

Catalog Number: HZ-1278-GMP

Data Sheet

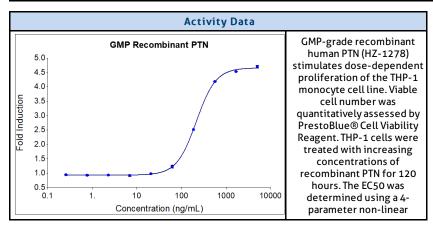


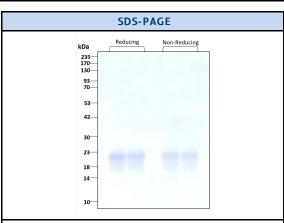
GMP HumanKine® Pleiotrophin (PTN) (Recombinant Human)

Animal Component-Free Human cell expressed Tag-Free Endotoxin Free

Product Description					
Animal-free Recombinant Human Pleiotrophin is expressed in Human 293 cells as a secreted unglycosylated monomer. PTN is a member of a family of heparin-binding proteins that share sequence, structural, and functional similarity. Other members of this family include midkine (MK), and chicken retinoic acid- induced heparin-binding protein (RI-HB), an avian homologue of MK. The expression of all these cytokines is restricted and highly regulated during development.					
Alternative Names HARP, HB GAM, HBBM, HBGF 8, HBGF8, HBNF, HBNF 1, HBNF1, Heparin binding brain mitogen, NEGF1, OSF 1, Osteoblast specific factor pleiotrophin, PTN					
Accession Number	P21246				
Source	ource Human Embryonic Kidney cells (HEK293). HEK293-derived Pleiotrophin (PTN) protein				
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses				

Specifications					
Test	Method Specification				
Activity	Dose-dependent stimulation of proliferation in the THP-1 Monocyte cell line	100-500 ng/mL			
Molecular Mass	SDS-PAGE	SDS-PAGE 18-21 kDa reduced, 17 to 20 kDa non-reduced, monomer, no glycosylated			
Purity	SDS-PAGE	DS-PAGE > 95%			
Endotoxin	LAL	<0.1 EU/ µ g			
Mycoplasma	PCR	Not Detected			





Purity of recombinant human PTN was determined by SDSpolyacrylamide 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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Data Sheet Version #:

Proteintech Group, Inc.

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Preparation				
Shipping Temperature ambient temperature				
Formulation 1 x PBS, 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 1x PB: containing 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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