

DESCRIPTION

Source *E. coli*-derived
Ala18-Glu144
Accession # P04141
Produced using non-animal reagents in an animal-free laboratory.
Manufactured and tested under cGMP guidelines.

N-terminal Sequence Analysis Ala-Pro-Ala-Arg-Ser-Pro-Ser-Pro-Ser-Thr

Predicted Molecular Mass 14.5 kDa

SPECIFICATIONS

SDS-PAGE 14 kDa, reducing conditions

Activity Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) *J. Cell Physiol.* **140**:323. The ED₅₀ for this effect is 6-30 pg/mL.
The specific activity of recombinant human GM-CSF is approximately 1.5 x 10⁴ IU/μg, which is calibrated against human GM-CSF WHO International Standard (NIBSC code: 88/646).

Endotoxin Level <0.10 EU per 1 μg of the protein by the LAL method.

Purity >97%, by SDS-PAGE under reducing conditions and visualized by silver stain.

Host Cell Protein <0.5 ng per μg of protein when tested by ELISA.

Mycoplasma Negative when tested in a ribosomal RNA hybridization assay.

Formulation Lyophilized from a 0.2 μm filtered solution in PBS. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution Reconstitute at 100-200 μg/mL in PBS.

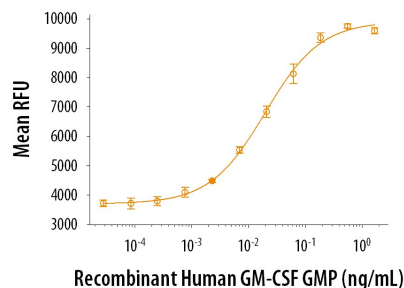
Shipping The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.

Stability & Storage Use a manual defrost freezer and avoid repeated freeze-thaw cycles.

- A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.
- 1 month, 2 to 8 °C under sterile conditions after reconstitution.
- 3 months, ≤ -20 °C under sterile conditions after reconstitution.

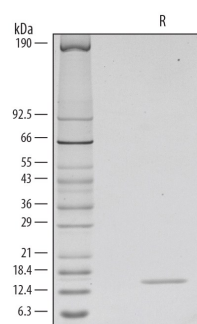
DATA

Bioactivity



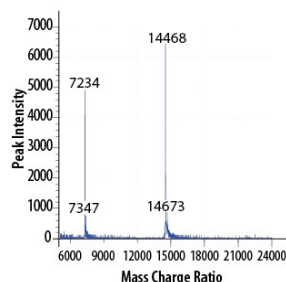
GMP-grade Recombinant Human GM-CSF (Catalog # 215-GMP) stimulates proliferation of TF-1 human erythroleukemic cell line. The ED₅₀ is 6-30 pg/mL.

SDS-PAGE



1 μg/lane of GMP-grade Recombinant Human GM-CSF (Catalog # 215-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 14 kDa.

Mass Spectrometry



MALDI-TOF analysis of GMP-grade Recombinant Human GM-CSF (Catalog # 215-GMP). The major peak corresponds to the calculated molecular mass, 14478 Da. The minor peak at 14673 Da is a matrix-associated artifact of the MALDI-TOF.

BACKGROUND

GM-CSF was initially characterized as a factor that can support the *in vitro* colony formation of granulocyte-macrophage progenitors. It is also a growth factor for erythroid, megakaryocyte, and eosinophil progenitors. GM-CSF is produced by a number of different cell types (including T cells, B cells, macrophages, mast cells, endothelial cells, fibroblasts, and adipocytes) in response to cytokine or inflammatory stimuli. On mature hematopoietic cells, GM-CSF is a survival factor for and activates the effector functions of granulocytes, monocytes/macrophages, and eosinophils (1, 2). GM-CSF promotes a Th1 biased immune response, angiogenesis, allergic inflammation, and the development of autoimmunity (3-5). It shows clinical effectiveness in ameliorating chemotherapy-induced neutropenia, and GM-CSF transfected tumor cells are utilized as cancer vaccines (6, 7). The 22 kDa glycosylated GM-CSF, similar to IL-3 and IL-5, is a cytokine with a core of four bundled α -helices (8-12). Mature human GM-CSF shares 63%-70% amino acid sequence identity with canine, feline, porcine, and rat GM-CSF and 54% with mouse GM-CSF. GM-CSF exerts its biological effects through a heterodimeric receptor complex composed of GM-CSF R α /CD116 and the signal transducing common β chain (CD131) which is also a component of the high-affinity receptors for IL-3 and IL-5 (13, 14). In addition, GM-CSF binds a naturally occurring soluble form of GM-CSF R α (15). Human GM-CSF is active on canine and feline cells but not on murine cells (16-18).

References:

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11. Lee, F. *et al.* (1985) *Proc. Natl. Acad. Sci.* **82**:4360.
12. Wong, G.G. *et al.* (1985) *Science* **228**:810.
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MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP <61> bioburden testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

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Production

- All molecular biology procedures use animal-free media and dedicated labware.
- Dedicated fermentors are utilized in committed animal-free areas.

Purification

- Protein purification columns are animal-free.
- Bulk proteins are filtered using animal-free filters.
- Purified proteins are stored in animal-free containers in a dedicated cold storage room.

Quality Assurance

- Low Endotoxin Level.
- No impairment of biological activity.
- High quality product obtained under stringent conditions.
- For *ex vivo* research or bioproduction, [additional documentation](#) can be provided.

[Please read our complete Animal-Free Statement.](#)

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