GMP Human GM-CSF Protein

Catalog # GMP-GMFH28

GMP Platform Advantages

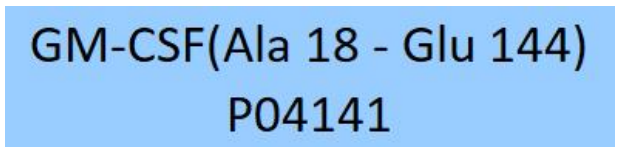
- **Quality Assurance**: Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance**: Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents**: Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory 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 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



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, 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.

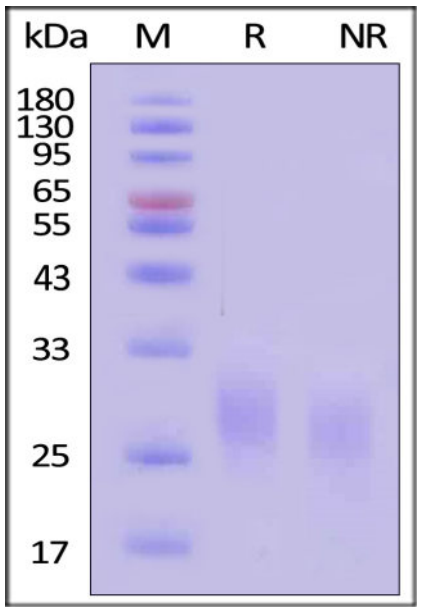
This product is stable after storage at:

- -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

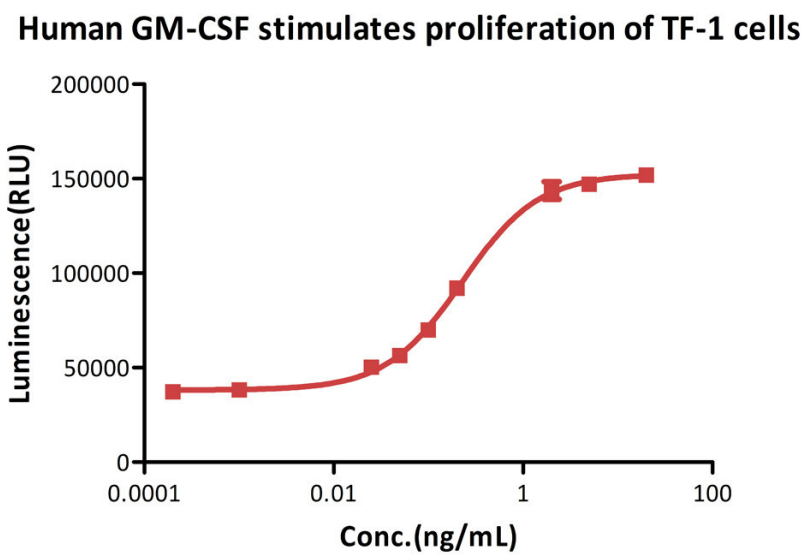
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE

