



Chengdu KaiJie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

<i>Product Name</i>		<i>Vapreotide Acetate</i>	
<i>CAS. No.</i>	103222-11-3	<i>Molecular Weight</i>	1132.5(net)
<i>Molecular Formula</i>	$C_{57}H_{72}N_{12}O_9S_2$	<i>Batch No.</i>	20090226
<i>Storage</i>	2 ~8 °C	<i>Expiry Date</i>	2 years
<i>Manufacturing Date</i>	02/26/2009	<i>Retest Date</i>	02/25/2011
<i>Sequence</i>	D-Phe-Cys-Tyr-D-Trp-Lys-Val-Cys-Trp-NH ₂		
<i>TEST</i>		<i>SPECIFICATION</i>	<i>RESULT</i>
1	<i>Appearance</i>	White or slightly yellowish powder	Complies
2	<i>Appearance of Solution</i>	Clear, colorless to slightly colored solution in water(10mg/ml)	Complies
3	<i>Identification by HPLC</i>	The retention is same with the reference substance	Complies
4	<i>Amino Acid Composition</i>	$\pm 15\%$ except Trp and Cys Trp: Detected Cys: 1.4~2.1	Complies
5	<i>Peptide Purity(By HPLC)</i>	≥ 98.0	99.79%
6	<i>Related Substance(By HPLC)</i>	Total Impurities(%) $\leq 2.0\%$ Largest Single Impurity(%) $\leq 1.0\%$	0.21 % 0.14%
7	<i>Acetate Content(By HPLC)</i>	$\leq 12\%$	5.8%
8	<i>Water Content(Karl Fischer)</i>	$\leq 5.0\%$	2.0 %
9	<i>Sterility</i>	≤ 10 CFU/100 mg	Complies
10	<i>Bacterial Endotoxins</i>	≤ 55.5 IU/mg	Complies
11	<i>Assay(By anhydrous,acetic acid-free)</i>	95% ~102%	97.5%

Quality Control By Zhouzhongbing Date: 2009-03-05

Quality Assurance Department