SARTORIUS

Product Datasheet

CellGenix® GMP Stem Cell Growth Medium (SCGM)

Xeno-Free, Serum-Free Media

Product Information

CellGenix® GMP SCGM is an optimized, xeno-free medium used for the serum-free expansion of low numbers of isolated human hematopoietic stem and progenitor cells (HSCs/CD34$^+$ cells). In addition, our SCGM has proven to be highly efficient for the expansion and cultivation of human natural killer cells (NK cells) and human cytokine induced killer cells (CIK cells).

CellGenix® GMP SCGM 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
- Reliable and consistent cultivation of HSCs and NK cells
- Drug Master File filed FDA CBER (USA) and PMDA (Japan)
- Designed following the recommendations of USP <1043> on ancillary materials
- Available in bottles and bags, with and 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

CellGenix® GMP SCGM is widely used for the standardized generation of autologous and allogeneic cell and gene therapies using HS, NK or CIK cells. Some clinical applications include: serum-free cultivation of HSCs, expansion and differentiation of NK cells, expansion and differentiation of CIK cells as well as generation of retroviral and lentiviral vector-producing cells.

Product Characteristics

Main components
Salts, sugars, amino acids, vitamins, buffers. Contains phenol red (in the Phenol Red version), β-Mercaptoethanol and L-glutamine.

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 or European regulations (HIV1/HIV2, HBV, HCV, and 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: the plasma used in the manufacture of HSA complies with the requirements of the Ph. Eur. Monograph "Human Plasma for Fractionation" (0853) and European regulations. The HSA is manufactured, tested, and released according to the current GMP requirements and the current Ph. Eur. The HSA manufacturer complies with directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

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

Intended use
For Further Manufacturing Use

Quality Parameters

Appearance	Clear and red liquid (with phenol red). Clear and colorless to light yellow liquid (without phenol red)
pH	7.2 – 7.5, determined according to Ph. Eur.
Osmolality	290 – 350 mOsm/kg H_2O, determined according to Ph. Eur.
Bioassay	Expansion of human $CD34^+$ cells
Endotoxin	≤ 1 EU/ml, determined according to Ph. Eur.
Mycoplasma	Not detected, 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. Light protection recommended

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 SCGM	500 mL Bottle	2–8 °C	20802-0500
CellGenix® GMP SCGM	500 mL Bag	2–8 °C	20902-0500
CellGenix® GMP SCGM w/o phenol red	500 mL Bottle	2–8 °C	20806-0500
CellGenix® GMP SCGM w/o phenol red	500 mL Bag	2–8 °C	20906-0500

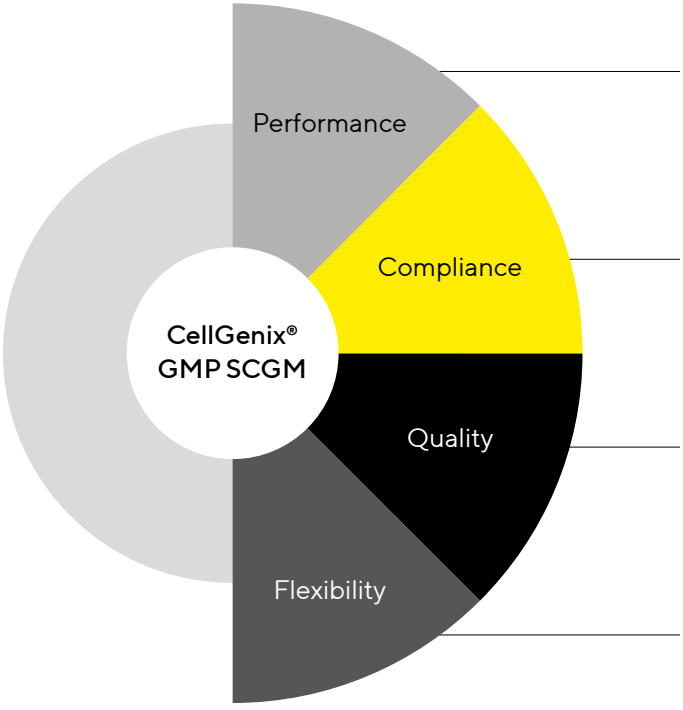
Sartorius is Your Reliable Supply Partner

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 HSC, NK cells and CIK 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 our media in bottles and bags.



- Highly efficient fold expansion
- Excellent % cell viability and % of human $CD34^+$ $CD45^+$ cells expression

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

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