

**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
- No animal derived peptone and lactose used in production process

Source

GMP Human FGF basic Protein(GMP-FGCH17) is expressed from E. coli cells.

It contains AA Pro 143 - Ser 288 (Accession # [P09038-4](#)).

Predicted N-terminus: Pro 143

Molecular Characterization

FGF basic(Pro 143 - Ser 288)
P09038-4

This protein carries no "tag".

The protein has a calculated MW of 16.5 kDa. The protein migrates as 17 kDa±3 kDa under reducing (R) condition (SDS-PAGE).

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.

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.

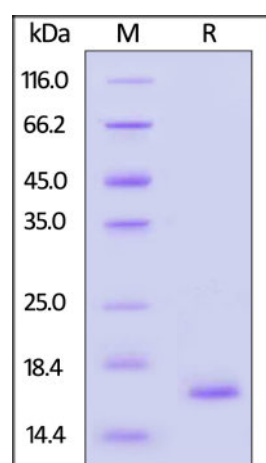
Storage

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

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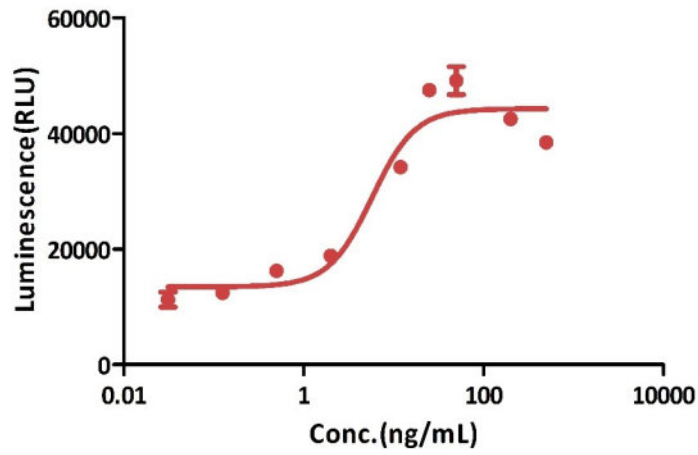




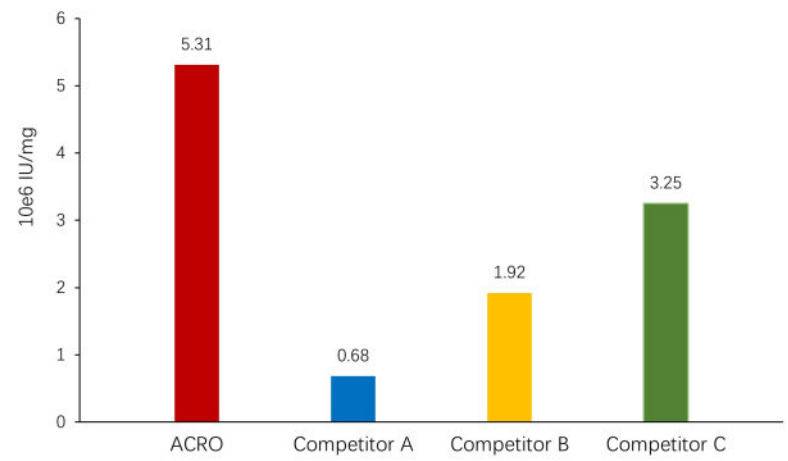
GMP Human FGF basic Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

Bioactivity-Bioactivity CELL BASE

GMP Human FGF basic Protein stimulates proliferation of NIH-3T3 cells



Human FGF basic stimulates proliferation NIH-3T3 cells



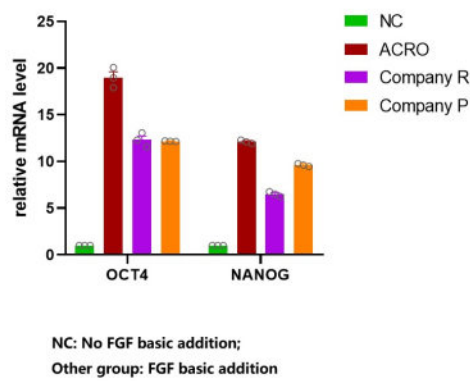
GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) stimulates proliferation of NIH/3T3 cells. The specific activity of GMP Human FGF basic Protein is $>2.50 \times 10^6$ IU/mg, which is calibrated against Basic Fibroblast Growth Factor WHO International Standard (NIBSC code: 90/712) (QC tested).

The activity of GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) was higher than other competing products.

