Recombinant Human GDNF GMP

Catalog Number: 212-GMP

DESCRIPTION

Source	Mouse myeloma cell line, NS0-derived Arg109-Ile211 Accession # P39905 Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Arg_{109}-Gly-Gln-Arg-Gly-Lys-Asn-Arg-Gly-(Cys)
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	11.6 kDa (monomer)

SPECIFICATIONS

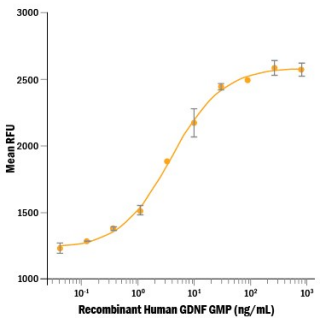
Activity	Measured in a cell proliferation assay using SH-SY5Y human neuroblastoma cells. The ED_{50} for this effect is 2-12 ng/mL in the presence of Recombinant Human GFRα-1/GDNF Rα-1 Fc Chimera (Catalog # 714-GR). The specific activity of recombinant human GDNF is approximately 3.1 x 10^3 units/µg, which is calibrated against recombinant human GDNF Reference Standard (NIBSC code: 09/266). Measured by its binding ability in a functional ELISA. Immobilized Recombinant Human GFRα-1/GDNF Rα-1 Fc Chimera (Catalog # 714-GR) at 1 µg/mL can bind Recombinant Human GDNF with an apparent K_d <1 nM.
Endotoxin Level	<1.0 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE with silver staining, under reducing conditions.
Mycoplasma	Negative when tested in a ribosomal RNA hybridization assay.
Formulation	Lyophilized from a 0.2 µm filtered solution in PBS. 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.

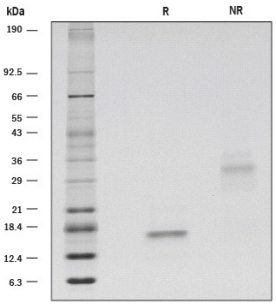
DATA

Bioactivity



GMP-grade Recombinant Human GDNF (Catalog # 212-GMP) stimulates proliferation in the SH-SY5Y human neuroblastoma cell line. The ED_{50} for this effect is 2-12 ng/mL in the presence of Recombinant Human GFRα-1/GDNF Rα-1 Fc Chimera (Catalog # 714-GR).

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human GDNF (Catalog # 212-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by silver staining, showing bands at 17 kDa and 33 kDa, respectively.

BACKGROUND

Glial Cell Line-derived Neurotrophic Factor (GDNF) is a neurotrophic factor that has been shown to promote the survival of various neuronal subpopulations in both the central as well as the peripheral nervous systems at different stages of their development. Neuronal subpopulations that have been shown to be affected by GDNF include motoneurons, midbrain dopaminergic neurons, Purkinje cells and sympathetic neurons.

Native GDNF, a disulfide-linked homodimeric glycoprotein, is a novel member of the TGF-β superfamily. Human GDNF cDNA encodes a 211 amino acid residue prepropeptide that is processed to yield a dimeric protein. Mature human GDNF was predicted to contain two 134 amino acid residue subunits. NS0 expressed mature human GDNF lacks 31 residues from the amino-terminus of the predicted sequence. This glycosylated recombinant mature human GDNF still contains the seven conserved Cys residues found in all members of the TGF-β superfamily and is biologically active. The GDNF sequence contains two potential glycosylation sites and insect cell-expressed recombinant rat GDNF proteins are glycosylated. Mature rat and human GDNF exhibit approximately 93% amino acid sequence identity and show considerable species cross-reactivity. Cells known to express GDNF include Sertoli cells, type 1 astrocytes, Schwann cells, neurons, pinealocytes and skeletal muscle cells.

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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: 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, 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)
- 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.

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