

Data Sheet

CellGenix® GMP Dendritic Cell Medium (DC), Serum-free, w/o Phenol Red

Order No.: 20805-0500 (500ml bottle), 20905-0500 (500ml bag)

Product Characteristics

Main components	Salts, sugars, amino acids, vitamins, buffers Contains L-glutamine
Human proteins	Transferrin (human plasma-derived), 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	Generation of dendritic cells
Intended use	For clinical <i>ex vivo</i> use. Not intended for human <i>in vivo</i> application.

Quality Parameters

Osmolality	260 - 320 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	Generation of human dendritic cells from CD14 ⁺ monocytes
Mycoplasma	Not detectable, determined according to Ph. Eur.
Appearance	Clear, colorless liquid

Shipment & Storage

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. Apart from one exception, the formulation does not contain animal derived components. (A synthetic lipid mixture contains chicken egg-derived lecithin. This lipid mixture is a licensed medicinal product for human use.)

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).