SARTORIUS

Product Datasheet

CellGenix® GMP Dendritic Cell Medium (DC)

Xeno-Free, Serum-Free Media

Product Information

CellGenix® GMP DC is an optimized, serum-free and xeno-free medium used for the generation of human dendritic cells (DCs). It promotes high yields of mature dendritic cells with the desired phenotype.

CellGenix® GMP DC 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
- Optimized formulation for the generation of DCs
- Drug Master File filed FDA CBER (USA)
- 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 DC is optimized for the differentiation of $CD14^+$ monocytes into mature DCs.

- Differentiation of $CD14^+$ monocytes into DCs
- Differentiation of $CD14^+$ monocytes into macrophages

Product Characteristics

Main components
Salts, sugars, amino acids, vitamins, buffers. Contains phenol red (in the Phenol Red version) 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 proteins have 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.

Transferrin: human plasma-derived.

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.

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	260 – 320 mOsm/kg H_2O, determined according to Ph. Eur.
Bioassay	Generation of human dendritic cells from $CD14^+$ monocytes
Endotoxin	≤ 1 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	36 month from date of production. Minimum 6 month from date of shipping
Storage	Store at +2 to +8 °C. Light protection is recommended

Packaging

Bottle	
Material of bottle	Copolymer PET (Polyethylene Terephthalate), Food Grade Certification
Material of bottle top	High-Density Polyethylene (HDPE), Food Grade Certification

Flexboy Bag	
Material	Ethylene-Vinyl Acetate (EVA)
Material Tubing	Ethylene-Vinyl Acetate (EVA) + Thermoplastic Elastomers (TPE), Classified USP Class VI
Ports	1x MPC Coupling ¼" with Sealing Cap (exclusively used for filling the media into the bag during the manufacturing process); 1x Male Luer Lock Port ¼"; 1x Female Luer Lock Port ⅜" with 1x Clave Connector

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
CellGenix® GMP DC	500 mL Bottle	2 – 8 °C	20801-0500
CellGenix® GMP DC	500 mL Bag	2 – 8 °C	20901-0500
CellGenix® GMP DC w/o phenol red	500 mL Bottle	2 – 8 °C	20805-0500
CellGenix® GMP DC w/o phenol red	500 mL Bag	2 – 8 °C	20905-0500

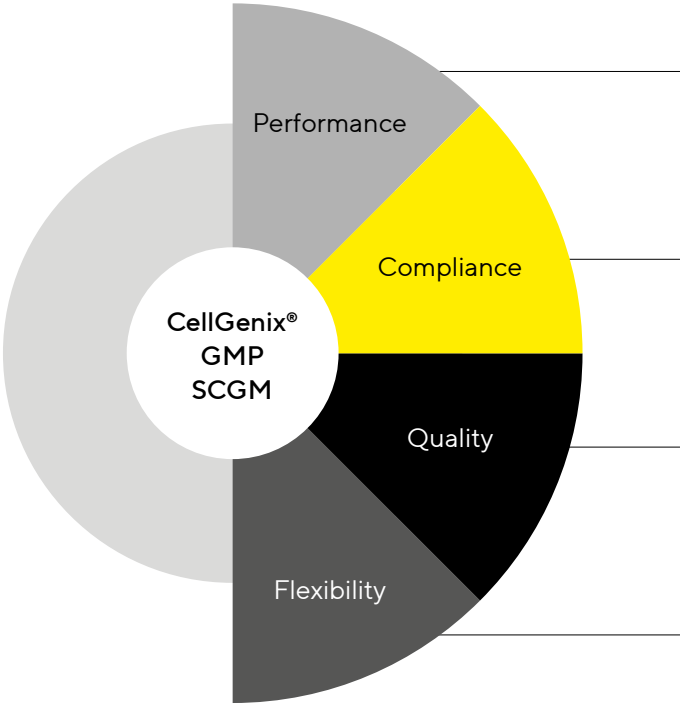
Sartorius is Your Reliable Supply Partner

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 dendritic 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 bags or bottles.



- Highly efficient fold expansion
- Achieve high yields of mature dendritic cells with the desired 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

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