

Data Sheet

CellGenix® GMP Stem Cell Growth Medium (SCGM), Serum-free, w/o Phenol Red, Xeno-free

Order No.: 20806-0500 (500ml bottle), 20906-0500 (500ml bag)

Product Characteristics

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|------------------------|--|
| Main components | Salts, sugars, amino acids, vitamins, buffers Contains β -Mercaptoethanol and L-glutamine |
| Human proteins | Albumin (human plasma-derived, licensed medicinal product for human use, complies with Ph. Eur.), 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 clinical <i>ex vivo</i> use. Not intended for human <i>in vivo</i> application. |

Quality Parameters

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|-------------------|---|
| Osmolality | 290 – 350 mOsm/kg H ₂ O, determined according to Ph. Eur. |
| pH | 7.2 -7.5, determined according to Ph. Eur. |
| Endotoxin | ≤ 1 EU/ml, determined according to Ph. Eur. |
| Sterility | Sterility test of the final product, determined according to Ph. Eur. |
| Bioassay | Expansion of human CD34 ⁺ cells |
| Mycoplasma | Not detectable, determined according to Ph. Eur. |
| Appearance | Clear, colorless liquid |

Shipment & Storage

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|------------------|---|
| Transport | Ambient temperature. Please refer to Technote (www.cellgenix.com). |
| Expiry | 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. 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).