



Chengdu Kaijie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name	<i>Oxytocin Acetate</i>		
CAS. No.	50-56-6	Standard	EP6.0/USP31
Molecular Formula	$C_{43}H_{66}N_{12}O_{12}S_2$	Molecular Weight	1007.19
Storage	2~8 °C	Batch No.	20110106
Manufacturing Data	01/06/2011	Retest Date	01/05/2013
Sequence	<div style="border: 1px solid black; width: fit-content; margin: 0 auto; padding: 2px;"> Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH₂ </div>		
TEST	SPECIFICATION		RESULT
Appearance	<i>White powder</i>		<i>Conforms</i>
Solubility	<i>Soluble in water or 1% acetic acid at a concentration of ≥ 1mg/ml to give a clear, colorless solution</i>		<i>Conforms</i>
Identification by HPLC	<i>The retention is same with the reference substance</i>		<i>Conforms</i>
Amino Acid Composition	<i>Asp: 0.90~1.10</i> <i>Glu: 0.90~1.10</i> <i>Pro: 0.90~1.10</i> <i>Gly: 0.90~1.10</i> <i>Leu: 0.90~1.10</i> <i>Ile: 0.90~1.10</i> <i>Tyr: 0.70~1.05</i> <i>Cys: 1.40~2.10</i>		0.98 1.03 1.08 1.00 0.96 0.95 0.99 1.71
PH	3.0~6.0		4.8
Specific Optical Rotation	C=1, 1%HAc		-21.25°
Peptide Purity (By HPLC)	$\geq 95.0\%$		99.08%
Related Substances(By HPLC)	<i>Total Impurities($\%$)$\leq 5.0\%$</i> <i>Largest Single impurity($\%$)$\leq 1.5\%$</i>		0.92% 0.36%
Acetic Acid(By HPLC)	6~10%		8.36%
Water Content(Karl Fischer)	$\leq 5.0\%$		2.15%
Bacterial Endotoxins	≤ 300 IU/mg		<i>Conforms</i>
Activity	A) 1mg of Oxytocin peptide is equivalent 600IU		599.8IU(Net)
	B) ≥ 480 IU/mg		536.8IU(Wt)
Assay	93.0 ~102.0%		99.05%

Quality Control By Zhouzhongbing Date: 2011-01-11

Quality Assurance Department