GMP Human SCF Protein (E. coli)

Catalog # GMP-SCFH13

Product Details

SCF (Stem Cell Factor, also known as KIT ligand) is a critical growth factor for the survival, proliferation, and maintenance of HSCs and early progenitor cells. In HSC expansion, SCF is essential for preventing apoptosis and sustaining stemness in culture. In iPSC differentiation toward HSCs, SCF supports the transition from mesoderm to hematopoietic progenitors and enhances the emergence of CD34+ hematopoietic stem and progenitor cells.

Product Features and Advantages

- **Specific HSC Expansion Driver**: Efficiently supports hematopoietic stem cell expansion and hPSC-derived hematopoietic stem and progenitor cell differentiation, validated in multiple clinical trials and cell manufacturing processes.
- **Reliable Large-Scale Supply**: Ensures batch production capacity, supporting robust and consistent manufacturing scale-up.
- **High Lot-to-Lot Consistency**: Ensures reliable and reproducible performance in every batch, supporting scalable applications.

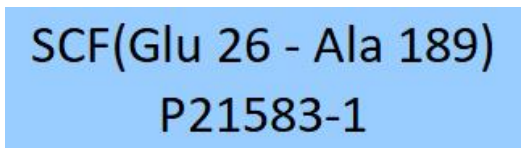
GMP Platform Advantages

- **Quality Assurance**: Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance**: Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents**: Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory Support**: Includes RSF and DMF to meet global requirements.
- **Resilient Supply Chain**: Intelligent modular facilities ensure a stable global supply.
- **Professional Support**: Extensive manufacturing and application expertise to accelerate development.

Source

GMP Human SCF Protein (*E. coli*) (GMP-SCFH13) is expressed from *E. coli* cells. It contains AA Glu 26 - Ala 189 (Accession # P21583-1).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 18.6 kDa. The protein migrates as 19 kDa±3 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

Met-Glu-Gly-Ile-Cys-Arg-Asn-Arg-Val-Thr-Asn-Asn-Val-Lys-Asp
(Routinely tested)

Endotoxin

Less than 10 EU/mg, tested by the rFC method in compliance with USP <86> and Ph. Eur. 2.6.32.

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

Sterility testing was performed using the membrane filtration method in compliance with 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.

Vial Specification

2R (13 mm neck finish)

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.

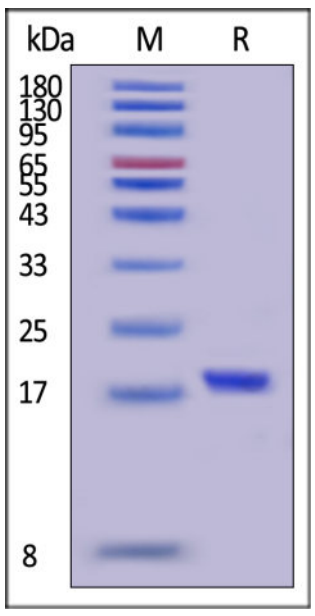
This product is stable after storage at:

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

ACRO Quality Management System

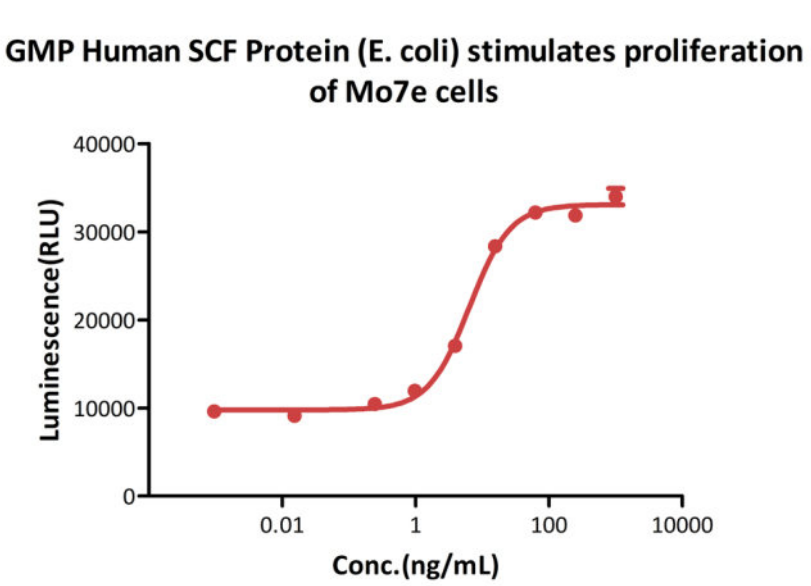
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



