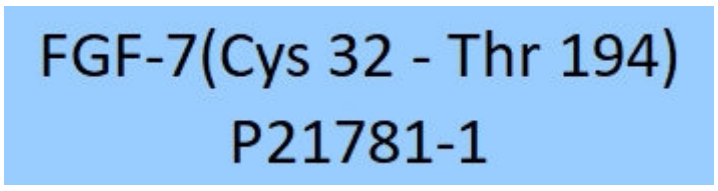
Features

- Specific Endoderm Differentiation Driver: Efficiently supports stem cell differentiation into definitive endoderm lineages, including pancreatic beta islet cells and other endodermal cell types.
- Reliable Large-Scale Supply: Ensures consistent batch production capacity exceeding 1 gram, supporting robust scale-up for manufacturing.
- Stringent Safety Profile: Incorporates comprehensive virus testing, validation, and ultra-low endotoxin levels (< 0.01 EU/μg) to meet stringent quality standards.
- Cost-Effective and Convenient: Achieves up to 50% cost savings versus conventional alternatives, with simplified reconstitution in water instead of hydrochloric acid for ease of use.

Source

GMP Human FGF-7 / KGF Protein (CHO)(GMP-FG7H35) is expressed from CHO cells. It contains AA Cys 32 - Thr 194 (Accession # P21781-1).
Predicted N-terminus: Cys 32

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 18.9 kDa. The protein migrates as 27 kDa±3 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, 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.

Shipping

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

Storage

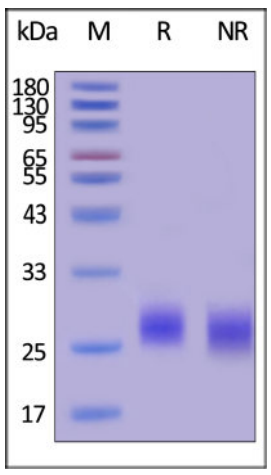
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

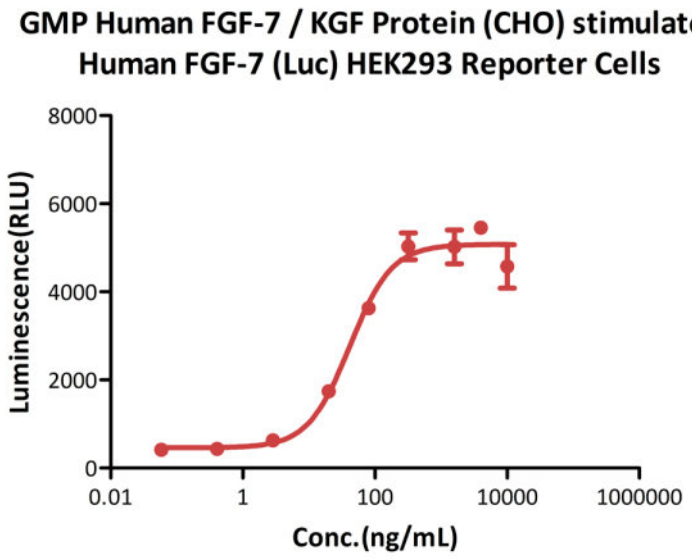
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE



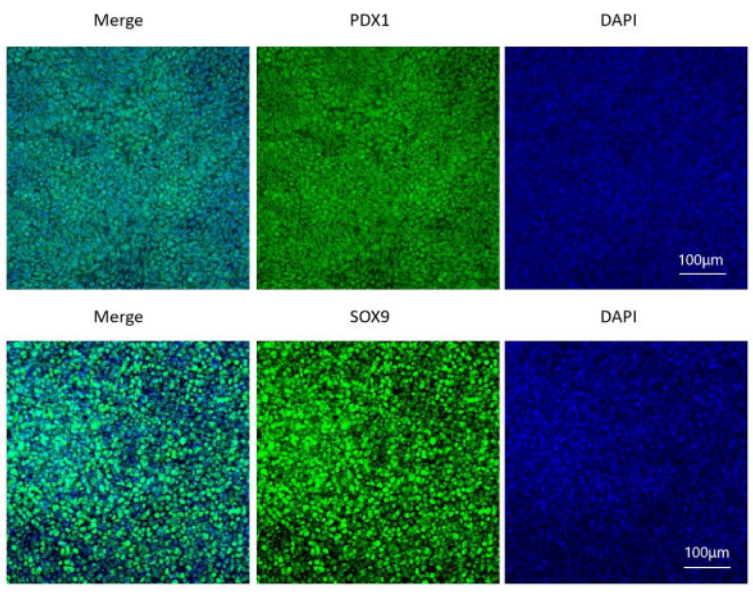
GMP Human FGF-7 / KGF Protein (CHO) on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE

