

BATCH QUALITY DOCUMENT

Certificate of Analysis

Batch-specific analytical results, QSC Peptidology in-house QC.

Product	Tirzepatide	Batch	TZ-2607
Mfg date	2026-07-28	Test date	2026-08-14
Retest date	2028-07-27	Quantity	33g
CAS No.	2023788-19-2	Standard	In house (injection-grade API)

Test Item	Acceptance Criteria	Test Result	Status
Appearance	White or off-white powder	White powder	PASS
Solubility	Should be freely soluble in water	Meet the requirements	PASS
Chromatographic Identification	Retention time correspond to standard	Meet the requirements	PASS
Average Molecular Weight	4813.5±1.0 Da	4813.6 Da	PASS
Specific rotation	-23.5°~-33.5°	-26.5°	PASS
Clarity and colour of solution	Solution be clear, colourless	Meet the requirements	PASS
pH	6.0-9.0	7.7	PASS
Peptide Content	NLT 85.0%	95.1%	PASS
Assay	95.0%~105.0% (anhydrous and sodium free)	97.5%	PASS
Chromatographic Purity	NLT 99%	99.2%	PASS
Related Substances	Individual unknown peaks, NMT 0.5% each Total impurities NMT 1%	0.03/0.01/0.02/0.04/0.18/0.11/0.28/0.09% (by RRT) 0.77%	PASS
Polymer	Maximum single impurity NMT 0.3% Total impurities NMT 1.0%	0.01% 0.03%	PASS
Water Content	NMT 10.0%	2.7%	PASS
Sodium Content	NMT 5.0%	1.4%	PASS
Residual Solvents	Acetonitrile NMT 410 ppm Methanol NMT 3000 ppm N,N-Dimethylformamide NMT 880 ppm	96ppm (LOD=25ppm) <LOD (LOD=180ppm) <LOD (LOD=53ppm)	PASS
Bacterial Endotoxins	Less than 5 EU per mg	Meet the requirements	PASS
Microbial Limit	Total aerobic bacteria NMT 100 cfu/g Total Yeasts and Molds NMT 100 cfu/g	<10cfu/g <10cfu/g	PASS

CONCLUSION Meets all specifications stated above.

