SARTORIUS

Product Datasheet

CellGenix® GMP T Cell Medium (TCM)

Xeno-Free, Serum-Free Media

Product Information

CellGenix® GMP TCM is a xeno-free medium optimized for the cultivation and expansion of T cells with no need to add serum. It generates highly functional CAR-T cells and promotes an early-memory phenotype. It is suitable for static and stirred bioreactor systems and supports the expansion of $CD4^+$ and $CD8^+$ T cells.

CellGenix® GMP TCM is produced following applicable GMP guidelines and allows for the safe use in accordance with USP Chapter <1043> and ISO 20399:2022. The formulation does not contain animal derived components (xeno-free).

Features and Benefits

- Xeno-free and serum-free medium
- Generates T cell therapy products with an early-memory T cell phenotype
- Supports expansion of $CD4^+$ and $CD8^+$ T cells
- Drug Master File filed FDA CBER (USA)
- Designed following the recommendations of USP <1043> on ancillary materials
- Available in bottle and bag, without Phenol Red

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

- Serum-free expansion and cultivation of human T cells
- Promotes highly functional CAR-T cells
- Can be used in static and simple stirred bioreactors

Product Characteristics

Main components
Salts, sugars, amino acids, vitamins, buffers.

Human proteins
Our media products contain human-derived components. These components present no apparent health hazard and are compliant with the currently valid note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01). When available and applicable, pharmaceutical grade materials are used. The relevant safety aspects as defined in USP <1043> have been considered for our products.

Human protein has been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods according to US and European regulations (HIV1/HIV2, HBV, HCV and less than 10^4 IU/mL for Parvovirus B19).

All materials used in production are formally approved by QM. As part of the raw material control they are procured from reliable manufacturers and suppliers and their animal- or human origin is assessed before use.

Albumin: human plasma-derived, complies with Ph. Eur. and USP. The HSA is manufactured, tested and released according to the current GMP requirements and the current Ph. Eur.

Insulin: human recombinant, yeast-derived, complies with Ph. Eur. and USP.

Transferrin: human recombinant, rice-derived. The transferrin is manufactured according to the current GMP requirements.

Intended use
For Further Manufacturing Use

Quality Parameters

Appearance	Clear, light yellow liquid
pH	7.2 -7.5, determined according to Ph. Eur. 2.2.3
Osmolality	280 – 320 mOsm/kg, determined according to Ph. Eur. 2.2.35
Bioassay	Expansion of primary human $CD3^+$ T cells
Endotoxin	≤ 0.5 EU/ml, determined according to Ph. Eur.
Mycoplasma	Not detectable, determined according to Ph. Eur.
Sterility	Sterility test of the final product, determined according to Ph. Eur.

Shipment and Storage

Transport	Ambient temperature
Shelf Life	24 month from date of production Minimum 6 month from date of shipping
Storage	Store at +2 to +8 °C. Protect from light. Do not freeze to maintain integrity

Packaging

Bottle	
Material of bottle	Polyethylene Terephthalate (PET), classified USP Class VI
Material of bottle top	High-Density Polyethylene (HDPE), classified USP Class VI

Flexboy Bag	
Material of bag chamber	Ethylene-Vinyl Acetate (EVA) with a core layer of Ethyl Vinyl Alcohol (EVOH) as gas barrier, classified USP Class VI
Material of bag tubing	Ethylene-Vinyl Acetate (EVA), Silicone, PVC (DEHP-free, suitable for sterile welding), classified USP Class VI
Ports	1x Male Luer Lock Port ⅛", 1x Female Luer Lock Port ⅜" with 1x Clave® Connector, 1x filling port (exclusively used for filling the media into the bag during the manufacturing process)

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
CellGenix® GMP TCM w/o phenol red	500 mL Bottle	2 – 8 °C	20814-0500
CellGenix® GMP TCM w/o phenol red	1000 mL Bag	2 – 8 °C	20914-1000

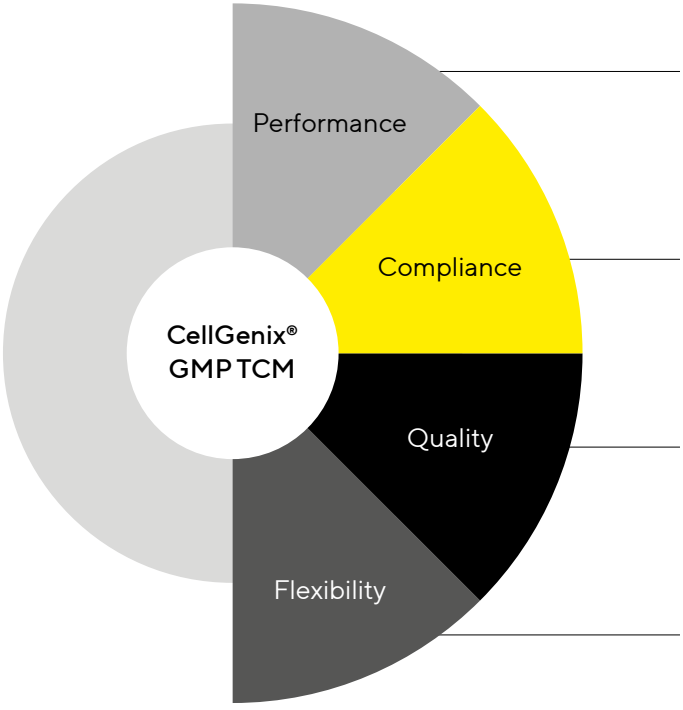
Sartorius is Your Reliable Supply Partner

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 Media 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.

We also offer the cytokines and growth-factors needed for optimal growth of T cells. This gives you the freedom to customize and create your own optimal cytokine mixture. To fit different cell and gene therapy manufacturing processes, we conveniently offer our media in bottles and bags.



- Highly efficient fold expansion
- Promotes an early-differentiated phenotype

- Manufactured in accordance with the applicable GMP guidelines
- Quality System ISO 9001:2015 certified
- US DMF available

- Xeno- and Serum-free
- Documented evidence of purity, potency, consistency and stability
- High batch to batch consistency

- Available in different packages and volumes to satisfy all needs

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

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