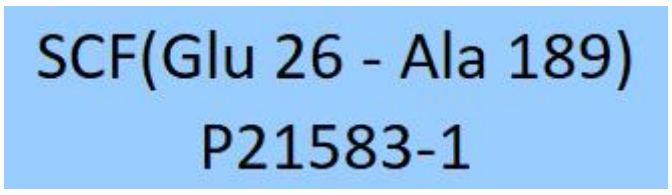
Features

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

Source

GMP Human SCF Protein(GMP-SCFH25) is expressed from human 293 cells (HEK293). It contains AA Glu 26 - Ala 189 (Accession # P21583-1).
Predicted N-terminus: Glu 26

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 18.5 kDa. The protein migrates as 30 kDa±3 kDa under reducing (R) condition (SDS-PAGE) due to glycosylation.

Endotoxin

Less than 10 EU/mg by the LAL method / rFC 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.

Sterility

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

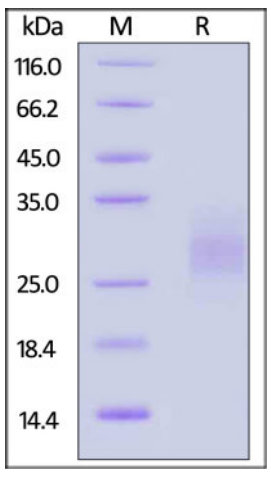
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

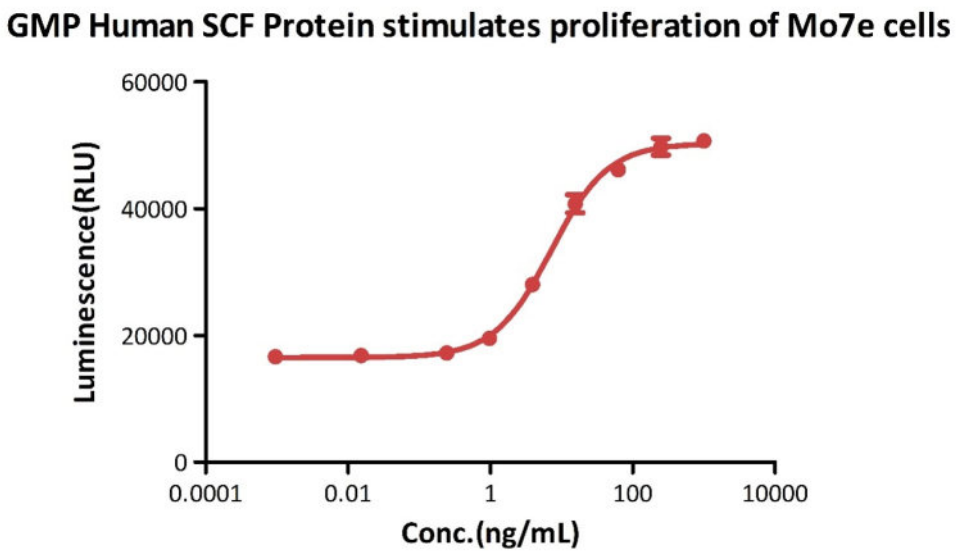
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE



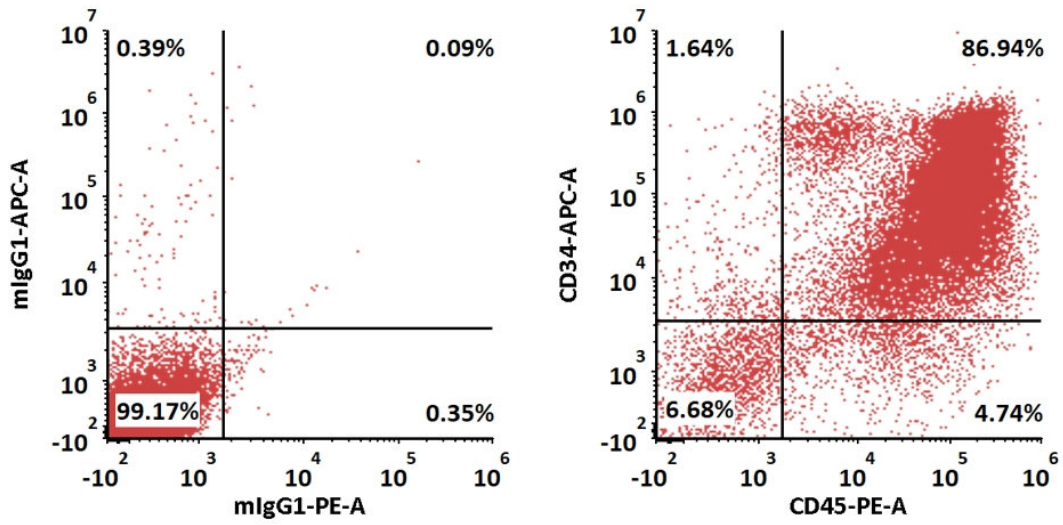
GMP Human SCF Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