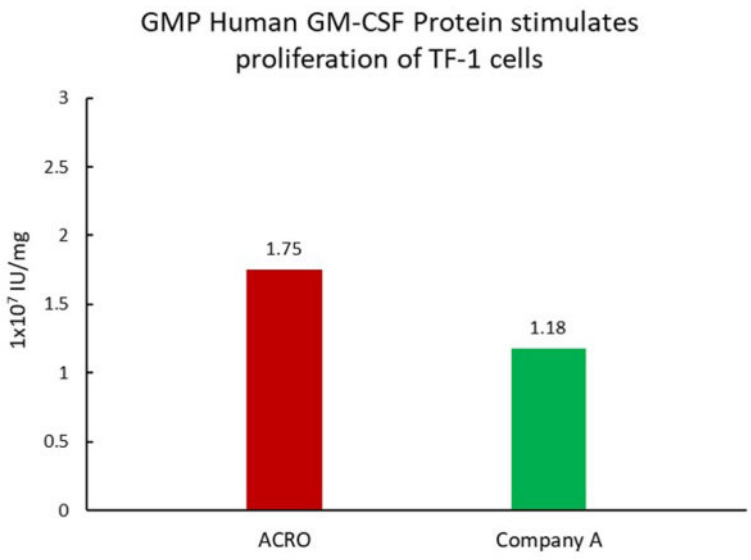


GMP Human GM-CSF Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE

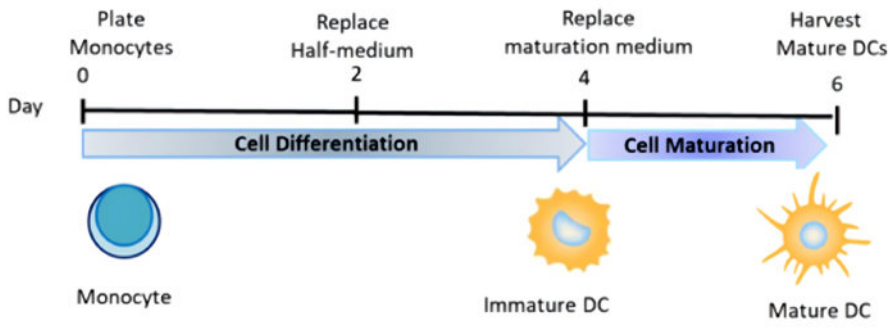


GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) stimulates proliferation of TF-1 cells. The specific activity of GMP Human GM-CSF Protein is > 5.00x10^6 IU/mg, which is calibrated against human GM-CSF WHO International Standard (NIBSC code: 88/646) (QC tested).

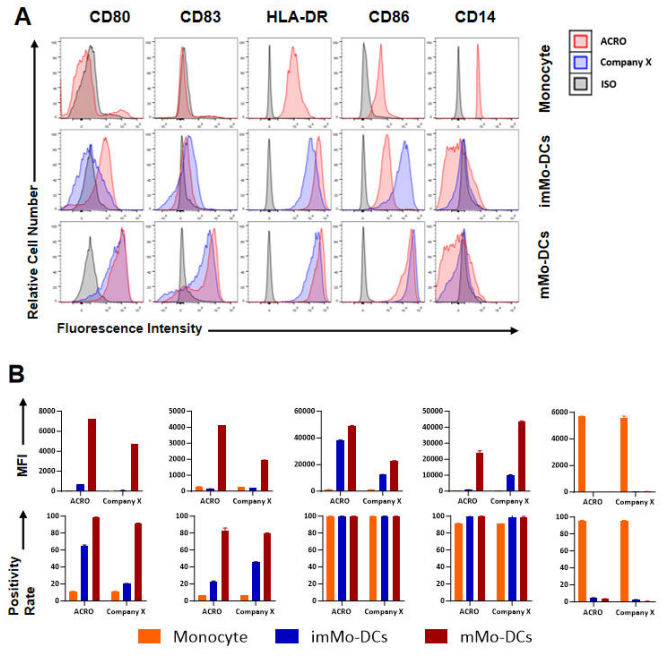


GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) exhibits superior activity compared to commercially available product.

