

DESCRIPTION

Source	<i>E. coli</i> -derived human GM-CSF protein 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

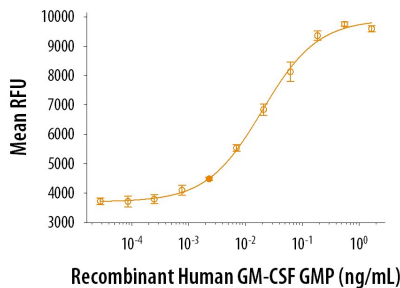
SDS-PAGE	14 kDa, reducing conditions
Activity	Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. <i>et al.</i> (1989) <i>J. Cell Physiol.</i> 140 :323. The ED ₅₀ for this effect is 6-30 pg/mL. The specific activity of recombinant human GM-CSF is >1.0 x 10 ⁷ IU/mg, which is calibrated against the 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 with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. <ul style="list-style-type: none"> • 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.

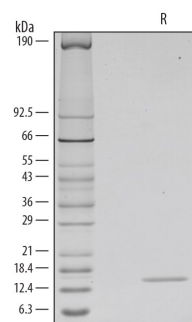
DATA

Bioactivity



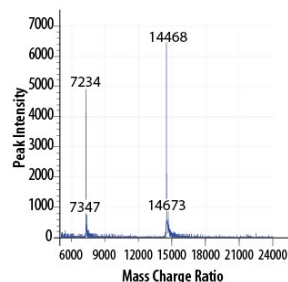
GMP-grade Recombinant Human GM-CSF (Catalog # 215-GMP) stimulates proliferation of TF-1 human erythroleukemic cell line. The ED₅₀ is 6-30 pg/mL.

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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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.

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- Raw material testing and vendor qualification/monitoring
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- 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 testing according to USP
- 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.

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