



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 GM-CSF Protein(GMP-GMFH28) is expressed from human 293 cells (HEK293). It contains AA Ala 18 - Glu 144 (Accession # [P04141](#)).
 Predicted N-terminus: Ala 18

Molecular Characterization

GM-CSF(Ala 18 - Glu 144)
P04141

This protein carries no "tag".

The protein has a calculated MW of 14.5 kDa. The protein migrates as 25 kDa±3 kDa when calibrated against [Star Ribbon Pre-stained Protein Marker](#) 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.

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

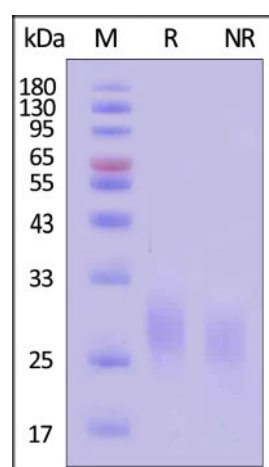
Upon receipt, store it immediately at -20°C or lower for long term storage.

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 GM-CSF Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The

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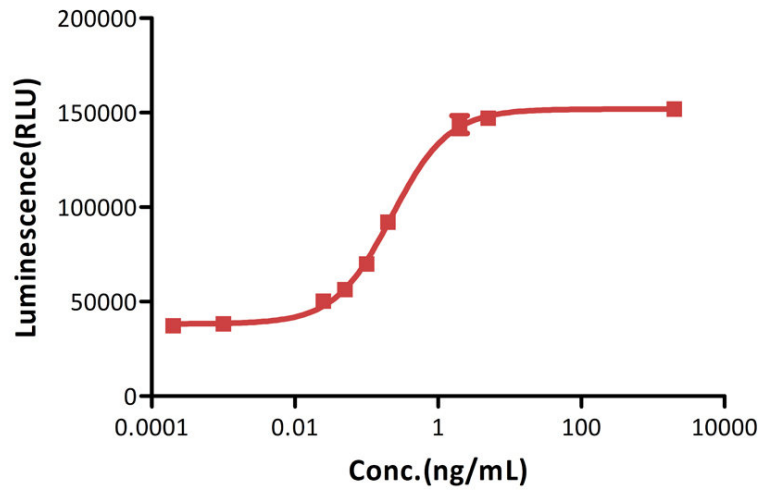




purity of the protein is greater than 95% (With [Star Ribbon Pre-stained Protein Marker](#)).

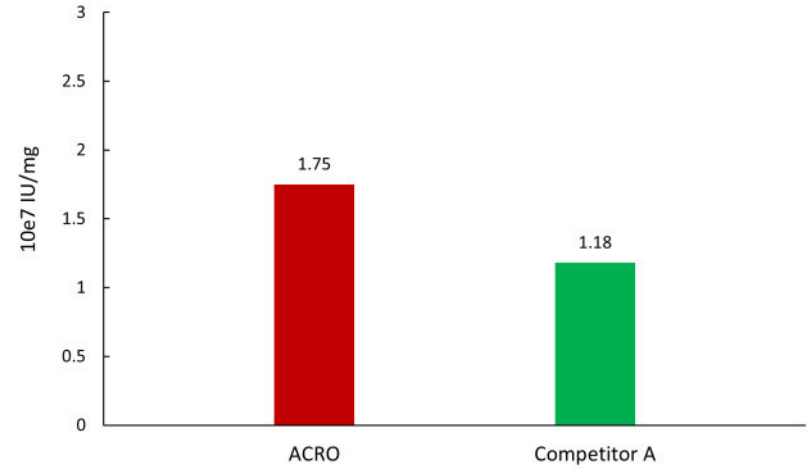
Bioactivity-Bioactivity CELL BASE

GMP Human GM-CSF stimulates proliferation of TF-1 cells



GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) stimulates proliferation of TF-1 cells. The specific activity of GMP Human GM-CSF Protein is $> 5.00 \times 10^6$ IU/mg, which is calibrated against human GM-CSF WHO International Standard (NIBSC code: 88/646) (QC tested).

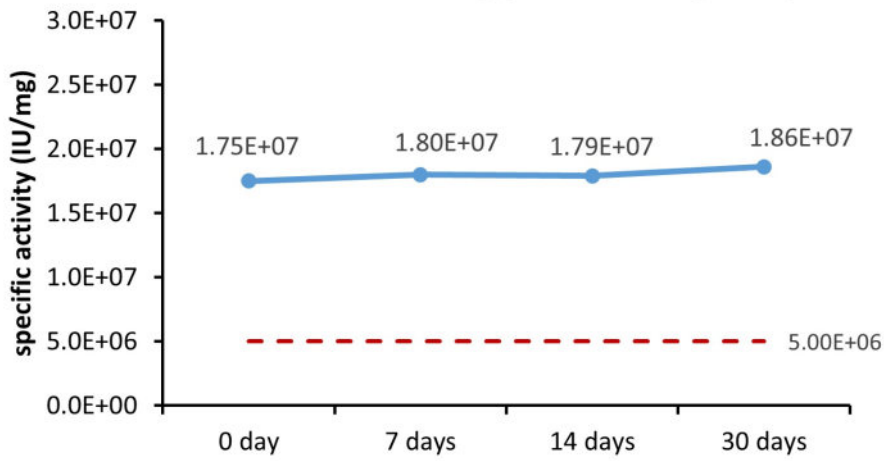
GMP Human GM-CSF Protein stimulates proliferation of TF-1 cells



