



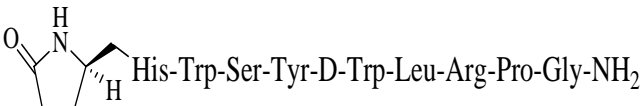
# Chengdu KaiJie Biopharm Co., Ltd.

**KAIJIE**

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## Certification of Analysis

<b>Product Name</b>		<b>Triptorelin Acetate</b>	
<b>CAS No.</b>	149194-24-7	<b>Molecular Formula</b>	$C_{64}H_{82}N_{18}O_{13}$
<b>Molecular Weight</b>	1311.46	<b>Batch No.</b>	20100520
<b>Storage</b>	2~8℃	<b>Expiry Date</b>	2 years
<b>Manufacturing Date</b>	05/20/2010	<b>Retest Date</b>	05/19/2012
<b>Sequence</b>			
<b>TEST</b>		<b>SPECIFICATION</b>	<b>RESULT</b>
1	<b>Appearance</b>	White powder	Conforms
2	<b>Solubility</b>	Soluble in water or 1% acetic acid at a concentration of $\geq 1\text{mg/ml}$ to give a clear, colorless solution	Conforms
3	<b>Amino Acid Composition</b>	$\pm 10\%$ of theoretical	Conforms
4	<b>Peptide Purity (By HPLC)</b>	$\geq 98.0\%$ by area integration	99.27%
5	<b>Related Substance (By HPLC)</b>	Total Impurities(%) $\leq 2.0\%$ Largest Single Impurity(%) $\leq 1.0\%$	0.73% 0.37%
6	<b>Acetate Content (By HPLC)</b>	$\leq 12.0\%$	8.41%
7	<b>Water Content (Karl Fischer)</b>	$\leq 5.0\%$	3.41%
8	<b>Specific Optical Rotation</b>	$-65.0 \sim -75.0^\circ [\alpha]_D^{20}$ (c=0.5, 95% HAc)	$-66.21^\circ$
9	<b>Peptide Content (N determination)</b>	$\geq 80.0\%$	87.33%
10	<b>Bacterial Endotoxins</b>	$\leq 5\text{EU/mg}$	Conforms
11	<b>Assay (By HPLC)</b>	95.0~105.0%	99.15%

 Quality Control By Zhouzhongling Date: 2010-05-21

Quality Assurance Department