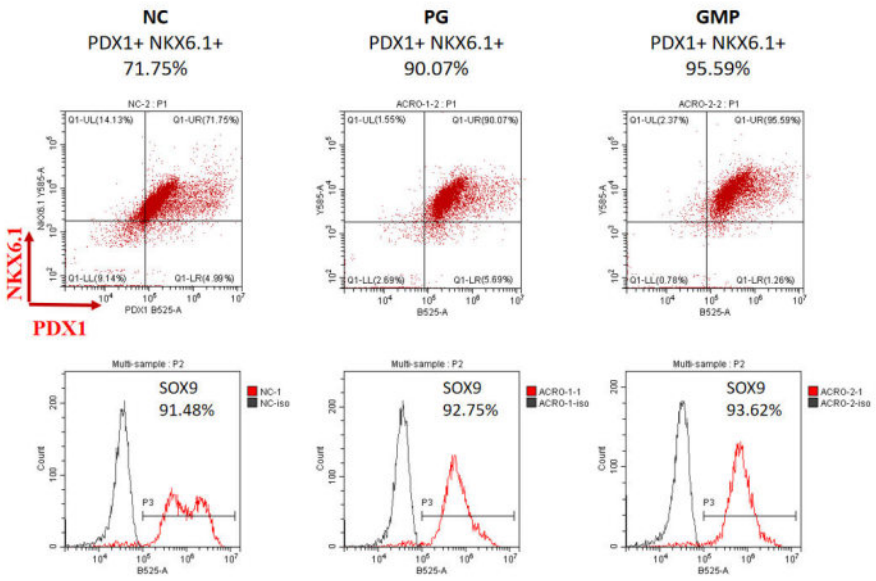


GMP Human FGF-7 / KGF Protein (CHO) (Cat. No. GMP-FG7H35) stimulates Human FGF-7 (Luc) HEK293 Reporter cells. The specific activity of GMP Human FGF-7 / KGF Protein (CHO) is > 5.00 x 10^5 IU/mg, which is calibrated against human FGF-7 WHO International Standard (NIBSC code: 03/150) (QC tested).

Application Data

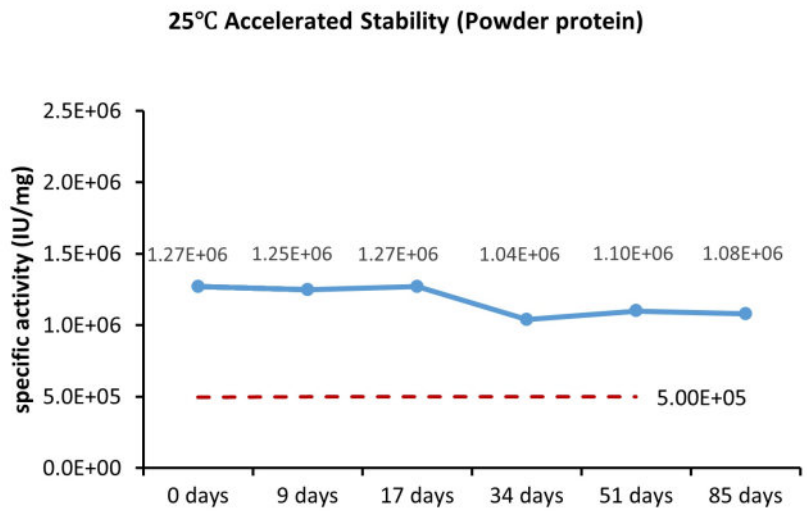


GMP Human FGF-7 / KGF Protein (Cat. No. GMP-FG7H35) could promote iPSCs differentiation into pancreatic progenitor cells, with high expression of PDX1 and SOX9.

