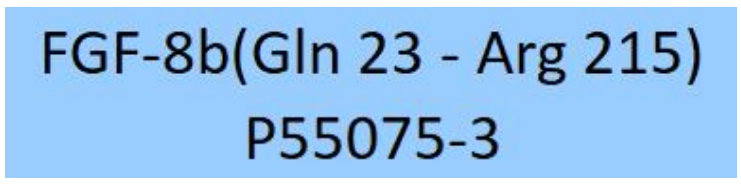
Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Batch-to-batch consistency
- Stringent quality control tests
- No animal derived peptone and lactose used in production process

Source

GMP Human FGF-8b Protein(GMP-FGBH16) is expressed from E. coli cells. It contains AA Gln 23 - Arg 215 (Accession # P55075-3).
Predicted N-terminus: Met

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 22.5 kDa. The protein migrates as 25 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.

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

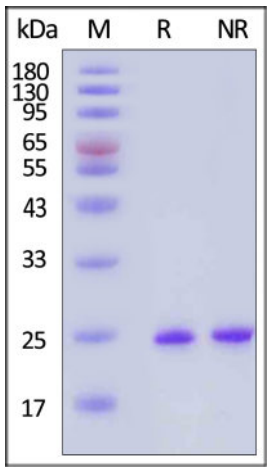
Upon receipt, store it immediately at -20°C or lower for long term storage.

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



GMP Human FGF-8b Protein 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).

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-8 is a member of the fibroblast growth factor family that was originally discovered as a growth factor essential for the androgen-dependent growth of mouse mammary carcinoma cells (1-3). Alternate splicing of mouse FGF-8 mR generates eight secreted isoforms, designated a-h, but only FGF-8a, b, e and f exist in humans (4). FGF-8 contains a 22 amino acid (aa) signal sequence, an N-terminal domain that varies according to the isoform (30 aa for FGF-8b; 20 aa for the shortest, FGF-8a), a 125 aa FGF domain and a 37 aa proline-rich C-terminal sequence. The FGF domain of FGF-8 shares the most aa identity with FGF17 (75%) and FGF-18 (67%), and the three form an FGF subfamily (2). Mouse FGF-8b shares 100% aa identity with human FGF-8b. FGF-8 is widely expressed during embryogenesis, and mediates epithelial-mesenchymal transitions. It plays an organizing and inducing role during gastrulation, and regulates patterning of the midbrain/hindbrain, eye, ear, limbs and heart in the embryo (2, 5 - 8). The isoforms may play different roles in development. FGF-8b shows the strongest receptor affinity and oncogenic transforming capacity although FGF-8a and FGF-8e are also transforming and have been found in human prostate, breast or ovarian tumors (1, 5, 9-12). FGF-8 shows limited expression in the normal adult, but low levels are found in the reproductive and genitourinary tract, peripheral leukocytes and bone marrow hematopoietic cells (3, 9, 13).

Clinical and Translational Updates