CellGenix
Now part of Sartorius

Data Sheet

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

Order No.: 1026-050 (50 µg)

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.

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 vialed 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.

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

HQ: Sartorius CellGenix GmbH | Am Flughafen 16 | 79108 Freiburg | GERMANY | Phone +49 761 888 89-0 | Fax +49 761 888 89-830
US: CellGenix Inc. | One New Hampshire Avenue, Suite 125 | Portsmouth, NH 03801 | USA | Phone +1 603 373 0408 | Fax +1 603 373 8104
www.cellgenix.com | info@cellgenix.com

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Shelf life	Minimum 6 months from date of shipping
Storage & 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.

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 with the exception of the production cell line, no animal or human-derived materials were used in production (ADCF Level 1). USP chapter <1043> has been considered in the design of this product. This product is compliant with the Ph. Eur. general chapter 5.2.12 and ISO 20399:2022.
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).

ZY-DS-1026d | 01/2023

HQ: Sartorius CellGenix GmbH | Am Flughafen 16 | 79108 Freiburg | GERMANY | Phone +49 761 888 89-0 | Fax +49 761 888 89-830
US: CellGenix Inc. | One New Hampshire Avenue, Suite 125 | Portsmouth, NH 03801 | USA | Phone +1 603 373 0408 | Fax +1 603 373 8104
www.cellgenix.com | info@cellgenix.com