



DATA SHEET

GMP Serum-free Stem Cell Growth Medium (SCGM)

Xeno-free

Order No.: 20802-0500 and 20802-0100 (bottle), 20902-0500 (bag)

Main components	Salts, Sugars, Amino Acids, Vitamins, Buffers Contains phenol-red (pH-indicator) Contains L-glutamine, β -Mercaptoethanol
Human proteins	Albumin (human-plasma-derived, licensed medicinal product for human use, Ph. Eur.) Insulin (human recombinant, yeast-derived, Ph.Eur., USP)
Applications	<ul style="list-style-type: none">• Cultivation of hematopoietic stem and progenitor cells• Expansion of NK-cells
Release specifications:	
Osmolality	290 – 350 (mOsm/kg H ₂ O), determined according to Ph.Eur.
pH	7.2 – 7.5, determined according to Ph.Eur.
Endotoxin	\leq 1 EU/ml, determined according to Ph.Eur.
Sterility	Sterility test of the final product determined according to Ph.Eur.
Functionality assay	Expansion of human CD34 ⁺ cells
Mycoplasma	Mycoplasma PCR-test of Vero cells, according to Ph.Eur.
Appearance	Clear, red liquid
Transport	Ambient temperature
Storage at	+2°C to +8°C. Light protection recommended
Shelf life	2 years from date of production Minimum 6 months from date of shipping
Intended use	For clinical ex vivo use. Not intended for human in vivo application.
Quality and raw material statement	<p>This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. USP chapter <1043> "ancillary materials for cell, gene, and tissue-engineered products" has been considered in the design of this product. The formulation does not contain animal derived components (xeno-free).</p> <p>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 (HIV1/HIV2, HBV, HCV, Parvovirus B19).</p>