

GMP Human IL-15

Cat. No. GMP-CKS-HE015

Description

Source	Recombinant GMP Human IL-15 is expressed from E.coli with no tag. It contains Asn49-Ser162.
Accession	P40933
Molecular Weight	The protein has a predicted MW of 12.8 kDa same as Bis-Tris PAGE result.
Endotoxin	≤ 0.01 EU per μg by the LAL method.
Purity	$\geq 95\%$ as determined by SEC-HPLC.
Mycoplasma	Negative
Sterility	No growth determined by membrane filtration method.
Residual Host Cell Protein	< 0.5 ng/ μg
Residual Host Cell DNA	< 0.02 ng/ μg

Bioactivity Measured in a cell proliferation assay using CTLL-2 cells. The specific activity of GMP Human IL-15 is $> 1 \times 10^7$ IU/mg, which is calibrated against the WHO reference standard (NIBSC code: 95/554) .

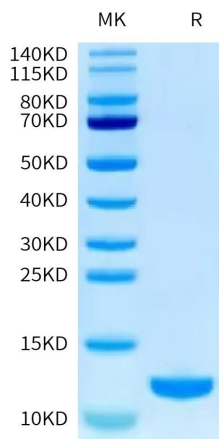
Formulation and Storage

Formulation	Lyophilized from 0.22 μm filtered solution in 20 mM Tris, 150 mM NaCl (pH 7.5). Normally 8% trehalose is added as protectant before lyophilization.
Reconstitution	Centrifuge the tube before opening. Reconstituting to a concentration more than 100 $\mu\text{g}/\text{ml}$ is recommended. Dissolve the lyophilized protein in distilled water.

Shipping and Storage The product is shipped with ice bag. Store it immediately at $-20^\circ\text{C} \pm 5^\circ\text{C}$ upon arrival. $-20^\circ\text{C} \pm 5^\circ\text{C}$ for 36 months in lyophilized state. Recommend to aliquot the protein into smaller quantities for optimal storage. Please minimize freeze-thaw cycles.

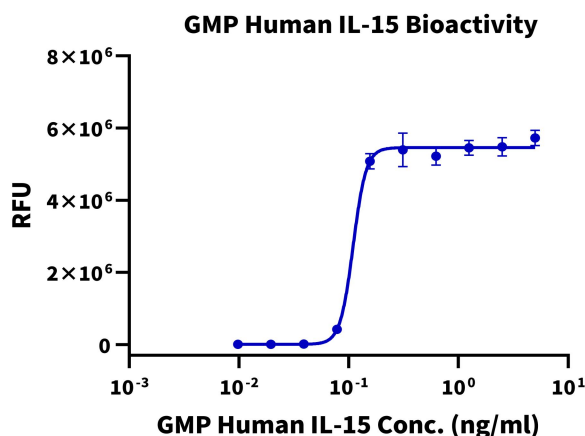
Assay Data

Bis-Tris PAGE



GMP Human IL-15 on Bis-Tris PAGE under reduced condition.

Cell Based Assay

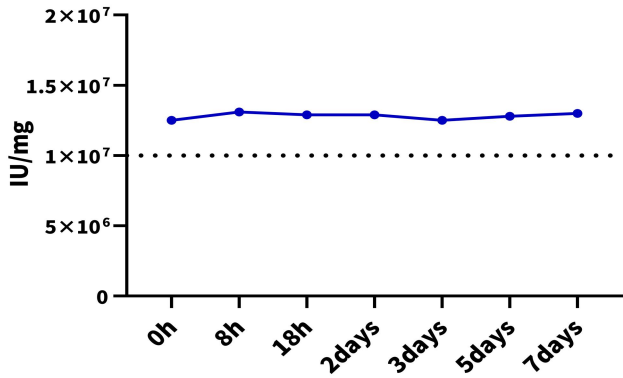


Measured in a cell proliferation assay using CTLL-2 cells. The ED50 for this effect is 0.1 - 0.3 ng/mL. The specific activity of GMP Human IL-15 is $> 1 \times 10^7$ IU/mg, which is calibrated against the human IL-15 WHO reference standard (NIBSC code: 95/554) (QC Test).

