proteintech®
Antibodies | ELISA kits | Proteins

Catalog Number: HZ-1256-GMP

Data Sheet

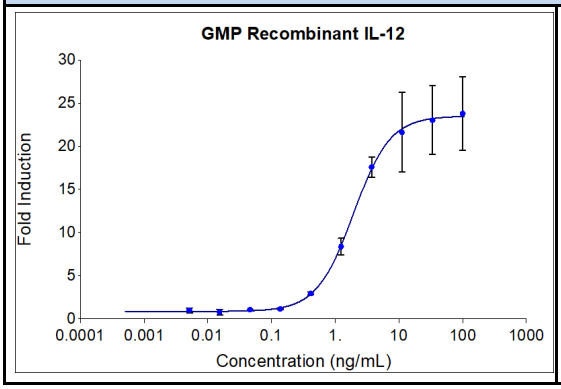
GMP HumanKine® IL-12 (Recombinant Human)

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

Product Description	
Animal-free Recombinant Human IL-12 is expressed in human 293 cells as a heterodimeric cytokine composed of two glycosylated and disulfide-linked subunits (p40 cysteine-linked to p35). Production in human 293 cells uses a serum-free, chemically defined media and offers authentic glycosylation. IL-12 is a potent regulator of cell mediated immune responses and it induces IFN-gamma production by NK and T cells. It is produced by activated monocytes/macrophage cells, B lymphocytes, and connective tissue type mast cells.	
Alternative Names	CLMF, CLMF p35, IL 12 subunit p35, IL 12A, IL12, IL-12, IL12A, Interleukin 12 subunit alpha, NFSK, NKSF1, P35
Accession Number	P29459 (p35 subunit) P29460 (p40 subunit)
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived IL-12 protein
Species Reactivity	human
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses

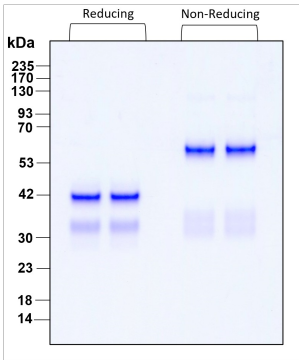
Specifications		
Test	**Method**	**Specification**
Activity	Dose-dependent induction of alkaline phosphatase production in a HEK293 reporter cell line.	0.8-4 ng/mL
Molecular Mass	SDS-PAGE	34 and 42 kDa reduced, 57 kDa non-reduced, heterodimer, glycosylated
Purity	SDS-PAGE	>95%
Endotoxin	LAL	<0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



GMP Recombinant human IL-12 (HZ-1256-GMP) stimulates dose-dependent induction of alkaline phosphatase production in a HEK293 reporter cell line. Alkaline phosphatase production was assessed using pNPP as a chromogenic substrate. The HEK293 reporter cell line was treated with increasing concentrations of GMP recombinant IL-12 for 24 hours before addition of

SDS-PAGE



Purity of recombinant human IL-12 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.

Proteintech Group, Inc.
5500 Pearl Street, Suite 400 Rosemont, IL 60612
t: 1-888-478-4522; f: 1-312-455-8408
Email: proteintech@ptglab.com

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 serum albumin (HSA). Gently swirl or tap vial to mix.

	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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