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 ex vivo use. Not intended for human in vivo 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).