Catalog Number: HZ-1254-GMP

Data Sheet

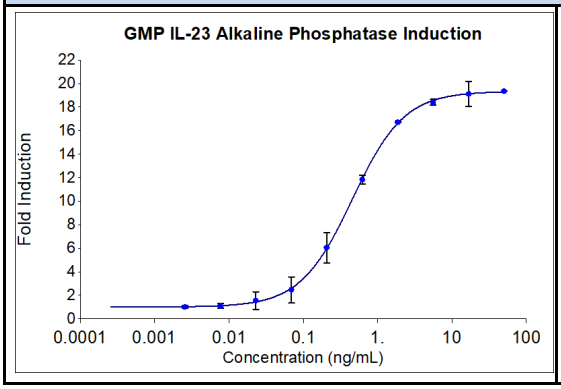
GMP HumanKine® IL-23 (Recombinant Human)

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

Product Description	
Animal-free Recombinant Human IL-23 is expressed in human 293 cells as a heterodimeric glycoprotein composed of two disulfide-linked subunits (p40 cystine linked to p19). IL-23 has been shown to enhance proliferation of memory T cells. It also stimulates the production of IFN-gamma in NK cells, induces IL-17 production, and drives Th17 mediated responses. Furthermore, it is known that IL-23 takes a vital part in the inflammation process and that it is associated with auto immune diseases.	
Alternative Names	IL 23, IL 23 A, IL 23 subunit alpha, IL 23A, IL 23p19, IL23, IL-23, IL23A, IL23P19, Interleukin 23 subunit alpha, Interleukin 23 subunit p19, P19, SGRF
Accession Number	Q9NPF7
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived IL-23 protein
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	0.2-1.2 ng/mL in HEK293 reporter cell line
Molecular Mass	SDS-PAGE	20 and 42 kDa reduced, 53 kDa non-reduced, heterodimer, glycosylated
Purity	SDS-PAGE	>95%
Endotoxin	LAL	< 0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



Recombinant human GMP IL-23 (HZ-1254-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 EC50 was determined using a 4-parameter non-linear regression model. Activity determination was conducted in triplicate on a

SDS-PAGE

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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 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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