

## Data Sheet

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

Order No.: 1012-050 (50 µg), 1012-1000 (1000 µg)

## Product Characteristics

Source	<i>E. coli</i>
Description	Human GM-CSF, accession # P04141, Ala 18-Glu144 Molecular mass 14.5 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution in 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 further manufacturing use.

## Quality Parameters

Identity	Confirmed by DNA-sequencing of the expression plasmid in end-of-production cells and N-terminal sequencing of the final product
Activity	8 - 14 x 10 <sup>6</sup> IU /mg calibrated against NIBSC #88/646 Measured in a cell proliferation assay using a GM-CSF-dependent cell line, TF1
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 10 % oligomers as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	≤ 200 ng/mg, as determined with a fluorimetric assay
Host-cell protein	≤ 1.0 µg/mg, as determined by ELISA
Endotoxin	≤ 50 EU/mg, as determined by LAL gel clot test according to Ph. Eur. and USP
Sterility	Sterility test according to Ph. Eur. and USP of the vial product
Mass per vial	<b>50 µg:</b> 43 - 57 µg, <b>1000 µg:</b> 900 - 1100 µg as determined by spectrophotometrical measurement
Animal-derived component-free	<b>ADCF Level 2:</b> 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

<b>Transport</b>	Ambient temperature. Please refer to Technote ( <a href="http://www.cellgenix.com">www.cellgenix.com</a> )
<b>Shelf life</b>	Minimum 6 months from date of shipping
<b>Storage &amp; Stability</b>	<p>Store lyophilized cytokine at -20 °C to -80 °C. Store a 250 µg/ml cytokine solution</p> <ul style="list-style-type: none"><li>• 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container.</li><li>• 4 months at -20 °C to -80 °C under sterile conditions after reconstitution. Store in 60 µl aliquots in polypropylene cryogenic vials.</li></ul> <p>Avoid repeated freeze/thaw cycles.</p>

## Handling Instructions

<b>Reconstitution</b>	Recommended in sterile water to a final concentration of 250 µg/ml for 50 µg vials or 500 µg/ml for 1000 µg vials.
<b>Dilution</b>	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

This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. 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). USP chapter <1043> has been considered in the design of this product. This product is compliant with Ph. Eur. general chapter 5.2.12 and ISO Technical Standard 20399.