

GMP HumanKine[®] HGH (Recombinant Human)



Animal Component-Free

Human cell expressed

Tag-Free

Endotoxin Free

Product Description

Animal-free Recombinant Human Human Growth Hormone (HGH) is expressed in human 293 cells with an apparent molecular mass of 22 kDa. It is also known as somatotropin and is a pleiotropic cytokine of the hematopoietic growth factor superfamily. The purity is greater than 95%. It is known primarily for its role in stimulating the development and differentiation of muscle, bone, and cartilage. This cytokine is produced in a serum-free, chemically defined media.

Alternative Names GH, GH N, GH1, GHN, Growth hormone, growth hormone 1, hGH N, Pituitary growth hormone, Somatotropin

Accession Number P01241

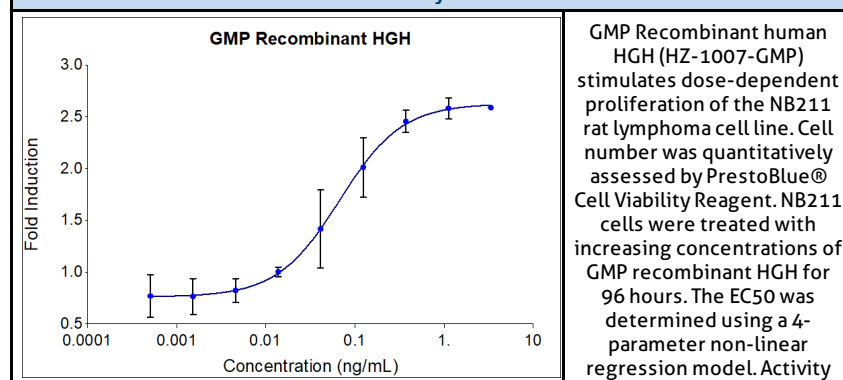
Source Human Embryonic Kidney cells (HEK293). HEK293-derived HGH protein

Adventitious Virus Master Cell Bank tested Negative for Adventitious Viruses

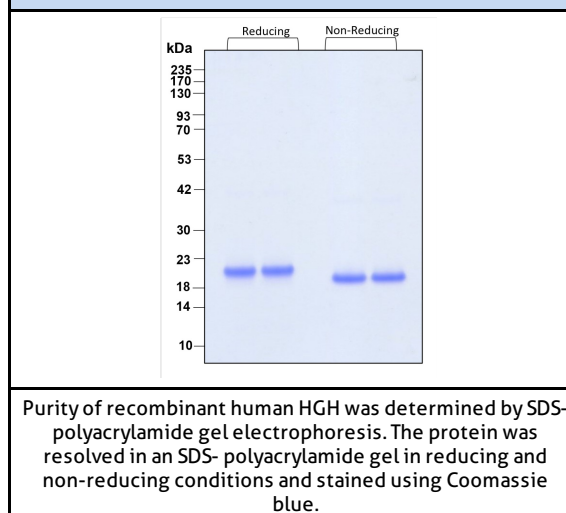
Specifications

| Test | Method | Specification |
|----------------|---|---|
| Activity | Dose-dependent stimulation of the proliferation of rat lymphoma line Nb2-11 cells (prolactin indicator cell line) | 0.05-0.5 ng/mL |
| Molecular Mass | SDS-PAGE | 22 kDa reduced, 20 kDa non-reduced, monomer, non-glycosylated |
| Purity | SDS-PAGE | >95% |
| Endotoxin | LAL | <0.1 EU/ μ g |
| Mycoplasma | PCR | Not Detected |

Activity Data



SDS-PAGE



| Preparation | |
|----------------------|---|
| Shipping Temperature | ambient temperature |
| Formulation | 1x 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 1xPBS pH 7.4 containing 0.1% endotoxin-free recombinant human serum albumin (HSA). Gently swirl or tap vial to mix. |

| 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

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.

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