The activity of GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) was higher than other competing products.

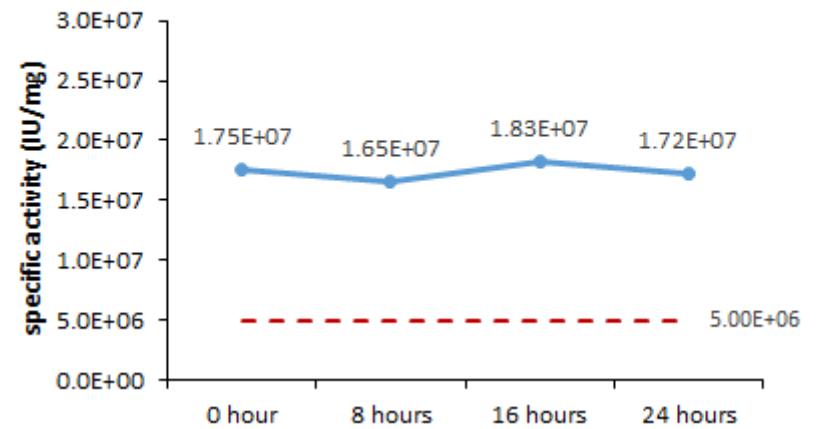
Bioactivity-Stability

4°C Accelerated Stability (Reconstituted protein)



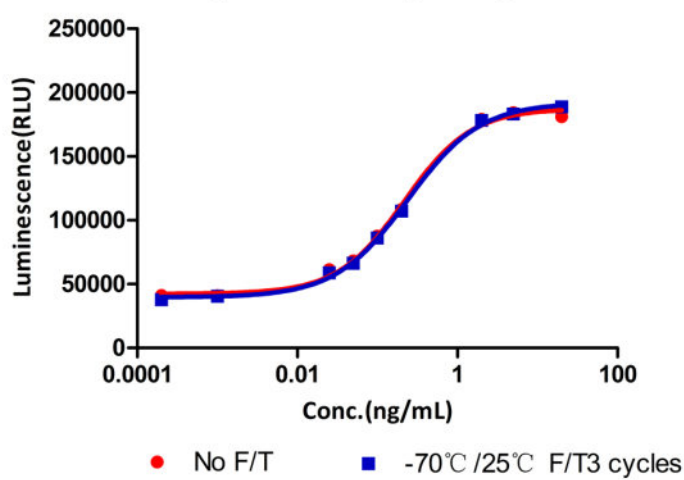
The Cell based assay shows that GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable at 4°C for 30 days.

37°C Accelerated Stability (Reconstituted protein)



The Cell based assay shows that GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable at 37°C for 24 hours.

Freeze & Thaw stability (Reconstituted protein)



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The Cell based assay shows that GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable after freezing and thawing 3 times.

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

Granulocyte-macrophage colony-stimulating factor (GM-CSF) is also known as Colony stimulating factor 2 (granulocyte-macrophage), is a cytokine initially characterized by its ability to induce colonies of granulocytes and macrophages from myeloid progenitor cells, and is secreted by macrophages, T cells, mast cells, endothelial cells and fibroblasts. GM-CSF is a cytokine that functions as a white blood cell growth factor. GM-CSF stimulates stem cells to produce granulocytes (neutrophils, eosinophils, and basophils) and monocytes. Monocytes exit the circulation and migrate into tissue, whereupon they mature into macrophages and dendritic cells. Thus, it is part of the immune/inflammatory cascade, by which activation of a small number of macrophages can rapidly lead to an increase in their numbers, a process crucial for fighting infection. The active form of the protein is found extracellularly as a homodimer. Human GM-CSF glycosylated in its mature form. As a part of the immune/inflammatory cascade, GM-CSF promotes Th1 biased immune response, angiogenesis, allergic inflammation, and the development of autoimmunity, and thus worthy of consideration for therapeutic target. GM-CSF has also recently been evaluated in clinical trials for its potential as a vaccine adjuvant in HIV-infected patients. The preliminary results have been promising. GM-CSF is also used as a medication to stimulate the production of white blood cells following chemotherapy.

Clinical and Translational Updates

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