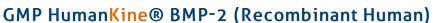


Catalog Number: HZ-1128-GMP

## **Data Sheet**





Animal Component-Free

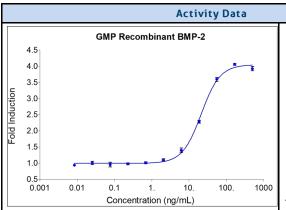
Human cell expressed

Tag-Free

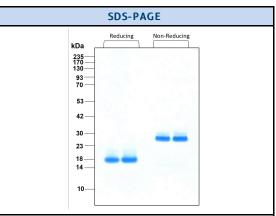
**Endotoxin Free** 

Product Description					
Animal-free Recombinant Human BMP-2 is expressed in human 293 cells an apparent molecular mass of 28 kDa. This cytokine is produced in a serum-free, chemically defined media.					
Alternative Names	ative Names BMP 2, BMP 2A, BMP2, BMP-2, BMP2A, bone morphogenetic protein 2, Bone morphogenetic protein 2A				
Accession Number	P12643				
Source	Source Human Embryonic Kidney cells (HEK293). HEK293-derived BMP-2 protein				
Adventitious Virus	Adventitious Virus Master Cell Bank tested Negative for Adventitious Viruses				

Specifications					
Test	Method	Specification			
Activity	Dose-dependent induction of alkaline phosphatase production in the ATDC-5 cell line (mouse chondrogenic cell line)	7.5-37.5 ng/mL			
Molecular Mass	SDS-PAGE	17 kDa reduced, 28 kDa non-reduced, homodimer, glycosylated			
Purity	SDS-PAGE	>95%			
Endotoxin	LAL	<0.1 EU/µg			
Mycoplasma	PCR	Not Detected			



Recombinant human BMP-2 (HZ-1128-GMP) stimulates dose-dependent induction of alkaline phosphatase production in the ATDC-5 mouse chondrogenic cell line. Alkaline phosphatase production was assessed using pNPP as a chromogenic substrate. ATDC-5 cells were treated with increasing concentrations of recombinant human BMP-2 for 72 hrs hours before lysis



Purity of recombinant human BMP-2 was determined by SDS- polyacrylamide gel electrophoresis. The protein was resolved in an SDS- polyacrylamide gel in reducing and non-reducing conditions and stained using Coomassie blue.

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Document #: FR-QA118-101 Rev 0
Data Sheet Version #: 1

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Preparation				
Shipping Temperature				
Formulation	mulation 2x PBS + 6% Ethanol, See Certificate of Analysis for details			
Reconstitution  Briefly centrifuge the vial before opening. It is recommended to reconstitute the protein to 0.2 mg/mL in sterile 0.1% endotoxin-free recombinant human serum albumin (HSA). Gently swirl or tap vial to mix				

	Product Form	Temperature Conditions	Storage Time (From Date of Receipt)	
	Lyophilized	-20°C to -80°C	Until Expiry Date	
Stability and Storage	Lyophilized	Room Temperature	2 weeks	
	Reconstituted as per CofA	-20°C to -80°C	6 months	
	Reconstituted as per CofA	4°C	1 week	
	Avoid repeated freeze-thaw cycles.			

## Proteintech GMP Quality Policy HumanKine® GMP Proteins

Invitro recombinant protein production can be prone to variability due to various reasons ranging from quality of raw materials to inconsistency in the process. Therefore, HumanKine®, a proteintech brand's GMP proteins are produced and tested under an ISO 13485 certified quality management system in a clean room facility. Proteintech manufactures the GMP HumanKine® products according to the applicable sections in the following documents: USP Chapter 1043 (Ancillary Materials for Cell, Gene, and Tissue-Engineered Products, USP Chapter 92 (Growth Factors and Cytokines Used in Cell Therapy Manufacturing), WHO TRS, No. 822, 1992 Annex 1 (Good Manufacturing Practices for Biological Products), Ph. Eur. General Chapter 5.2.12, and EudraLex – Volume 4 – Part IV (Guidelines on GMP specific to ATMPs). Proteintech strives to achieve the utmost quality GMP raw material ensuring all applicable guidelines are taken into consideration.

The QMS is built to provide our customers with consistent and pure product delivered by documented processes, qualified personnel, validated processes, qualified equipment, qualified vendors, and a stringent final product release process. Although the final product release process is important, Proteintech performs in-process QC steps after each major manufacturing stage. Production records and facilities may be available for an inspection by approved personnel.

Our GMP policy covers all the aspects of production; from raw materials, facility, equipment, and Instruments to training and personal hygiene of staff. It also guarantees that the process is explicit, validated and well documented for transparency and traceability.

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