



Chengdu Kaijie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name	<i>Terlipressin Acetate</i>	CAS. No.	14636-12-5
Molecular Formula	$C_{52}H_{74}N_{16}O_{15}S_2$	Molecular Weight	1227.37
Storage	2~8 °C	Batch No.	20100723
Manufacturing Date	07/23/2010	Retest Date	07/22/2012
Sequence	Gly-Gly-Gly- $\overbrace{\text{Cys-Tyr-Phe-Gln-Asn-Cys}}^{\text{---}}\text{-Pro-Lys-Gly-NH}_2$		
TEST		SPECIFICATION	RESULT
1	Appearance	<i>White to Off-white powder</i>	<i>Complies</i>
2	Solubility	<i>Soluble in water or 1% acetic acid</i>	<i>Complies</i>
3	Identity by HPLC	<i>The retention is same with the reference</i>	<i>Complies</i>
4	Specific Optical Rotation	$-95 \sim -105^\circ$ (C=0.5, 1%HAc)	-101.65°
5	Amino Acid Composition	<i>Cys:1.30~2.20</i> <i>Lys:0.90~1.20</i> <i>Phe:0.90~1.20</i> <i>Pro:0.90~1.20</i> <i>Tyr:0.90~1.20</i> <i>Asp:0.90~1.30</i> <i>Glu:0.90~1.30</i> <i>Gly:3.60~4.40</i>	<i>1.82</i> <i>1.05</i> <i>1.06</i> <i>1.12</i> <i>0.96</i> <i>0.98</i> <i>0.96</i> <i>4.08</i>
6	Peptide Purity (By HPLC)	$\geq 98.0\%$ by area integration	99.17%
7	Related Substance (By HPLC)	<i>Total Impurities $\leq 2.0\%$</i> <i>Largest Single Impurity $\leq 1.0\%$</i>	<i>0.83%</i> <i>0.37%</i>
8	Acetate Content (By HPLC)	$\leq 15.0\%$	8.27%
9	Water Content (Karl Fischer)	$\leq 10.0\%$	2.93%
10	Bacterial Endotoxins	$\leq 50\text{EU/mg}$	<i>Complies</i>
11	Assay (By HPLC)	95.0%~105.0%	100.82%

Quality Control By Zhouzhongbing Date: 2010-08-18

Quality Assurance Department