

**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 ED<sub>50</sub> for this effect is typically 6-30 pg/mL.  
The specific activity of recombinant human GM-CSF is approximately 1.5 x 10<sup>4</sup> 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.

**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.

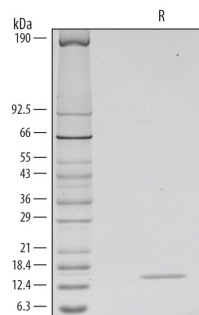
**Shipping** The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.

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

- 12 months, -20 to -70 °C as supplied.
- 1 month, 2 to 8 °C under sterile conditions after reconstitution.
- 3 months, -20 to -70 °C under sterile conditions after reconstitution.

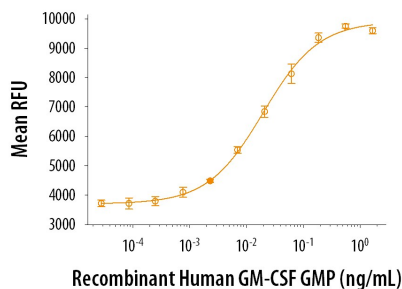
**DATA**

**SDS-PAGE**



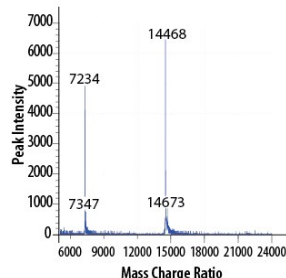
1 μg/lane of GMP-grade Recombinant Human GM-CSF (Catalog # 215-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 14 kDa.

**Bioactivity**



GMP-grade Recombinant Human GM-CSF (Catalog # 215-GMP) stimulates proliferation of TF-1 human erythroleukemic cell line. The ED<sub>50</sub> is typically 6-30 pg/mL.

**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

R&D Systems' 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:

- Manufacturing and testing under an ISO 9001:2008 and ISO 13485:2003 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, mass spec results, 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)

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP sterility 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.

R&D Systems sells its GMP grade recombinant protein products for research use or further manufacturing use in *ex vivo* cell therapy applications. They are not for *in vivo* use or for use as therapeutic or other drugs, biologic products or devices. Please read the following End User Terms prior to using this product.

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