

Data Sheet

CellGenix® T Cell Medium (TCM) GMP-Prototype

Serum-free, Xeno-free

Order No.: 24814-0500 (500 ml bottle)

Product Characteristics

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|-----------------|---|
| Main components | Salts, sugars, amino acids, vitamins, buffers |
| Human proteins | Albumin (human plasma-derived, complies with Ph. Eur. and USP), Insulin (human recombinant, yeast-derived, complies with Ph. Eur. and USP), Transferrin (human recombinant, rice-derived) |
| Application | Serum-free <i>ex vivo</i> cultivation of human T cells |
| Intended use | For preclinical <i>ex vivo</i> use. Not intended for therapeutic use. |

Quality Parameters

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|------------|---|
| Appearance | Clear, light yellow liquid |
| pH | 6.9 -7.3, determined according to Ph. Eur. 2.2.3 |
| Osmolality | 0.280 – 0.320 Osm/kg, determined according to Ph. Eur. 2.2.35 |
| Bioassay | <i>Ex vivo</i> -culture of primary human CD3 ⁺ T cells |
| Endotoxin | ≤ 0.5 EU/ml, determined according to Ph. Eur. 2.6.14 |
| Mycoplasma | Not detectable, determined according to Ph. Eur. 2.6.7 and 2.6.21 |
| Sterility | Sterility test of the final product, determined according to Ph. Eur. 2.6.1 |

Shipment & Storage

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| Transport | Ambient temperature. |
| Shelf life | 1 year from date of production. |
| Storage | Store at +2 °C to +8 °C. Store protected from light. NOTICE: Do not freeze to maintain integrity. |

Quality Statement

USP chapter <1043> has been considered in the design of this product. This product is compliant with ISO Technical Standard 20399. The formulation does not contain animal-derived components (xeno-free).

HSA 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 and European regulations (HIV1/HIV2, HBV, HCV)