GMP Human BMP-4 / BMP2B (improved sequence) Protein

Catalog # GMP-BM4H18

Product Details

Bone Morphogenetic Protein 4 (BMP4), a key member of the TGF-β superfamily binds to cell surface receptors to activate the Smad signaling pathway. Notably, in stem cells, BMP4 plays a pivotal role in inducing the differentiation of mesenchymal stem cells into osteoblasts, guiding their fate towards bone-forming cells. It is also involved in various physiological processes such as embryonic development, tissue repair, and maintaining tissue homeostasis.

Product Features and Advantages

- **Specific Differentiation Driver**: Highly supports hPSC differentiation towards mesoderm lineages, including hematopoietic stem cells (HSC), T cells, and NK cells.
- **Seamless Clinical Translation**: GMP grade enables a reliable and compliant transition from R&D to clinical trials and manufacturing.
- **Significant Cost Efficiency**: Achieves substantial savings, reducing production costs by up to 50% in comparison to conventional alternatives.
- **High Lot-to-Lot Consistency**: Ensures reliable and reproducible performance in every batch, supporting scalable applications.

GMP Platform Advantages

- **Quality Assurance**: Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance**: Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents**: Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory Support**: Includes RSF and DMF to meet global requirements.
- **Resilient Supply Chain**: Intelligent modular facilities ensure a stable global supply.
- **Professional Support**: Extensive manufacturing and application expertise to accelerate development.

Source

GMP Human BMP-4 (improved sequence) Protein (GMP-BM4H18) is expressed from *E. coli* cells. It is a variant of BMP-4 to suit cell culture applications better.

Molecular Characterization

This protein carries no "tag".

The protein has a calculated MW of 13.2 kDa. The protein migrates as 13 kDa±3 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

Endotoxin

Less than 50 EU/mg, tested by the LAL method in compliance with USP <85> and Ph. Eur. 2.6.14.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Sterility

Sterility testing was performed using the membrane filtration method in compliance with USP <71> and Ph. Eur. 2.6.1.

Mycoplasma

Negative

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 μm filtered solution in 20 mM Citric acid, pH2.2 with protectants.

Contact us for customized product form or formulation.

Vial Specification

6R (20 mm neck finish)

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.

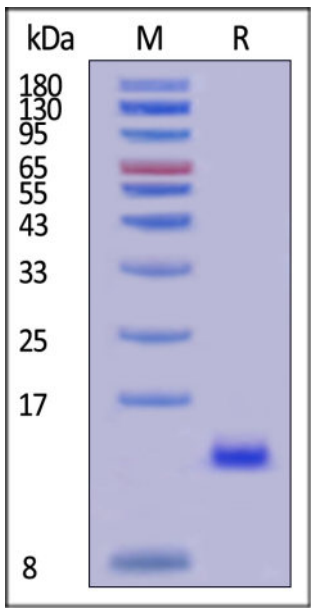
This product is stable after storage at:

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

ACRO Quality Management System

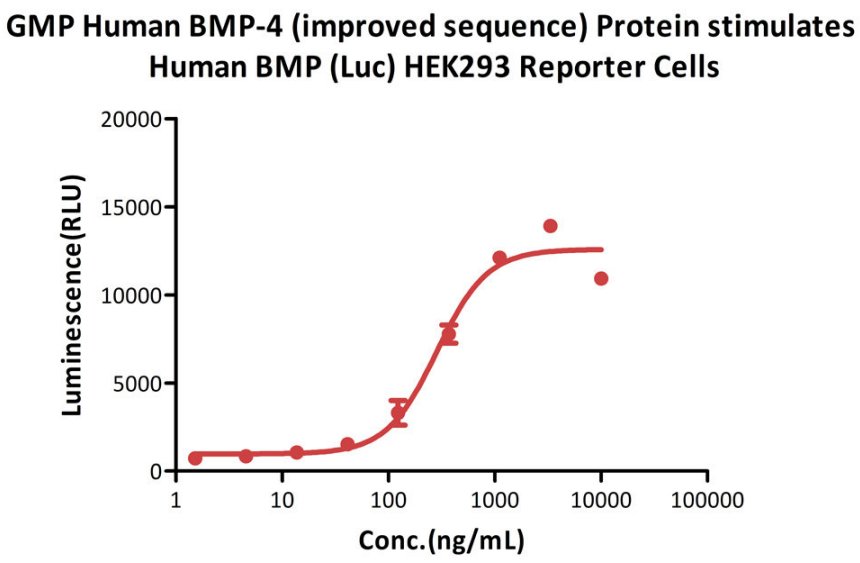
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



