

DESCRIPTION

Source *E. coli*-derived human FGF basic protein
Pro143-Ser288, with an N-terminal Ala
Accession # P09038
Produced using non-animal reagents in an animal-free laboratory.
Manufactured and tested under cGMP guidelines.

N-terminal Sequence Analysis Ala-Pro₁₄₃-Ala-Leu-Pro-Glu-Asp-Gly-Gly-Ser

Predicted Molecular Mass 16.5 kDa

SPECIFICATIONS

SDS-PAGE 17 kDa, reducing conditions

Activity Measured in a cell proliferation assay using NR6R-3T3 mouse fibroblast cells. Raines, E.W. *et al.* (1985) *Methods Enzymol.* **109**:749. The ED₅₀ for this effect is 0.1-0.6 ng/mL.
The specific activity of Recombinant Human FGF basic GMP is approximately 800 IU/μg, which is calibrated against human FGF basic WHO International Standard (NIBSC code: 90/712).

Endotoxin Level <0.10 EU per 1 μg of the protein by the LAL method.

Purity >97%, by SDS-PAGE with silver staining.

Host Cell Protein < 0.5 ng per μg of protein when tested by ELISA.

Mycoplasma Negative when tested in a ribosomal RNA hybridization assay.

Formulation Lyophilized from a 0.2 μm filtered solution in Tris-HCl and NaCl. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution Reconstitute at 100 μg/mL in PBS.

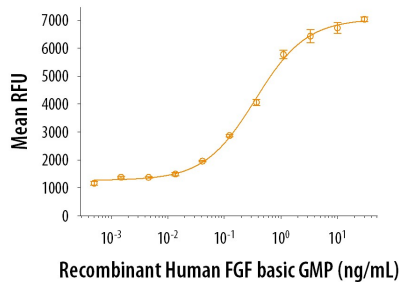
Shipping The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.

Stability & Storage **Use a manual defrost freezer and avoid repeated freeze-thaw cycles.**

- A minimum of 12 months when stored at ≤ -20 °C as supplied. Refer to lot specific COA for the Use by Date.
- 1 month, 2 to 8 °C under sterile conditions after reconstitution.
- 3 months, ≤ -20 °C under sterile conditions after reconstitution.

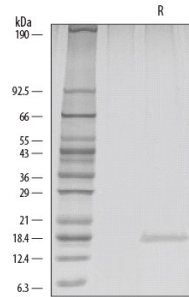
DATA

Bioactivity



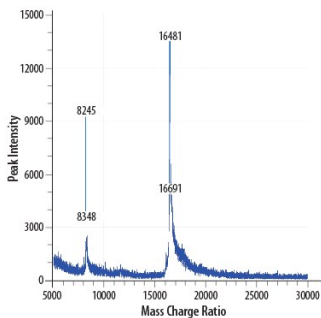
GMP-grade Recombinant Human FGF basic (Catalog # 233-GMP) stimulates proliferation of the NR6R-3T3 mouse fibroblast cell line. The ED₅₀ is 0.1-0.6 ng/mL.

SDS-PAGE



1 μg/lane of GMP-grade Recombinant Human FGF basic (Catalog # 233-GMP) was resolved by SDS-PAGE with silver staining, under reducing (R) conditions, showing a single band at 17 kDa.

Mass Spectrometry



MALDI-TOF analysis of GMP-grade Recombinant Human FGF basic (Catalog # 233-GMP). The major peak corresponds to the calculated molecular mass, 16479 Da. The minor peak at 16691 Da is a matrix-associated artifact of the MALDI-TOF.

BACKGROUND

FGF basic is a member of the FGF family of at least 23 related mitogenic proteins which show 35-60% amino acid conservation. FGF acidic and basic, unlike the other members of the family, lack signal peptides and are apparently secreted by mechanisms other than the classical protein secretion pathway. FGF basic has been isolated from a number of sources, including neural tissue, pituitary, adrenal cortex, corpus luteum, and placenta. This factor contains four cysteine residues, but reduced FGF basic retains full biological activity, indicating that disulfide bonds are not required for this activity. A variety of forms of FGF basic are produced as a result of N-terminal extensions. These extensions affect localization of FGF basic in cellular compartments but do not affect biological activity. Binding of FGF to heparin or cell surface heparan sulfate proteoglycans is necessary for binding of FGF to high affinity FGF receptors. FGF acidic and basic appear to bind to the same high affinity receptors and show a similar range of biological activities. FGF basic stimulates the proliferation of all cells of mesodermal origin and many cells of neuroectodermal, ectodermal, and endodermal origin. FGF basic induces neuron differentiation, survival, and regeneration. FGF basic also modulates embryonic development and differentiation. These observed *in vitro* functions of FGF basic suggest FGF basic may play a role *in vivo* in the modulation of such normal processes as angiogenesis, wound healing and tissue repair, embryonic development and differentiation, and neuronal function and neural degeneration. Additionally, FGF basic may participate in the production of a variety of pathological conditions resulting from excessive cell proliferation and excessive angiogenesis.

References:

1. Coulier, F. *et al.* (1997) *J. Mol. Evol.* **44**:43.
2. Chen, C.H. *et al.* (2004) *Curr. Vasc. Pharmacol.* **2**:33.
3. Mohammadi, M. *et al.* (2005) *Curr. Opin. Struct. Biol.* **15**:506.
4. Fernig, D. *et al.* (1994) *Prog. Growth Factor Res.* **5**:353.

MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.

R&D Systems' quality focus includes:

- Manufactured and tested under an ISO 9001:2015 and ISO 13485:2016 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, mass spectrometry results, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)
- Host Cell Protein testing performed by ELISA
- Mycoplasma testing by ribosomal RNA hybridization assay

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP <61> bioburden testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells GMP grade products for preclinical or clinical *ex vivo* use. They are not for *in vivo* use. Please read the following End User Terms prior to using this product.

Animal-Free Manufacturing Conditions

Our dedicated controlled-access animal-free laboratories ensure that at no point in production are the products exposed to potential contamination by animal components or byproducts. Every stage of manufacturing is conducted in compliance with R&D Systems' stringent Standard Operating Procedures (SOPs). Production and purification procedures use equipment and media that are confirmed animal-free.

Production

- All molecular biology procedures use animal-free media and dedicated labware.
- Dedicated fermentors are utilized in committed animal-free areas.

Purification

- Protein purification columns are animal-free.
- Bulk proteins are filtered using animal-free filters.
- Purified proteins are stored in animal-free containers in a dedicated cold storage room.

Quality Assurance

- Low Endotoxin Level.
- No impairment of biological activity.
- High quality product obtained under stringent conditions.

[Please read our complete Animal-Free Statement.](#)

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