Catalog Number: HZ-1298-GMP

Data Sheet

GMP HumanKine® IFN beta (Recombinant Human)

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

Product Description

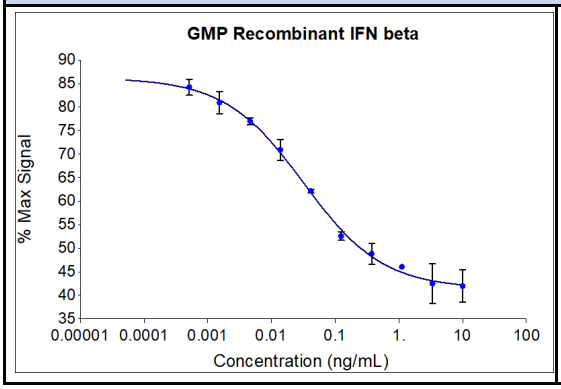
Animal-free Recombinant Human IFN beta (IFN beta 1/ IFN beta 1a), is a member of type I family of interferons. It binds to a heterodimeric receptor, known as the IFNα/β receptor (IFNAR) resulting in activation of a number of Jak/ STAT proteins. Activation of this signaling pathway results in activation of genes that inhibit viral infection and regulate MHC class I antigens. It is primarily produced by fibroblasts and monocytes. In addition to inhibiting viral infection, IFN beta is also involved in regulating and activating immune response against bacteria, parasite and tumor cells. Multiple sclerosis is characterized by a deficiency of IFN beta 1. An injectable form of IFN beta 1 is used for MS treatment.

Alternative Names	Fibroblast interferon, IFB, IFF, IFN beta, IFNB, IFNB1, Interferon beta, interferon, beta 1, fibroblast
Accession Number	P01574
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived IFN beta protein
Species Reactivity	human
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses

Specifications

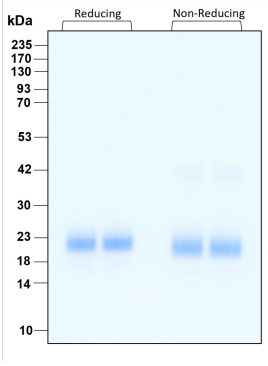
Test	Method	Specification
Activity	Dose dependent inhibition of proliferation of TF-1 cells (human erythroleukemic indicator cell line)	0.015-0.08 ng/mL EC50
Molecular Mass	SDS-PAGE	21 to 24 kDa reduced, 20 to 23 and 38 to 42 non-reduced, glycosylated
Purity	SDS-PAGE	> 95%
Endotoxin	LAL	<0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



GMP Recombinant human IFN beta (HZ-1298-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 recombinant IFN beta for 72 hours. The EC50 was determined using a 4-parameter non-linear regression model. Activity

SDS-PAGE



Purity of GMP recombinant human IFN beta 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.

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Preparation	
Shipping Temperature	ambient temperature
Formulation	Sodium Acetate pH 4.8 + 150mM NaCl + CHAPS, See Certificate of Analysis for details
Reconstitution	Briefly centrifuge the vial before opening. It is recommended to reconstitute the protein in sterile water.

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.

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