

Catalog Number: 207-GMP

DESCRIPTION

Source E. coli-derived human IL-7 protein

Asp26-His177, with an N-terminal Met

Accession # P13232

Produced using non-animal reagents in an animal-free laboratory.

Manufactured and tested under cGMP guidelines

N-terminal Sequence Met-Asp-(Cys)-Asp-Ile-Glu-Gly-Lys-Asp-Gly

Analysis

Predicted Molecular 17 kDa

Mass

SPECIFICATIONS

Activity Measured in a cell proliferation assay using PHA-activated human peripheral blood lymphocytes (PBL). Yokota, T. et al. (1986) Proc. Natl.

Acad. Sci. USA 83:5894

The ED₅₀ for this effect is 0.1-0.5 ng/mL.

The specific activity of Recombinant Human IL-7 is approximately 4.4 x 105 units/µg, which is calibrated against human IL-7 WHO Standard

(NIBSC code: 90/530).

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

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

Host Cell Protein < 0.5 ng per μg of protein when tested by ELISA

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

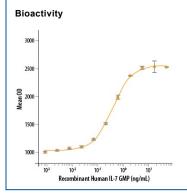
Reconstitution Reconstitute at 100 µg/mL in PBS.

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

Stability & Storage Use a manual defrost freezer and avoid repeated freeze-thaw cycles.

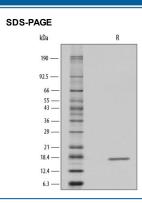
- A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.
- 1 month, 2 to 8 °C under sterile conditions after reconstitution.
- 3 months, ≤ -20 °C under sterile conditions after reconstitution

DATA

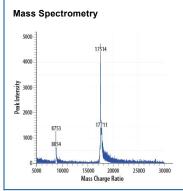


GMP-grade Recombinant Human IL-7 (Catalog # 207-GMP) stimulates proliferation of PHA-activated human peripheral blood lymphocytes. The ED₅₀ for this effect is

0.1-0.5 ng/mL.



1 ug/lane of GMP-grade Recombinant Human IL-7 (Catalog # 207-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 18 kDa



MALDI-TOF analysis of GMP-grade Recombinant Human IL-7 (Catalog # 207-GMP). The major peak corresponds to the calculated molecular mass, 17518 Da. The minor peak at 17711 Da is a matrixassociated artifact of the MALDI-TOF.

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BACKGPOUND

IL-7 (interleukin-7) is a 25 kDa cytokine of the hemopoietin family that plays important roles in lymphocyte differentiation, proliferation, and survival (1-4). Human IL-7 cDNA encodes 177 amino acids (aa) that include a 25 aa signal peptide (3). Human IL-7 shares approximately 60-63% aa sequence identity with mouse, rat, canine and feline IL-7, and 72-76% with equine, bovine, ovine, porcine, feline and canine IL-7. Human and mouse IL-7 exhibit cross-species activity (2, 3). IL-7 is produced by a wide variety of cells in primary and secondary lymphoid tissues, including stromal epithelial cells of the thymus, bone marrow, and intestines (1, 2, 5). Circulating IL-7 is limiting in healthy animals, but increases during lymphopenia (1, 6). IL-7 signals through a complex of the IL-7 Receptor alpha subunit (IL-7 R α , also known as CD127) with the common γ chain (γ_c) (1). The γ_c is also a subunit of the receptors for IL-2, -4, -9, -15, and -21 (1). IL-7 R α is expressed on double negative (CD4*CD8*) and CD4* or CD8* single positive naïve and memory T cells, but undergoes IL-7-mediated down-regulation and shedding during antigen-driven T cell proliferation, and is absent on regulatory T cells (1, 2, 6-11). IL-7 contributes to the maintenance of all naïve and memory T cells, mainly by promoting expression of the anti-apoptotic protein Bcl-2 (9-11). It is required for optimal T cell-dendritic cell interaction (6). IL-7 is expressed early in B cell development prior to the appearance of surface IgM (1, 5, 9). In mouse, IL-7 activation of IL-7 R α is critical for both T cell and B cell lineage development, while in humans, it is required for T cell but not for B cell development (4, 9, 12, 13). However, IL-7 functions in both mouse and human pro-B cells to suppress premature Ig light chain recombination during proliferative growth (14, 15).

References:

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- 2. Barata, J.T. et al. (2006) Exp. Hematol. 34:1133.
- 3. Goodwin, R.G. et al. (1990) Proc. Natl. Acad. Sci. USA 86:302.
- 4. Namen, A.E. et al. (1988) Nature 333:571.
- Shalapour, S. et al. (2012) PLoS ONE 7: e31939.
- 6. Saini, M. et al. (2009) Blood 113:5793.
- 7. Park, J.H. et al. (2004) Immunity 21:289.
- 8. Vranjkovic, A. et al. (2007) Int. Immunol. 19:1329.
- 9. Sudo, T. et al. (1993) Proc. Natl. Acad. Sci. 90:9125.
- Seddon, B. et al. (2003) Nat. Immunol. 4:680.
- 11. Schluns, K.S. et al. (2000) Nat. Immunol. 5:426.
- 12. Peschon, J.J. et al. (1994) J. Exp. Med. 180:1955.
- 13. Pribyl, J.A. and T.W. LeBien (1996) Proc. Natl. Acad. Sci. 93:10348.
- 14. Johnson, K. et al. (2012) J. Immunol. 188:6084.
- 15. Nodland, S.E. et al. (2011) Blood 118:2116.





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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)
- Host Cell Protein testing performed by ELISA
- 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.

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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Our dedicated controlled-access animal-free laboratories ensure that at no point in production are the products exposed to potential contamination by animal components or byproducts. Every stage of manufacturing is conducted in compliance with R&D Systems' stringent Standard Operating Procedures (SOPs). Production and purification procedures use equipment and media that are confirmed animal-free.

Production

- All molecular biology procedures use animal-free media and dedicated labware.
- Dedicated fermentors are utilized in committed animal-free areas.

Purification

- Protein purification columns are animal-free.
- Bulk proteins are filtered using animal-free filters.
- Purified proteins are stored in animal-free containers in a dedicated cold storage room.

Quality Assurance

- Low Endotoxin Level.
- No impairment of biological activity.
- High quality product obtained under stringent conditions.

Please read our complete Animal-Free Statement.





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