Recombinant Human IL-4 GMP

Catalog Number: 204-GMP

DESCRIPTION

Source	*E. coli*-derived His25-Ser153, with an N-terminal Met Accession # P05112 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Met-His_{25}-Lys-(Cys)-Asp-Ile-Thr-Leu-Gln-Glu
Predicted Molecular Mass	15.1 kDa

SPECIFICATIONS

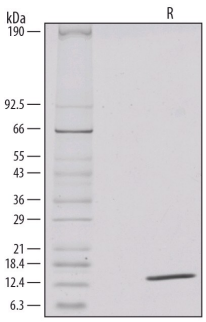
SDS-PAGE	14 kDa, reducing conditions
Activity	Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) J. Cell Physiol. **140**:323. The ED_{50} for this effect is typically 0.05-0.2 ng/mL. The specific activity of recombinant human IL-4 is approximately 2.9 x 10^4 IU/µg, which is calibrated against human IL-4 WHO International Standard (NIBSC code: 88/656).
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.

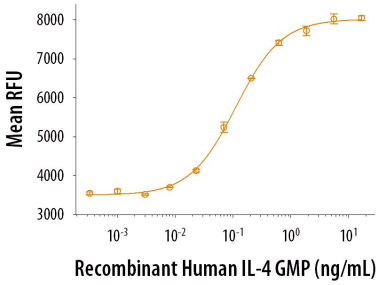
DATA

SDS-PAGE



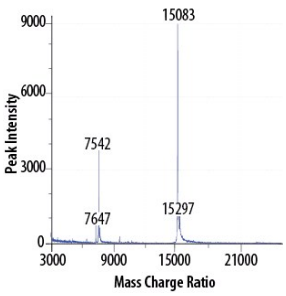
1 µg/lane of GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 14 kDa.

Bioactivity



GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP) stimulates proliferation of TF-1 human erythroleukemic cells. The ED_{50} is typically 0.05-0.2 ng/mL.

Mass Spectrometry



MALDI-TOF analysis of GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP). The major peak at 15083 Da corresponds to the calculated molecular mass, 15094 Da. The minor peak at 15297 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.

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