

CellGenix[®] Preclinical Recombinant Human Interferon-gamma (rh IFN- γ)



Product Information

CellGenix[®] Recombinant Human IFN- γ reliably promotes the maturation of monocyte-derived dendritic cells (Mo-DCs) and the generation of cytokine induced killer cells (CIK cells). Final manufacturing steps and QC are performed in a GMP facility. No animal- or human-derived components are present in the final product and no animal- or human-derived materials were used in production (ADCF Level 2).

Features and Benefits

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

Application

Interferon-gamma (IFN- γ) is a cytokine that is critical for innate and adaptive immunity against viral, some bacterial and protozoal infections. It is the only member of the type II class of interferons and is predominantly produced by natural killer cells (NK cells) and T cells.

IFN- γ is used in the cell and gene therapy space for the *ex vivo* maturation of Mo-DCs, *ex vivo* generation of CIK cells and stimulation of monocytes, macrophages and microglia.

Product Characteristics

Source	<i>E. coli</i>
Description	Human Interferon-gamma, accession # P01579, Gln24-Arg162 N-terminal Met Molecular mass 16.5 kDa
Formulation	Lyophilized from a 0.2 μ m-filtered solution containing 20 mM succinate, pH 5.0.
Intended use	For preclinical <i>ex vivo</i> use. Not intended for therapeutic use.

Quality Parameters

Activity	$\geq 10 \times 10^6$ IU/mg calibrated against Imukin® Measured in a cell cytotoxicity assay using a IFN- γ -sensitive cell line, HT-29
Purity	$\geq 95\%$, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Endotoxin	≤ 1000 EU/mg, as determined by LAL gel clot test
Sterility	Sterility test of the vial product
Mass per vial	$\geq 40 \mu$ g
Animal-derived component-free	ADCF Level 2: The final product contains neither animal- nor human-derived materials. ADCF Level 2 cytokines are produced in our dedicated animal-free facility. No animal-derived components are used throughout the complete production process. All ADCF Level 2 cytokines are produced in <i>E. coli</i> .

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. Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 μ g/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.

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 μ g 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 IFN- γ	50 μ g	-20 °C to -80 °C	1425-050

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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