T&L Biotechnology Ltd Product QC Report

Report number: 20230056

Name	Recombinant human IL-21 Protein	**Catalog number**	GMP-TL509-0050
Batch number	2302020	**Specification**	50μg/piece
Production Date	2023.03.02	**Storage condition**	2~8°C
Validity period	2025.03.01	**Report date**	2023.017

Test items:

Project	Reference range	Result
Identify	SDS-PAGE（Reduction/non-reduction）	Compliance
Physical behavior	Freeze-dried preparation, white loose body in form, clear liquid after resolution	Compliance
Visible foreign matter	Should be no foreign bodies visible	Compliance
Deliverable volume	Not lower than the indicated value	Compliance
Mycoplasma	Should be negative	Negative
Sterility test	No bacteria should grow	Ungrown bacteria
Moisture	≤3.0%	Compliance
Endotoxin	<0.01EU/μg	<0.01EU/μg
Purity	SDS-PAGE	Compliance
Host cell DNA remains	The DNA residue in the samples was determined by Q-PCR to be less than 100pg/ml	Compliance
Host cell protein residues	The residue of host protein in the samples was determined by ELISA method to be less than 100ppm	Compliance
Biological activity	By inducing human natural destruction lymphoma NK-92 cells to secretory IFN-γ, the effect ED50≤ 50ng/ml	ED_{50}为16.3ng/ml
Conclusion	This product in accordance with the Chinese pharmacopoeia & Tonglihaiyuan enterprise internal standards test, the results meet the requirements	

Reported by: _____ **Report date:** 2023.03.17

Approved by: _____ **Date of approval:** 2023.03.17