

## RayBiotech, Inc.

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# Certificate of Analysis and Data Sheet

# Recombinant Human Granulocyte Macrophage-Colony Stimulating Factor

**Catalog No.** 228-10551

Source

Escherichia Coli.

#### **Synonyms**

CSF-2, MGI-1GM, GM-CSF, Pluripoietin-alpha, Molgramostin, Sargramostim, MGC131935, MGC138897.

## Introduction

GMCSF is a cytokine that controls the production, differentiation, and function of granulocytes and macrophages. The active form of the protein is found extracellularly as a homodimer. This gene has been localized to a cluster of related genes at chromosome region 5q31, which is known to be associated with interstitial deletions in the 5q- syndrome and acute myelogenous leukemia. Other genes in the cluster include those encoding interleukins 4, 5, and 13.

GM-CSF stimulates the growth and differentiation of hematopoietic precursor cells from various lineages, including granulocytes, macrophages, eosinophils and erythrocytes.

## Description

Granulocyte Macrophage Colony Stimulating Factor Human Recombinant produced in E.Coli is a single, non-glycosylated, polypeptide chain containing 127 amino acids and having a molecular mass of 14477 Dalton. GM-CSF is purified by proprietary chromatographic techniques.

## Physical Appearance

Sterile Filtered White lyophilized (freeze-dried) powder.

#### **Formulation**

GM-CSF was lyophilized after extensive dialysis against 2 mM sodium phosphate buffer pH= 7.4±0.1.

## **Solubility**

It is recommended to reconstitute the lyophilized Granulocyte Macrophage Colony Stimulating Factor in sterile  $18M\Omega$ -cm  $H_2O$  not less than  $100~\mu g/ml$ , which can then be further diluted to other aqueous solutions.



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## Stability

Lyophilized Granulocyte Macrophage Colony Stimulating Factor although stable at room temperature for 3 weeks, should be stored desiccated below -18°C. Upon reconstitution GMCSF should be stored at 4°C between 2-7 days and for future use below -18°C.

For long term storage it is recommended to add a carrier protein (0.1% HSA or BSA).

Please prevent freeze-thaw cycles.

## **Purity**

Greater than 98.0% as determined by:

- 1. Analysis by RP-HPLC.
- 2. Analysis by SDS-PAGE.

## Amino acid sequence

The sequence of the first five N-terminal amino acids was determined and was found to be Ala-Pro-Ala-Arg-Ser. N-terminal methionine has been completely removed enzymatically.

## Biological Activity

The ED50 as determined by the dose-dependant stimulation of the proliferation of human TF-1 cells (human erythroleukemic indicator cell line) is < 0.1 ng/ml, corresponding to a Specific Activity of  $11.1 \times 10^6$  IU/mg.

#### Protein content

GM-CSF quantitation was carried out by two independent methods:

- 1. UV spectroscopy at 280 nm using the absorbency value of 0.963 as the extinction coefficient for a 0.1% (1mg/ml) solution. This value is calculated by the PC GEN computer analysis program of protein sequences (IntelliGenetics).
- 2. Analysis by RP-HPLC, using a standard solution of GM-CSF as a Reference Standard.