

Data Sheet

CellGenix® Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rh GM-CSF)

Preclinical Grade – Order No.: 1412-010 (10 µg)*, 1412-050 (50 µg)

Product Characteristics

Source	<i>E. coli</i>
Description	Human GM-CSF, accession # P04141, Ala18-Glu144 Molecular mass 14.5 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 1.5 mM potassium phosphate, 8.1 mM sodium phosphate, 2.7 mM potassium chloride, and 137 mM sodium chloride, pH 7.5.
Intended use	For preclinical ex vivo use. Not intended for therapeutic use.

Quality Parameters

Activity	≥ 6 x 10 ⁶ IU/mg calibrated against NIBSC #88/646 Measured in a cell proliferation assay using a GM-CSF-dependent cell line, TF1
Purity	≥ 95 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Endotoxin	< 1000 EU/mg, as determined by LAL gel clot test
Sterility	Sterility test of the vial product
Mass per vial	1412-010: 10 µg, 1412-050: 50 µg
Animal-derived component-free	ADCF Level 2: The final product contains neither animal- nor human-derived materials. ADCF Level 2 cytokines are produced in our dedicated animal-free facility. No animal-derived components are used throughout the complete production process. All ADCF Level 2 cytokines are produced in <i>E. coli</i> .

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Shelf life	3 years from date of shipment
Storage & Stability	Store lyophilized cytokine at -20 °C to -80 °C. Store a 250 µg/ml cytokine solution: <ul style="list-style-type: none">• 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container.• 4 months at -20 °C to -80 °C under sterile conditions after reconstitution. Store in aliquots in polypropylene cryogenic vials. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 100 µg/ml (for 10 µg vials) or 250 µg/ml (for 50 µg vials)
Dilution	Recommended in CellGenix® serum-free media. For dilution with protein free medium, a carrier protein (0.1-1 % albumin or 1-10 % appropriate serum) has to be included. Failure to dilute product according to these instructions may result in loss of activity.

Quality Statement

Final manufacturing steps and QC are performed in a GMP facility. No animal- or human-derived components are present in the final product and no animal- or human-derived materials were used in production (ADCF Level 2).