

GMP HumanKine[®] Pleiotrophin (PTN) (Recombinant Human)



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

Product Description

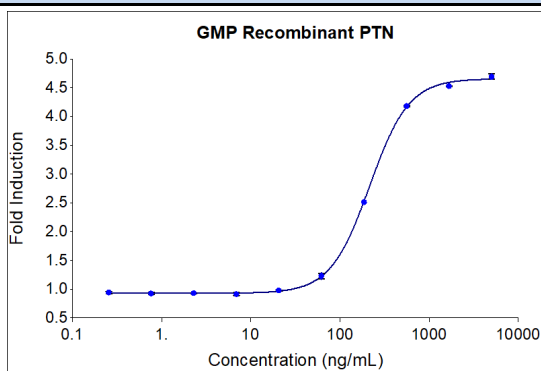
Animal-free Recombinant Human Pleiotrophin is expressed in Human 293 cells as a secreted unglycosylated monomer. PTN is a member of a family of heparin-binding proteins that share sequence, structural, and functional similarity. Other members of this family include midkine (MK), and chicken retinoic 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 1, pleiotrophin, PTN |
| Accession Number | P21246 |
| Source | Human Embryonic Kidney cells (HEK293). HEK293-derived Pleiotrophin (PTN) protein |
| Adventitious Virus | Master Cell Bank tested Negative for Adventitious Viruses |

Specifications

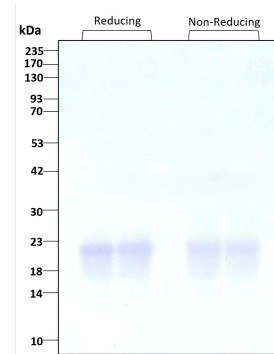
| Test | Method | Specification |
|----------------|---|--|
| Activity | Dose-dependent stimulation of proliferation in the THP-1 Monocyte cell line | 100-500 ng/mL |
| Molecular Mass | SDS-PAGE | 18-21 kDa reduced, 17 to 20 kDa non-reduced, monomer, non-glycosylated |
| Purity | SDS-PAGE | > 95% |
| Endotoxin | LAL | <0.1 EU/ μ g |
| Mycoplasma | PCR | Not Detected |

Activity Data



GMP-grade recombinant human PTN (HZ-1278) stimulates dose-dependent proliferation of the THP-1 monocyte cell line. Viable cell number was quantitatively assessed by PrestoBlue[®] Cell Viability Reagent. THP-1 cells were treated with increasing concentrations of recombinant PTN for 120 hours. The EC₅₀ was determined using a 4-parameter non-linear

SDS-PAGE



Purity of recombinant human PTN 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.

| 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 in sterile 1xPBS pH 7.4 containing 0.1% endotoxin-free recombinant human serum albumin (HSA). |

| Stability and Storage | Product Form | Temperature Conditions | Storage Time (From Date of Receipt) |
|------------------------------------|---------------------------|------------------------|-------------------------------------|
| | Lyophilized | -20°C to -80°C | Until Expiry Date |
| | 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

In vitro 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.

www.ptglab.com

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

Proteintech Group, Inc.
5500 Pearl Street, Suite 400 Rosemont, IL 60612
t: 1-888-478-4522; f: 1-312-455-8408
Email: proteintech@ptglab.com