

Data Sheet: CellGro® / CellGenix™**GMP Recombinant Human Interleukin-4 (rh IL-4), USP grade**

Order No.: 1003-050

Source	A DNA sequence encoding the mature IL-4 protein (Yakota, T. et al., 1986, PNAS 83:5894) was expressed in <i>E. coli</i>
Molecular mass	The methionyl form of the <i>E. coli</i> expressed mature human IL-4 contains 130 amino acid residues and has a molecular mass of 14 kDa
Identity	Confirmed by DNA-sequencing of the expression plasmid in end of production (EOP)-cells, Western Blot, and N-terminal sequencing of the final product
Purity	≥ 97%, as determined by SDS-PAGE (under reducing and non-reducing conditions) and visualized by Silver staining
Endotoxin level	< 50 EU/mg, as determined by LAL gel clot test according to Ph.Eur.
Residual host-cell DNA	≤ 1 ng/mg, as determined with the Threshold® system
Activity	0.5x10 ⁷ – 2x10 ⁷ USP units per mg ¹ Measured in a cell proliferation assay using a human factor-dependent cell line, TF-1 (Kitamura, T. et al., 1989, J. Cell Physiol. 140:323-334) ¹ USP units are equivalent to international units (IU)
Sterility	Sterility test according to Ph.Eur. of the vialled product (direct inoculation)
Formulation	Lyophilized from a 250 µm/ml, 0.2µm sterile-filtered solution in PBS without any carrier materials and preservatives
Amount per vial	50 ± 7.5 µg, as determined by spectrophotometrical measurement at 280 nm using PBS as reference (A ₂₈₀ = 0.63 for a concentration of 1 mg/ml IL-4 in PBS)
Transport	Ambient temperature
Storage at	-20°C or below. Avoid repeated freeze-thaw cycles
Shelf life	Minimum 6 months from date of shipping
Intended use	For clinical ex vivo use. Not intended for human in vivo application
Quality statement	This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. No animal- or human-derived materials were used during manufacturing. This product complies with USP chapter <92> “growth factors and cytokines used in cell therapy manufacturing”. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered products” has been considered in the design of this product.

Manufacturer

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