



上海苏豪逸明制药有限公司

Shanghai Soho-Yiming Pharmaceuticals Co., Ltd.

Address: No.1277, Huaqing Road, Qingpu District, Shanghai, China.

CERTIFICATE OF ANALYSIS			
Name of Product:	Oxytocin Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH ₂		
Batch No.:	2503009	Analyzed on:	2025-04-21
Date of Manufacture:	2025-04-19	Quantity:	303g
CAS No.:	[50-56-6]	Expiry Date:	2027-04-18
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		5.2
4. Related substances (HPLC)	Impurity A ≤ 1.0% Impurity B ≤ 1.0% Impurity D ≤ 1.0% Impurity E ≤ 1.0% Impurity I ≤ 1.0% Other single impurity ≤ 0.5% Total impurities ≤ 5.0%		0.01% 0.02% 0.09% 0.02% 0.12% 0.03% 0.4%
5. Acetic acid (HPLC)	6.0%-10.0%		6.8%
6. Water(KF)	NMT 5.0%		1.6%
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%		100.1%
on powder	NLT 85.0 %		91.7%
	NLT 510 IU/mg		550IU/mg

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

CEP No.: CEP 2011-003-Rev 01

METAPHARMACEUTICAL

N DE LOTE:

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