

Catalog Number: HZ-1004-GMP

Data Sheet

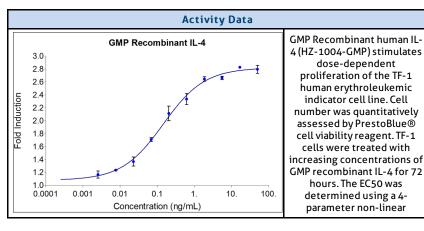


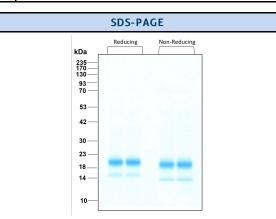
HumanKine® recombinant human IL-4 protein- GMP grade

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

Product Description					
Animal-free Recombinant Human IL-4 is expressed in human 293 cells with an apparent molecular mass of 34 kDa. This cytokine is produced in a serum-free, chemically defined media.					
Alternative Names	ernative Names B cell stimulatory factor 1, Binetrakin, BSF 1, BSF1, IL 4, IL-4, interleukin 4, Pitrakinra				
Accession Number	P05112				
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived IL-4 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 human TF-1 cells (human erythroleukemic indicator cell line).	0.07-0.4 ng/mL			
Molecular Mass	SDS-PAGE	15 and 21 kDa reduced, 13 and 19 kDa non-reduced, monomer, glycosylated			
Purity	SDS-PAGE	>95%			
Endotoxin	LAL	<0.1 EU/µg			
Mycoplasma	PCR	Not Detected			





Purity of recombinant human IL-4 was determined by SDSpolyacrylamide 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				
Formulation	ormulation 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 10 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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