SARTORIUS

Product Datasheet

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

Product Information

CellGenix® Recombinant Human GM-CSF reliably supports the differentiation of CD14+ monocytes into mature dendritic cells (DCs). It is produced in our dedicated animal-free facility ensuring maximum safety for optimal use in ATMP manufacturing. 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).

Features and Benefits

- Seamless transition from early development to clinical stages with consistent product quality & performance
- Manufactured in compliance with applicable GMP guidelines and in accordance with USP Chapter <1043>, Ph. Eur. General Chapter 5.2.12 and ISO 20399:2022
- We offer expert regulatory support in all phases from development to post-approval to assist you in safely bringing your product to the market. Drug Master File filed FDA CBER (USA)

Application

Granulocyte-macrophage colony-stimulating factor (GM-CSF), also known as CSF2, is an important hematopoietic growth factor and immune modulator. It is produced by a variety of cell types including; T cells, macrophages, natural killer cells, endothelial cells and fibroblasts. Its' role is to promote neutrophil proliferation and maturation. GM-CSF is used in the cell and gene therapy space for its ability to promote DC differentiation and function as well as macrophage activity. It is considered a critical factor for the development of DC therapies.

Product Characteristics

Source	*E. coli*
Description	Human GM-CSF, accession # P04141, Ala18-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 10^6 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 vialed 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 *E. coli.*

Shipment and Storage

Transport	Ambient temperature. Please refer to Technical Note "Shipment of CellGenix® Preclinical and GMP Cytokines at Ambient Temperatures".
Shelf Life	Minimum 6 months from date of shipping
Storage and Stability	Store lyophilized cytokine at -20 °C to -80 °C. Store a 250 µg/mL cytokine solution ▪ 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 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.

Packaging

CellGenix® cytokines are provided in glass vials, closed with vacuum rubber stoppers and sealed with aluminum tear off caps. The following material is used:

Glass vials
For 50 µg vials: Glass vials (2 mL; colorless; 35.00 x 13.75 mm) with DIN Crimp Neck N13-2 made from borosilicate glass hydrolytic type I (in compliance with Ph. Eur. 3.2.1 and USP <660> glass containers for pharmaceutical use).

For 1 mg vials: Glass vials (6 mL; colorless; 40.00 x 22.00 mm) with DIN Crimp Neck N20 made from borosilicate glass hydrolytic type I (in compliance with Ph. Eur. 3.2.1 and USP <660> glass containers for pharmaceutical use).

Vacuum rubber stoppers, Type I butyl rubber
The formulation is 4023/50/grey. This corresponds to bromobutyl rubber with a hardness of 50 (hardness measured in shore A). This is compliant with Ph. Eur. 3.2.9 Type 1 and with the physicochemical tests as described in USP General Chapter <381> "Elastomeric Closures for Injections".

Aluminum tear off caps
Aluminum tear off caps (13 mm; gold) are produced in accordance to valid quality criteria for metal caps.

The container closure has been validated after a storage period of up to 5 years at -80 °C by verification of sterility. In addition, the container closure has been demonstrated according to USP <671>.

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
CellGenix® GMP rh GM-CSF	50 µg	-20 °C to - 80 °C	1012-050
CellGenix® GMP rh GM-CSF	1 mg	-20 °C to - 80 °C	1012-1000

Sartorius is Your Reliable Supply Partner

High-quality raw materials are essential to ensure safety, efficacy and batch-to-batch consistency. We propose premium-grade raw materials suitable from preclinical development to the manufacturing of the therapy. Our GMP grade products allow for the safe use in clinical trials and commercial manufacturing.

Our GMP cytokines include documented evidence of lot specific sterility, activity, and shelf-life. Our experts will help simplify your raw material qualification and validation efforts. We provide customized solutions to your enquiries, as well as quality control services to ensure the quality of our products. Our regulatory expertise guarantees a suited service to your regulatory procedures, ensuring an extensive support every step of the process.

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