



Data Sheet: CellGro® / CellGenix™
Recombinant Human
Tumor Necrosis Factor alpha (TNF-α)
ex vivo grade - Order No.: 1006

Source	A DNA sequence encoding the mature TNF-α protein (Pennica, D. et al., 1984, Nature 312:724-729) was expressed in <i>E. coli</i>
Raw Material Statement	Produced without the use of animal derived components (ADCF)
Production	Produced under GMP conditions
Molecular Mass	The methionyl form of the <i>E. coli</i> expressed mature human TNF-α contains 158 amino acid residues and has a molecular mass of 17,5 kDa
Identity	Confirmed by DNA-sequencing of the expression plasmid in EOP-cells 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	< 0.1 ng per 1 µg (< 1000 EU/mg), as determined by LAL gel clot test according to Eur.Pharm.; typically < 0.01 ng per 1 µg (< 100 EU/mg)
Residual Host-Cell DNA	≤ 200 ng per 1 mg, as determined by a fluorimetric assay
Activity	Measured in a cell cytotoxicity assay using a murine factor-sensitive cell line, L-929, in the presence of the metabolic inhibitor actinomycin D (Bharat B.B., Methods Enzymol. 116, 1985, 441-448) ED50 is typically 0.01 – 0.05 ng/ml (8×10^7 – 2×10^7 IU/mg) calibrated with the 1 st International Standard NIBSC, # 87/650
Sterility	Sterility test according to Eur.Pharm. of the vialled product (direct inoculation)
Formulation	Lyophilized from a 250 µg/ml, 0.2µm-sterile-filtered solution in HEPES without any carrier materials and preservatives
Amount per Vial	50 ± 5 µg, as determined by spectrophotometrical measurement at 280 nm using HEPES as reference ($A_{280} = 1.62$ for a concentration of 1 mg/ml TNF-α in HEPES)
Transport	Ambient temperature
Storage at	-20°C to -80°C. Avoid repeated freeze-thaw cycles
Shelf life	2 years from date of production Minimum 6 months from date of shipping
Intended Use	For research or clinical ex vivo cell culture use only. Not intended for human in vivo application.

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