Recombinant Human PDGF-BB GMP

Catalog Number: 220-GMP

DESCRIPTION

Source	*E. coli*-derived Ser82-Thr190 Accession # Q6FHE7 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Ser-Leu-Gly-Ser-Leu-Thr-Ile-Ala-Glu-Pro
Structure / Form	Disulfide-linked homodimer
Predicted Molecular Mass	12.3 kDa (monomer)

SPECIFICATIONS

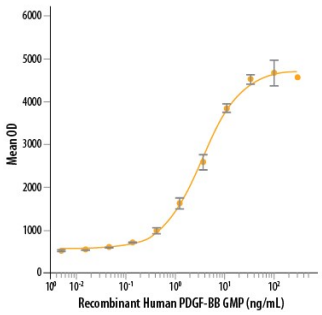
Activity	Measured in a cell proliferation assay using NR6R-3T3 mouse fibroblast cells. Raines, E.W. *et al.* (1985) Methods Enzymol. **109**:749. The ED_{50} for this effect is 1.5-6 ng/mL. The specific activity of recombinant human PDGF-BB is approximately 5.8 x 10^3 IU/µg, which is calibrated against recombinant human PDGF-BB WHO International Standard (NIBSC code: 94/728).
Endotoxin Level	<0.01 EU per 1 µg of the protein by the LAL method.
Purity	>97%, 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 Acetonitrile and TFA. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 100 µg/mL in 4 mM HCl.
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 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.

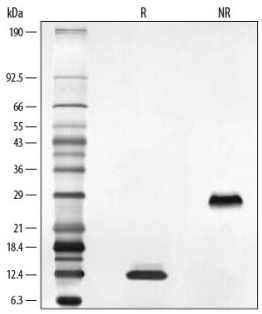
DATA

Bioactivity



GMP-grade Recombinant Human PDGF-BB (Catalog # 220-GMP) stimulates cell proliferation of the NR6R-3T3 mouse fibroblast cell line. The ED_{50} for this effect is 1.5-6 ng/mL.

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human PDGF-BB (Catalog # 220-GMP) was resolved with SDS-PAGE under reducing (R) and non-reducing (NR) conditions and visualized by silver staining, showing single bands at 13 kDa and 26 kDa, respectively.

BACKGROUND

Platelet-derived growth factor (PDGF) was discovered as a major mitogenic factor present in serum but absent from plasma. It was found to be secreted from the α-granules of platelets activated during the coagulation of blood to form serum. Subsequent studies have demonstrated that PDGF is not one molecule but three, each a dimeric combination of two distinct but structurally related peptide chains designated A and B. The dimeric isoforms PDGF-AA, AB and BB are differentially expressed in various cell types and their effects are mediated through two distinct receptors, termed α and β. Differences exist in isoform binding to each receptor. In general, PDGF isoforms are potent mitogens for connective tissue cells, including dermal fibroblasts, glial cells, arterial smooth muscle cells and some epithelial and endothelial cells. In addition to its activity as a mitogen, PDGF is chemotactic for fibroblasts, smooth muscle cells, neutrophils and mononuclear cells. Other reported activities for PDGF include stimulation of granule release by neutrophils and monocytes, facilitation of steroid synthesis by Leydig cells, stimulation of neutrophil phagocytosis, inhibition of natural killer (NK) cell activity, stimulation of collagen synthesis, modulation of thrombospondin expression and secretion, stimulation of collagenase activity and secretion, induction of contraction of rat aorta strips *in vitro*, and transient induction of T cell IL-2 secretion accompanied by a down-regulation of IL-4 and IFN-γ production, temporary effects that may allow clonal expansion of antigen-activated B and T helper lymphocytes prior to differentiation. PDGF also appears to be ubiquitous in neurons throughout the CNS, where it is suggested to play an important role in neuron survival and regeneration, and in mediation of glial cell proliferation and differentiation.

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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)
- 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.

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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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.
- For *ex vivo* research or bioproduction, **additional documentation** can be provided.

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