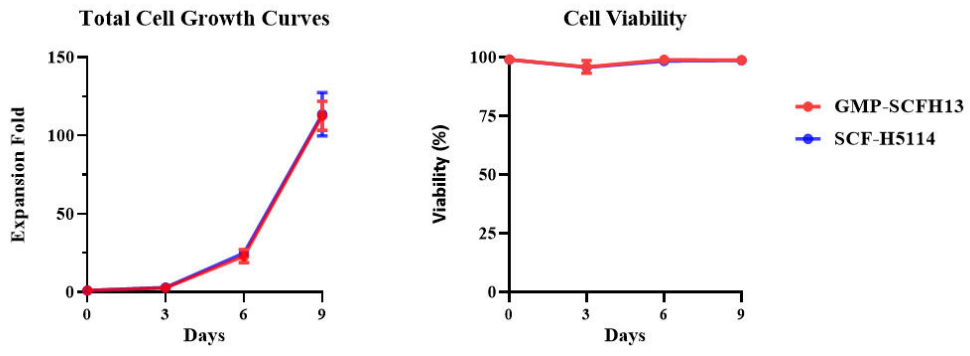
GMP Human SCF Protein (*E. coli*) on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE

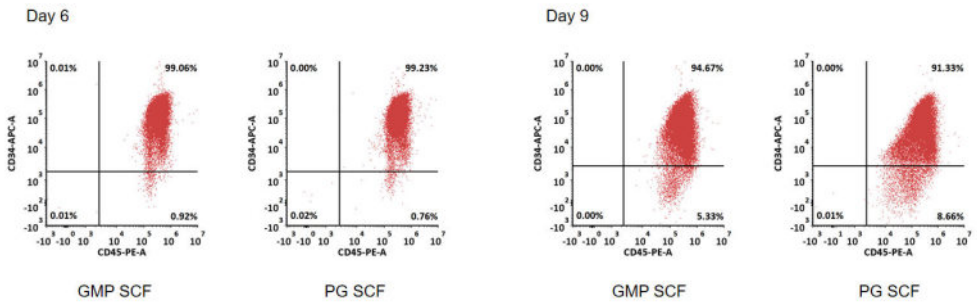


GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13) stimulates proliferation of Mo7e cell line. The specific activity of GMP Human SCF Protein (*E. coli*) is > 6.00x10^5 IU/mg, which is calibrated against human SCF WHO International Standard (NIBSC code: 91/682) (QC tested).

Application Data

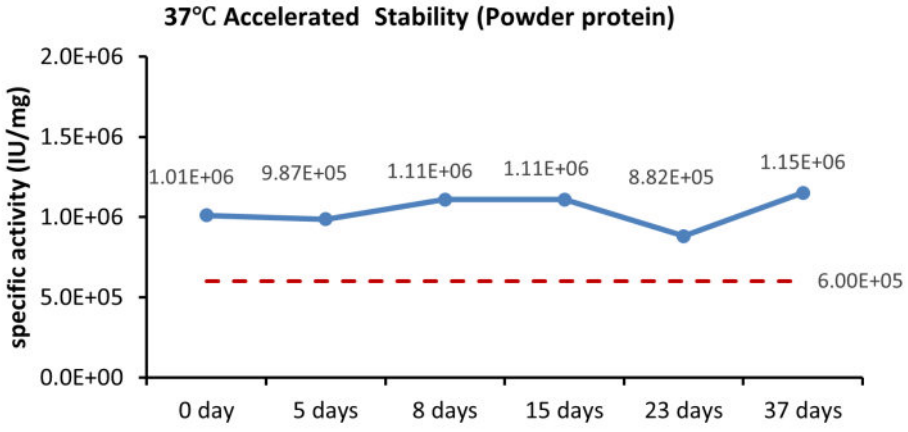


Human CD34+ hematopoietic stem cells (HSCs) were expanded ex vivo for 9 days using a cytokine cocktail containing GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13), GMP Human Flt-3 Ligand Protein (*E. coli*) (Cat. No. GMP-FLLH13), and GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25). The cell growth curve and cell viability are analyzed by AO/PI staining. The results demonstrate that GMP Human SCF Protein (*E. coli*) effectively promoted HSC expansion and maintained stemness, exhibiting performance comparable to that of Human SCF (26-189) Protein (*E. coli*), premium grade (Cat. No. SCF-H5114).

