proteintech®
Antibodies | ELISA kits | Proteins

Catalog Number: HZ-1103-GMP

Data Sheet

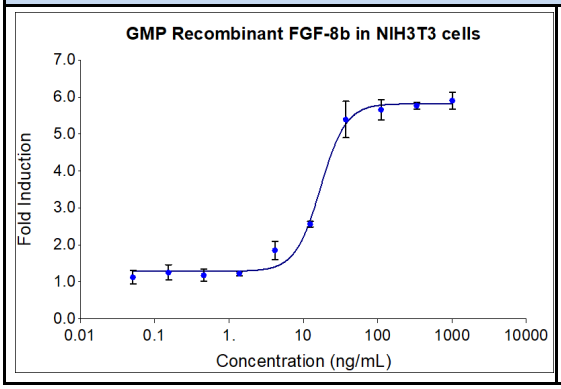
HumanKine® recombinant human FGF-8b protein-GMP grade

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

Product Description	
Animal-free Recombinant Human FGF-8b is expressed in human 293 cells as a monomeric glycoprotein with an apparent molecular mass of 30 to 45 kDa. This wide molecular mass is due to glycosylation, which is absent when this cytokine is expressed in E. coli. Production in human 293 cells offers authentic glycosylation. Glycosylation contributes to stability in cell growth media and other applications. The cytokine is greater than 95% pure.	
Alternative Names	AIGF, Androgen induced growth factor, FGF 8, FGF8, FGF-8b, Fibroblast growth factor 8, HBGF 8, KAL6, FGF8b
Accession Number	P55075
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived FGF-8b protein
Species Reactivity	human,mouse
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses

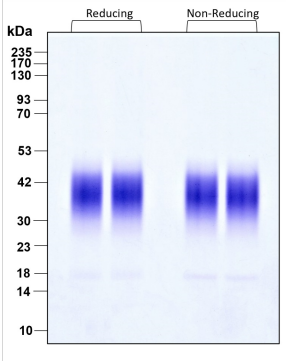
Specifications		
Test	**Method**	**Specification**
Activity	Dose-dependent stimulation of the proliferation of the Balb/c 3T3 cell line. Dose-Dependent Proliferation of the NIH3T3 Cell Line in defined media	10-60 ng/mL EC50
Molecular Mass	SDS-PAGE	30 to 45 kDa reduced and non-reduced, monomer, glycosylated
Purity	SDS-PAGE	>95%
Endotoxin	LAL	<0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



GMP Recombinant human FGF-8b (HZ-1103-GMP) stimulates dose-dependent proliferation of the NIH/3T3 mouse fibroblast cell line. Viable cell number was quantitatively assessed by Prestoblue Cell Viability Reagent. NIH/3T3 cells were serum starved in 0.02% FBS with 1 ug/mL heparin during treatment with increasing concentrations of recombinant human FGF-8b for 72hrs. Activity

SDS-PAGE



Purity of recombinant human FGF-8b 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	10 mM Tris-HCl pH 7.4 + 800 mM NaCl, See Certificate of Analysis for details
Reconstitution	Briefly centrifuge the vial before opening. It is recommended to reconstitute the protein in sterile water containing 0.1% endotoxin-free recombinant human serum albumin (HSA).

	Product Form	Temperature Conditions	Storage Time (From Date of Receipt)
Stability and Storage	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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