

Catalog Number: HZ-1072-GMP

Data Sheet

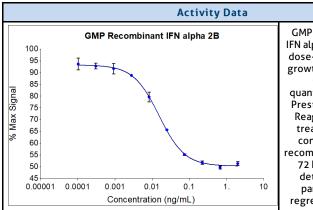


HumanKine® recombinant human IFN alpha 2B protein- GMP grade

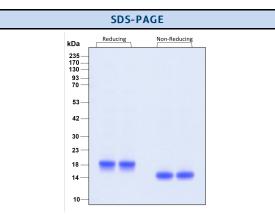
Animal Component-Free Human cell expressed Tag-Free Endotoxin Free

| Product Description | | | | | |
|---|---|--|--|--|--|
| Animal-free Recombinant Human IFN alpha 2B is expressed in human 293 cells as a monomeric glycoprotein with an apparent molecular mass of 16 kDa. This cytokine is produced in a serum-free, chemically defined media. Production in human 293 cells offers authentic glycosylation which contributes to stability in cell growth media and other applications. The purity is greater than 95%. | | | | | |
| Alternative Names IFN alpha 2, IFNA, IFNA2, INFA2, Interferon alpha 2, Interferon alpha A, interferon, alpha 2, LeIF A | | | | | |
| Accession Number | cession Number P01563 | | | | |
| Source | Source Human Embryonic Kidney cells (HEK293). HEK293-derived IFN alpha 2B protein | | | | |
| Species Reactivity | Species Reactivity human | | | | |
| Adventitious Virus Master Cell Bank tested Negative for Adventitious Viruses | | | | | |

| Specifications | | | | | |
|-------------------|--|---|--|--|--|
| Test | Method | Specification | | | |
| Activity | Dose-dependent cytotoxicity of the human TF -1 cell line (human erythroleukemic indicator cell line) | 0.004-0.02 ng/mL | | | |
| Molecular Mass | SDS-PAGE | 18 to 22 kDa reduced, 16 to 18 kDa non-reduced, monomer, glycosylated | | | |
| Purity | SDS-PAGE | >95% | | | |
| Endotoxin | LAL | <0.1 EU/µg | | | |
| Mycoplasma | PCR | Not Detected | | | |



GMP Recombinant human IFN alpha 2B (HZ-1072-GMP) dose-dependently inhibits growth of the TF-1 cell line. Cell number was quantitatively assessed by PrestoBlue® Cell Viability Reagent. TF-1 cells were treated with increasing concentrations of GMP recombinant IFN alpha 2B for 72 hours. The EC50 was determined using a 4-parameter non-linear regression model. Activity



Purity of recombinant human IFN alpha 2B 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

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| Preparation | | | | |
|--|---|--|--|--|
| Shipping Temperature | | | | |
| Formulation | 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 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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