



Data Sheet: CellGro® / CellGenix™
Recombinant Human Granulocyte-Macrophage
Colony Stimulating Factor (GM-CSF)
ex vivo grade - Order No.: 1012

Source	A DNA sequence encoding the mature GM-CSF protein (Cantrell, M. et al., 1985, PNAS 82:6250-6254; Lee, F. et al., 1985, PNAS 82:4360-4364; and Wong. et al., 1985, Science 228:810-815) was expressed in <i>E. coli</i>
Raw Material Statement	Produced without the use of animal derived components (ADCF)
Production	Produced under GMP conditions
Molecular Mass	The methionyl form of the <i>E. coli</i> expressed mature human GM-CSF contains 128 amino acid residues and has a molecular mass of approximately 14.5 kDa
Identity	Confirmed by DNA-sequencing of the expression plasmid in EOP-cells and N-terminal sequencing of the final product
Purity	≥ 97%, as determined by SDS-PAGE (under reducing and non-reducing conditions) and visualized by Silver staining
Endotoxin Level	< 0.1 ng per 1 µg (< 1000 EU/mg), as determined by LAL gel clot test according to Eur.Pharm.; typically < 0.01 ng per 1 µg (< 100 EU/mg)
Residual Host-Cell DNA	≤ 200 ng per 1 mg, as determined by a fluorimetric assay
Activity	Measured in a cell proliferation assay using a human factor-dependent cell line, TF-1 (Kitamura, T. et al., 1989, J. Cell Physiol. 140:323-334) ED50 is typically 0.01 – 0.04 ng/ml (2.5×10^7 – 0.8×10^7 IU/mg) calibrated with the 1 st International Standard NIBSC, # 88/646
Sterility	Sterility test according to Eur.Pharm. of the vialled product (direct inoculation)
Formulation	Lyophilized from a 250 µg/ml, 0.2µm-sterile-filtered solution in PBS without any carrier materials and preservatives
Amount per Vial	50 ± 5 µg, as determined by spectrophotometrical measurement at 280 nm using PBS as reference ($A_{280} = 0.96$ for a concentration of 1 mg/ml GM-CSF in PBS)
Transport	Ambient temperature
Storage at	-20°C to -80°C. Avoid repeated freeze-thaw cycles
Shelf life	2 years from date of production Minimum 6 months from date of shipping
Intended Use	For research or clinical ex vivo cell culture use only. Not intended for human in vivo application.

Manufacturer
CellGenix Technologie Transfer GmbH
Am Flughafen 16 – 79108 Freiburg – Germany
Tel: +49 761 88889 – 0
Fax: +49 761 88889 – 830
www.cellgenix.com - info@cellgenix.com