



# 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>Ziconotide Acetate</i>	<b>CAS. No.</b>	<i>107452-89-1</i>
<b>Molecular Formula</b>	$C_{102}H_{172}N_{36}O_{32}S_7$	<b>Batch No.</b>	<i>20090828</i>
<b>Molecular Weight</b>	<i>2639.18</i>	<b>Manufacturing Date</b>	<i>08/28/2009</i>
<b>Storage</b>	<i>2 ~ 8 °C</i>	<b>Retest Date</b>	<i>08/27/2011</i>
<b>Sequence</b>	H-Cys-Lys-Gly-Lys-Gly-Ala-Lys-Cys-Ser-Arg-Leu-Met-Tyr -Asp-Cys-Cys-Thr-Gly-Ser-Cys-Arg-Ser-Gly-Lys-Cys-NH <sub>2</sub> (Cys1-Cys16, Cys8-Cys20, Cys15-Cys25)		

<b>TEST</b>		<b>SPECIFICATION</b>	<b>RESULT</b>
1	<b>Appearance</b>	<i>White powder</i>	<i>White powder</i>
2	<b>Solubility</b>	<i>Soluble in water or 1% acetic acid at a concentration of <math>\geq 1</math>mg/ml to give a clear, colorless solution</i>	<i>Conforms</i>
3	<b>MS indentification</b>	<i>2639.18<math>\pm</math>1</i>	<i>2639.1</i>
3	<b>Amino Acid Composition</b>	<i><math>\pm 20\%</math> of theoretical except for Cys and Ser</i>	<i>Conforms</i>
4	<b>Peptide Purity (By HPLC)</b>	<i><math>\geq 95.0\%</math> by area integration</i>	<i>99.05%</i>
5	<b>Related Substance (By HPLC)</b>	<i>Total Impurities (%) <math>\leq 5.0\%</math> Largest Single Impurity (%) <math>\leq 2.0\%</math></i>	<i>0.95% 0.47%</i>
6	<b>Acetate Content (By HPLC)</b>	<i><math>\leq 15.0\%</math></i>	<i>13.5%</i>
7	<b>Water Content (Karl Fischer)</b>	<i><math>\leq 6.0\%</math></i>	<i>2.86%</i>
8	<b>Bacterial Endotoxins</b>	<i><math>\leq 5</math> EU/mg</i>	<i>Conforms</i>
9	<b>Assay (By Anhydrous, Acetic Acid-free)</b>	<i>95.0 ~ 105.0%</i>	<i>98.5%</i>

Quality Control By Zhouzhongbing

Date: 2009-09-09

Quality Assurance Department