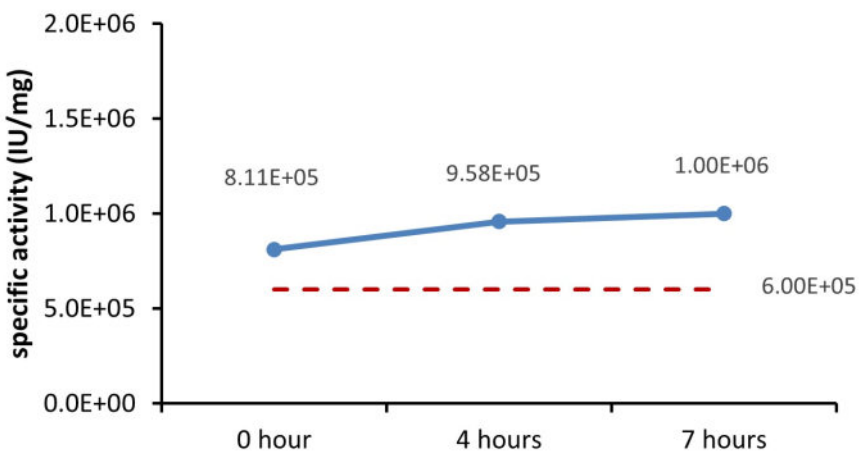


Human CD34+ hematopoietic stem cells (HSCs) were expanded ex vivo for 9 days using a cytokine cocktail containing GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13), GMP Human Flt-3 Ligand Protein (*E. coli*) (Cat. No. GMP-FLLH13), and GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25). The expression of HSC markers, CD34 and CD45, was subsequently analyzed by flow cytometry. The results demonstrate that GMP Human SCF Protein (*E. coli*) effectively promoted HSC expansion and maintained stemness, exhibiting performance comparable to that of Human SCF (26-189) Protein (*E. coli*), premium grade (Cat. No. SCF-H5114).

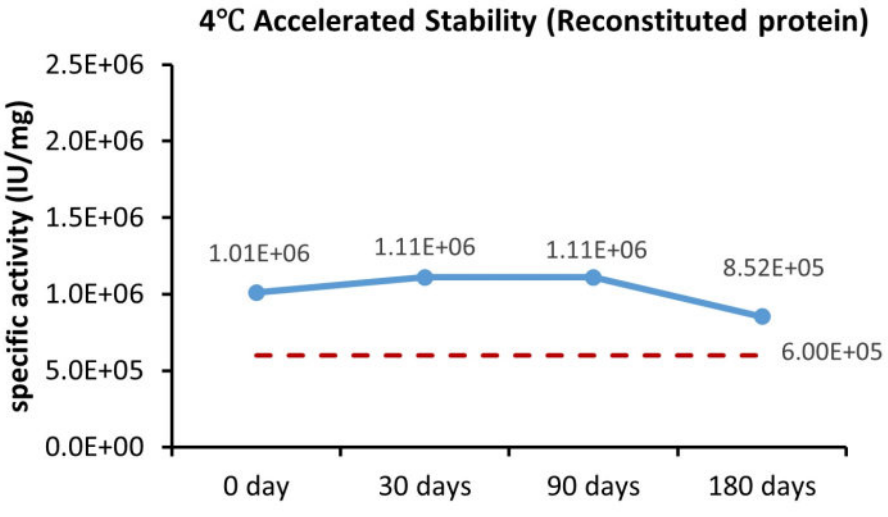
Bioactivity-Stability



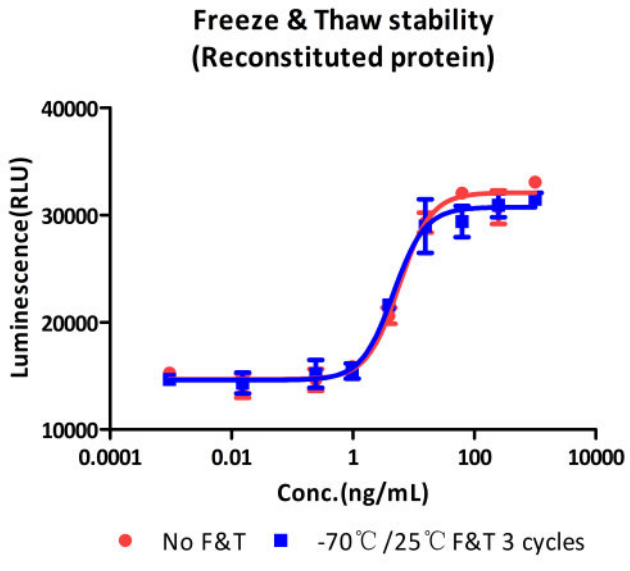
Cell-based assay demonstrates that the lyophilized GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13) is stable at 37°C for 37 days.



Cell-based assay demonstrates that the reconstituted GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13) is stable at 37°C for 7 hours.



Cell-based assay demonstrates that the reconstituted GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13) is stable at 4°C for 180 days.



Cell-based assay demonstrates that the reconstituted GMP Human SCF Protein (*E. coli*) (Cat. No. GMP-SCFH13) is stable after 3 freeze-thaw cycles.

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.

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：

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies
- Fully batch production and control records
- Equipment maintenance and calibration

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

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