

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

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| 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

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| 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 ⁶ 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 | 50 µg: 43 - 57 µg, 1000 µg: 900 - 1100 µg as determined by spectrophotometrical measurement |
| 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

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| Transport | Ambient temperature. Please refer to Technote (www.cellgenix.com) |
| Shelf life | Minimum 6 months from date of shipping |
| Storage & Stability | <p>Store lyophilized cytokine at -20 °C to -80 °C. Store a 250 µg/ml cytokine solution</p> <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. <p>Avoid repeated freeze/thaw cycles.</p> |

Handling Instructions

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| Reconstitution | Recommended in sterile water to a final concentration of 250 µg/ml for 50 µg vials or 500 µg/ml for 1000 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

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 20399:2022.