

Data Sheet: CellGro[®] / CellGenix[™]**GMP Recombinant Human basic Fibroblast Growth Factor****(rh bFGF, rh FGF-2)**

Order No.: 1008-050

Source	A DNA sequence encoding the natural 18 kDa variant of bFGF was expressed in <i>E. coli</i>
Molecular mass	The methionyl form of the <i>E. coli</i> expressed mature human bFGF contains 161 amino acid residues (including a C-terminal His6-tag) and has a molecular mass of 18 kDa
Identity	Confirmed by DNA-sequencing of the expression plasmid in end of production (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	< 1000 EU/mg, as determined by LAL gel clot test according to Ph.Eur.; typically < 100 EU/mg
Residual host-cell DNA	≤ 200 ng/mg, as determined by a fluorimetric assay
Activity	0.6-2.4x10 ⁶ IU/mg calibrated with the 1 st International Standard NIBSC, # 90/712 Measured in a cell proliferation assay using a bovine factor-dependent cell line, FBHE
Sterility	Sterility test according to Ph.Eur. of the vialled product (direct inoculation)
Formulation	Lyophilized from a 250 µg/ml, 0.2 µm sterile-filtered solution without carrier protein
Amount per vial	50 ± 5 µg, as determined by spectrophotometrical measurement at 280 nm using formulation buffer as reference ($A_{280} = 0.88$ for a concentration of 1 mg/ml bFGF in formulation buffer)
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. Contains no animal or human derived materials. 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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