#### Catalog # GMP-BM4H18



Features	Sterility
• Designed under ISO 9001:2015 and ISO 13485:2016	The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.
• Manufactured and QC tested under a GMP compliance factory	Mycoplasma
• Animal-Free materials	Negative.
Beta-lactam materials free	
Batch-to-batch consistency	Purity
Stringent quality control tests	>95% as determined by SDS-PAGE.
<ul> <li>No animal derived peptone and lactose used in production process</li> </ul>	Formulation
Source	Lyophilized from 0.22 $\mu$ m filtered solution in 20 mM Citric acid, pH2.2 with
GMP Human BMP-4 (improved sequence) Protein (GMP-BM4H18) is	protectants.
expressed from E. coli cells. It is a variant of BMP-4 to suit cell culture	Contact us for customized product form or formulation.
applications better. Predicted N-terminus: Met	Shipping
Molecular Characterization	This product is supplied and shipped with blue ice, please inquire the shipping cost.
This protein carries no "tag".	Storage
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	Upon receipt, store it immediately at -20°C or lower for long term storage.

Endotoxin

Less than 50 EU/mg by the LAL method.

reducing (R) condition (SDS-PAGE).

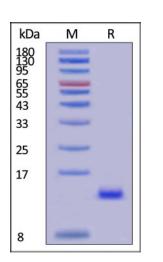
## **Host Cell Protein**

<0.5 ng/µg of protein tested by ELISA.

## **Host Cell DNA**

<0.02 ng/µg of protein tested by qPCR.

## **SDS-PAGE**



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 BMP-4 (improved sequence) Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity





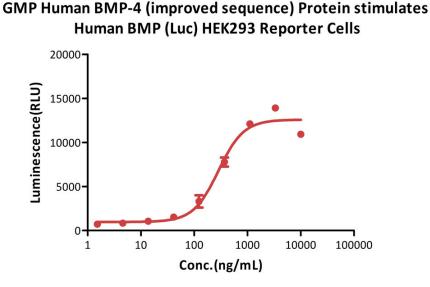


## GMP Human BMP-4 / BMP2B (improved sequence) Protein

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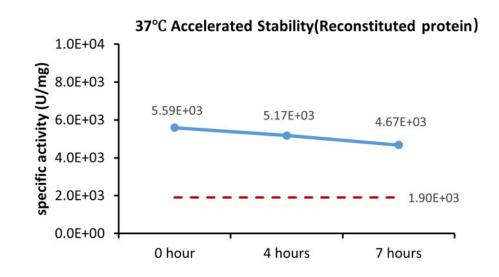
of the protein is greater than 95% (With <u>Star Ribbon Pre-stained Protein</u> <u>Marker</u>).

### **Bioactivity-Bioactivity CELL BASE**

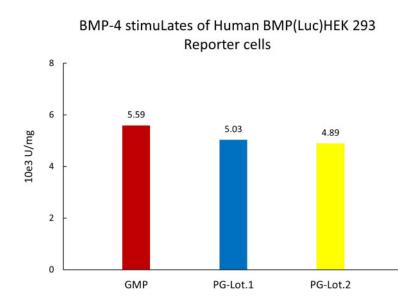


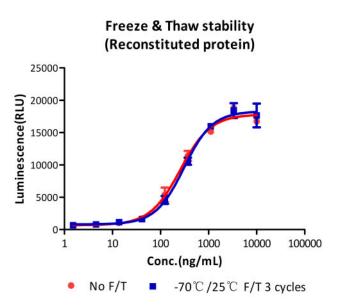
GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) stimulates Human BMP (Luc) HEK293 Reporter Cell. The specific activity of GMP Human BMP-4 (improved sequence) Protein is > 1.90 x 10^3 U/mg (QC tested).

## **Bioactivity-Stability**



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





The Cell based assay shows that GMP Human BMP-4 (improved sequence) Protein (Cat. No. GMP-BM4H18) is stable after freezing and thawing 3 times.





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

# 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

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





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### 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.

## **Clinical and Translational Updates**



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