

Data Sheet

CellGenix® T Cell Medium (TCM) GMP-Prototype

Serum-free, Xeno-free

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

Product Characteristics

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

Appearance	Clear, light yellow liquid
pH	7.2 -7.5, 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

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)