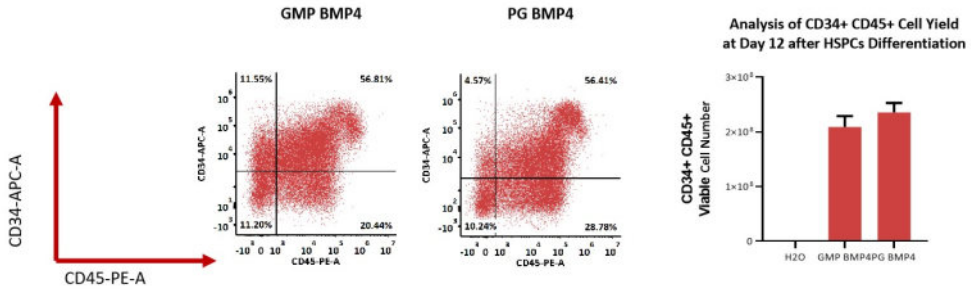
GMP Human BMP-4 (improved sequence) Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE



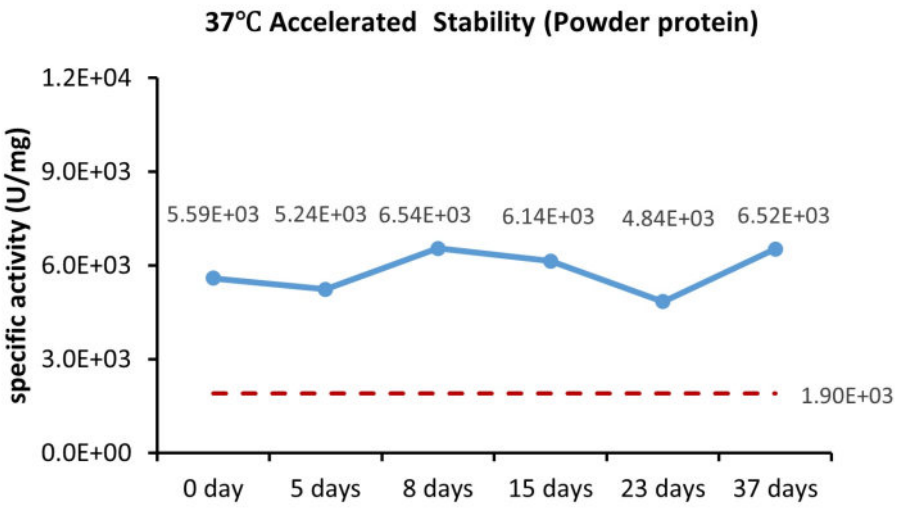
GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) stimulates Human BMP (Luc) HEK293 Reporter Cell. The specific activity of GMP Human BMP-4 (improved sequence) Protein is > 1.90 x 10^3 U/mg (QC tested).

Application Data

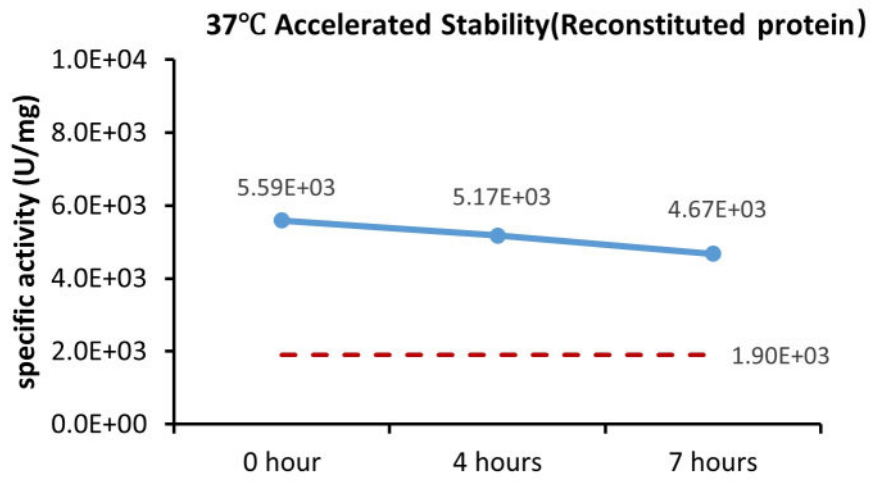


GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) could significantly induce iPSC derived HSPC differentiation, with high expression of CD34 and CD45 (HSPC markers) by flow cytometry analysis and the increase of viable numbers of CD34+ CD45+ cells by cell counting. GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) has a similar performance with Human BMP-4 (improved sequence) Protein, premium grade (Cat. No. BM4-H5118).

