



Chengdu KaiJie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name	Vasopressin, 8-L (Argipressin)		
CAS No.	113-79-1	Standard	USP31-NF26
Molecular Formula	$C_{46}H_{65}N_{15}O_{12}S_2$	Batch No.	20100203
Molecular Weight	1084.24	Manufacturing Date	02/03/2010
Storage	$\leq -20^{\circ}C$	Retest Date	02/02/2012
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	97.92%
8	Related Substance (By HPLC)	Total Impurities (%) $\leq 5.0\%$ Largest Single Impurity (%) $\leq 2.0\%$	2.08% 1.04%
9	Acetate Content (By HPLC)	$\leq 15.0\%$	13.5%
10	Water Content (Karl Fischer)	$\leq 5.0\%$	2.8%
11	Microbial limits	$\leq 200\text{ cfu/g}$	Complies
12	Endotoxin	$\leq 5\text{IU/mg}$	Complies
13	Potency	$\geq 300\text{IU/mg}$	350 IU/mg
14	TFA Content (By HPLC)	$\leq 0.3\%$	Nd
15	Residual Solvents (by GC)	EtOH $\leq 5000\text{ ppm}$ MeOH $\leq 3000\text{ ppm}$ DMF $\leq 810\text{ ppm}$	Nd Nd 150 ppm

 Quality Control By Zhouzhongbing

 Date: 2010-02-06

Quality Assurance Department