GMP Human 4-1BB Ligand Protein, Fc Tag

Catalog # GMP-41LH26

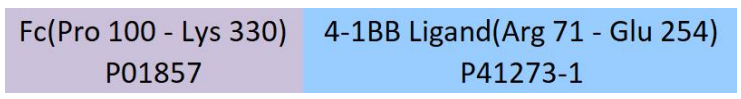
Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Batch-to-batch consistency
- Stringent quality control tests

Source

GMP Human 4-1BB Ligand Protein, Fc Tag(GMP-41LH26) is expressed from human 293 cells (HEK293). It contains AA Arg 71 - Glu 254 (Accession # P41273-1).
Predicted N-terminus: Pro

Molecular Characterization



This protein carries a human IgG1 Fc tag at the N-terminus.

The protein has a calculated MW of 87.5 kDa. The protein migrates as 95 kDa±5 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE) due to glycosylation.

Endotoxin

Less than 10 EU/mg by the LAL method.

Protein A

<5 ppm of protein tested by ELISA.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Sterility

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.

Mycoplasma

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 μm filtered solution in PBS, pH7.4 with protectants.

Contact us for customized product form or formulation.

Shipping

This product is supplied and shipped with blue ice, please inquire the shipping cost.

Storage

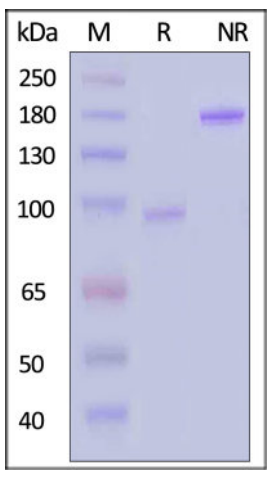
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

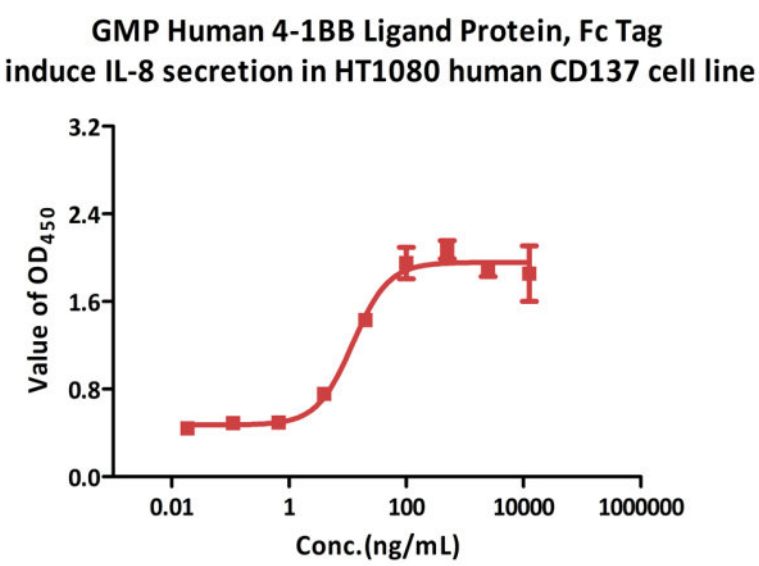
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE

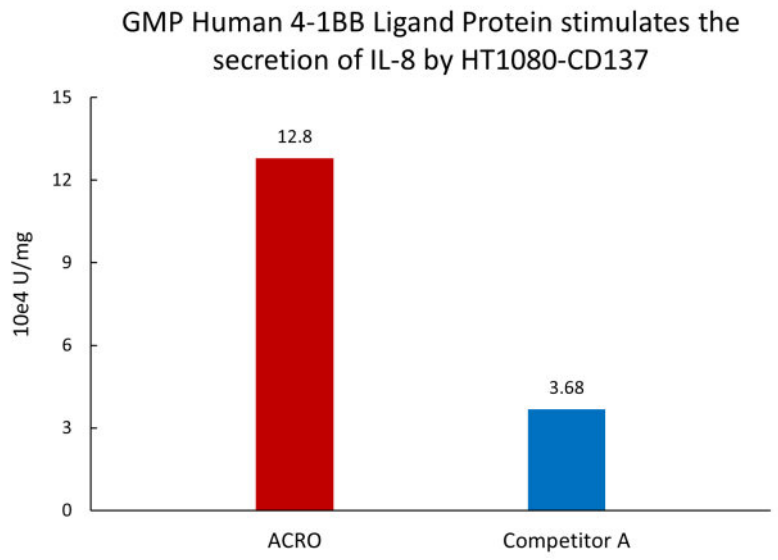


GMP Human 4-1BB Ligand Protein, Fc Tag on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-Bioactivity CELL BASE

