

Data Sheet

CellGenix® GMP Recombinant Human Interleukin-6 (rh IL-6)

Order No.: 1004-050 (50 µg), 1004-1000 (1000 µg)

Product Characteristics

Source	<i>E. coli</i>
Description	Human Interleukin-6, accession # P05231, Pro29-Met212 N-terminal Met and C-terminal 6xHis-tag Molecular mass 21.9 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 further manufacturing use.

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	80 - 250 x 10 ⁶ IU /mg calibrated against NIBSC #89/548 Measured in a cell proliferation assay using an IL-6-dependent cell line, B9
Purity	≥ 98 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 15 % oligomers as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	≤ 200 ng/mg, as determined with a fluorimetric assay
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
Mass per vial	50 µg: 43 - 57 µg, 1000 µg: 900 - 1100 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> .

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Shelf life	Minimum 6 months from date of shipping
Storage & Stability	<p>Store lyophilized cytokine at -20 °C to -80 °C.</p> <p>Store a 100 µg/ml reconstituted cytokine solution:</p> <ul style="list-style-type: none">• 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container.• 4 months at -20 °C to -80 °C under sterile conditions after reconstitution. Store in 80 µl aliquots in polypropylene cryogenic vials. <p>Avoid repeated freeze/thaw cycles.</p>

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 µg/ml for 50 µg vials and for 1000 µg vials. We recommend to not vortex the solution. The solution can be turbid, this however does not influence the activity.
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. No animal- or human-derived components are present in the final product and no animal- or human-derived materials were used in production (ADCF Level 2). USP chapter <1043> has been considered in the design of this product. This product is compliant with Ph. Eur. general chapter 5.2.12 and ISO Technical Standard 20399.