

Catalog Number: HZ-1161-GMP

Data Sheet

**HumanKine® recombinant human pro-IGF-II protein-
GMP grade**



Animal Component-Free

Human cell expressed

Tag-Free

Endotoxin Free

Product Description

Animal-free Recombinant Human pro-IGF-II is expressed in human 293 cells as a monomeric glycoprotein with an apparent molecular mass of 25 kDa. Glycosylation contributes to stability in cell growth media and other applications. IGF-II expressed in E. coli is typically 7.5 kDa and nonglycosylated. This cytokine is produced in a human cell expression system with serum-free, chemically defined media.

Alternative Names C11orf43, FLJ22066, FLJ44734, IGF II, IGF2, INSIGF, Insulin like growth factor II, pp9974, Somatomedin A

Accession Number P01344

Source Human Embryonic Kidney cells (HEK293). HEK293-derived pro-IGF-II protein

Species Reactivity human

Adventitious Virus Master Cell Bank tested Negative for Adventitious Viruses

Specifications

| Test | Method | Specification |
|----------------|--|---|
| Activity | Dose-dependent stimulation of the proliferation of MCF-7 cells (human breast cancer cell line) | 12-80 ng/mL |
| Molecular Mass | SDS-PAGE | 25 kDa reduced and non-reduced, monomer, glycosylated |
| Purity | SDS-PAGE | >95% |
| Endotoxin | LAL | <0.1 EU/μg |
| Mycoplasma | PCR | Not Detected |

SDS-PAGE

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| Preparation | |
|----------------------|--|
| Shipping Temperature | ambient temperature |
| Formulation | 10 mM Tris-HCl pH 7.4 + 350 mM NaCl, 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 PBS 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

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.

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