Recombinant Human BDNF GMP

Catalog Number: BT-BDNF-GMP

DESCRIPTION

Source	*E. coli*-derived human BDNF protein Arg134 - Arg247, with an N-terminal Met Accession # P23560.1 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Met-Arg134-Arg-Gly-Glu-Leu-Ser-Val-(Cys)-Asp
Predicted Molecular Mass	13.1 kDa

SPECIFICATIONS

SDS-PAGE	12 kDa, under reducing conditions.
Activity	Measured in a cell proliferation assay using BaF mouse pro-B cells transfected with TrkB. The ED_{50} for this effect is 0.100-1.00 ng/mL. The specific activity of Recombinant Human BDNF is >8.0 x 10^5 units/mg, which is calibrated against the human BDNF WHO Standard (NIBSC code: 96/534).
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 13121 Da ± 50 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 PBS with Trehalose. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute the 25 µg size at 250 µg/mL in PBS. Reconstitute all other sizes at 500 µg/mL in PBS.
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.** • 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.

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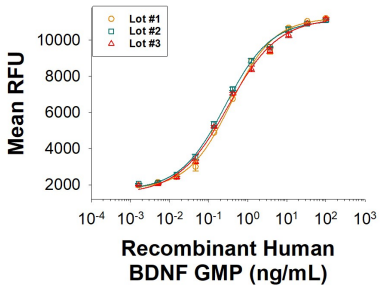
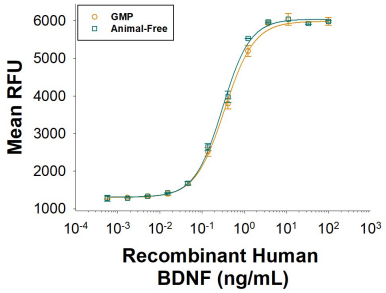
DATA

Bioactivity



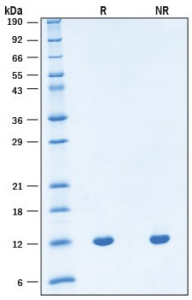
Recombinant Human BDNF GMP Protein Bioactivity. GMP-grade Recombinant Human BDNF Protein (Catalog # BT-BDNF-GMP) as measured in a cell proliferation assay using BaF mouse pro-B cells transfected with TrkB. Three independent lots were tested for activity and plotted on the same graph to show lot-to-lot consistency of GMP BDNF.

Bioactivity



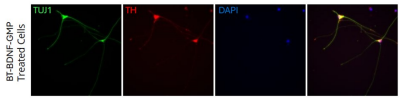
Equivalent Bioactivity of GMP and Animal-Free grades of Recombinant Human BDNF. Equivalent bioactivity of GMP (Catalog # BT-BDNFGMP) and Animal-Free (Catalog # BT-BDNF-AFL) grades of Recombinant Human BDNF as measured in a cell proliferation assay using BaF mouse pro-B cells transfected with TrkB (orange and green, respectively).

SDS-PAGE



Recombinant Human BDNF GMP Protein SDS-PAGE. 2 µg/lane of Recombinant Human BDNF GMP Protein (Catalog # BT-BDNF-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by Coomassie® Blue staining, showing bands at 12 kDa, under reducing conditions.

Immunofluorescence



Confirmation of Dopaminergic Neuron Identity via Immunofluorescence Dopaminergic neurons were successfully differentiated from human iPSCs using Recombinant Human GMP BDNF (Catalog # BT-BDNF-GMP). Neurons show bright co-staining of beta tubulin 3 (TUJ1; green), tyrosine hydroxylase (TH; red), and DAPI (blue) to confirm dopaminergic neuron identity. BDNF successfully supported the derivation and maintenance of dopaminergic neurons.

BACKGROUND

Brain-derived neurotrophic factor (BDNF) is a member of the neurotrophin family of growth factors that are required for the differentiation and survival of specific neuronal subpopulations in both the central as well as the peripheral nervous system.

BDNF is often utilized as a cell culture supplement to promote neural differentiation in regenerative medicine studies and clinical manufacturing protocols.

The neurotrophin family is comprised of at least four proteins including BDNF, nerve growth factor (NGF), neurotrophin-3 (NT3), and NT4/5. Human BDNF is initially expressed as a proprotein, which is then cleaved to yield a mature protein. Mature BDNF is a non-covalently linked homodimer, with each monomer containing antiparallel beta -strands and a characteristic cystine knot motif. Within the mature domain, human BDNF shares the identical amino acid sequence with mature mouse and rat BDNF.

BDNF is strongly expressed in various regions of the brain, including the hippocampus and cerebellum, and weaker expression has been detected in the thymus, liver, spleen, heart, and lung. BDNF participates in axonal growth and pathfinding and in the modulation of dendritic growth and morphology and in later stages of development regulates synaptic transmission and plasticity and acts as a central modulator of pain. BDNF binds with high affinity and specifically activates the TrkB tyrosine kinase receptor. BDNF signaling via TrkB is essential for adult synaptic plasticity and the formation of memories.

The BDNF signaling pathway utilizes both AKT and ERK pathways to exert its pleiotrophic effects in the central nervous system. Decreased expression of BDNF is seen in many neurological diseases such as Alzheimer's disease, Parkinson's disease, Huntington's disease, and autism. Further, BDNF is proposed as a biomarker for psychiatric disorders such as bipolar disease and depression and has been implicated in posttraumatic stress disorder, phobia, and panic disorder. A single amino acid substitution, Val66Met, has been shown to lead to reduced, activity-dependent BDNF secretion and memory impairment.

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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, 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.

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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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