

Data Sheet

CellGenix® GMP Recombinant Human Fibroblast Growth Factor-2 (rh FGF-2)

Order No.: 1021-050 (50 µg), 1021-1000 (1000 µg)

Product Characteristics

Source	<i>E. coli</i>
Description	Human FGF-2, accession # P09038, Ala135-Ser288 N-terminal Met Molecular mass 17.3 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 25 mM sodium phosphate, 400 mM sodium chloride, 10 mM glutathione (red.) and 5 % mannitol, pH 6.5
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	0.9 – 3.6 x 10 ⁶ IU /mg calibrated against NIBSC #90/712 Measured in a cell proliferation assay using a FGF-2-dependent cell line, FBHE
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing conditions, visualized by Coomassie staining) and RP-HPLC
Product-related proteins	≤ 20 % oligomers, as determined by SDS-PAGE (under reducing conditions, visualized by Coomassie staining) and ≤ 20 % oxidized species, as determined by RP-HPLC
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 (direct inoculation)
Mass per vial	50 µg: 43 – 57 µg, 1000 µg: 900 – 1100 µg as determined by spectrophotometrical measurement
Animal-derived component-free	ADCF Level 1: The final product contains neither animal- nor human-derived materials.

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. Store a 250 µg/ml cytokine solution <ul style="list-style-type: none">• 4 months at -20°C to -80°C under sterile conditions after reconstitution. Store in 60 µl aliquots in polypropylene cryogenic vials. <i>(optional)</i> 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.