

DESCRIPTION

Source	<i>Spodoptera frugiperda</i> , 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)

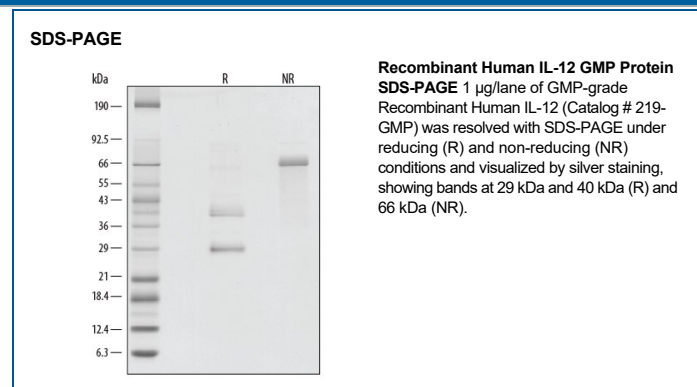
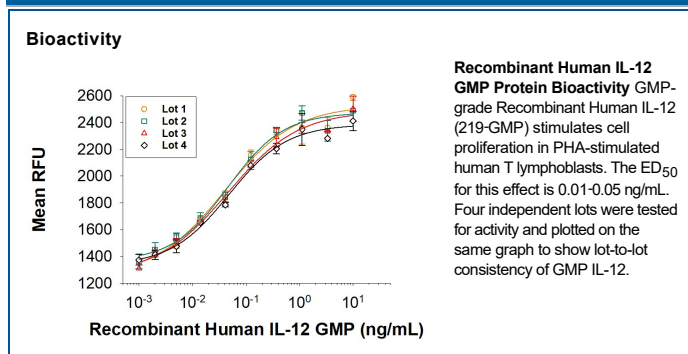
SPECIFICATIONS

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. <i>et al.</i> (1987) in Lymphokines and Interferons, a Practical Approach. Clemens, M.J. <i>et al.</i> (eds): IRL Press. 272. The ED ₅₀ for this effect is 0.01-0.05 ng/mL. The specific activity of recombinant human IL-12 is >9.0 x 10 ⁶ units/mg, which is calibrated against the 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 with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. <ul style="list-style-type: none"> • 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.

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- 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

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- 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 testing according to USP
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost.

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