Bioactivity-CELL BASE

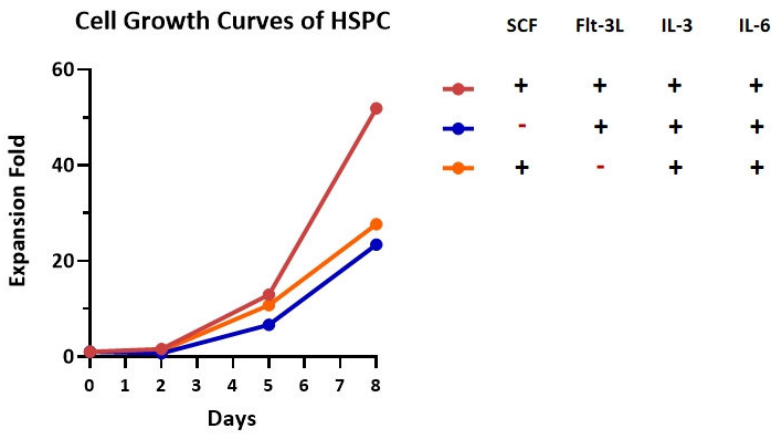


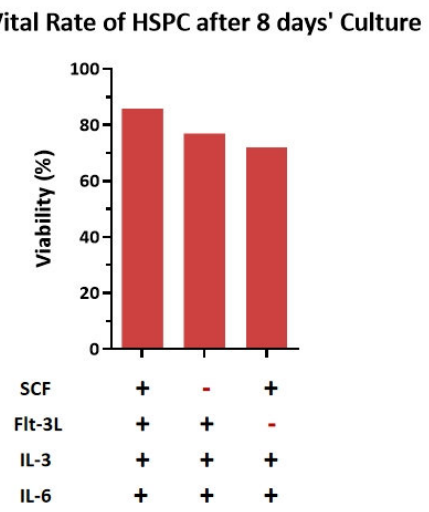
GMP Human SCF Protein (Cat. No. GMP-SCFH25) stimulates proliferation of Mo7e cell line. The specific activity of GMP Human SCF Protein is > 5.00x10^5 IU/mg, which is calibrated against human SCF WHO International Standard (NIBSC code: 91/682) (QC tested).

Application Data



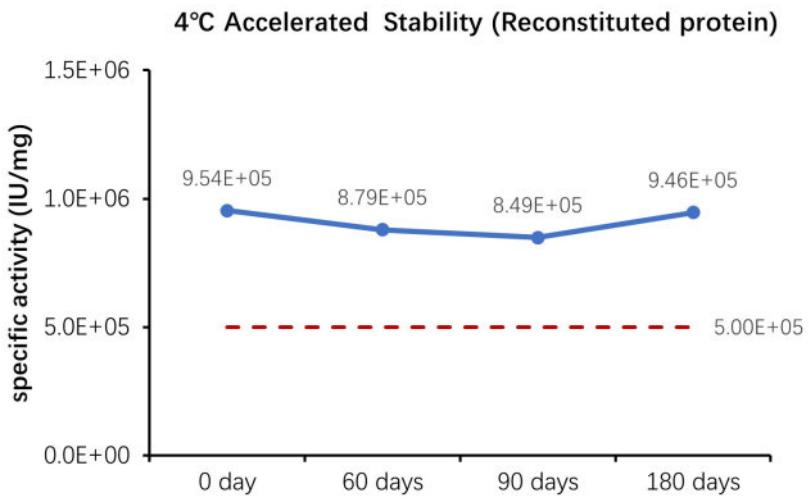
GMP Human SCF Protein (Cat. No. GMP-SCFH25), GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25), GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) and GMP Human VEGF165 Protein (Cat. No. GMP-VE5H23) could significantly promote the iPSC differentiation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



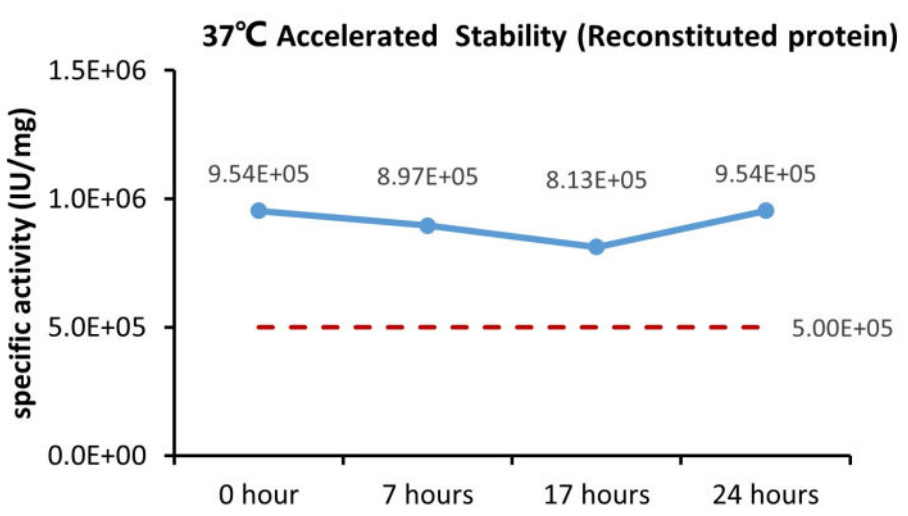


GMP Human SCF Protein (Cat. No. GMP-SCFH25), Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human IL-3 Protein (Cat. No. GMP-L03H18) and GMP Human IL-6 Protein (Cat. No. GMP-L06H27) could support the rapid cell expansion and good cell viability of CD34+ hematopoietic stem cells.

