

Certificate of Analysis

Product	Melanotan 1 (Afamelanotide)	CAS No.:	75921-69-6
Product No.:	MT	Molecular Formula	C ₇₈ H ₁₁₁ N ₂₁ O ₁₉
Sequence	Ac-Ser-Tyr-Ser-Nle-Glu-His-D-Phe-Arg-Trp-Gly-Lys-Pro-Val-NH ₂ [Nle4,D-Phe7]-α-MSH, 13-aa; C-terminal amide (acetate salt)		
Molecular Weight	1646.87	Quantity	25.0g
Batch No.	MT-2807G	Storage Temp.	-20±5°C
Mfg. Date	Apr.21 st , 2026	Retest Date	Apr.21 st , 2028

【ITEMS】		【SPECIFICATIONS】	【RESULTS】
Appearance		White or almost white powder	White powder
Solubility		Soluble in water	Conforms
Solution clarity and color		Clear and colorless liquid	Conforms
Identification	HPLC	The retention time of the principal peak of the test solution corresponds to that of the reference solution, as obtained in the Assay.	Conforms
	Mass spectrum	1646.9±1.5	1646.2
Amino acid content		Ser: 1.8~2.2	2.0
		Tyr: 0.9~1.1	1.0
		Nle: should be detected	Detected
		Glu: 0.9~1.1	1.0
		His: 0.9~1.1	1.0
		D-Phe: 0.9~1.1	1.0
		Arg: 0.9~1.1	1.0
		Trp: should be detected	Detected
		Gly: 0.9~1.1	1.0
		Lys: 0.9~1.1	1.0
		Pro: 0.9~1.1	1.0
		Val: 0.9~1.1	1.0
Related substances (HPLC)		Largest single impurity: NMT 1.0%	0.28%
		Total impurities: NMT 2.0%	1.19%
Purity (HPLC)		NLT 99.0%	99.55%
pH		4.0~7.0	6.3
Acid group ions		Trifluoroacetate ion (TFA residue): NMT 1.0%	N.D
		Acetate ion (acetic acid, counter-ion): NMT 15.0%	11.1%
Water content (KF)		NMT 8.0%	2.1%
Peptide content		NLT 80.0%	85.8%
Residual solvent		Acetonitrile NMT 410ppm	174ppm
		Methanol NMT 3000ppm	N.D
		Methyl tert-butyl ether NMT 5000ppm	N.D
Bacterial endotoxins		NMT 10EU/mg	4.1EU/mg
Microbial Limits		Total aerobic bacteria ≤100cfu/g	Conforms
		Mould & Yeast ≤10cfu/g	Conforms
		Bile tolerant enterobacteria: absence in 1g	absent
		Pseudomonas aeruginosa: absence in 1g	absent
		Staphylococcus aureus: absence in 1g	absent
Assay		95.0%~105.0% (Calculated on anhydrous, acetate-free basis)	101.2%
Storage		Keep in tight container, protect from light, store at a temperature of -20±5°C.	
Report		Date: Jun. 8 th , 2026	
Reviewer		Date: Jun. 8 th , 2026	
Conclusion: This batch of product complies with Enterprise Standard.			

合格