

DESCRIPTION

Source	<i>E. coli</i> -derived human KGF/FGF-7 protein Cys32 - Thr194, with an N-terminal Met Accession # P21781.1 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	(Cys) ₃₂ -Asn-Asp-Met-Thr-Pro-Glu-Gln-Met-Ala Asn ₃₃ -Asp-Met-Thr-Pro-Glu-Gln-Met-Ala-Thr
Predicted Molecular Mass	19 kDa

SPECIFICATIONS

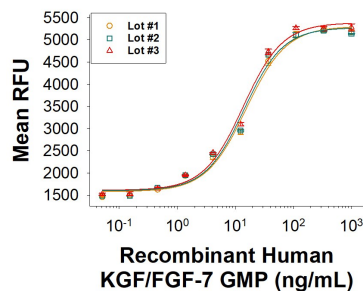
SDS-PAGE	20 kDa, under reducing conditions.
Activity	Measured in a cell proliferation assay using Ba/F3 mouse pro B cells transfected with human FGF RIIb. The ED ₅₀ for this effect is 6.00-60.0 ng/mL. The specific activity of recombinant human KGF/FGF-7 is >8.16 x 10 ⁵ units/mg, which is calibrated against the human KGF/FGF-7 WHO Standard (NIBSC code: 03/150).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with quantitative densitometry by Coomassie® Blue Staining.
Mass Spectrometry	The molecular weight by mass spectrometry is 18927 Da ± 61 Da.
Host Cell Protein	<0.500 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 MOPS, Na ₂ SO ₄ and EDTA with Trehalose. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute 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.

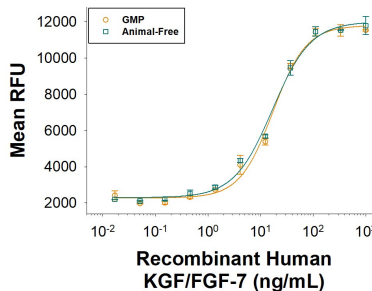
DATA

Bioactivity



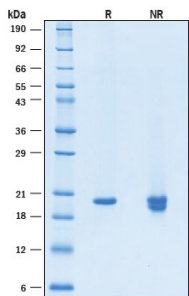
Recombinant Human KGF/FGF-7 GMP Protein Bioactivity. The bioactivity of Recombinant Human KGF/FGF-7 GMP Protein (Catalog # BT-KGF-GMP) was measured in a cell proliferation assay using Ba/F3 mouse pro B cells transfected with human FGF RIIb. The ED₅₀ for this effect is 6.00 - 60.0 ng/mL. Three independent lots were tested for bioactivity and plotted on the same graph to show lot-to-lot consistency of GMP KGF/FGF-7 protein.

Bioactivity



Equivalent Bioactivity of GMP and Animal-Free grades of Recombinant Human KGF/FGF-7. Equivalent bioactivity of GMP (Catalog # BT-KGF-GMP) and Animal-Free (Catalog # BT-KGF-AFL) grades of Recombinant Human KGF/FGF-7 measured in a cell proliferation assay using Ba/F3 mouse pro B cells transfected with human FGF RIIb (orange and green, respectively).

SDS-PAGE



Recombinant Human KGF/FGF-7 GMP Protein SDS-PAGE. 2 µg/lane of Recombinant Human KGF/FGF-7 GMP Protein (Catalog # BT-KGF-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing bands at 20 kDa, under reducing conditions.

BACKGROUND

Keratinocyte Growth Factor (KGF), or Fibroblast Growth Factor-7 (FGF-7), is an important component in many cell culture protocols. It is widely used to promote the growth and differentiation of epithelial cells, including skin keratinocytes, and lung, corneal, and intestinal epithelia. It is a part of tissue engineering and organoid culture protocols, where it can enhance the generation of complex tissues such as liver, gastrointestinal tract, lung, and mammary gland. Furthermore, KGF/FGF-7 has been shown to stimulate the proliferation of pancreatic endocrine progenitor cells and promote their differentiation into mature insulin-secreting beta cells. In these capacities KGF/FGF-7 has significant clinical relevance in studies to better understand gastrointestinal disorders, wound healing, respiratory disease, and diabetes.

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

END USER TERMS OF USE OF PRODUCT

The following terms are offered to you upon your acceptance of these End User Terms of Use of Product. By using this product, you indicate your acknowledgment and agreement to these End User Terms of Use of Product. If you do not agree to be bound by and comply with all of the provisions of these End User Terms of Use of Product, you should contact your supplier of the product and make arrangements to return the product.

We suggest you print and retain a copy of these End User Terms of Use of Product for your records.

The End User is aware that R&D Systems, Inc. sells GMP products for preclinical or clinical *ex vivo* use and not for *in vivo* use. The End User further agrees, as a condition of the sale of R&D Systems' GMP products that: a) the End User will not use this GMP Product in any procedure wherein the product may be directly or indirectly administered to humans, unless the End User has obtained, or prior to their use will have obtained, an Investigational New Drug (IND) exemption from the FDA and will use the product only in accordance with the protocols of such IND and of the Institutional Review Board overseeing the proposed research, or b) the End User will use the products outside of the United States in accordance with the protocols of research approved by the Institutional Review Board or authorized ethics committee and regulatory agencies to which the End User is subject to in their territory.

R&D Systems, Inc. has the right, at its sole discretion, to modify, add or remove any terms or conditions of these End User Terms of Use without notice or liability to you. Any changes to these End User Terms of Use are effective immediately following the printing of such changes on this product insert. The most recent version of these End User Terms of Use of Product may be found at: RnDSystems.com/Legal.

You agree to review these End User Terms of Use of Product to ensure any subsequent use by you of R&D Systems' GMP Products following changes to these End User Terms of Use of Product constitutes your acceptance of all such changes.

TERMS AND CONDITIONS

The following limitation applies to R&D Systems' warranty and liability for damages: All products are warranted to meet R&D Systems' published specifications when used under normal laboratory conditions.

R&D SYSTEMS DOES NOT MAKE ANY OTHER WARRANTY OR REPRESENTATION WHATSOEVER, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO ITS PRODUCTS. IN PARTICULAR, R&D SYSTEMS DOES NOT MAKE ANY WARRANTY OF SUITABILITY, NONINFRINGEMENT, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

NOTWITHSTANDING ANY OTHER PROVISIONS OF THESE TERMS AND/OR ANY OTHER AGREEMENT BETWEEN R&D SYSTEMS AND PURCHASER FOR THE PURCHASE OF THE PRODUCTS, R&D SYSTEMS' TOTAL LIABILITY TO PURCHASER ARISING FROM OR IN RELATION TO THESE TERMS, AN AGREEMENT BETWEEN THE PARTIES OR THE PRODUCTS, WHETHER ARISING IN CONTRACT, TORT OR OTHERWISE SHALL BE LIMITED TO THE TOTAL AMOUNT PAID BY PURCHASER TO R&D SYSTEMS FOR THE APPLICABLE PRODUCTS. IN NO EVENT WILL R&D SYSTEMS BE LIABLE FOR THE COST OF PROCUREMENT OF SUBSTITUTE GOODS.

Full details of R&D Systems' Terms and Conditions of Sale can be found online at: RnDSystems.com/Legal.