

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Oxytocin (CAS: 50-56-6)

Batch No.: DR20140209	Quantity: 5g
Manufacture Date: 2014.02.09	Expiry Date: 2016.02.08

TESTS:

Items	Specification	Results
Appearance	White or almost white powder.	White powder
Identification	A:HPLC :Retention time conforms to that of the reference standard	Conforms
	B. 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
PH	3.0-6.0	5.0
Related sub < stances(HPLC)	Impurity A \leq 1.0%	0.04%
	Impurity B \leq 1.0%	0.19%
	Impurity C \leq 1.5%	0.1%
	Other single impurity \leq 0.5%	0.08%
	Total impurities \leq 5.0%	0.4%
Acetic acid (HPLC)	6.0%-10.0%	7.8%
Water(KF)	\leq 5.0%	1.3%
Bacterial endotoxins	< 300 IU/mg	Conforms
AcN(GC)	\leq 0.041%	Conforms
MeOH(GC)	\leq 0.3%	Conforms
Triethylamine(GC)	\leq 0.032%	Conforms

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Assay		
Calculated with reference to anhydrous, acetic acid free substance	93.0%-102.0%	99.7%
on powder	≥80.0 %	90.7%
	≥480 IU/mg	544IU/mg
Conclusion: The results conform with theEP7.0		



Analyst: Joe Yu Checker: Agnes Zhong QA.Manager: Sun Wenhui

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