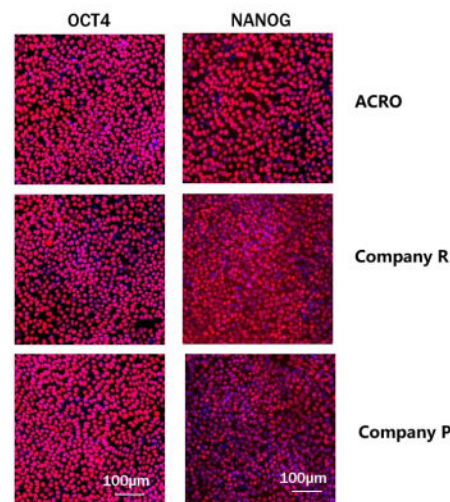
Application Data

Pluripotent stem cell marker mRNA expression

High expression of pluripotent stem cell marker



Pluripotent stem cell marker phenotype



FGF basic (Cat. No. GMP-FGCH17) could highly support stemness maintenance in ESC/iPSC compared to other companies.

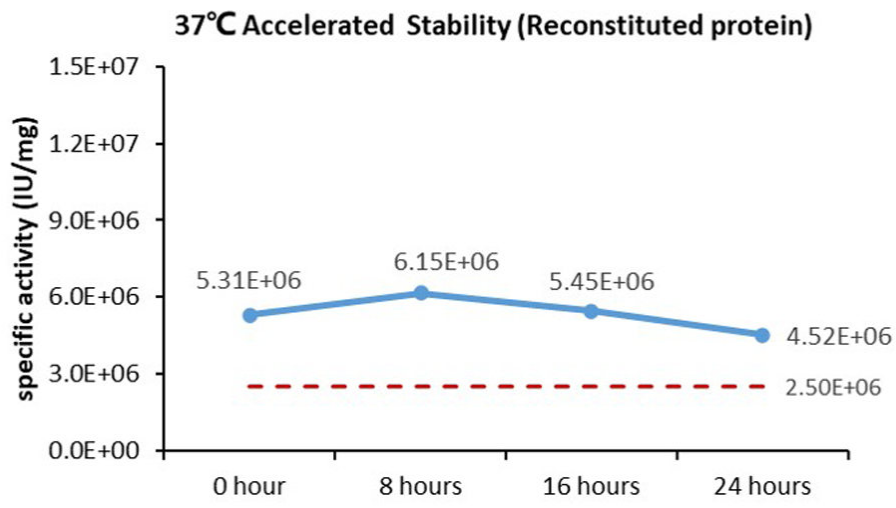
Left: The mRNA expression of pluripotent stem cell markers (Oct4, Nanog) was higher in Acro than in company R and company P.

Right: When FGF basic (35 µg/mL) is added into the culture media (StemSure hPSC medium) for iPSC, the cells remain high expression of pluripotent (Oct4+ or Nanog+; pink) markers.

