

DESCRIPTION

Source	<i>E. coli</i> -derived human FGF basic/FGF2/bFGF protein Ala135-Ser288 (with modifications) Accession # NP_001997.5 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ala135-Ala-Gly-Ser-Ile-Thr-Thr-Leu-Pro-Ala & Ala136-Gly-Ser-Ile-Thr-Thr-Leu-Pro-Ala-Leu
Predicted Molecular Mass	17 kDa

SPECIFICATIONS

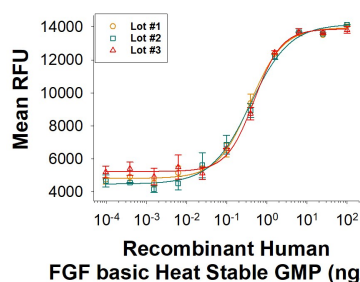
SDS-PAGE	16-19 kDa, under reducing conditions.
Activity	Measured in a cell proliferation assay using NR6R-3T3 mouse fibroblast cells. Raines, E.W. <i>et al.</i> (1985) <i>Methods Enzymol.</i> 109 :749. The ED ₅₀ for this effect is 0.0500-0.600 ng/mL. The specific activity of Recombinant Human FGF basic Heat Stable GMP is >1.6 x 10 ⁶ IU/mg, which is calibrated against the human FGF basic/FGF2 WHO International Standard (NIBSC code: 90/712).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>95%, by SDS-PAGE with quantitative densitometry by Coomassie® Blue Staining.
Mass Spectrometry	17192 Da ± 20 Da.
Host Cell Protein	<0.100 ng per µg of protein when tested by ELISA.
Mycoplasma	Negative for Mycoplasma
Host Cell DNA	<0.00150 ng per µg of protein when tested by PCR.
Formulation	Lyophilized from a 0.2 µm filtered solution in HEPES and Sodium Sulfate with Trehalose. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute the 25 µg size at 250 µg/mL in sterile water. Reconstitute all other sizes at 500 µg/mL in sterile water.
Shipping	The product is shipped with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. <ul style="list-style-type: none"> • 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.

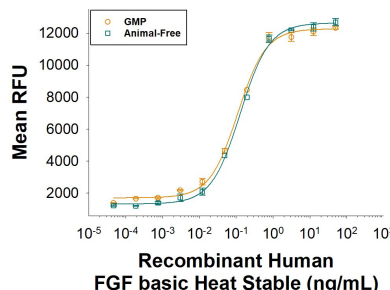
DATA

Bioactivity



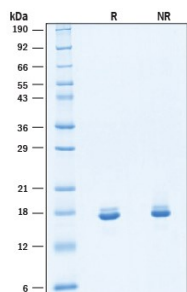
Recombinant Human FGF basic Heat Stable GMP Protein Bioactivity. The bioactivity of Recombinant Human FGF basic Heat Stable GMP Protein (Catalog # BT-FGFBHS-GMP) was measured in a cell proliferation assay using NR6R-3T3 mouse fibroblast cell line. The ED₅₀ for this effect is 0.0500-0.600 ng/mL. Three independent lots were tested for bioactivity and plotted on the same graph to show lot-to-lot consistency of GMP FGF basic/FGF2 Heat Stable protein.

Bioactivity



Equivalent bioactivity of GMP and Animal-Free grades of recombinant human FGF basic heat-stable proteins. Equivalent bioactivity of GMP (BT-FGFBHS-GMP) and Animal-Free (Catalog # BT-FGFBHS-AFL) grades of Recombinant Human FGF basic Heat Stable proteins as measured in a cell proliferation assay using NR6R-3T3 mouse fibroblast cells (orange and green, respectively).

SDS-PAGE



Recombinant Human FGF basic Heat Stable GMP Protein SDS-PAGE. 2 µg/lane of Recombinant Human FGF basic Heat Stable GMP Protein (Catalog # BT-FGFBHS-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing bands at 16-19 kDa, under reducing conditions.

BACKGROUND

FGF basic (also known as FGF-2 and HBGF-2) is an 18-34 kDa, heparin-binding member of the FGF superfamily of molecules. As a growth factor, FGF basic is expressed in a variety of cell types and involved in the regulation of cell proliferation, differentiation, migration and survival. FGF basic promotes self-renewal and upregulates pluripotency markers such as Oct4, Sox2 and Nanog, making it well-known for maintenance of pluripotency in embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs). These functions make FGF basic an important cell culture supplement in stem cell applications for regenerative medicine and clinical manufacturing protocols.

Our Heat Stable FGF basic has been engineered for thermostability and maintains its activity at 37°C when compared to wild-type. Heat-stable FGF basic can enhance the flexibility and efficiency of cell culture by reducing the need for frequent media changes.

MANUFACTURING SPECIFICATIONS

GMP Proteins

R&D Systems, a Bio-Techne Brand's GMP proteins are produced according to relevant sections of the following documents: USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and Eu. Ph. 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products.

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, 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 testing according to USP <71>
- 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.

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](#)

PRODUCT SPECIFIC NOTICES

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