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Antibodies | ELISA kits | Proteins

Catalog Number: HZ-1211-GMP

Data Sheet

GMP HumanKine® Cystatin C (Recombinant Human)

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

Product Description

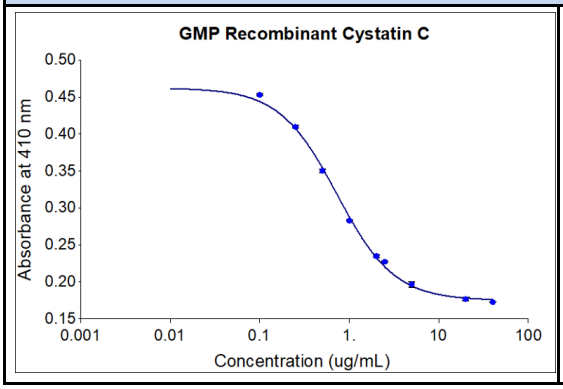
Animal-free Recombinant Human Cystatin C (Cys-C) is expressed in human 293 cells as a monomer with an apparent molecular mass of 12 to 13 kDa. Native Cys-C in human urine is found in two different forms: one with pI 9.2 and the other with pI 7.8 by elimination of small basic peptides or amino acids from the N-terminal end of protein. Cystatin C has been studied for its role in predicting newonset or deteriorating cardiovascular disease. This cytokine is produced in a serum-free, chemically defined media.

Alternative Names	ARMD11, CST3, Cystatin 3, cystatin C, Gamma trace, Post gamma globulin
Accession Number	P01034
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived Cystatin C protein
Species Reactivity	human
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses

Specifications

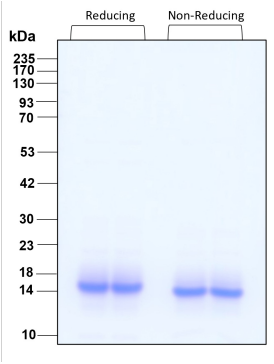
Test	Method	Specification
Activity	Dose-dependent inhibition of Papain protease activity by colorimetric assay using L-BAPA as the substrate.	0.5-2.6 μg/mL EC50
Molecular Mass	SDS-PAGE	15 to 18 kDa reduced, 14 to 17 kDa non-reduced, monomer, non-glycosylated
Purity	SDS-PAGE	>95%
Endotoxin	LAL	<0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



Recombinant Human GMP Cystatin C (HZ-1211-GMP) inhibits papain protease activity in a dose-dependent manner. Papain protease activity was measured by colorimetric assay using L-BAPA as the substrate. The EC50 was determined using a 4-parameter non-linear regression model. Activity determination was conducted in triplicate on a validated bioassay. The EC50 values range form 0.5-2.6

SDS-PAGE



Purity of GMP recombinant human Cystatin C 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	1x PBS, See Certificate of Analysis for details
Reconstitution	Briefly centrifuge the vial before opening. It is recommended to reconstitute the protein in sterile 1x PBS pH 7.4.

	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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