Catalog # GMP-FLLH28



#### Features

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

#### Source

GMP Human Flt-3 Ligand Protein(GMP-FLLH28) is expressed from human 293 cells (HEK293). It contains AA Thr 27 - Pro 185 (Accession # <u>P49771-1</u>). Predicted N-terminus: Thr 27

#### **Molecular Characterization**

Flt-3 Ligand(Thr 27 - Pro 185) P49771-1

This protein carries no "tag".

The protein has a calculated MW of 18.0 kDa. The protein migrates as 24 kDa & 27 kDa±3 kDa under reducing (R) condition (SDS-PAGE) due to glycosylation.

#### Endotoxin

Less than 10 EU/mg by the LAL method.

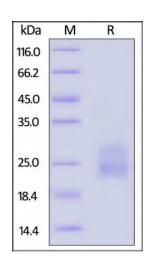
#### **Host Cell Protein**

<0.5 ng/µg of protein tested by ELISA.

#### Host Cell DNA

<0.02 ng/µg of protein tested by qPCR.

## **SDS-PAGE**



## 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  $\mu$ m 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.

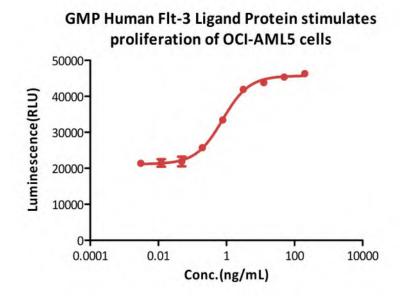
GMP Human Flt-3 Ligand Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.





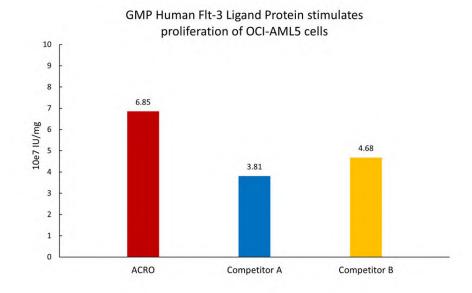
Catalog # GMP-FLLH28

#### **Bioactivity-Bioactivity CELL BASE**

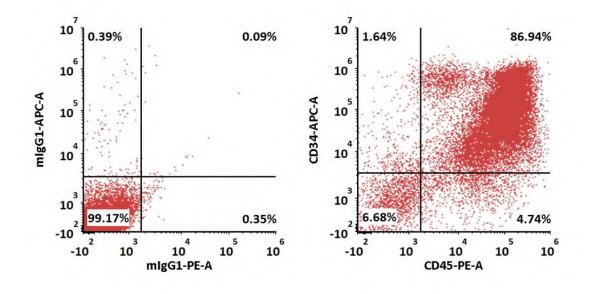


GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28) stimulates proliferation of OCI-AML5 cells. The specific activity of GMP Human Flt-3 Ligand Protein is  $> 5.00 \times 10^{5}$  IU/mg, which is calibrated against WHO Reference Reagent FMS-LIKE TYROSINE KINASE 3 LIGAND (NIBSC code: 96/532) (QC tested).

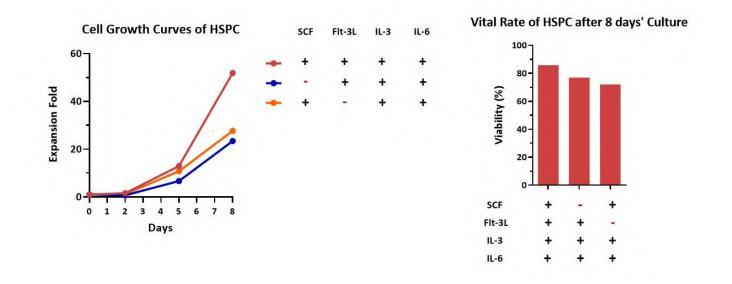
## **Application Data**



The activity of GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28) was higher than other competing products.



