



Chengdu KaiJie Biopharm Co., Ltd.

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Certification of Analysis

Product Name	Vasopressin, 8-L-lysine(Lypressin)		
CAS No.	50-57-7	Standard	USP31-NF26
Molecular Formula	$C_{46}H_{65}N_{13}O_{12}S_2$	Batch No.	20100605
Molecular Weight	1056.22	Manufacturing Date	06/05/2010
Storage	2~8 °C	Retest Date	06/04/2012
Sequence	Cys-Tyr-Phe-Gln-Asn-Cys-Pro-Arg-Gly-NH ₂		

TEST	SPECIFICATION	RESULT
1 Appearance	White amorphous powder	Complies
2 Solubility	Soluble in water or acetic acid at a concentration of $\geq 1\text{mg/ml}$ to give a clear, colorless solution	Complies
3 Identification	Retention time of the sample must be approximately the same as the retention time of the reference	Complies
4 Bioidentity	Vasopressor activity of the sample comparable to that of the reference	Complies
5 Oxytocic activity	$\leq 1.2\text{USP Oxytocin Units/ml}$	Complies
6 Amino Acid Composition	$\pm 10\%$ of theoretical except for Cys	Complies
7 Peptide Purity (By HPLC)	$\geq 95.0\%$ by area integration	98.68%
8 Related Substance (By HPLC)	Total Impurities($\%$) $\leq 5.0\%$ Largest Single Impurity($\%$) $\leq 2.0\%$	1.32% 0.43%
9 Acetate Content (By HPLC)	$\leq 15.0\%$	12.5%
10 Water Content (Karl Fischer)	$\leq 5.0\%$	2.60%
11 Microbial limits	$\leq 200\text{ cfu/g}$	Complies
12 Endotoxin	$\leq 5\text{IU/mg}$	Complies
13 TFA Content (By HPLC)	$\leq 0.3\%$	Nd
14 Residual Solvents (by GC)	EtOH $\leq 5000\text{ ppm}$ MeOH $\leq 3000\text{ ppm}$ DMF $\leq 810\text{ ppm}$	Nd Nd 160 ppm

Quality Control By Zhouzhongbing

Date: 2010-06-21

Quality Assurance Department