

CellGenix® GMP Recombinant Human Transforming Growth Factor-beta 1 (rh TGF-β1)



Product Information

CellGenix® Recombinant Human TGF-β1 reliably promotes the expansion of induced pluripotent stem cells (iPSC), embryonic stem cells (ESC), mesenchymal stem cells (MSC) as well as regulatory T cells (Tregs). It also stimulates the differentiation of T cells into Tregs.

CellGenix® Recombinant Human TGF-β1 is produced using a human amniocyte cell line (CAP®). By using the CAP® technology we are able to produce this difficult to express glyco-protein with authentic human post-translational modifications. These human post-translational modifications are not accessible by bacterial expression.

No animal or human-derived components are present in the final product, and with the exception of the production cell line, no animal or human-derived materials were used in production (ADCF Level 1). The production cell line was derived from a human amniocyte cell line (CAP®) and was characterized following ICH Guidelines Q5A and Q5D. For the originating CAP® cell bank a Biologics Master File (BB-MF) was submitted to the U.S. Food and Drug Administration (FDA).

Features and Benefits

- Native folding & glycosylation: expressed in human CAP® cells
- Safe and ADCF: CAP® cell line extensively characterized and tested for viruses
- 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

Transforming Growth Factor-beta 1 (TGF-β1) is a member of the growth factor beta superfamily and plays a role in various cellular functions like cell differentiation, proliferation and apoptosis. It is secreted by most immune cells and especially interacts with T cells, B cells, macrophages and monocytes.

TGF-β1 is used in the cell and gene therapy space to promote expansion of iPSC, ESC, MSC and Tregs.

Product Characteristics

Source	Human amniocyte cell line (CAP® ¹)
Description	Human Transforming Growth Factor-beta 1, accession # P01137, Ala279-Ser390 Molecular mass 25.6 kDa per homodimer
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 1% Mannitol
Intended use	For further manufacturing use

¹CAP® is a registered trademark of CEVEC Pharmaceuticals GmbH, Germany.

Quality Parameters

Identity	Confirmed by Immunoblotting and N-terminal sequencing of the final product.
Activity	9 - 36 x 10 ⁶ IU/mg calibrated against NIBSC #89/514 Measured in a cell proliferation assay using a TGF-β1-dependent cell line, HT2 clone A5E
Purity	≥ 97%, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 5%, as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	≤ 20 ng/mg, as determined by qPCR
Endotoxin	≤ 10 EU/mg, as determined by LAL gel clot test according to Ph. Eur. and USP
Mycoplasma	No mycoplasma detected, as determined by qPCR according to Ph. Eur.
Sterility	Sterility test according to Ph. Eur. and USP of the vial product
Mass per vial	≥ 43 µg, as determined by spectrophotometrical measurement
Animal-derived component-free	ADCF Level 1: The final product contains neither animal- nor human-derived materials. Please refer to Technical Note "Animal-Derived Component-Free Policy CellGenix® Preclinical and GMP Cytokines".

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. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 µg/mL (for 50 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).

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 TGF-β1	50 µg	-20 °C to -80 °C	1026-050

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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