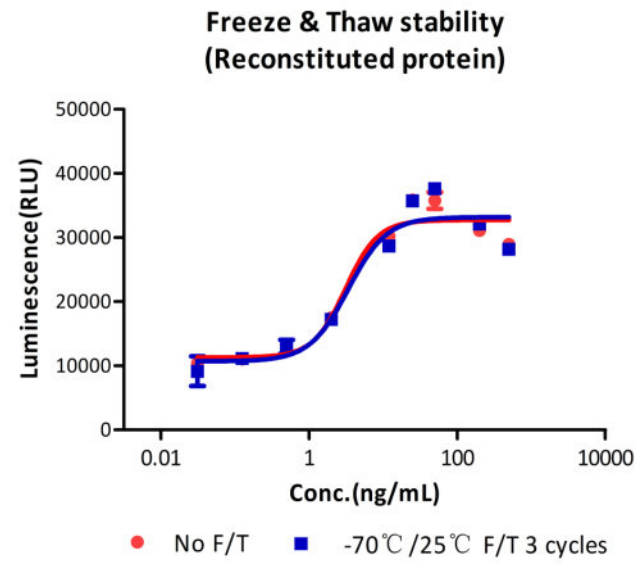
Bioactivity-Stability

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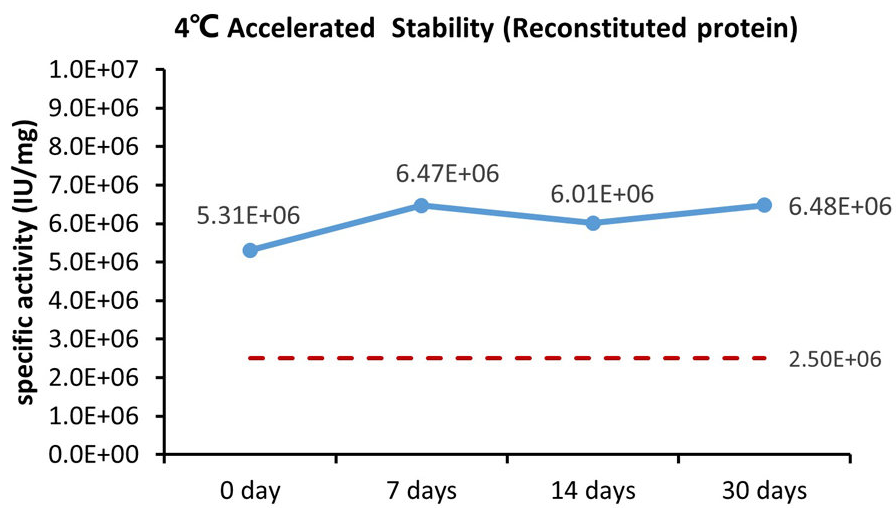




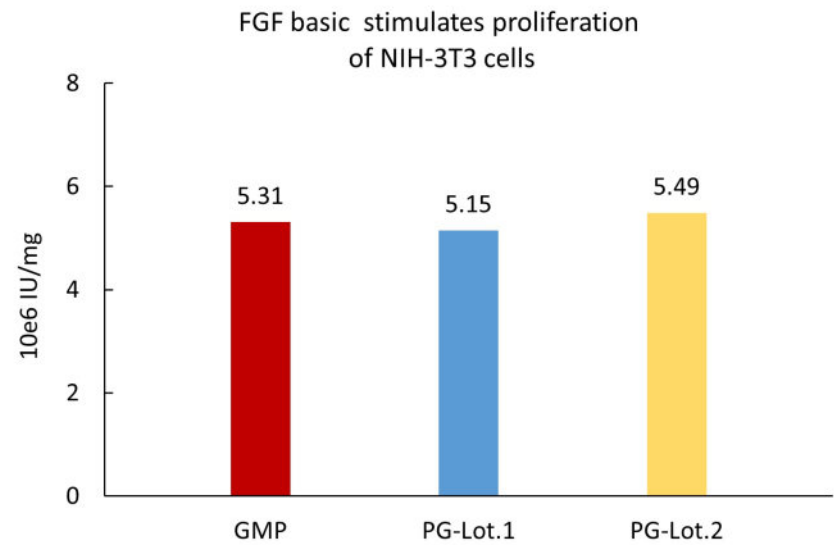
The Cell based assay shows that GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable at 37°C for 24 hours.



The Cell based assay shows that GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable after freezing and thawing 3 times.



The Cell based assay shows that GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable at 4°C for 30 days.



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

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

FGF basic (also known as FGF2 and HBGF-2) is an 18-34 kDa, heparin-binding member of the FGF superfamily of molecules (1-3). Superfamily members are characterized by the presence of a centrally placed beta -trefoil structure. FGF acidic (FGF-1) and FGF basic (FGF2) were the first two identified FGFs, and the designations acidic and basic refer to their relative isoelectric points. Human FGF basic is 288 amino acids (aa) in length. There are multiple start sites, four of which utilize atypical CUG codons, and one that initiates at an AUG start site (4 - 6). The four CUG start sites generate high molecular weight (HMW) FGF basic. There is a 34 kDa, 288 aa form, a 24 kDa, 210 aa form, a 22.5 kDa, 201 aa form, and a 22 kDa, 196 aa form. All are retained intracellularly, undergo extensive methylation, and possess one or more nuclear localization signals (NLS) (7-9). The AUG initiating form is 18 kDa and 155 aa in length. There is no signal sequence (ss). It is, however, secreted directly through the plasma membrane via a mechanism that appears to be dependent upon tertiary structure (10). In place of a ss, there is purportedly a 9 aa N-terminal prosegment that precedes a 146 aa mature segment (11). Early isolations of 18 kDa bovine FGF basic yielded 146 aa molecules, an effect attributed to the presence of acid proteases (12). The molecule contains a heparin-binding site (aa residues 128-144), and undergoes phosphorylation at Ser117 (13). There is also an ill-defined C-terminal NLS that may be more “functional” (or 3-dimensional) than structural (7). Human 146 aa FGF basic is 97% aa identical to mouse FGF basic (14).

Clinical and Translational Updates

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