GMP Human SCF Protein (Cat. No. GMP-SCFH25), GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25), GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) and GMP Human VEGF165 Protein (Cat. No. GMP-VE5H23) could significantly promote the iPSC differentiation to HSPCSs after 14 days, highly expressed hematopoietic stem cell markers CD34 and CD45.







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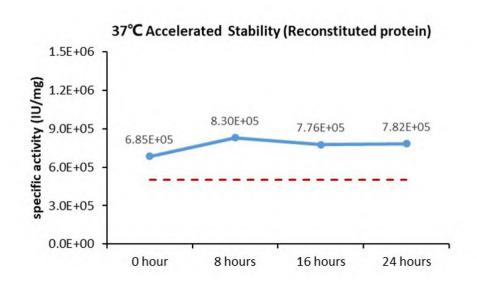


Catalog # GMP-FLLH28

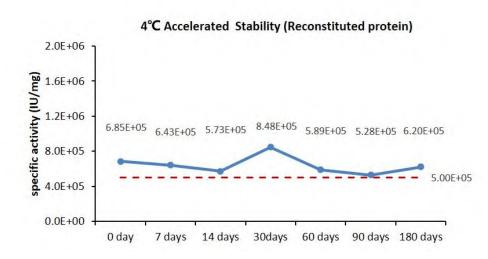
Sumise Inside

GMP Human SCF Protein (Cat. No. GMP-SCFH25), Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human IL-3 Protein (Cat. No. GMP-L03H18) and GMP Human IL-6 Protein (Cat. No. GMP-L06H27) could support the rapid cell expansion and good cell viability of CD34+ hematopoietic stem cells.

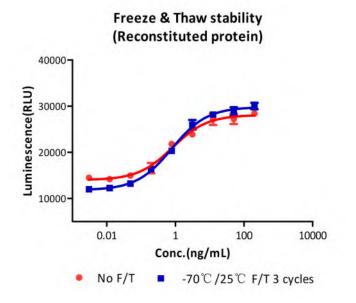
#### **Bioactivity-Stability**



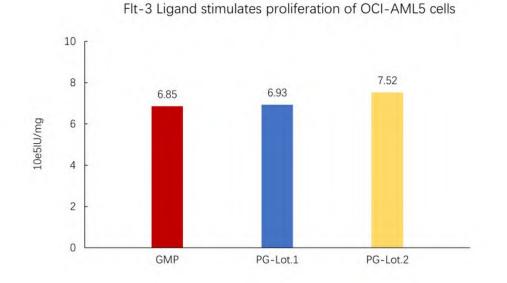
The Cell based assay shows that GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28) is stable at 37°C for 24 hours.



The Cell based assay shows that GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28) is stable at 4°C for 180 days.



The Cell based assay shows that GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28) is stable after freezing and thawing 3 times.



The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG Flt-3 Ligand.

## 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



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Catalog # GMP-FLLH28



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

FMS-like tyrosine kinase 3 ligand (Flt-3 Ligand) is also known as FL, Flt3L and FLT3LG, is an α-helical cytokine that promotes the differentiation of multiple hematopoietic cell lineages. FLT3LG is expressed as a noncovalentlylinked dimer by T cells and bone marrow and thymic fibroblasts. Each 36 kDa chain carries approximately 12 kDa of N- and O- linked carbohydrates. FLT3LG is structurally homologous to stem cell factor (SCF) and colony stimulating facor 1 (CSF-1). FLT3LG acts as a growth factor that increases the number of immune cells by activating the hematopoietic progenitors. It also induces the mobilization of the hematopoietic progenitors and stem cells in vivo which may help the system to kill cancer cells. FLT3LG induces the expansion of monocytes and immature dendritic cells as well as early B cell lineage differentiation. FLT3LG cooperates with IL2, IL6, IL7, and IL15 to induce NK cell development and with IL3, IL7 and IL11 to induce terminal B cell maturation. Animal studies also show FLT3LG to reduce the severity of experimentally induced allergic inflammation. FLT3LG is crucial for steady-state pDC and cDC development. A lack of FLT3L results in low levels of DCs.

## **Clinical and Translational Updates**



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