

Data Sheet

CellGenix® GMP Stem Cell Growth Medium (SCGM), Serum-free, Xeno-free
 Order No.: 20802-0500 (500 ml bottle), 20902-0500 (500 ml bag)

Product Characteristics

Main components	Salts, sugars, amino acids, vitamins, buffers Contains phenol red, β-Mercaptoethanol, and L-glutamine
Human proteins	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.
Application	Cultivation of hematopoietic stem and progenitor cells, expansion and differentiation of NK-cells
Intended use	For further manufacturing use.

Quality Parameters

Appearance	Clear, red liquid
pH	7.2 -7.5, determined according to Ph. Eur.
Osmolality	290 – 350 mOsm/kg H ₂ O, determined according to Ph. Eur.
Bioassay	Expansion of human CD34 ⁺ cells
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 & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com).
Shelf life	2 years from date of production. Minimum 6 months from date of shipping.
Storage	Store at +2 °C to +8 °C. Light protection is recommended.

Quality Statement

This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. USP chapter <1043> has been considered in the design of this product. This product is compliant with ISO 20399:2022. The formulation does not contain animal derived components (xeno-free).

Human Albumin 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 (HIV1/HIV2, HBV, HCV, Parvovirus B19).