

Data Sheet: CellGro® / CellGenix™
**GMP Recombinant Human Granulocyte Macrophage-
Colony Stimulating Factor (rh GM-CSF)**
Order No.: 1012-050

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>
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 end of production (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 Coomassie staining
Endotoxin level	< 1000 EU/mg, as determined by LAL gel clot test according to Ph.Eur.; typically < 100 EU/mg
Residual host-cell DNA	≤ 200 ng/mg, as determined by a fluorimetric assay
Activity	0.5x10 ⁷ – 2.0x10 ⁷ IU/mg calibrated with the 1 st International Standard NIBSC, # 88/646 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)
Sterility	Sterility test according to Ph.Eur. of the vial 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 ± 7.5 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 or below. Avoid repeated freeze-thaw cycles
Shelf life	Minimum 6 months from date of shipping
Intended use	For clinical ex vivo use. Not intended for human in vivo application
Quality statement	This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. No animal- or human-derived materials were used during manufacturing. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered products” has been considered in the design of this product.

Manufacturer

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