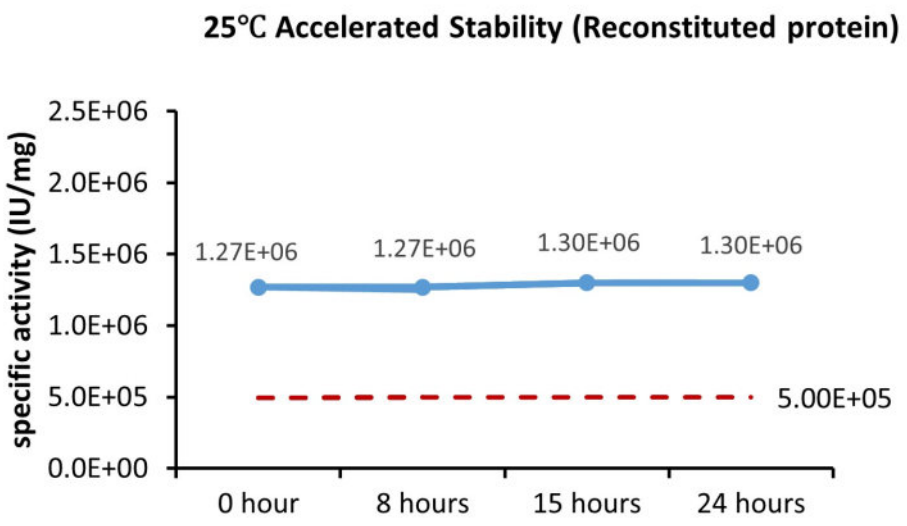


GMP Human FGF-7 / KGF Protein (Cat. No. GMP-FG7H35) and Human FGF-7 / KGF Protein, premium grade (Cat. No. FG7-H5318) could efficiently induce iPSC differentiation to PP2 (Pancreatic Progenitor), with high expression of PP2 markers (NKX6.1, PDX1, and SOX9) by flow cytometry.

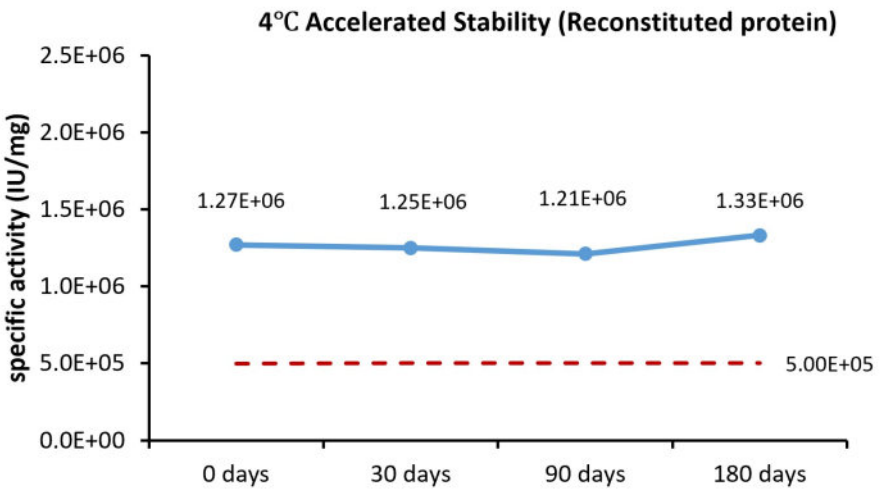
Bioactivity-Stability



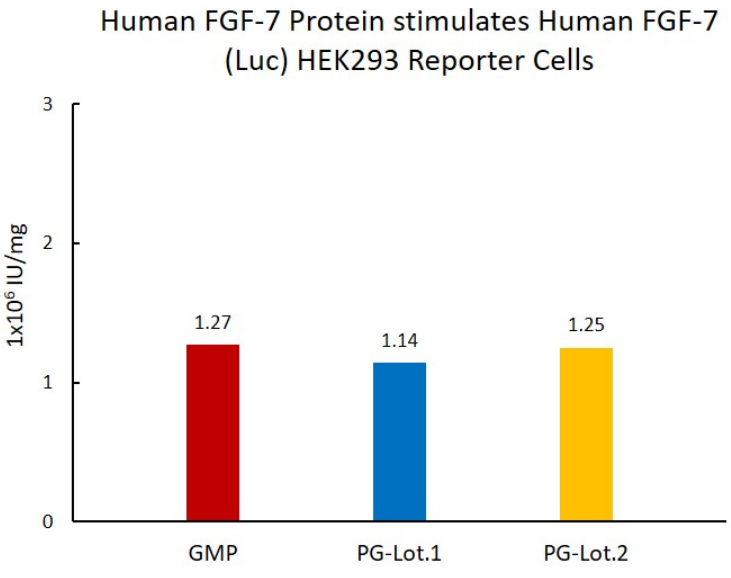
Cell-based assay demonstrates that the lyophilized GMP Human FGF-7 / KGF Protein (CHO) (Cat. No. GMP-FG7H35) is stable at 25°C for 85 days.



Cell-based assay demonstrates that the reconstituted GMP Human FGF-7 / KGF Protein (CHO) (Cat. No. GMP-FG7H35) is stable at 25°C for 24 hours.



Cell-based assay demonstrates that the reconstituted GMP Human FGF-7 / KGF Protein (CHO) (Cat. No. GMP-FG7H35) is stable at 4°C for 180 days.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG FGF-7.

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

Fibroblast growth factor (FGF) 7 (is also known as Keratinocyte growth factor (KGF)), a member of FGF family, is initially found to be secreted from mesenchymal cells to repair epithelial tissues. As a well-characterized paracrine growth factor for tissue growth and regeneration, fibroblast growth factor 7 (FGF7) is involved in a number of physiological and pathological processes, including lung disease and cancer. The stromal-derived FGFs, such as FGF7 and FGF10, control epithelial cell resident FGFR2IIIb activities, promote net tissue homeostasis, and restraint tumor cells from progression to malignancy.