No. GMP-IFGH24) is stable after freezing and thawing 3 times.







IU/mg







The Cell based assay shows that GMP Human IFN-gamma Protein (Cat. No. GMP-IFGH24) is stable at 4°C for 6 months.

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

# 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

Interferon-gamma (IFN-γ/IFNG) is a dimerized soluble cytokine that is the only member of the type II class of interferon. This interferon was originally called macrophage-activating factor, a term now used to describe a larger family of proteins to which IFN-γ belongs. IFN-gamma has been used in a wide variety of clinical indications. Interferon-gamma (IFNgamma) is a central regulator of the immune response and signals via the Janus Activated Kinase (JAK)-Signal Transducer and Activator of Transcription (STAT) pathway. Interferon gamma has broader roles in activation of innate and adaptive immune responses to viruses and tumors, in part through upregulating transcription of genes involved in cell cycle regulation, apoptosis, and antigen processing/presentation. Despite this, rodent and human trophoblast cells show dampened responses to IFNG that reflect the resistance of these cells to IFNG-mediated activation of major histocompatibility complex (MHC) class II transplantation antigen expression.

# **Clinical and Translational Updates**



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