Recombinant Human IL-3 GMP

Catalog Number: 203-GMP

DESCRIPTION

Source	*E. coli*-derived Ala20-Phe152, with and without an N-terminal Met Accession # AAC08706 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Met-Ala-Pro-Met-Thr-Gln-Thr-Thr-Ser-Leu Ala-Pro-Met-Thr-Gln-Thr-Thr-Ser-Leu-Lys
Predicted Molecular Mass	15 kDa

SPECIFICATIONS

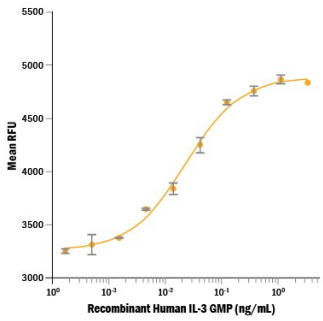
Activity	Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) J. Cell Physiol. **140**:323. The ED_{50} for this effect is 0.02-0.1 ng/mL. The specific activity of recombinant human IL-3 is approximately 1.8 x 10^3 IU/µg, which is calibrated against recombinant human IL-3 WHO International Standard (NIBSC code: 91/510).
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.
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.
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 6 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.

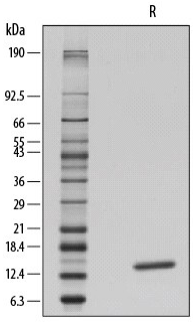
DATA

Bioactivity



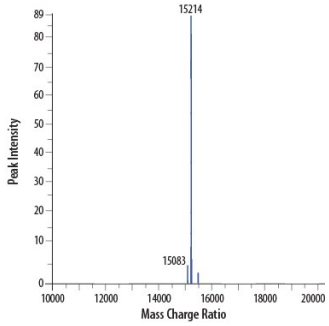
GMP-grade Recombinant Human IL-3 (Catalog # 203-GMP) stimulates proliferation of TF-1 human erythroleukemic cells. The ED_{50} for this effect is 0.02-0.1 ng/mL.

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human IL-3 (Catalog # 203-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver stain, showing a single band at 15 kDa.

Mass Spectrometry



ESI analysis of GMP-grade Recombinant Human IL-3 (Catalog # 203-GMP). The labeled peaks at 15214 Da and 15083 Da correspond to the calculated molecular mass with the N-terminal Met, 15213 Da, and without the N-terminal Met, 15081 Da, respectively.

bio-techne
bio-techne.com
Global info@bio-techne.com techsupport@bio-techne.com
North America TEL 800 343 7475 Europe | Middle East | Africa TEL +44 (0)1235 529449
China info.cn@bio-techne.com TEL +86 (21) 52380373
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BACKGROUND

Interleukin 3 is a pleiotropic factor produced primarily by activated T cells that can stimulate the proliferation and differentiation of pluripotent hematopoietic stem cells as well as various lineage committed progenitors. In addition, IL-3 also affects the functional activity of mature mast cells, basophils, eosinophils and macrophages. Because of its multiple functions and targets, it was originally studied under different names, including mast cell growth factor, P-cell stimulating factor, burst promoting activity, multi-colony stimulating factor, thy-1 inducing factor and WEHI-3 growth factor. In addition to activated T cells, other cell types such as human thymic epithelial cells, activated murine mast cells, murine keratinocytes and neurons/astrocytes can also produce IL-3. At the amino acid sequence level, mature human and murine IL-3 share only 29% sequence identity. Consistent with this lack of homology, IL-3 activity is highly species-specific and human IL-3 does not show activity on murine cells.

IL-3 exerts its biological activities through binding to specific cell surface receptors. The high affinity receptor responsible for IL-3 signaling is composed of at least two subunits, an IL-3 specific α chain which binds IL-3 with low affinity and a common β chain that is shared by the IL-5 and GM-CSF high-affinity receptors. Although the β chain itself does not bind IL-3, it confers high-affinity IL-3 binding in the presence of the α chain. Receptors for IL-3 are present on bone marrow progenitors, macrophages, mast cells, eosinophils, megakaryocytes, basophils and various myeloid leukemic cells.

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bio-techne.com
Global info@bio-techne.com techsupport@bio-techne.com
North America TEL 800 343 7475 Europe | Middle East | Africa TEL +44 (0)1235 529449
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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.

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.

Animal-Free Manufacturing Conditions
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.
- For *ex vivo* research or bioproduction, **additional documentation** can be provided.

Please read our complete Animal-Free Statement

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bio-techne.com
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North America TEL 800 343 7475 Europe | Middle East | Africa TEL +44 (0)1235 529449
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