

T&L Biotechnology Ltd Product QC Report

Report number: 20230148

Name	Anti-Human CD3 Monoclonal Antibody	Catalog number	GMP-TL101-500
Batch number	2305006	Specification	500 μ g
Production Date	2023.05.08	Storage condition	2~8 $^{\circ}$ C
Validity period	2025.05.07	Report date	2023.05.23

Test items:

Project	Reference range	Result
Identify	The electrophoretic bands are consistent with the molecular weight of the product	Compliance
Appearance	Should be colorless transparent liquid	Compliance
Visible foreign matter	Should be no foreign bodies visible	Compliance
pH	6.5~7.5	7.3
Concentration	1.0 mg/ml~1.5mg/ml	1.2mg/ml
Endotoxin	<0.01EU/ μ g	<0.01EU/ μ g
Purity	SDS-PAGE	Compliance
Mycoplasma	Should be negative	Negative
Sterility test	No bacteria should grow	Ungrown bacteria
Host protein residue	\leq 100ppm	Compliance
Host DNA residue	\leq 50ng/mg	Compliance
Biological activities assay	Binding rate with Jurkat cells is not less than 90%	93.8%
Conclusion	This product in accordance with the Chinese pharmacopoeia & Tonglihaiyuan enterprise internal standards test, the results meet the requirements	

 Reported by: Tingting Wang Report date: 2023.05.23

 Approved by: Zhaoliang Zhang Date of approval: 2023.05.23