

## 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 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	0.9 – 3.6 x 10 <sup>6</sup> 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
Mass per vial	<b>50 µg:</b> 43 – 57 µg, <b>1000 µg:</b> 900 – 1100 µg as determined by spectrophotometrical measurement
Animal-derived component-free	<b>ADCF Level 1:</b> The final product contains neither animal- nor human-derived materials.

## Shipment & Storage

Transport	Ambient temperature. Please refer to Technote ( <a href="http://www.cellgenix.com">www.cellgenix.com</a> )
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"><li>• 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></li></ul> 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 (ADCF Level 1). 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 20399:2022.