

DESCRIPTION

Source *E. coli*-derived
Val77-Leu233
Accession # P01375
Produced using non-animal reagents in an animal-free laboratory.
Manufactured and tested under cGMP guidelines.

N-terminal Sequence Analysis Val₇₇-Arg-Ser-Ser-Ser-Arg-Thr-Pro-Ser-Asp

Predicted Molecular Mass 17.4 kDa

SPECIFICATIONS

SDS-PAGE 17 kDa, reducing conditions

Activity Measured in a cytotoxicity assay using L-929 mouse fibroblast cells in the presence of the metabolic inhibitor actinomycin D. Matthews, N. and M.L. Neale (1987) in *Lymphokines and Interferons, A Practical Approach*. Clemens, M.J. *et al.* (eds): IRL Press. 221.
The ED₅₀ for this effect is typically 25-100 pg/mL.
The specific activity of recombinant human TNF- α GMP is approximately 7.6×10^4 IU/ μ g, which is calibrated against human TNF- α WHO International Standard (NIBSC code: 88/786).

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

Purity >97%, by SDS-PAGE with silver staining.

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

PREPARATION AND STORAGE

Reconstitution Reconstitute at 100-200 μ g/mL in PBS.

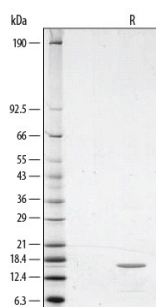
Shipping The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.

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.

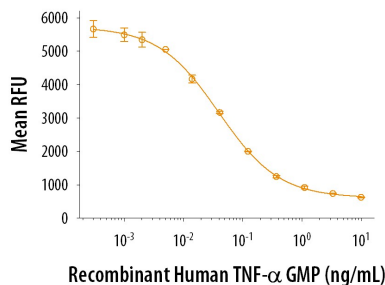
DATA

SDS-PAGE



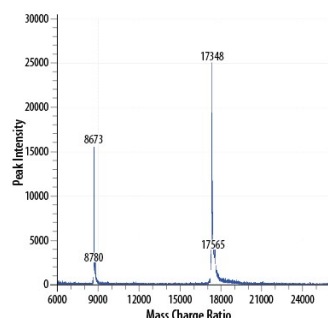
1 μ g/lane of GMP-grade Recombinant Human TNF- α (Catalog # 210-GMP) was resolved by SDS-PAGE with silver staining, under reducing (R) conditions, showing a single band at 17 kDa.

Bioactivity



GMP-grade Recombinant Human TNF- α (Catalog # 210-GMP) induces cytotoxicity in the L-929 mouse fibroblast cell line in the presence of the metabolic inhibitor actinomycin D. The ED₅₀ is typically 25-100 pg/mL.

Mass Spectrometry



MALDI-TOF analysis of GMP-grade Recombinant Human TNF- α (Catalog # 210-GMP). The major peak corresponds to the calculated molecular mass, 17353 Da. The minor peak at 17565 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 spectrometry 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.

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