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Certificate of Analysis (CoA)

PeproGMP® Recombinant Human IL-21

Catalog# GMP200-21-50UG
Lot# 1023G226J3023
Manufacture Date: Oct. 2023

Manufacturing Site: Cranbury, NJ, USA
Final Fill Site: Cranbury, NJ, USA
Expiration Date: Oct. 2028

Manufactured under strict animal-free conditions using no animal-derived raw or contact materials; therefore, considered BSE/TSE free.

Table of Contents

1. Product Description

Description	IL-21 is a pleiotropic cytokine produced by CD4+ T cells in response to antigenic stimulation. Its action generally enhances antigen-specific responses of immune cells. Recombinant Human IL-21 is a 15.4 kDa protein consisting of 132 amino acid residues.
Source	*E.coli*
Formulation	Sterile filtered through a 0.2 micron filter. Lyophilized from 10mM Sodium Phosphate, pH 7.5.
Purity	≥98% by SDS-PAGE Gel and HPLC
Transport	Lyophilized products are stable when shipped at ambient temperature for at least 2 weeks.
Storage	Lyophilized PeproGMP® Recombinant Cytokines should be stored at -20˚C to -80˚C immediately upon receipt. Avoid repeated freeze-thaw cycles.
Country Of Origin	USA

2. Instructions for Use

Reconstitution

- Disinfect surface of the vial before use.
- Lift tab on cap and disinfect surface of the rubber stopper.
- Use appropriate sterile syringe and sterile needle.
- Reconstitute using sterile water (i.e. WFI) to a concentration of 0.1-1.0 mg/ml.
- Puncture the rubber stopper using the needle and add the sterile water (i.e. WFI) carefully along the side of the wall of the vial. Mix gently, avoiding foam formation. DO NOT shake or vortex.
- Further dilutions should be made in a buffer containing HSA or BSA.
- Avoid repeated freeze-thaw cycles.

3. Product Use Limitations

PeproTech products have been manufactured to be GMP-compliant products, wherein GMP compliance is consistent with provisions of the United States Food and Drug Administration (FDA). Products sold by PeproTech, however, do not have approval or clearance by any worldwide regulatory authority, including the FDA. PeproTech products, which are, or may be, used to manufacture human or veterinary drug products, food additives, diagnostic reagents, medical devices, dietary supplements, or cosmetics as defined or described by the United States Federal Food, Drug and Cosmetic Act (FFDCA), are not intended for direct human use. The products are intended for *in vitro* or *ex vivo* use only. Unless otherwise indicated, all products are distributed and sold for use in the manufacture or production of a therapeutic product or for chemical purposes only. Thus, PeproTech products are not intended for direct human exposure by any route, including but not limited to intravenous injection, oral ingestion, topical application, or inhalation. All products sold by PeproTech are to be used by qualified professionals only.

4. Certificate of Compliance

PeproTech certifies that PeproGMP® Recombinant Human IL-21 has been manufactured, tested and released in accordance with a Quality System that complies with relevant US FDA Good Manufacturing Practice and ISO 9001:2015 standard requirements.

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5. Product Specifications

Analysis	Method	Specification	Results
Concentration	UV Spectroscopy (A280)	+/- 15% @ 1mg/ml	**Pass**
Endotoxin	Charles River PTS – kinetic LAL	≤ 0.1 EU/µg	**< 0.01 EU/µg**
Protein Content	SDS-PAGE Gel 4-20% Tris-glycine	(-/+) Single band nearest 14.4 kDa marker	**Pass**
Sterility	Direct inoculation in accordance with USP	No Growth	**No Growth**
N-terminal AA Sequence	Protein Sequencing System	M Q D R H M	**M Q D R H M**
Purity (Elution)	HPLC	43 - 51 % Elution Peak	**Pass**
Protein Mass	Mass Spectrometry	Two Peaks; 7.7 - 7.86 kDa and 15.4 - 15.68 kDa	**Pass**
Biological Activity	Proliferation of ANBL-6 cells	0.04-0.92 ng/ml	**0.24 - 0.36 ng/ml**
Identity	Western Blot	Compare to Control	**Pass**
Mycoplasma	Tested in accordance with USP <63> and EP General Chapter 2.6.7	Negative/Not Detected	**Not Detected**
Residual *E.coli* DNA	^{32}P-labeled *E.coli* DNA probe generated from E.coli genomic DNA	≤500 pg DNA/ml	**Pass**

6. Regulatory Compliance

Purchasers of PeproTech products agree to comply with all provisions of applicable federal, state and local statutes, rules, regulations, ordinances, and orders in any use they may make of PeproTech products. Products sold by PeproTech do not have clearance or approval of any regulatory authority, including the FDA. Because PeproTech products are intended for research use or use in the manufacture of products intended for use in humans, the products may require listing on the United States Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA) Inventory. Purchasers assume the responsibility to ensure that any PeproTech product purchased are approved under TSCA, if applicable, and to ensure that the products are in compliance with any relevant TSCA provisions. Purchasers assume similar responsibilities to ensure that any products they purchase are in compliance with other relevant regulatory authority provisions.

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Document Reviewed by

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