



上海苏豪逸明制药有限公司

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12/12/2025

CERTIFICATE OF ANALYSIS

Name of Product:	Oxytocin $\text{Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH}_2$		
Batch No.:	2510022	Analyzed on:	2025-10-27
Date of Manufacture:	2025-10-23	Quantity:	319g
CAS No.:	[50-56-6]	Expiry Date:	2027-10-22
TEST	SPECIFICATION		RESULTS
1. Characteristic	White or almost white powder.		White powder
2. Identification A. HPLC	Retention time conforms to that of the reference standard		Conforms
C. Amino acids	Asp: 0.90-1.10; Glu: 0.90-1.10 Pro: 0.90-1.10; Gly: 0.90-1.10 Leu: 0.90-1.10; Tyr: 0.7-1.05 Half-Cys: 1.4-2.1; Ile: 0.90-1.10		Conforms
3. pH	3.0-6.0		5.0
4. Related substances (HPLC)	Impurity A $\leq 1.0\%$ Impurity B $\leq 1.0\%$ Impurity D $\leq 1.0\%$ Impurity E $\leq 1.0\%$ Impurity I $\leq 1.0\%$ Other single impurity $\leq 0.5\%$ Total impurities $\leq 5.0\%$		0.01% 0.01% 0.12% 0.05% 0.20% 0.10% 0.6%
5. Acetic acid (HPLC)	6.0%-10.0%		7.0%
6. Water(KF)	NMT 5.0%		1.4%
7. Bacterial endotoxins	Less than 300 IU/mg		Conforms
8. AcN(GC)	Not more than 0.041%		Conforms
9. MeOH(GC)	Not more than 0.3%		Conforms
10. Triethylamine(GC)	Not more than 0.032%		Conforms
11. TAMC	Not more than 10^3 cfu/g		Conforms
12. TYMC	Not more than 10^2 cfu/g		Conforms
13. Assay Calculated with reference to anhydrous, acetic acid free substance	95.0%-102.0%		97.9%
on powder	NLT 85.0 %		89.7%
	NLT 510 IU/mg		538IU/mg

Conclusion: Meets Ph. Eur. 11.2 and In-house Standard.

CEP No.: CEP 2011-003-Rev 01