Application Data

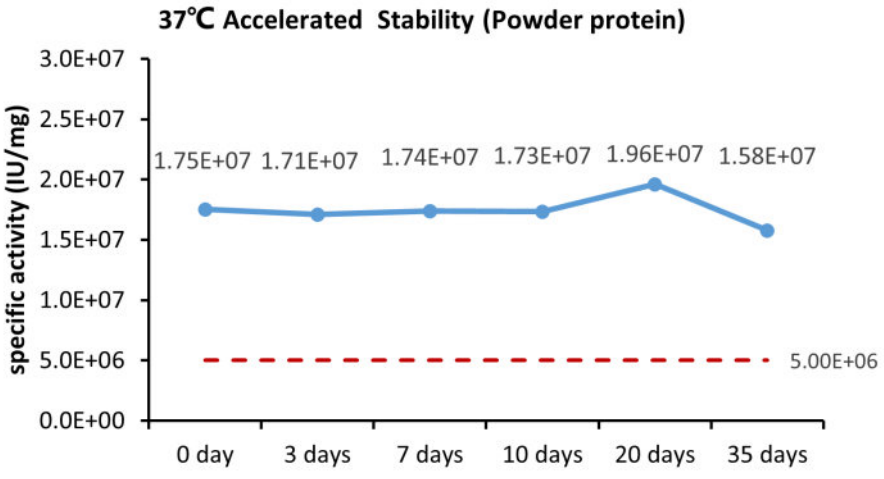


Schematic diagram of monocyte differentiation into dendritic cells.

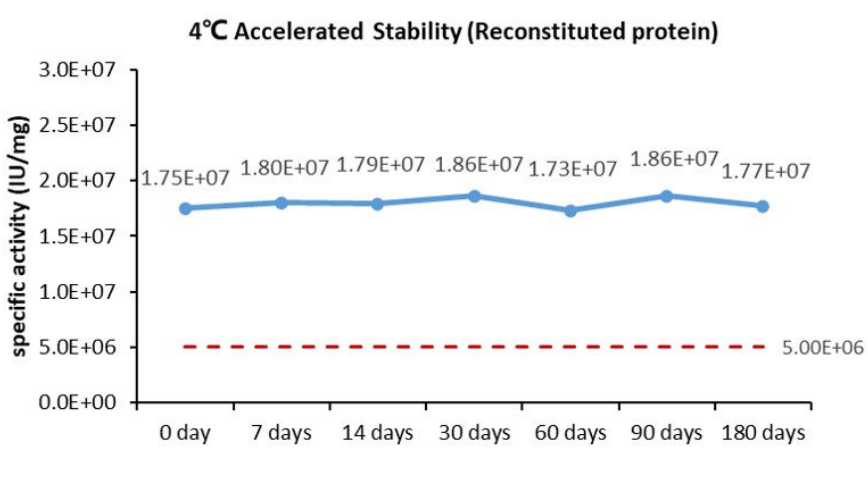


Detection of differentiation markers during monocyte-to-DC differentiation.
Representative histograms showing surface expression of CD14, CD83, HLA-DR, CD80, and CD86 on monocytes, immature monocyte-derived DCs (imMo-DCs), and mature Mo-DCs (mMo-DCs) cultured in either ACRO medium or Company X medium. Both media effectively induced differentiation of monocytes into DCs, as evidenced by marked upregulation of CD83, HLA-DR, CD80, and CD86 and downregulation of CD14. Compared with imMo-DCs, mMo-DCs showed further increases in the expression of CD80, CD83, and CD86. Marker-specific staining is shown in red (ACRO) or blue (Company X), and isotype controls are shown in gray. Histograms are from one representative experiment (A). Corresponding mean fluorescence intensity (MFI) values for each marker from three technical replicates. Data are presented as mean ± SD (B).

