GMP Human PDGF-BB Protein

Catalog # GMP-PDBH19



Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Batch-to-batch consistency
- Stringent quality control tests
- No animal derived peptone and lactose used in production process

Source

GMP Human PDGF-BB Protein(GMP-PDBH19) is expressed from E. coli cells. It contains AA Ser 82 - Thr 190 (Accession # <u>P01127-1</u>). Predicted N-terminus: Met

Molecular Characterization

PDGF-BB(Ser 82 - Thr 190) P01127-1

This protein carries no "tag".

The protein has a calculated MW of 12.4 kDa. The protein migrates as 13 kDa±3 kDa under reducing (R) condition (SDS-PAGE).

Endotoxin

Less than 10 EU/mg by the LAL method.

Host Cell Protein

<0.5 ng/µg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/µg of protein tested by qPCR.

SDS-PAGE



Sterility

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.

Mycoplasma

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 μ m filtered solution in 20 mM Citric acid - Sodium Citrate, pH3.0 with protectants.

Contact us for customized product form or formulation.

Shipping

This product is supplied and shipped with blue ice, please inquire the shipping cost.

Storage

Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

GMP Human PDGF-BB Protein on SDS-PAGE under reducing (R) and nonreducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.



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Bioactivity-Bioactivity CELL BASE



GMP Human PDGF-BB Protein (Cat. No. GMP-PDBH19) stimulates proliferation of NIH/3T3 cells. The specific activity of GMP Human PDGF-BB Protein is >5.00 x 10^5 IU/mg, which is calibrated against human PDGF-BB WHO International Standard (NIBSC code: 94/728) (QC tested).

Bioactivity-Stability



The Cell based assay shows that GMP Human PDGF-BB Protein (Cat. No. GMP-PDBH19) is stable at 4°C for 30 days.

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents:

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

Animal-Free materials

Materials purchased from the approved suppliers by QA



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ISO 5 clean rooms and automatic filling equipment Qualified personnel Quality-related documents review and approve by QA Fully batch production and control records Equipment maintenance and calibration Validation of analytical procedures Stability studies conducted Comprehensive regulatory support files Request For Regulatory Support Files (RSF)

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

SDS-PAGE Protein content Endotoxin level Residual Host Cell DNA content Residual Host Cell Protein content Biological activity analysis Microbial testing Mycoplasma testing In vitro virus assay Residual moisture Batch-to-batch consistency

Background

PDGFs are mitogenic during early developmental stages, driving the proliferation of undifferentiated mesenchyme and some progenitor populations. During later maturation stages, PDGF signalling has been implicated in tissue remodelling and cellular differentiation, and in inductive events involved in patterning and morphogenesis. In addition to driving mesenchymal proliferation, PDGFs have been shown to direct the migration, differentiation and function of a variety of specialised mesenchymal and migratory cell types, both during development and in the adult animal. Other growth factors in this family include vascular endothelial growth factors B and C (VEGF-B, VEGF-C)which are active in angiogenesis and endothelial cell growth, and placenta growth factor (PIGF) which is also active in angiogenesis. PDGF plays a role in embryonic development, cell proliferation, cell migration, and angiogenesis. PDGF is a required element in cellular division for fibroblast, a type of connective tissue cell. PDGF is also known to maintain proliferation of oligodendrocyte progenitor cells. Platelet-derived growth factor subunit B is also known as PDGFB, FLJ12858, PDGF2, SIS, SSV, c-sis, is a member of the platelet-derived growth factor family. PDGFB can exist either as a homodimer

(PDGF-BB) or as a heterodimer with the platelet-derived growth factor alpha polypeptide (PDGF-AB), where the dimers are connected by disulfide bonds. Mutations in this gene are associated with meningioma.

Clinical and Translational Updates

