

CTGrade GMP rh IL-21

Catalog #	Product	Size
500-09	CTGrade GMP rh IL-21	50µg, 100µg, 1mg lyophilized

Intended Use

This product is for research or further manufacturing use only. Not for injection or diagnostic procedures. The safety and efficacy of this product in diagnostic or other clinical procedures has not been established.

Product Description

This product is produced from *E. coli* and is manufactured in a facility that does not use or process beta-lactam containing materials. No animal- or human-derived materials were used during manufacturing or as ingredients. As such, the risk for BSE/TSE contamination can be considered negligible. This product is manufactured, tested, and released in an ISO 9001:2015 certified facility and follows cGMP practices. USP chapter <1043> for ancillary materials has been considered in the manufacture of this product.

Synonyms: None

NIH Accession Number: Q9HBE4

Background: Interleukin 21 (IL-21) is a common chain cytokine regulating many cell types of the immune system (1). It plays a pivotal role in Hodgkin's lymphoma and suppresses contact hypersensitivity reactions (2). The IL-21 receptor (IL-21R) activates the JAK/STAT signaling pathway and is expressed on T, B, and natural killer (NK) cells (3). IL-21 plays an important role in the development of humoral immunity through its effects on B cell biology including differentiation, affinity maturation, and memory responses (4). IL-21 regulates T cell responses including survival of CD8+ T cells and inhibition of Treg cells. In adoptive cellular therapies such as CAR T, IL-21 promotes a less differentiated phenotype while promoting the effector functions of the engineered cells (5).

Specifications

Formulation:	CTGrade GMP rh IL-21 lyophilized at 1mg/ml in 10 mM Sodium Phosphate, pH 7.5, 0.2µm filtered.
Protein Purity:	≥97% determined by reducing and non-reducing SDS-PAGE analysis.
Endotoxin:	<0.05 EU/µg using USP <85>/ EP 2.6.14
Bioactivity:	ED50 is determined by the dose-dependent Proliferation of B9 cell cells. The ED50 is typically less than 5 ng/mL. Activity is >1.1 x 10 ⁶ U/mg, when calibrated against internal standard IL-21 measured in cell proliferation assay using B9 cells.
Quality:	Carrier-free and no animal- or human-derived materials were used during manufacturing.

Quality Assurance

All quality control test results are reported on a lot specific Certificate of Analysis, which is available at www.irvinesci.com or upon request.

Shipping

This product is shipped at ambient temperature. Immediately upon receipt, store at the recommended temperature below.

Storage Instructions and Stability

Upon receipt, store the lyophilized protein at -20°C in a manual defrost freezer. Unopened vials are stable for 36 months from the date of manufacture. Reconstituted material should be apportioned in working volumes and stored at or below -20°C in manual defrost freezer.

For short term storage reconstituted material is stable for 4-6 weeks when stored at 2-8°C. Stability can be increased by adding at least 0.1% carrier protein.

Precautions

For *ex vivo* use only. Not for injection or diagnostic procedures. The safety and efficacy of this product in diagnostic or other clinical uses has not been established. Please refer to the Safety Data Sheet for information regarding hazards and safe handling practices.

Directions for Use

1. Reconstitution

Allow the vial and sterile water (e.g. FUJIFILM Irvine Scientific, Inc. P/N 9309 Water for Injection) to equilibrate to room temperature. Draw up desired volume of reconstitution buffer. Aseptically puncturing through rubber stopper with sterile needle, inject the buffer to achieve the desired concentration (0.1-0.5 mg/mL). Swirl the vial gently, **do not vortex**. Allow protein to rehydrate for 10-15 minutes at room temperature with occasional gentle mixing.

2. Optimum Concentration

The optimum concentration varies depending on cell type and culture conditions. Working concentration should be determined for each specific application.

Related Products

Catalog #	Product	Size
91154	PRIME-XV T Cell CDM	1L
91141	PRIME-XV T Cell Expansion XSFM	1L
91215	PRIME-XV NK Cell CDM	1L
9309	Water for Injection	1L

References

1. Tangye, SG. (2015) *Curr. Opin. Immunol.* 34:107. PMID: 25801685
2. Scheeren FA, *et al.* (2008) *Blood.* 111:9. PMID: 18296629
3. Asao, H, *et al.* (2001) *J. Immunol.* 167:1. PMID: 11418623
4. Ozaki, K, *et al.* (2004) *J. Immunol.* 173: 9. PMID: 15494482
5. Hinrichs, CS, *et al.* (2008) *Blood.* 111:11. PMID: 18276844

Technical Support

CONTACT US

For more information or assistance contact Customer Service at:

- Email: fisitmrequest@fujifilm.com
- Direct line: +1 800 577 6097

WEBSITE RESOURCES

Visit the website at www.irvinesci.com for technical resources and information including:

- Safety Data Sheets (SDS)
- Certificate of Analysis (CoA) (when available)
- FAQs
- Product literature

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REVISION HISTORY

Version 01 Effective on 03-Nov-2022

Initial

Version 02 Effective on 20-Dec-2022

Updated Logo

Version 03 Effective on 01-Apr-2024

Added BSE/TSE statement, added GMP in name and internal standard activity

Version 04 Effective on 08-Apr-2024

Added the word against after word calibrated in IU section

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

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