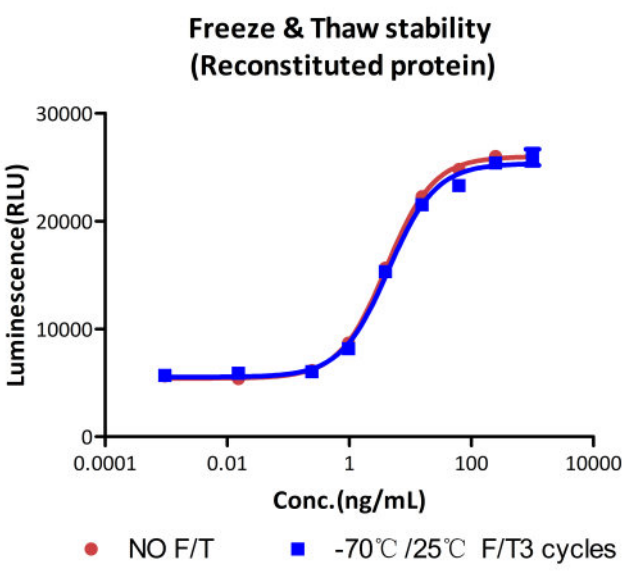
Bioactivity-Stability



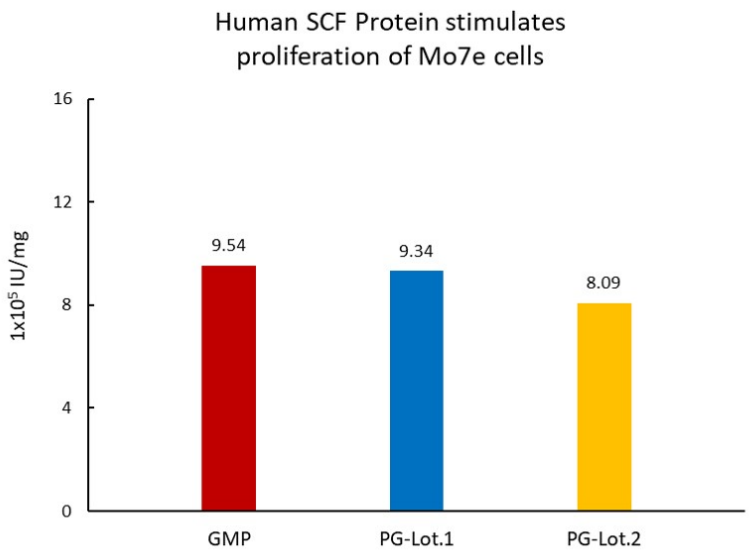
The Cell based assay shows that GMP Human SCF Protein (Cat. No. GMP-SCFH25) is stable at 4°C for 180 days.



The Cell based assay shows that GMP Human SCF Protein (Cat. No. GMP-SCFH25) is stable at 37°C for 24 hours.



The Cell based assay shows that GMP Human SCF (Cat. No. GMP-SCFH25) is stable after freezing and thawing 3 times.



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

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

Stem Cell Factor is also known as SCF, kit-ligand, KL, steel factor, KITLG, FPH2, KL-1, Kitl, MGF, SCF, SF, or SHEP7, and is a cytokine that binds to the c-Kit receptor (CD117). SCF can exist both as a transmembrane protein and a soluble protein. This cytokine plays an important role in hematopoiesis (formation of blood cells), spermatogenesis, and melanogenesis. The soluble and transmembrane forms of the protein are formed by alternative splicing of the same R transcript.Soluble and transmembrane SCF is produced by fibroblasts and endothelial cells. Soluble SCF has a molecular weight of 18,5 KDa and forms a dimer. SCF plays an

important role in the hematopoiesis during embryonic development. Sites where hematopoiesis takes place, such as the fetal liver and bone marrow, all express SCF. During development, the presence of the SCF also plays an important role in the localization of melanocytes, cells that produce melanin and control pigmentation. SCF plays a role in the regulation of HSCs in the stem cell niche in the bone marrow. SCF may be used along with other cytokines to culture HSCs and hematopoietic progenitors. The expansion of these cells ex-vivo (outside the body) would allow advances in bone-marrow transplantation, in which HSCs are transferred to a patient to re-establish blood formation.