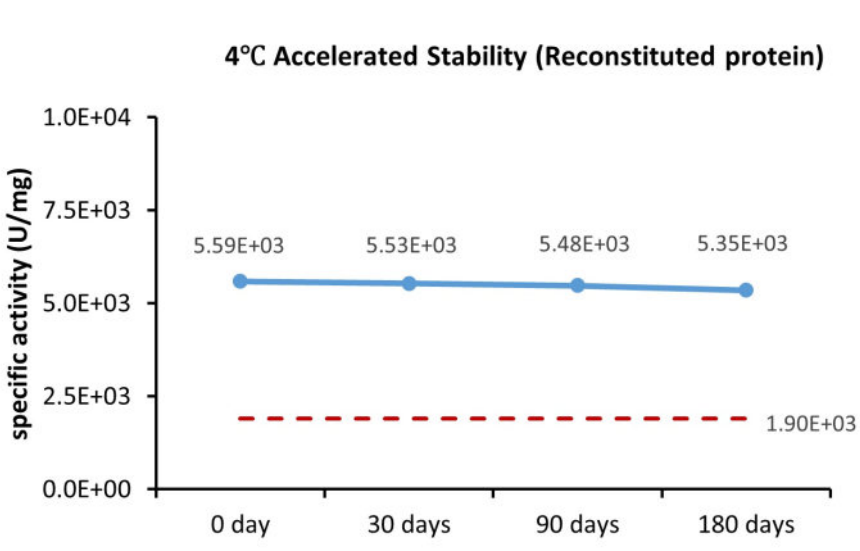
Bioactivity-Stability



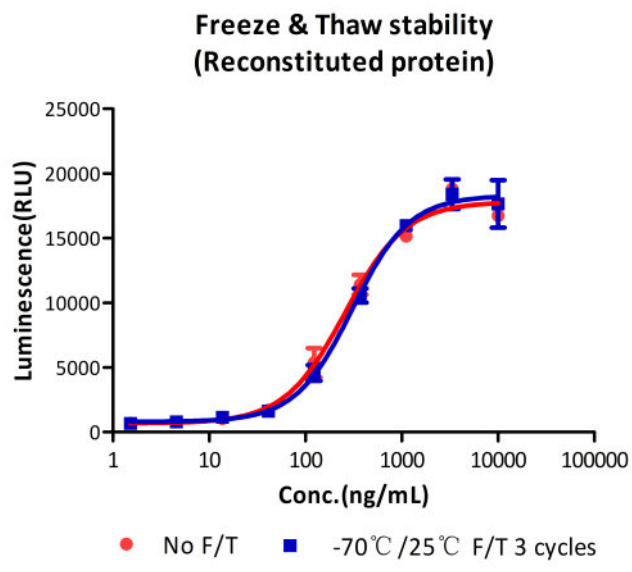
Cell-based assay demonstrates that the lyophilized GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) is stable at 37°C for 37 days.



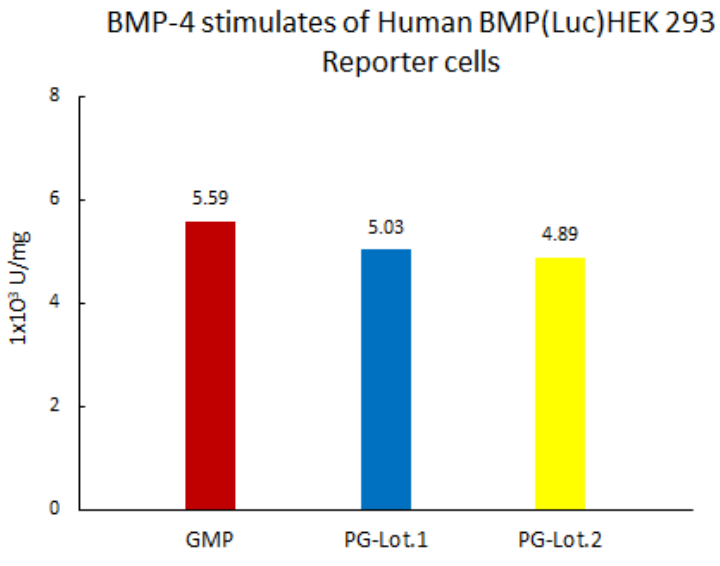
Cell-based assay demonstrates that the reconstituted GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) is stable at 37°C for 7 hours.



Cell-based assay demonstrates that the reconstituted GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) is stable at 4°C for 180 days.



Cell-based assay demonstrates that the reconstituted GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG BMP-4 (improved sequence).

Background

Bone Morphogenetic Protein 4 (BMP4) is a member of growth factor of the TGF-beta superfamily that plays essential roles in many developmental processes, including neurogenesis, vascular development, angiogenesis and osteogenesis. BMP-4 Initiates the canonical BMP signaling cascade by associating with type I receptor BMPR1A and type II receptor BMPR2. BMP-4 can acts in concert with PTHLH/PTHRP to stimulate ductal outgrowth during embryonic mammary development and to inhibit hair follicle induction.

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：

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies
- Fully batch production and control records
- Equipment maintenance and calibration

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

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