



# Chengdu KaiJie Biopharm Co., Ltd.

**KAIJIE**

Segment 1, Industrial Road, Dayi county, Chengdu, Sichuan, P. R. China, 611330

Tel: 86-28-88208155, Fax: 86-28-88203632 WEB: www.kjpep.com

## Certification of Analysis

<b>Product Name</b>	<i>Exenatide Acetate</i>	<b>CAS. No.</b>	<i>141732-76-5</i>
<b>Molecular Formula</b>	<i>C<sub>184</sub>H<sub>282</sub>N<sub>50</sub>O<sub>60</sub>S</i>	<b>Batch No.</b>	<i>20100506</i>
<b>Molecular Weight</b>	<i>4186.6</i>	<b>Manufacturing Date</b>	<i>05/06/2010</i>
<b>Storage</b>	<i>2 ~ 8 °C</i>	<b>Retest Date</b>	<i>05/05/2012</i>
<b>Sequence</b>	His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys- Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu- Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro- Pro-Pro-Ser-NH <sub>2</sub>		

	<b>TEST</b>	<b>SPECIFICATION</b>	<b>RESULT</b>
1	<b>Appearance</b>	<i>White powder</i>	<i>White powder</i>
		<i>Soluble in water or 1% acetic acid</i>	
2	<b>Solubility</b>	<i>at a concentration of <math>\geq 1</math>mg/ml to</i>	<i>Conforms</i>
		<i>give a clear, colorless solution</i>	
3	<b>Amino Acid Composition</b>	<i><math>\pm 20\%</math> of theoretical except for Trp</i>	<i>Conforms</i>
4	<b>Specific Optical Rotation</b>	<i>-45 °~-65 °(c=1, 1% HAc)</i>	<i>-47.78 °</i>
5	<b>Peptide Purity (By HPLC)</b>	<i><math>\geq 98.0\%</math> by area integration</i>	<i>99.35%</i>
6	<b>Related Substance (By HPLC)</b>	<i>Total Impurities(%) <math>\leq 2.0\%</math></i>	<i>0.65%</i>
		<i>Largest Single Impurity(%) <math>\leq 1.0\%</math></i>	<i>0.17%</i>
7	<b>Acetate Content</b>	<i><math>\leq 15.0\%</math></i>	<i>4.11%</i>
8	<b>Water Content (Karl Fischer)</b>	<i><math>\leq 6.0\%</math></i>	<i>2.73%</i>
9	<b>Peptide Content (N determination)</b>	<i><math>\geq 80.0\%</math></i>	<i>90.76%</i>
10	<b>Assay (By Anhydrous, Acetic Acid-free)</b>	<i>95.0 ~ 105.0%</i>	<i>98.6%</i>
11	<b>Bacterial Endotoxins</b>	<i><math>\leq 5</math> EU/mg</i>	<i>Conforms</i>

 Quality Control By Zhouzhongbing

 Date: 2010-05-13

Quality Assurance Department