

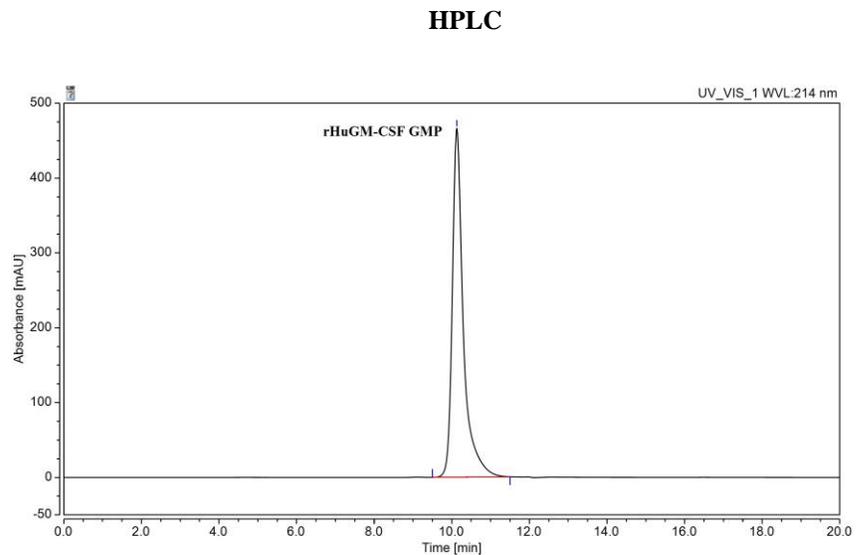
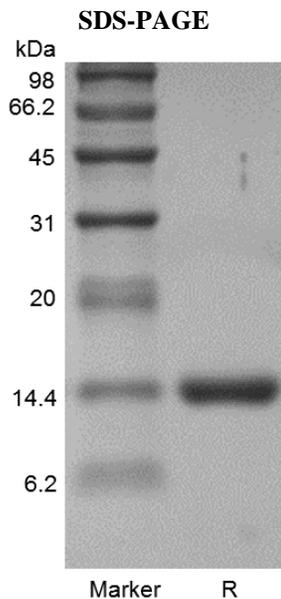
Recombinant Human Granulocyte-Macrophage Colony Stimulating Factor GMP (rHuGM-CSF GMP)

PrimeGene Technical DataSheet

Catalog Number:	GMP-102-03
Source:	<i>Escherichia coli</i>
Molecular Weight:	Approximately 14.5 kDa, a single non-glycosylated polypeptide chain containing 127 amino acids.
Size:	5 µg/100 µg/1 mg
Sequence:	APARSPSPST QPWEHVNAIQ EARRLLNLSR DTAEMNETV EWISEMFDLQ EPTCLQTRLE LYKQGLRGSL TKLKGPLTMM ASHYKQHCPP TPETSCATQI ITFESFKENL KDFLLVIPFD CWEPVQE
Purity:	> 98% by SDS-PAGE and HPLC analyses.
Biological Activity:	Fully biologically active when compared to standard. The ED ₅₀ as determined by a cell proliferation assay using human TF-1 cells is less than 0.1 ng/mL, corresponding to a specific activity of > 1.0 × 10 ⁷ IU/mg, which is calibrated against rHuGM-CSF WHO International Standard (NIBSC code: 88/646).
Physical Appearance:	Sterile filtered white lyophilized (freeze-dried) powder.
Formulation:	Lyophilized from a 0.2 µm filtered concentrated solution in PBS, pH 7.4.
Endotoxin:	Less than 0.01 EU/µg of rHuGM-CSF GMP as determined by LAL method.
Sterility:	Negative.
Mycoplasma:	Negative.
Host Cell Protein:	Less than 0.05% when tested by ELISA.
Host Cell DNA:	Less than 20 ng/mg when tested by qPCR.
In Vitro Virus Assay:	Negative.
Reconstitution:	Prior to opening, it is recommended to centrifuge the vial briefly to bring the contents down the bottom. Reconstitute in sterile distilled water or aqueous buffer containing 0.1% BSA to a concentration of 0.1-1.0 mg/mL. If animal-origin-free condition is expected in your product, then sterile distilled water is recommended. Stock solutions should be apportioned into working aliquots and stored at ≤ -20 °C. Further dilutions should be made in appropriate buffered solutions.
Shipping:	The product is shipped with polar packs. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage:	Use a manual defrost freezer and avoid repeated freeze-thaw cycles. <ul style="list-style-type: none">● A minimum of 12 months from date of receipt, when stored at ≤ -20 °C as supplied.● 1 month, 2 to 8 °C under sterile conditions after reconstitution.● 3 months, -20 to -70 °C under sterile conditions after reconstitution.● Refer to lot-specific CoA for the Expiry Date.
Usage:	This material is offered by Shanghai PrimeGene Bio-Tech for research, laboratory, or further evaluation purposes. NOT FOR HUMAN USE.
Quality Statement:	The manufacturing and testing of these products comply with ICH Q7 guidelines.

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Background:

Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) is secreted by a number of different cell types (including activated T cells, B cells, macrophages, mast cells, endothelial cells and fibroblasts) in response to cytokine or immune and inflammatory stimulation. It was initially characterized as a growth factor that can support the in vitro colony formation of granulocyte-macrophage progenitors and has functions of stimulates the growth and differentiation of hematopoietic precursor cells from various lineages. GM-CSF has also been reported to have a functional role on non-hematopoietic cells and can induce human endothelial cells to migrate and proliferate. Additionally, it can stimulate the proliferation of a number of tumor cell lines, including osteogenic sarcoma, carcinoma and adenocarcinoma cell lines. Human GM-CSF shares 54% sequences identity with mouse GM-CSF, but has no biological effects across species. GM-CSF is used as a medication to stimulate the production of white blood cells following chemotherapy and has also recently been evaluated in clinical trials for its potential as a vaccine adjuvant in HIV-infected patients.

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