Recombinant Human TGF-β1 GMP

Catalog Number: 240-GMP

DESCRIPTION

Source	Chinese Hamster Ovary cell line, CHO-derived Ala279-Ser390 Accession # P01137 Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ala-Leu-Asp-Thr-Asn-Tyr-(Cys)-Phe-Ser-Ser
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	12.8 kDa (monomer)

SPECIFICATIONS

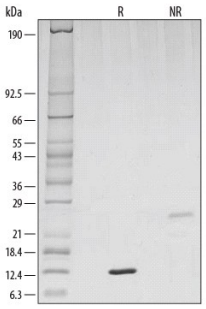
SDS-PAGE	12 kDa, reducing conditions 24 kDa, non-reducing conditions
Activity	Measured by its ability to inhibit the IL-4-dependent proliferation of HT-2 mouse T cells. Tsang, M. *et al.* (1995) Cytokine **7**:389. The ED_{50} for this effect is typically 0.04-0.2 ng/mL. The specific activity of recombinant human TGF-β1 GMP is approximately 2.5 x 10^4 U/µg, which is calibrated against human TGF-β1 Standard (NIBSC code: 89/514).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with silver staining.
Formulation	Lyophilized from a 0.2 µm filtered solution in Acetonitrile and TFA. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 100 µg/mL in 4 mM HCl.
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.

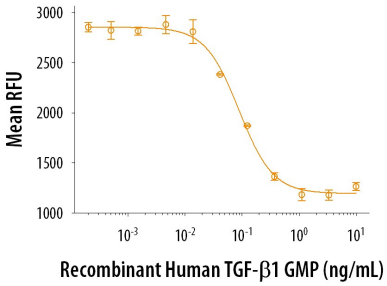
DATA

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human TGF-β1 (Catalog # 240-GMP) was resolved with SDS-PAGE under reducing (R) and nonreducing (NR) conditions and visualized by silver staining, showing single bands at 12 kDa and 24 kDa, respectively.

Bioactivity



GMP-grade Recombinant Human TGF-β1 (Catalog # 240-GMP) inhibits Recombinant Mouse IL-4 (Catalog # 404-ML) induced proliferation in the HT-2 mouse T cell line. The ED_{50} for this effect is typically 0.04-0.2 ng/mL.

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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.

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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