

Adventitious Virus

Catalog Number: HZ-1301-GMP

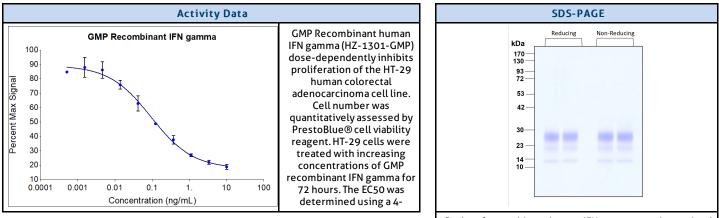
Data Sheet



	Animal Component-Free	Human cell expressed	Tag-Free	Endotoxin Free			
[Product Desc	cription				
	Animal-free Recombinant Huma	Recombinant Human IFN gamma is expressed in human 293 cells with an apparent molecular mass of 17, 21-32 kDa. This cytokine is produced in a serum-free, chemically defined media.					
ſ	Alternative Names	IFG, IFI, IFN gamma, IFNG, Immune interferon, Interferon gamma, interferon, gamma					
	Accession Number	sion Number P01579					
ſ	Source	Human Embryonic Kidney d	ells (HEK293). HEK293-derived IFN gamma protein				

Master Cell Bank tested Negative for Adventitious Viruses

	Specifications				
Test	Method	Specification			
Activity	Dose dependent inhibition of proliferation of HT-29 cells	0.02-0.14 ng/mL			
Molecular Mass	SDS-PAGE	17 and 21 to 32 kDa reduced and non-reduced, homodimer, glycosylated > 95%			
Purity	SDS-PAGE				
Endotoxin	LAL	< 0.1 EU/µg			
Mycoplasma	PCR	Not Detected			



Purity of recombinant human IFN gamma 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.

ISC

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	Preparation		
Shipping Temperature	ambient temperature		
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 1x PBS pH 7.4 containing 0.1% endotoxin-free recombinant human 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

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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