GMP Recombinant Human Fibronectin fragment

Catalog # GMP-FINH18

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
- No animal derived peptone and lactose used in production process

Source

GMP Recombinant Human Fibronectin fragment(GMP-FINH18) is expressed from E. coli cells. It contains AA Pro 1361 - Ser 1637 & Ala 1812 - Thr 2107 (Accession # P02751-15).
Predicted N-terminus: Met

Molecular Characterization

This protein carries no "tag".

The protein has a calculated MW of 62.6 kDa. The protein migrates as 60 kDa±3 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

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.

>90% as determined by SEC-HPLC.

Formulation

Supplied as 0.2 μm filtered solution in 12.5 mM Citric acid, pH6.2 with protectants.

Contact us for customized product form or formulation.

Shipping

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

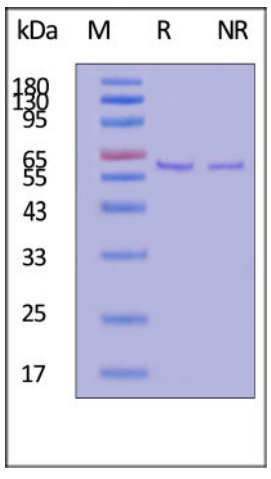
Storage

Please avoid repeated freeze-thaw cycles.

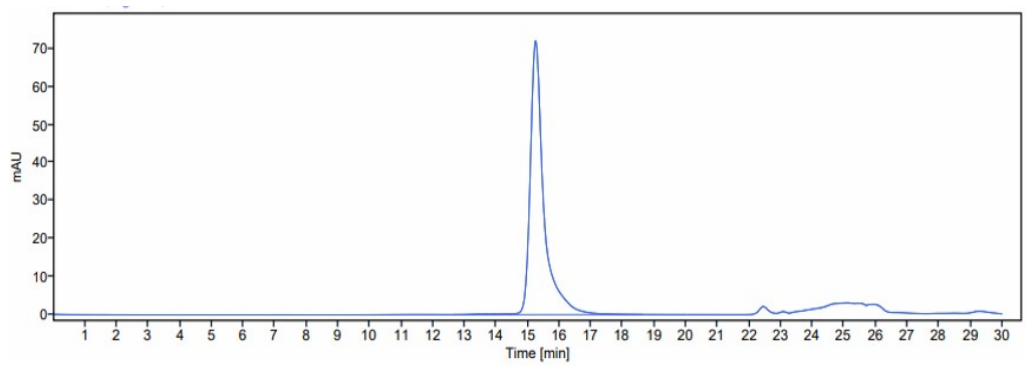
This product is stable after storage at:

- -20°C±10°C for 3 years under sterile conditions.