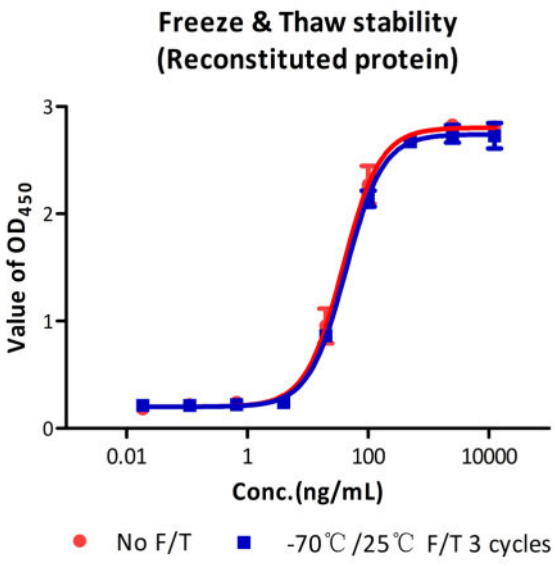


GMP Human 4-1BB Ligand Protein, Fc Tag (Cat. No. GMP-41LH26) induce IL-8 secretion in HT1080 human CD137 cell line. The specific activity of GMP Human 4-1BB Ligand Protein, Fc Tag is＞1.00 x 10^5 U/mg (QC tested).

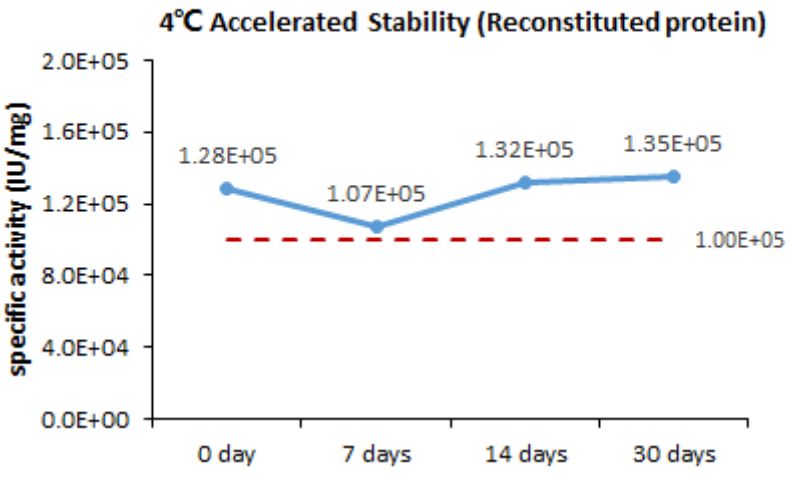


The activity of GMP Human 4-1BB Ligand Protein, Fc Tag (Cat. No. GMP-41LH26) was higher than other competing products.

Bioactivity-Stability



The Cell based assay shows that GMP Human 4-1BB Ligand Protein, Fc Tag (Cat. No. GMP-41LH26) is stable after freezing and thawing 3 times.



The Cell based assay shows that GMP Human 4-1BB Ligand Protein, Fc Tag (Cat. No. GMP-41LH26) is stable at 4°C for 30 days.

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents：

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

Animal-Free materials

Materials purchased from the approved suppliers by QA

ISO 5 clean rooms and automatic filling equipment

Qualified personnel

Quality-related documents review and approve by QA

Fully batch production and control records

Equipment maintenance and calibration

Validation of analytical procedures

Stability studies conducted

Comprehensive regulatory support files

Request For Regulatory Support Files（RSF）

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

SDS-PAGE

Protein content

Endotoxin level

Residual Host Cell DNA content

Residual Host Cell Protein content

Biological activity analysis

Microbial testing

Mycoplasma testing

In vitro virus assay

Residual moisture

Batch-to-batch consistency

Background

Tumor necrosis factor ligand superfamily member 9 (4-1BBL) is also known as 4-1BB ligand, CD137L or TNFSF9, which is a cytokine that binds to TNFRSF9. 4-1BBL is the high affinity ligand of 4-1BB. 4-1BBL induces the proliferation of activated peripheral blood T-cells. Also, 4-1BBL may have a role in activation-induced cell death (AICD). Furthermore, 4-1BBL may play a role in cognate interactions between T-cells and B-cells/macrophages. As for diseases, 4-1BBL is involved in cancers, infectious diseases and autoimmune diseases.

Clinical and Translational Updates