Catalog Number: HZ-1192-GMP

Data Sheet

HumanKine® recombinant human M-CSF protein-GMP grade

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

Product Description

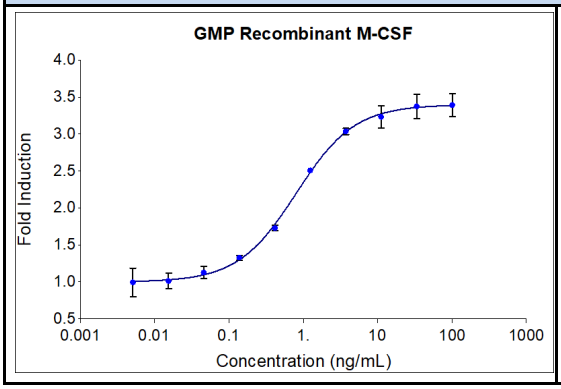
Animal-free Recombinant Human M-CSF is expressed in human 293 cells and has an apparent molecular mass of 35 to 40 kDa due to glycosylation. M-CSF is a potent hematopoietic factor produced by a variety of cells including lymphocytes, monocytes, fibroblasts, endothelial cells, myoblasts, and osteoblasts. It is a key regulator of cellular proliferation, differentiation, and survivial of blood monocytes, tissue macrophages, and their progenitor cells. This cytokine is produced in a human cell expression system with serum-free, chemically defined media.

Alternative Names	CSF 1, CSF1, Lanimostim, M CSF, MCSF, M-CSF
Accession Number	P09603
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived M-CSF protein
Species Reactivity	human,mouse
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses

Specifications

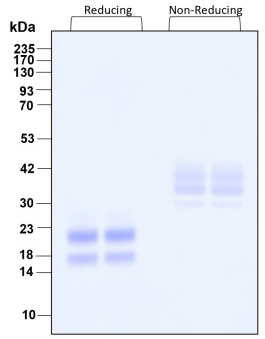
Test	Method	Specification
Activity	Dose-dependent stimulation of the proliferation of murine M-NFS-60 cells (Mouse myeloid leukemia indicator cell line)	0.7-4.0 ng/mL
Molecular Mass	SDS-PAGE	19 and 23 kDa reduced, 35 and 40 kDa non-reduced, homodimer, glycosylated
Purity	SDS-PAGE	>95%
Endotoxin	LAL	<0.1 EU/μg
Mycoplasma	PCR	Not Detected

Activity Data



GMP recombinant human M-CSF (Cat no: HZ-1192-GMP) stimulates dose-dependent proliferation of the murine mouse myloid leukemia (M-NFS-60) cell line. Cell number was quantitatively assessed by Prestoblue® Cell Viability Reagent. M-NFS-60 cells were treated with increasing concentrations of recombinant M-CSF for 48 hours. Activity determination was

SDS-PAGE



Purity of recombinant human M-CSF 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 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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