SDS-PAGE



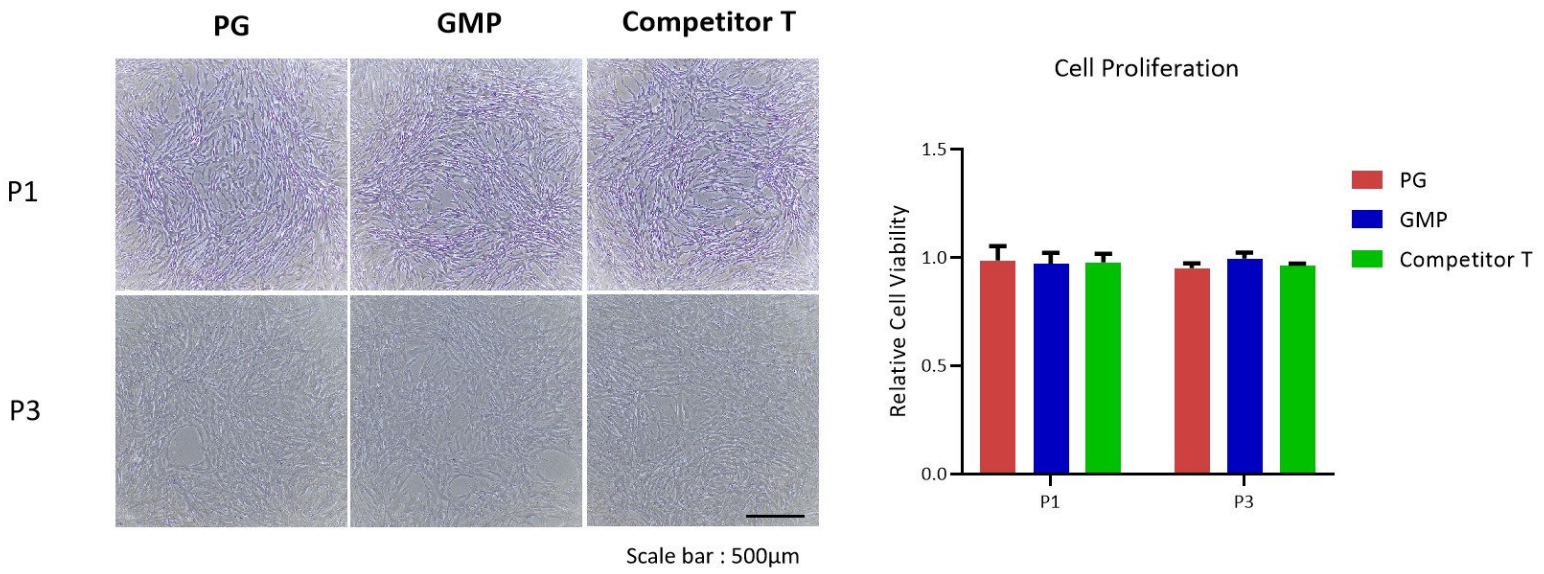
SEC-HPLC



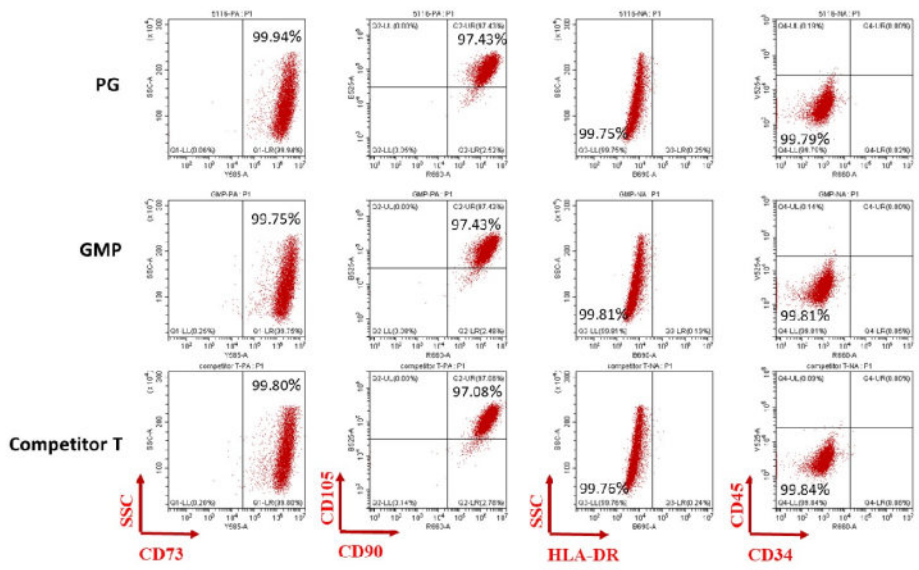
GMP Recombinant Human Fibronectin fragment on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

The purity of GMP Recombinant Human Fibronectin fragment (Cat. No. GMP-FINH18) was greater than 90% as determined by SEC-HPLC.

Application Data



GMP Recombinant Human Fibronectin fragment (Cat. No. GMP-FINH18) could promote mesenchymal stem cell attachment and proliferation in several passages, comparable with Competitor T. The bioactivity of GMP Recombinant Human Fibronectin fragment (Cat. No. GMP-FINH18) is similar to Recombinant Fibronectin fragment, premium grade (Cat. No. FIN-H5116).



GMP Recombinant Human Fibronectin fragment (Cat. No. GMP-FINH18) could maintain the stemness of MSC in several passages, with high expression of MSC markers CD73, CD90 and CD105 and negative expression of HLA-DR, CD34 and CD45. The stemness ability of GMP Recombinant Human Fibronectin fragment (Cat. No. GMP-FINH18) is comparable with Competitor T and similar to Recombinant Fibronectin fragment, premium grade (Cat. No. FIN-H5116).

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

Batch-to-batch consistency

Background

Fibronectin (Fn) is a glycoprotein whose size ranges from 230 to 270 kDa and usually exists as a dimer, covalently linked by a pair of disulfide bonds at the C-termini. Each monomer consists of three repeating units: 12 Type I, 2 Type II, and 15–17 Type III domains which combined account for 90% of the FN sequence. The extracellular matrix (ECM) plays a key role as both structural scaffold and regulator of cell signal transduction in tissues. Fibronectin is one of the major ECM proteins in the trabecular meshwork (TM). It is found in the sheath material surrounding the elastin tendons that enter the TM from the ciliary muscle within the ciliary body. In times of ECM assembly and turnover, cells upregulate assembly of the ECM protein, FN. FN is assembled by cells into viscoelastic fibrils that can bind upward of 40 distinct growth factors and cytokines. These fibrils play a key role in assembling a provisional ECM during embryonic development and wound healing. Fibril assembly is also often upregulated during disease states, including cancer and fibrotic diseases.