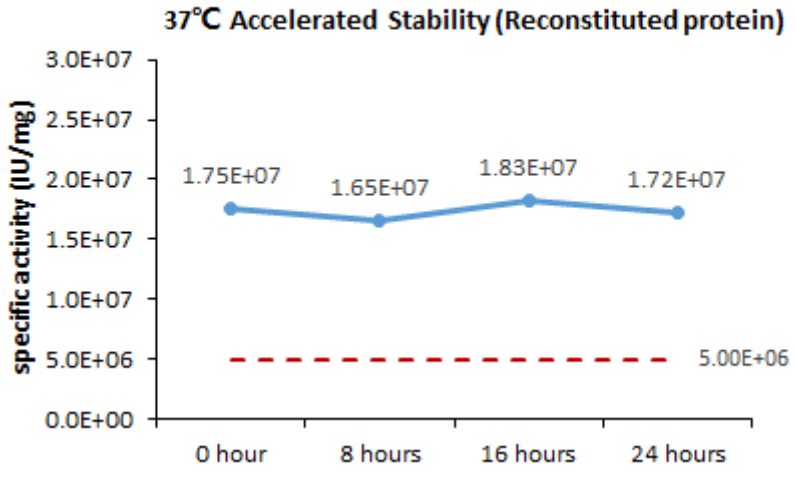
Bioactivity-Stability



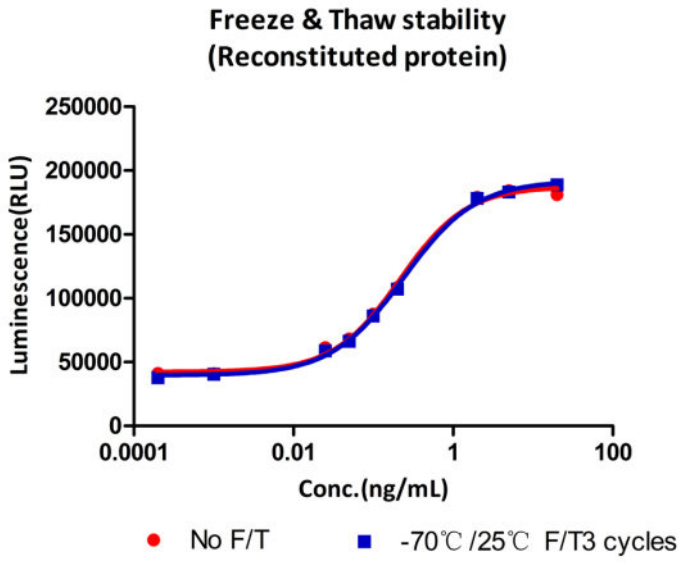
Cell-based assay demonstrates that the lyophilized GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable at 37°C for 35 days.



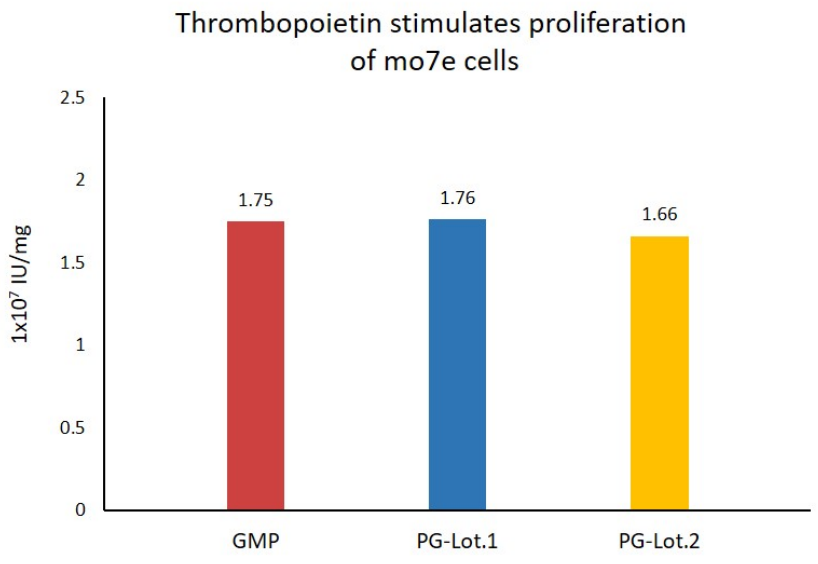
Cell-based assay demonstrates that the reconstituted GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable at 4°C for 180 days.



Cell-based assay demonstrates that the reconstituted GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable at 37℃ for 24 hours.



Cell-based assay demonstrates that the reconstituted GMP Human GM-CSF Protein (Cat. No. GMP-GMFH28) is stable after 3 freeze-thaw cycles.



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

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 exitthe 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.

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

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