Assay Data

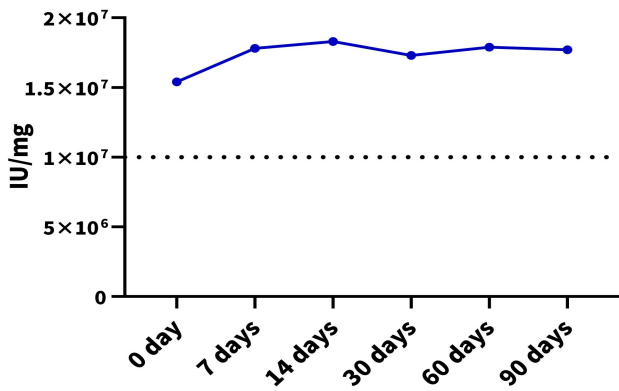
Stability

37°C Accelerated Stability



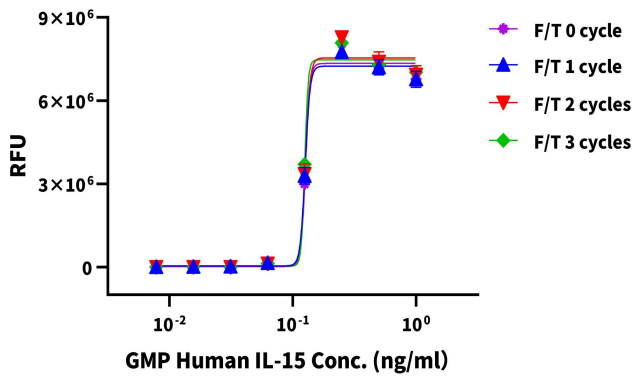
GMP Human IL-15 (reconstituted protein) was stored at 37°C, the protein is stable for 7 days determined by cell based assay.

4°C Accelerated Stability



GMP Human IL-15 (reconstituted protein) was stored at 4°C, the protein is stable for 90 days determined by cell based assay.

Freeze-Thaw Stability



GMP Human IL-15 (reconstituted protein) was repeatedly frozen at -80°C and thawed at 37°C, the protein is stable after freezing and thawing 3 cycles determined by cell based assay.

Quality Advantages

KACTUS GMP grade cytokines are manufactured and tested in accordance with relevant GMP guidelines and regulatory requirements, and are in compliance with ISO 13485:2016 certified quality system.

- Personnel training programs
- Clean rooms and facility
- Facility maintenance and equipment calibration & verification
- Raw material testing and supplier evaluation and approval
- Animal-free manufacturing
- Rigorous quality control
- Stability testing (freeze-thaw and accelerated stability of reconstituted protein; long-term stability in lyophilized state)
- Comprehensive support files, including COA, COO, MSDS, TSE/BSE statement, etc.

We conduct comprehensive quality control testing to ensure that KACTUS GMP grade cytokines meet strict standards for identification, purity, safety, bioactivity and batch-to-batch consistency.

- Identification by Bis-Tris PAGE
- Purity by SEC-HPLC
- Endotoxin level
- Residual host cell protein
- Residual host cell DNA
- Mycoplasma testing
- Sterility testing
- Bioactivity (Specific activity against standards of WHO if applicable)
- Batch-to-batch consistency

Background

IL-15 belongs to the common gamma chain cytokine family and has pleiotropic immunological functions, and the protein is mainly produced by monocytes, dendritic cells, and epithelial cells. IL-15 plays a crucial role in the development, homeostasis, and function of T, NK and NK-T cells, and is additionally required for various functions of the B cells, dendritic cells (DC), macrophages, and mast cells. Stimulation by IL15 requires interaction of IL15 with components of the IL2 receptor, including IL2RB and probably IL2RG but not IL2RA.

Disclaimer

KACTUS GMP Human IL-15 is for research or ex vivo cell processing use, not for human or animal in vivo application.