

DESCRIPTION

Source	<i>E. coli</i> -derived Pro143-Ser288 Accession # NP_001997 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Pro ₁₄₃ -Ala-Leu-Pro-Glu-Asp-Gly-Gly-Ser-Gly Ala ₁₄₄ -Leu-Pro-Glu-Asp-Gly-Gly-Ser-Gly-Ala
Predicted Molecular Mass	16 kDa

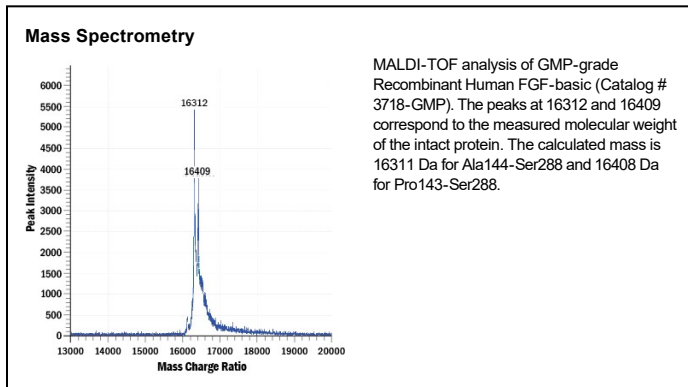
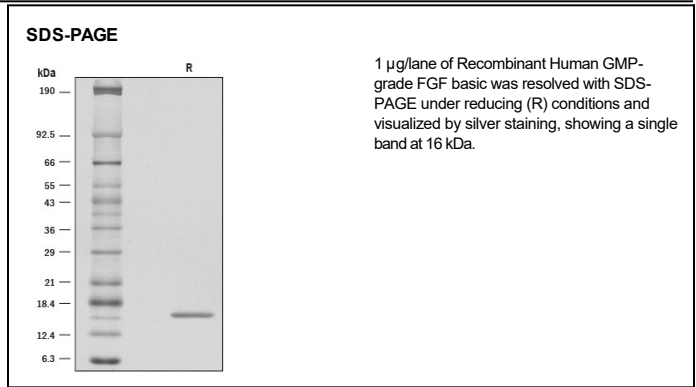
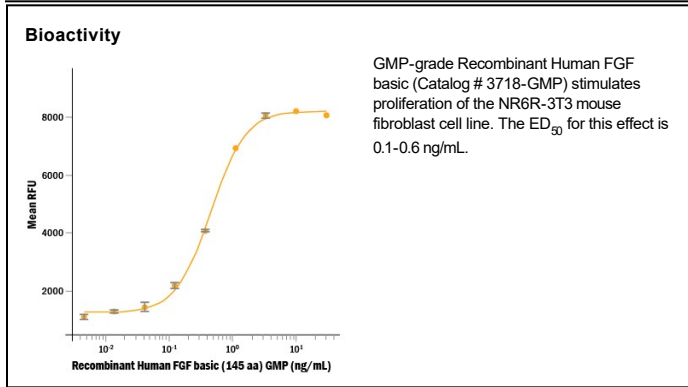
SPECIFICATIONS

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 0.1-0.6 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	<0.01 EU per 1 μg of the protein by the LAL method.
Purity	>95%, by SDS-PAGE with silver staining, under reducing conditions.
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. <ul style="list-style-type: none"> ● A minimum of 6 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



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 (1-3). Superfamily members are characterized by the presence of a centrally placed β -trefoil structure. FGF acidic (FGF-1) and FGF basic (FGF-2) 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).

References:

1. Sorenson, V. *et al.* (2006) *BioEssays* **28**:504.
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5. Prats, H. *et al.* (1989) *Proc. Natl. Acad. Sci. USA* **86**:1836.
6. Arnaud, E. *et al.* (1999) *Mol. Cell. Biol.* **19**:505.
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12. Klagsbrun, M. *et al.* (1987) *Proc. Natl. Acad. Sci. USA* **84**:1839.
13. Bailly, K. *et al.* (2000) *FASEB J.* **14**:333.
14. Hebert, J.M. *et al.* (1990) *Dev. Biol.* **138**:454.

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
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- 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, 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.

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- 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.
- For *ex vivo* research or bioproduction, [additional documentation](#) can be provided.

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