

Data Sheet

CellGenix® GMP Recombinant Human Interleukin-4 (rh IL-4), USP grade Order No.: 1003-050 (50 µg), 1003-1000 (1000 µg)

Product Characteristics

Source	<i>E. coli</i>
Description	Human Interleukin-4, accession # P05112, His25-Ser153 N-terminal Met Molecular mass 15.1 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	8 - 14 x 10 ⁶ IU/mg ¹ calibrated against the NIBSC #88/656 Measured in a cell proliferation assay using an IL-4-dependent cell line, TF1
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by silver staining)
Product-related proteins	≤ 10 % oligomers as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by silver staining)
Host-cell DNA	≤ 1.0 ng/mg, as determined with the Threshold® system ² or qPCR
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> .

¹ USP units are equivalent to International Units per mg (IU/mg)

² Threshold® System is a trademark of Molecular Devices, Inc.

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Shelf life	Minimum 6 months from date of shipping
Storage & Stability	Store lyophilized cytokine at -20 °C to -80 °C. Store a 250 µg/ml cytokine solution <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 aliquots in polypropylene cryogenic vials. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 µg/ml for 50 µg vials or 500 µg/ml for 1000 µg vials.
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 USP chapter <92>, Ph. Eur. general chapter 5.2.12 and ISO 20399:2022.