

Data Sheet

CellGenix® GMP Recombinant Human Interleukin-10 (rh IL-10)

Order No.: 1014-050 (50 µg)

Product Characteristics

Source	<i>E. coli</i>
Description	Human Interleukin-10, accession # P22301, Ser19-Asn178 N-terminal Met and C-terminal 6xHis-tag Molecular mass 19.6 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 1.5 mM potassium phosphate, 8.1 mM sodium phosphate, 2.7 mM potassium chloride and 137 mM sodium chloride, pH 7.5.
Intended use	For clinical <i>ex vivo</i> use. Not intended for human <i>in vivo</i> application.

Quality Parameters

Identity	Confirmed by DNA-sequencing of the expression plasmid in end-of-production cells and N-terminal sequencing of the final product
Activity	3 - 50 x 10 ⁶ IU/mg calibrated against NIBSC #93/722 Measured in a cell proliferation assay using an IL-10-dependent cell line, MC/9
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 10 % oligomers, as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	≤ 200 ng/mg, as determined with the Threshold® system ¹
Host-cell protein	≤ 1.0 µg/mg, as determined by ELISA
Endotoxin	≤ 50 EU/mg, as determined by LAL gel clot test according to Ph. Eur. and USP
Sterility	Sterility test according to Ph. Eur. and USP of the vial product (direct inoculation)
Mass per vial	43 - 57 µg, as determined by spectrophotometrical measurement
Animal-derived component-free	ADCF Level 2: The final product contains neither animal- nor human-derived materials. ADCF Level 2 cytokines are produced in our dedicated animal-free facility. No animal-derived components are used throughout the complete production process. All ADCF Level 2 cytokines are produced in <i>E. coli</i> .

¹ Threshold® System is a trademark of Molecular Devices, Inc.

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Expiry	Minimum 6 months from date of shipping
Storage & Stability	Store lyophilized cytokine at -20°C to -80°C. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 µg/ml.
Dilution	Recommended in CellGenix® serum-free media. For dilution with protein free medium, a carrier protein (0.1-1 % albumin or 1-10 % appropriate serum) has to be included. Failure to dilute product according to these instructions may result in loss of activity.

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 Ph. Eur. general chapter 5.2.12.