

CellGenix® GMP Recombinant Human Tumor Necrosis Factor-alpha (rh TNF-α)



Product Information

CellGenix® Recombinant Human TNF-α reliably stimulates the maturation of immature dendritic cells (DCs). CellGenix® rh TNF-α is produced in our dedicated animal-free GMP facility ensuring maximum safety for optimal use in ATMP manufacturing. 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 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.

Application

Tumor necrosis factor alpha (TNF- α) is a cytokine that plays a central role in inflammation, immune system development, apoptosis, and lipid metabolism. It is mainly produced by monocytes and macrophages as a response to infection, injury, or tumor burden. TNF- α can also be produced from a range of other cell types such as T cells, natural killer cells (NK cells) and neutrophils.

CellGenix® TNF- α is used in the cell and gene therapy space for the *ex vivo* maturation of immature DCs.

Product Characteristics

Source	<i>E. coli</i>
Description	Human TNF-alpha, accession # P01375, Val77-Leu233 N-terminal Met Molecular mass 17.5 kDa
Formulation	Lyophilized from a 0.2 μ m-filtered solution containing 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	20-80 x 10 ⁶ IU/mg calibrated against current NIBSC reference standard Measured in a cell cytotoxicity assay using a TNF- α -sensitive cell line, L929
Purity	\geq 97%, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	\leq 10% oligomers as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	\leq 200 ng/mg, as determined with a fluorimetric assay
Host-cell protein	\leq 1.0 μ g/mg, as determined by ELISA
Endotoxin	\leq 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	43-57 μ g, 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 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. <ul style="list-style-type: none">Store a 250 μg/mL reconstituted cytokine solution for 4 weeks at 2°C to 8°C under sterile conditions after reconstitution. Store in the original container.Store a 100 μg/mL reconstituted cytokine solution for 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
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).

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".

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
CellGenix® GMP rh TNF-α	50 µg	-20 °C to -80 °C	1006-050

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>.

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.

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

Sartorius CellGenix GmbH
Am Flughafen 16
79108 Freiburg
Phone +49 761 88889 0
Fax + 49 761 88889 830
info-freiburg@sartorius.com

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178



For more information, visit

[sartorius.com](https://www.sartorius.com)