

DESCRIPTION

Source *Spodoptera frugiperda*, Sf 21 (baculovirus)-derived human IL-12 protein

Human IL-12 p40 (Ile23–Ser328) Accession # P29460
Human IL-12 p35 (Arg23–Ser219) Accession # P29459

N-terminus C-terminus

Manufactured and tested under current Good Manufacturing Practice (GMP) guidelines.

N-terminal Sequence Analysis Ile-Trp-Glu-Leu-Lys-Lys-Asp-Val-Tyr-Val (p40)
Arg-Asn-Leu-Pro-Val-Ala-Thr-Pro-Asp-Pro (p35)

Structure / Form Disulfide-linked heterodimer

Predicted Molecular Mass 34.7 kDa (p40) & 22.5 kDa (p35)

SPECIFICATIONS

SDS-PAGE 41 kDa (p40) and 29 kDa (p35), reducing conditions

Activity Measured in a cell proliferation assay using PHA-stimulated human T lymphoblasts. Symons, J.A. *et al.* (1987) in *Lymphokines and Interferons, a Practical Approach*. Clemens, M.J. *et al.* (eds): IRL Press. 272.
The ED₅₀ for this effect is 0.01-0.05 ng/mL.
The specific activity of recombinant human IL-12 is approximately 1.1 x 10⁴ units/μg, which is calibrated against recombinant human IL-12 WHO Standard (NIBSC code: 95/544).

Endotoxin Level <1.0 EU per 1 μg of the protein by the LAL method.

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

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

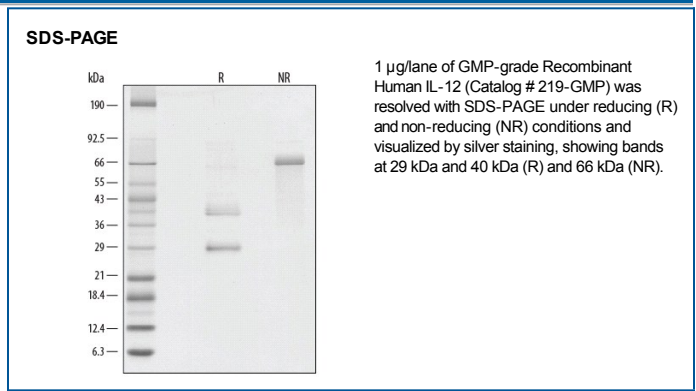
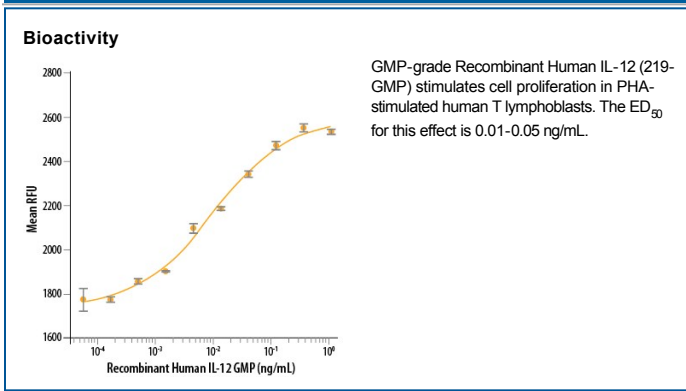
Reconstitution Reconstitute at 100 μg/mL in PBS.

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.

- 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



BACKGROUND

Interleukin 12, also known as natural killer cell stimulatory factor (NKSF) or cytotoxic lymphocyte maturation factor (CLMF), is a pleiotropic cytokine originally identified in the medium of activated human B lymphoblastoid cell lines. The p40 subunit of IL-12 has been shown to have extensive amino acid sequence homology to the extracellular domain of the human IL-6 receptor while the p35 subunit shows distant but significant sequence similarity to IL-6, G-CSF, and chicken MGF. These observations have led to the suggestion that IL-12 might have evolved from a cytokine/soluble receptor complex. Human and murine IL-12 share 70% and 60% amino acid sequence homology in their p40 and p35 subunits, respectively. IL-12 apparently shows species specificity with human IL-12 reportedly showing minimal activity in the murine system.

IL-12 is produced by macrophages and B lymphocytes and has been shown to have multiple effects on T cells and natural killer (NK) cells. These effects include inducing production of IFN- γ and TNF by resting and activated T and NK cells, synergizing with other IFN- γ inducers at both the transcriptional and post-transcriptional levels. This interaction induces IFN- γ gene expression, enhancing the cytotoxic activity of resting NK and T cells, inducing and synergizing with IL-2 in the generation of lymphokine-activated killer (LAK) cells, acting as a co-mitogen to stimulate proliferation of resting T cells, and inducing proliferation of activated T and NK cells. Current evidence indicates that IL-12, produced by macrophages in response to infectious agents, is a central mediator of the cell-mediated immune response by its actions on the development, proliferation, and activities of TH1 cells. In its role as the initiator of cell-mediated immunity, it has been suggested that IL-12 has therapeutic potential as a stimulator of cell-mediated immune responses to microbial pathogens, metastatic cancers, and viral infections such as AIDS.

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.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 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, 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)
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP <61> bioburden testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

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