

Data Sheet

CellGenix® GMP T Cell Medium (TCM)

Serum-free, Xeno-free

Order No.: 20814-0500 (500 ml bottle), 20914-1000 (1000 ml bag)

Product Characteristics

Main components	Salts, sugars, amino acids, vitamins, buffers
Human proteins	<p>Albumin: human plasma-derived, complies with Ph. Eur. and USP. The HSA is manufactured, tested and released according to the current GMP requirements and the current Ph. Eur.</p> <p>Insulin: human recombinant, yeast-derived, complies with Ph. Eur. and USP.</p> <p>Transferrin: human recombinant, rice-derived. The transferrin is manufactured according to the current GMP requirements.</p>
Application	Serum-free ex vivo cultivation of human T cells.
Intended use	For further manufacturing use.

Quality Parameters

Appearance	Clear, light yellow liquid
pH	7.2 -7.5, determined according to Ph. Eur. 2.2.3
Osmolality	280 – 320 mOsm/kg, determined according to Ph. Eur. 2.2.35
Bioassay	Expansion of primary human CD3 ⁺ T cells
Endotoxin	≤ 0.5 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	24 months from date of production. Minimum 6 months from date of shipping.
Storage	Store at +2 °C to +8 °C. Protect from light. Do not freeze to maintain integrity.

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).