SARTORIUS

Product Datasheet

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

Product Information

CellGenix® Recombinant Human FGF-2, also known as bFGF, reliable improves proliferation of mesenchymal stem cells (MSCs). In addition, it supports proliferation and differentiation of chondrocytes and supports propagation of undifferentiated pluripotent stem cells (PSCs). Final manufacturing steps and QC are performed in a GMP facility. No animal- or human-derived components are present in the final product (ADCF Level 1).

Features and Benefits

- Seamless transition from early development to clinical stages with consistent product quality & performance

Application

Fibroblast Growth Factor-2 (FGF-2) is a basic fibroblast growth factor. It amongst others plays an important role in wound healing and tumor development by mediating the formation of new blood vessels.

FGF-2 is used in the cell and gene therapy space for the expansion of bone marrow and adipose tissue derived MSCs.

Product Characteristics

Source	*E. coli*
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 preclinical *ex vivo* use. Not intended for therapeutic use.

Quality Parameters

Activity	≥ 0.9 x 10^6 IU/mg calibrated against NIBSC #90/712 Measured in a cell proliferation assay using an FGF-2-dependent cell line, FBHE
Purity	≥ 95 %, as determined by SDS-PAGE (under reducing conditions, visualized by Coomassie staining) and RP-HPLC
Endotoxin	≤ 1000 EU/mg, as determined by LAL gel clot test
Sterility	Sterility test of the vialed product
Mass per vial	1421-010: 10 µg, 1421-050: ≥ 40 µg
Animal-derived component-free	**ADCF Level 1:** The final product contains neither animal- nor human-derived materials. Please refer to Technical Note "Animal-Derived Component-Free Policy CellGenix® Preclinical and GMP Cytokines".

Shipment and Storage

Transport	Ambient temperature. Please refer to Technical Note "Shipment of CellGenix® Preclinical and GMP Cytokines at Ambient Temperatures".
Shelf Life	3 years from date of shipment
Storage and Stability	Store lyophilized cytokine at -20 °C to -80 °C. ▪ 4 months at -20 °C to -80 °C under sterile conditions after reconstitution. Store in aliquots in polypropylene cryogenic vials. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 100 µg/mL for 10 µg vials or 250 µg/mL for 50 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.

Packaging

CellGenix® cytokines are provided in glass vials, closed with vacuum rubber stoppers and sealed with aluminum tear off caps. The following material is used:

Glass vials
For 50 µg vials: Glass vials (2 mL; colorless; 35.00 x 13.75 mm) with DIN Crimp Neck N13-2 made from borosilicate glass hydrolytic type I (in compliance with Ph. Eur. 3.2.1 and USP <660> glass containers for pharmaceutical use).

Vacuum rubber stoppers, Type I butyl rubber
The formulation is 4023/50/grey. This corresponds to bromobutyl rubber with a hardness of 50 (hardness measured in shore A). This is compliant with Ph. Eur. 3.2.9 Type 1 and with the physicochemical tests as described in USP General Chapter <381> "Elastomeric Closures for Injections".

Aluminum tear off caps
Aluminum tear off caps (13 mm; gold) are produced in accordance to valid quality criteria for metal caps.

The container closure has been validated after a storage period of up to 5 years at -80 °C by verification of sterility. In addition, the container closure has been demonstrated according to USP <671>.

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
CellGenix® Preclinical rh FGF-2	50 µg	-20 °C to - 80 °C	1421-050
CellGenix® Preclinical rh FGF-2	10 µg	-20 °C to - 80 °C	1421-010*

* This size is no longer in production. We are offering the remaining stock while supplies last.

Sartorius is Your Reliable Supply Partner

High-quality raw materials are essential to ensure safety, efficacy and batch-to-batch consistency. We propose premium-grade raw materials suitable from preclinical development to the manufacturing of the therapy. Our GMP grade products allow for the safe use in clinical trials and commercial manufacturing.

Our GMP cytokines include documented evidence of lot specific sterility, activity, and shelf-life. Our experts will help simplify your raw material qualification and validation efforts. We provide customized solutions to your enquiries, as well as quality control services to ensure the quality of our products. Our regulatory expertise guarantees a suited service to your regulatory procedures, ensuring an extensive support every step of the process.

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Status: 09 | 2024